97379-2

Court of Appeal Case No. 50914-8-II

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

DIANA SHERMAN, Petitioner

v.

PLIVA, INC.; TEVA PHARMACEUTICALS USA, INC.; and BARR LABORATORIES, INC., Respondents

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PETITION FOR REVIEW

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I. Identity of Petitioner.

Diana Sherman, Plaintiff-Appellee below, asks this Court to review the decision of the Court of Appeals, Division II designated below, which reversed the trial court's denial of summary judgment to PLIVA, Inc. and Teva Pharmaceuticals, Inc. (the "Generic Defendants," Respondents here) and terminated interlocutory review.

II. Court of Appeals Decision.

The Court of Appeals, Division II, held in Part C of its decision filed on April 30, 2019, that a generic drug manufacturer owes no duty under the Washington Product Liability Act, RCW § 7.72.030 ("WPLA"), to provide warnings of a drug's known risks to prescribing physicians, even though established Washington law makes those physicians, as learned intermediaries, the sole advisors of patients who might sustain injuries stemming from those risks. Sherman seeks review of Part C of Division II's decision because it conflicts with decisions of this Court establishing and refining the learned intermediary doctrine, and because it involves an issue of substantial public interest regarding interpretation and application of the WPLA in the unique context of prescription drugs, where Washington State's citizens rely on their learned-intermediary physicians to take drug warnings into account in their prescribing decisions.

Division II denied Sherman's motion for reconsideration on May 31, 2019. A copy of Division II's decision is in the Appendix at pages A-001 through A-016. A copy of the order denying petitioner's motion for reconsideration is in the appendix at page A-017.

III. Issue Presented for Review.

> Do prescription drug manufacturers have a duty under the WPLA to communicate drug-risk warnings to prescribing physicians who, under the learned-intermediary doctrine established in *Terhune v. A. H. Robins Co.*, 90 Wn.2d 9, 577 P.2d 975 (1978) and its progeny, are the only conduit by which health care providers might ever come to know of those risks and possess the information necessary to inform patients' decisions whether to expose themselves to risk of injury by ingesting those dangerous drugs?

IV. Statement of the Case.

A. Factual Background.

Plaintiff-Petitioner Diana Sherman ingested generic metoclopramide as prescribed by her doctor to treat digestive ailments for a continuous period exceeding six years, from September 2004 to December 2010. (CP 183-84, 443-448, 481-89, 541.) Respondents PLIVA, Inc.; Teva Pharmaceuticals, Inc.; and Barr Laboratories, Inc. manufactured most of the metoclopramide that Sherman ingested in accordance with her doctor's advice. (CP 444.)[1]

[1] Some of the metoclopramide the pharmacy dispensed to Sherman was manufactured by three other generic manufacturers who, along with three brand name manufacturers have settled Sherman's claims against them.

Throughout the time that Sherman was taking metoclopramide, the drug-risk warnings approved and required by the federal Food and Drug Administration ("FDA") evolved in their strength and severity. In the early 2000s, the metoclopramide label indicated only that "Therapy longer than 12 weeks has not been evaluated and cannot be recommended." (CP 716.) In July 2004, the FDA approved strengthened warnings requested by the brand-version's manufacturer to state explicitly, in two locations in bold type, that "**Therapy should not exceed 12 weeks in duration.**" (CP 280, 617, 700, 970.) *In re Reglan Litigation*, 226 N.J. 315, 336, 142 A.3d 725, 738 (2016). Five years later in 2009, the FDA again upgraded the drug's warnings 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. (CP 476-79.) The Black Box label added in 2009 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.

While the FDA mandated increasingly serious warnings associated with metoclopramide use in 2004 and again in 2009, neither the brand name defendants who requested the strengthened warnings nor any of the Generic Defendants ever communicated these revised warnings to physicians or the physician community, as by a Dear Healthcare Provider letter, advertisement in medical periodicals, dissemination of peer-reviewed scientific research, sponsoring educational programs, or otherwise. (CP 33-35; 554-55); *In re Reglan Litigation*, 226 N.J. at 336. As a result of these failures, neither Sherman, her prescribing physician Dr. Bruce Silverman, nor any of his medical-practice partners,[2] 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.[3] (CP 175, 446, 533, 953.)

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[2] Dr. Silverman and his medical practice, Gastroenterology Associates, PLLC (collectively, the "Physician Defendants"), were also named as defendants in Sherman's Complaint. (CP 1-121 (Complaint and Amended Complaint).) Her claims against the Physician Defendants remain pending for trial upon remand from these appellate proceedings.

[3] Dr. Silverman testified that he does not read prescription drug labels, which are placed on or within the containers of medication distributed to pharmacies, and therefore may never actually pass across prescribing

Dr. Silverman finally learned of the serious risks associated with long-term metoclopramide use in a letter he received from Sherman's counsel in 2013, prior to the filing of this case. (CP 747.) Shortly after receiving that information, his practice adopted a new 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 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

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physicians' 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.*)

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.

Sherman does not challenge the procedural history as stated in Division II's opinion, except for the court's mistaken belief that Sherman's Complaint includes two claims against Teva and PLIVA: first, a claim that they failed to update their label and second, a claim that they failed to communicate their label warnings to learned intermediaries. It is true Teva and PLIVA did not update their label in a timely manner, but Sherman does not contend that this failure to update was a proximate cause of her injuries. Instead, her sole claim against Teva and PLIVA is that they both failed to adequately communicate revised warnings to any learned intermediaries.

C. The Court of Appeals' Decision.

This interlocutory appeal ensued when Division II granted Generic Defendants' request for discretionary interlocutory review of the trial court's decision. On April 30, 2019, Division II reversed the trial court's

denial of summary judgment. As relevant here,[4] the court held in Part C that the WPLA does not support a duty on the part of Generic Defendants to communicate strengthened drug warnings to physicians in ways other than the package insert provided with the drug when it is dispensed to the patient at the pharmacy. (A-013 through A-016.) This holding is erroneous

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[4] In Part B of its decision, Division II held that summary judgment was proper on Sherman's so-called "failure to update" claim because Dr. Silverman's testimony that he does not read drug container labels or package insert negates proximate causation between Generic Defendants' failure to timely update their labels/inserts with the upgraded warnings in 2004 and 2009. (A-009 through A-012.) This Part of the court's decision is inherently flawed, as a threshold matter, because Sherman's sole cause of action against Generic Defendants is not premised on their failure to update product labels but instead arises from their failure over the entire time that Sherman ingested metoclopramide on her physician's instruction to communicate those warnings to the physician community in ways that might actually reach them. Moreover, when Sherman's claim against PLIVA and Teva is properly construed, it is plain that, as the trial court concluded, ample evidence exists to support the requisite causal link between both Brand and Generic Defendants' communication failures and Sherman's injuries. In particular, as soon as Dr. Silverman and his medical practice learned of the upgraded warnings via a letter from Sherman's counsel in October 2012, they immediately adopted a practice-wide policy counseling against prescribing metoclopramide for periods in excess of 12 weeks and requiring express informed patient consent. (CP 633, 825-27.)

These facts amply establish a genuine issue of material fact as to causation, so that the trial court's denial of summary judgment was proper. 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)).

because conflicts with Washington law adopting and refining the learned intermediary doctrine, and because it thereby exposes Washington's citizens to substantial risk of injury by depriving their prescribing physicians of critical drug-warning information. This Court should therefore grant review to correct these errors and provide needed clarity regarding application of the WPLA to the unique prescription-drug setting.

V. Argument: Why Review Should Be Accepted.

This Court should grant review of Division II's erroneous decision that drug manufacturers owe no duty to communicate drug-risk warnings to physicians under either or both of RAP 13.4(b)(1) and 13.4(b)(4). First, the court's holding that a drug manufacturer satisfies its duty under the WPLA, RCW § 7.72.030, by providing drug-risk warnings only on the package inserts that go to pharmacies and not to learned-intermediary physicians conflicts with this Court's decisions like *Terhune v. A. H. Robins Co.*, 90 Wn.2d 9, 14, 577 P.2d 975 (1978) which render the physician the sole source of drug-warning information to patients. The court's decision that drug manufacturers have no duty to inform prescribing physicians of drug warnings cannot be squared with the learned intermediary doctrine since it means that those physicians may never learn of a drug's known risks and therefore cannot adequately inform their patients. As such, review is necessary under RAP 13.4(b)(1) because Division II's decision is in conflict

with Supreme Court decisions establishing and refining the learned intermediary doctrine.

Second, review is also warranted under RAP 13.4(b)(4) because the issue presented calls for interpretation of the WPLA as applied to prescription drugs, a context that is uniquely distinct from other failure-to-warn-type product liability cases and of pervasive daily application throughout this state. Prescription drugs, unlike many other dangerous products, are not sold directly to consumers. The "sale" of a prescription drug begins when a physician, taking into account the patient's total health and needs, decides to issue a prescription. The patient then takes that prescription to a pharmacy for filling and consumes it in accordance with her physician's and pharmacist's instructions. As such, the warnings that may be provided "with the product" (*see* RCW § 7.72.030(b)) inherently will not reach the person – the learned-intermediary physician – who sets the sale process in motion. Moreover, prescriptions are often (as in Sherman's case) issued *in seriatim*, so that "sales" of the same product take place repeatedly over a period of time. The WPLA establishes different standards as to the adequacy of warnings, whether provided "with the product" (*see* RCW § 7.72.030(b)) or "after the product was manufactured" (*see* RCW § 7.72.030(c)), but it does not clarify whether one, the other, or both of these provisions govern prescription drugs. Given these unique

characteristics applicable to the sale of prescription drugs, and the pervasiveness with which such sales occur throughout the State, this Court should grant review to resolve this issue of substantial public interest regarding how the WPLA applies to prescription drugs.

A. The Court's Interpretation of RCW 7.72.030 Conflicts Directly with Established Washington Law Adopting the Learned Intermediary Doctrine.

The principal error in Part C of Division II's decision is that it leaves patients in Washington, like Diana Sherman, exposed to a grave risk of drug-induced injury by insulating drug-manufacturers from liability when they merely issue FDA-required warnings in "package inserts" that may or may not be distributed to patients by pharmacies and indisputably do not routinely reach learned-intermediary physicians. This holding conflicts with Washington common law, which is premised upon the physician's knowledge of all relevant drug information and risks. For a physician cannot and will not know of a drug's risks if the manufacturer, who possesses superior knowledge of them, does not provide warnings in ways that are reasonably calculated to reach them.

The learned intermediary doctrine in Washington dates back to at least 1978, when this Court adopted it as law and explained its rationale rooted in a practical appreciation of who will truly utilize the manufacturer's product warnings. *Terhune*, 90 Wn.2d at 14 . The central guiding premise

underlying this doctrine is that the physician, and the physician alone, is best positioned to know and understand a medical product's risks as applied to the patient. Because of this, the drug manufacturer, who may be the first to know of a drug's risks, *must inform the physician* of those risks, so that the physician may, in turn, inform the patient in the context of the doctor-patient relationship. *Id.*; *see also id.* at 17 ("It is our conclusion that the manufacturer of a product…fulfills its duty if it informs the physician of the dangers attendant upon its use…."). Indeed, the highlighted portion of the *Terhune* decision above states explicitly that the manufacturer's duty is not just to properly label its product, but *also* to ensure that the product "carries the necessary instructions and warnings to fully apprise the physician of the proper procedures for use and the dangers involved." *Id.* at 14. To be sufficient, then, instructions and warnings must be disseminated in such a way as to actually reach, *i.e.* "fully apprise" physicians. *Id.* Undoubtedly, a package insert directed to a pharmacy does not satisfy this standard.

This Court's subsequent decisions reflect reliance on the central premise described above, *i.e.* that the manufacturer must inform the physician of a drug's known risks so that the physician, as learned intermediary, may inform his patients. In *McKee v. American Home Products*, 113 Wn.2d 701 (1989), the plaintiff sought recovery for drug-induced debilitating injuries from the pharmacists who dispensed the drug

plegine to her pursuant to her doctor's prescriptions over a ten-year period, while the drug's label warned against use in excess of a few weeks. *Id.* at 703-04. Relying squarely on the central premise of the learned intermediary doctrine as established in *Terhune* – that the physician is the proper conduit for all drug-risk information relayed by the manufacturer to the patient – this Court held, *en banc*, that the pharmacist owed no duty to provide drug warnings to patients. *Id.* at 709. Critical to this holding is the manufacturer's duty to inform the physician, for the physician cannot know of a drug's risks unless the manufacturer informs him. *Id*. ("[W]e held in *Terhune*…that a prescription drug manufacturer's duty to warn of dangers associated with its product runs only to the physician….").

The Court again reaffirmed this principle just two years ago, in *Taylor v. Intuitive Surgical, Inc.*, 187 Wn.2d 743 (2017). The plaintiff in *Taylor* sought recovery under the WPLA from the manufacturer of an injurious medical device. The trial court refused to instruct the jury that the manufacturer owed a WPLA duty to warn the hospital, independent of its duty to warn the physician under the learned intermediary doctrine. *Id.* at 751-52. On review, the Court reversed, holding that the WPLA does impose on manufacturers a duty to inform hospitals, as purchasers of medical devices, of such devices' known risks. *Id.* at 753. Practically, hospitals need the information to properly certify physicians as competent in the use

of such devices. The Court based its holding on the text of the WPLA, which references warnings provided "with the product." *Id.* at 753-55 (citing RCW § 7.72.030(1). In so holding, the Court reiterated and reaffirmed the learned intermediary doctrine and the WPLA's requirement that *manufacturers inform physicians* of drug risks, since physicians are the sole source of prescription drug information relayed to patients. *Id.* at 757-58.

All of these relevant Washington Supreme Court cases rest upon the same critical underlying premise, *i.e.*, that a manufacturer owes a duty under the WPLA to inform physicians of a prescription drug's known risks, so that the physician, as the learned intermediary, may be sufficiently informed to relay those warnings, as appropriate, to patients. Division II's decision directly contradicts the central premise of these cases by holding that the package insert is sufficient to meet a manufacturer's duty to warn, while it is undisputed (or, at least a genuine question of fact) that physicians do not regularly receive package inserts, which are disseminated only with the drug itself at pharmacy locations geographically and associationally distinct from the physicians' medical offices. (*See* CP 549, 554-55 (testimony of Teva Pharmaceuticals USA via Rule 30(b)(6) deposition that Teva does not disseminate metoclopramide warnings to physicians but instead merely

includes them on package inserts directed only to "trade customers").[5] As such, Division II's decision creates a gaping loophole in Washington law that insulates manufacturers from liability when they fail to provide adequate warnings to physicians – under *Terhune*, patients are expected to get warnings from learned-intermediary physicians, and under *McKee*, patients will *not* receive warnings from pharmacists, but yet, the court of appeals held that a manufacturer satisfies its duty to warn by providing warning information solely on package inserts that do *not* go to physicians but instead are disseminiated only to pharmacies. This Court must review Division II's decision in order to correct this error and clarifty that drug manufacturerss' duty to warn is satisfied only by providing adequate warnings to learned-intermediary physicians.[6]

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[5] It is virtually never the case that physicians would have occasion to review labeling or other materials actually prepared by a generic manufacturer like Teva. Teva, as a generic manufacturer, does not engage in promotion or detailing of its products to physicians, and does not reproduce its labeling in the Physician's Desk Reference ("PDR"). Moreover, prescribing physicians typically are unaware of the identity of the manufacturer of generic substitute drugs dispensed to patients when they write a prescription for a brand name drug to be filled generically. (CP 879.)

[6] The Division II also relied on the text of the WPLA, which it misinterpreted to state that a manufacturer's duty is only to provide warnings "with the product." To the contrary, however, the statute's unequivocal requirement is that "adequate warnings" be "provided." RCW § 7.72.030(1). In an explanatory paragraph (b), the statute provides that, as to dangers known at the time of manufacture, a manufacturer has *not* provided adequate warnings *if* warnings were not provided "with the product" *and* two additional criteria are met: (1) the

B. This Petition Presents An Issue of Substantial Public Interest Regarding Interpretation and Application of the WPLA to the Sale of Prescription Drugs.

The conflict between Division II's decision and this Court's cases establishing and refining the learned intermediary doctrine alone necessitates this Court's review, but review is also warranted because this case presents an opportunity for the Supreme Court to provide critical clarity regarding the WPLA's application to the sale of prescription drugs. The sale of prescription drugs is a unique process, dissimilar in key aspects from the sale of other potentially unsafe products covered by the WPLA, in that a drug available only by prescription cannot be sold to a consumer without a physician first prescribing it. The sale therefore begins when the

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manufacturer's "warnings and instructions" (*i.e.*, those that were provided, albeit not "with the product") were inadequate given the likelihood and severity of the drug's harms, and (2) "the manufacturer could have provided the warnings and instructions which the claimant alleges would have been adequate." *Id.* The Court's decision interprets this provision to mean that, so long as a manufacturer provides warnings "with the product," it has fulfilled its duty to warn, regardless of what those warnings say, to whom they are directed, or whether they are in any other respect inadequate. This reading of the statute must be erroneous, though, because (a) the the statute refers only to warnings not provided with the product but does *not* state that a manufacturer's warnings are *per se* adequate if provided "with the product."; and (b) such an interpretation conflicts directly with the learned intermediary doctrine as described above, because it condones provision of warnings solely in a format not reasonably calculated to reach learned-intermediary physicians.

physician learns of a drug and then makes the decision, informed by his medical training and judgment, to prescribe it to a particular patient. At that point, the patient takes the prescription to a pharmacy for filling, at which point the product is "provided" to its ultimate consumer. Thereafter, the patient might be "provided" the product again, perhaps multiple times, pursuant to prescription refill orders or new prescriptions for the same drugs again issued by the physician.

The WPLA does not address this unique sale process. Under the WPLA, warning requirements fall in two categories – those provided "with the product" and those provided "after the product was manufactured." RCW § 7.72.030(1)(b), (c). A prescription drug could fall in either or both of these categories.

Considering these provisions in the context of Sherman's case illustrates the lack of clarity in how these provisions apply. On one hand, the drug packaging "provided with the [metoclopramide] product" when Sherman filled her prescriptions at the pharmacy contained whatever warnings the manufacturer was then providing, whether what was currently required by the FDA or not. Division II assumed that this provision governed prescription drugs, and held that whatever warnings were

provided "with the product" were therefore adequate.[7] But that is not the only plausible way to interpret the statute in this context, for the adequacy of the warnings could also be assessed under the standard applicable to those provided "after the product was manufactured." RCW § 7.72.030(1)(c). That provision goes on to contemplate that a manufacturer might learn, some time after a product is manufactured, that it is dangerous in ways that it did not previously know or understand. *Id.* In that situation, the manufacturer's duty is to act "as a reasonably prudent manufacturer would act," and, more specifically, to "exercise[] reasonable care to inform product users." *Id.*

In this case, all of the manufacturers of metoclopramide (both brand and generic) learned "after the product [was] manufactured" that it was more dangerous than they originally understood. The FDA required increasingly serious warnings as a result of this new information. The manufacturers, however, never exercised reasonable care to inform product "users" of those warnings – under the learned intermediary doctrine, the "user" must include the physician who prescribes it since the sale cannot occur without that occurring, but physicians were never informed.

[7] The problem with this interpretation, as explained above, is that those warnings did not ever reach the person making the decision that Sherman should purchase it.

This Court should grant review in order to clarify how the WPLA applies in this unique and pervasive context. Indeed, a thorough review of pertinent case law did not reveal any cases in which this Court interpreted and applied the WPLA duty to warn in the context of prescription drugs. Yet every day, throughout this state and beyond,[8] patients are filling prescriptions and consuming drugs that have the potential to cause them harm. Interpreting the WPLA warning provisions to require that manufacturers must inform learned-intermediary physicians of drug warnings best serves the purpose of the warning requirements and best protects drug consumers who rely heavily or exclusively on the informed judgment of their doctors.

VI. Conclusion.

This Court should grant review of Division II's decision because it conflicts directly with Washington's well-established learned intermediary

[8] The fact that this issue reaches well beyond this case is illustrated not only by the generalized frequency with which prescription drugs are dispensed, but also by the fact that, in the context of metoclopramide in particular, claims have been filed by thousands of other people who have been diagnosed with tardive dyskinesia and other neurologic disorders as a result of overexposure, where their physicians could not take the drug's warnings into account because those physicians never learned of them. Indeed, Teva and PLIVA have already cited Division II's decision in an attempt to influence other courts throughout the country to hold, as Division II did here, that a generic drug manufacturer owes no duty whatsoever to inform physicians of drug warnings. Pliva Motion for Summary Judgment in Zitney v Wyeth, et al. Pennsylvania Court of Common Pleas (APP 042).

doctrine, establishes untenable Washington law, and exposes the public to grave risk of drug injury. Upon review, this Court shold clarify that under Washington law, drug manufacturers owe a duty to inform learned-intermediary physicians of a drug's known risks so that those physicians can guide their patients in making informed decisions about the drug's use, and should reverse the decision of the intermediate court that summary judgment was warranted. This case should then be remanded for trial on the merits.

DATED this 1st day of July, 2019

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APPENDIX

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Division Two

April 30, 2019

IN THE COURT OF APPEALS OF THE STATE OF WASHINGTON

DIVISION II

DIANA SHERMAN and MARK SHERMAN,

Respondents,

v.

PFIZER, INC., WYETH LLC (formerly known as WYETH, INC); WYETH HOLDINGS CORPORATION; WYETH PHARMACEUTICALS INC., SCHWARZ PHARMA, INC.; UCB, INC; ALAVEN PHARMACEUTICAL LLC, QUALITEST PHARMACEUTICALS, INC., GENERICS BIDCO I, LLC, RANBAXY PHARMACEUTICALS, INC.; GASTROENTEROLOGY ASSOCIATES, PLLC., GRACE KIM, RPh, ROBERTA MATTHEWS, RPh, RITE AID CORPORATION,

Defendants,

BRUCE A. SILVERMAN, M.D.,

Respondent,

TEVA PHARMACEUTICALS, INC., PLIVA, INC., BARR LABORATORIES, INC.,

Appellants.

No. 50914-8-II

PUBLISHED OPINION

MAXA, C.J. – PLIVA, Inc., Teva Pharmaceuticals USA, Inc., and Barr Laboratories, Inc. (collectively Generic Defendants) appeal the trial court's denial of their summary judgment motion in a products liability lawsuit filed by Diana Sherman.

The Generic Defendants are manufacturers of metoclopramide, the generic version of the prescription drug Reglan. Sherman developed a movement disorder called tardive dyskinesia after taking metoclopramide for six years as prescribed by Dr. Bruce Silverman. She filed a lawsuit against the Generic Defendants, alleging that they had violated the Washington Product Liability Act (WPLA), chapter 7.72 RCW, by failing to provide adequate warnings about the risk of developing tardive dyskinesia associated with using metoclopramide.

Sherman's duty to warn claim against the Generic Defendants derives from federally approved changes to the Reglan label, also known as the "package insert," that in 2004 and 2009 strengthened the warnings about using metoclopramide. Sherman claims that the Generic Defendants violated their duty to warn in two ways. First, they failed to update their package inserts for generic metoclopramide to reflect the strengthened warnings on the revised Reglan labels. Second, they failed to communicate the strengthened warnings to Dr. Silverman and the physician community in general in other ways besides in their package inserts.

We hold that the trial court erred in denying the Generic Defendants' summary judgment motion regarding (1) Sherman's "failure to update" claim because Dr. Silverman's testimony that he did not read any package inserts precluded any genuine issue of fact as to whether the Generic Defendants' failure to update their metoclopramide warnings proximately caused her tardive dyskinesia; and (2) Sherman's "failure to communicate" claim because, under the facts of this case, the Generic Defendants had no duty under the WPLA to communicate warnings by means other than the package insert.[1]

[1] The Generic Defendants also argue that federal law preempts any state law claims for failing to provide the strengthened warnings. Because we reverse on other grounds, we do not address this argument.

Accordingly, we reverse the trial court's order denying the Generic Defendants' summary judgment motion and remand for the trial court to dismiss Sherman's claims against the Generic Defendants.

FACTS

Prescription for Metoclopramide

Metoclopramide is a prescription medication that is used for the treatment of gastroesophageal reflux. A known risk of using metoclopramide includes the development of tardive dyskinesia, a neurological disorder characterized by abnormal involuntary movements.

Sherman first saw Dr. Silverman in 2003 for severe digestive issues. After other treatments failed to relieve Sherman's symptoms, Dr. Silverman prescribed metoclopramide. While on metoclopramide, Sherman's digestive symptoms improved significantly. She stayed on metoclopramide from September 2004 to December 2010.

Dr. Silverman evaluated Sherman regularly while she was on metoclopramide and before 2010 did not see any indication that she was experiencing involuntary movements. However, in June 2010, Sherman began experiencing involuntary movements. In August 2011, she was diagnosed with tardive dyskinesia.

Package Insert Warnings

Beginning in 1985, the package insert for Reglan contained a warning stating that tardive dyskinesia may develop in patients treated with metoclopramide. The warning stated that the risk of developing the syndrome was "believed to increase with the duration of treatment and the total cumulative dose." Clerk's Papers (CP) at 715. The warning also stated that "[e]xtrapyramidal symptoms, manifested primarily as acute dystonic reactions, occur in approximately 1 in 500 patients" treated with metoclopramide. CP at 715. Under the dosage and

administration section, the package insert stated that "[t]herapy longer than 12 weeks has not been evaluated and cannot be recommended." CP at 716.

In 2004, the brand-name manufacturer revised the Reglan package insert. Both the indications and usage section and the dosage and administration section of the revised package insert contained a statement that therapy with metoclopramide "should not exceed 12 weeks in duration." CP at 766. There was no change to the reference to tardive dyskinesia in the warnings section.

In 2009, the Food and Drug Administration (FDA) required the brand-name manufacturer to add a "black box warning" to the Reglan package insert. CP at 84. The warning was placed at the top of the package insert and stated:

> 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.
>
> See WARNINGS.

CP at 503.

The warnings section of the revised package insert contained additional information about tardive dyskinesia, including that "one published study reported a TD [tardive dyskinesia] prevalence of 20% among patients treated for at least 12 weeks." CP at 507. The warning concluded, "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 TD." CP at 507.

Complaint

In 2013, Sherman filed a complaint against the Generic Defendants and others.[2] In her amended complaint, she asserted a WPLA claim against the Generic Defendants for failing to provide adequate warnings to doctors regarding the use of metoclopramide. Specifically, Sherman alleged that the Generic Defendants had breached their duty to provide adequate warnings by failing (1) to update their package inserts for metoclopramide to match the strengthened warnings added to the Reglan label in 2004 and 2009, and (2) to communicate the new warning information in the revised Reglan labels to doctors through other means.

In his deposition, Dr. Silverman stated that he was aware when he prescribed metoclopramide for Sherman that one of the potential risks was development of some sort of movement disorder. For any patient on metoclopramide, including Sherman, he would always watch for movement disorders. Dr. Silverman stated that he was not aware of any clinician who had actually observed tardive dyskinesia associated with using metoclopramide, but that at some point "word got around" that tardive dyskinesia was something for which doctors should be looking. CP at 192.

However, Dr. Silverman testified that he did not read package inserts and did not recall ever reading a package insert. He did not use package inserts to learn about medications. Specifically, Dr. Silverman testified that he had never read a package insert for Reglan or

[2] Sherman also named as defendants Dr. Silverman and his medical group, the brand-name manufacturers of Reglan, and the pharmacy and pharmacist who filled the prescription. Sherman apparently settled her claims with the brand-name manufacturers, and the trial court dismissed her claims against the pharmacy and pharmacist. The claims against Dr. Silverman and his medical group apparently are pending.

metoclopramide. He also did not recall ever seeing a "Dear Doctor" letter[3] from a drug manufacturer. CP at 178. He said that such letters might have been in a stack of mail he received every day that he never opened. But he generally did not learn new information about medications through the mail.

Regarding his treatment of Sherman, Dr. Silverman testified that he did not rely on any package insert for Reglan or for generic metoclopramide when deciding whether to initially prescribe metoclopramide and whether to continue prescribing metoclopramide. Similarly, he stated that any changes to the package inserts for metoclopramide did not impact his prescription decision because he did not look at them. Instead, he relied on his clinical training and experience, the experience of his colleagues and associates, and his mentors and people in the academic world who he respected.

The Generic Defendants filed a motion for summary judgment. In support, they relied on Dr. Silverman's deposition testimony to argue that any failure to warn could not be the proximate cause of Sherman's condition as a matter of law. The trial court denied the summary judgment motion.

The Generic Defendants filed a motion for discretionary review of the trial court's ruling. A commissioner of this court granted the motion. Ruling Granting Review, *Sherman v. PLIVA, Inc*., No. 50914-8-II (Wash. Ct. App. Feb. 28, 2018).[4]

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[3] A "Dear Doctor" letter is a communication drug manufacturers send to doctors providing additional information regarding medications they produce. *See PLIVA, Inc. v. Mensing*, 564 U.S. 604, 615, 131 S. Ct. 2567, 180 L. Ed. 2d 580 (2011); 21 C.F.R. 200.5.

[4] Sherman initially argues that we should hold that the commissioner erred in granting discretionary review under RAP 2.3(b)(1) because the trial court did not commit obvious error. However, to challenge the commissioner's ruling, Sherman was required to file a motion to modify that ruling under RAP 17.7(a). She failed to file a motion to modify. Therefore, we decline to consider this argument.

ANALYSIS

A. LEGAL PRINCIPLES

1. Summary Judgment Standard of Review

We review a trial court's decision on a summary judgment motion de novo. *Zonnebloem, LLC v. Blue Bay Holdings, LLC*, 200 Wn. App. 178, 182, 401 P.3d 468 (2017). We view all facts and reasonable inferences drawn from those facts in the light most favorable to the nonmoving party. *Id.* Summary judgment is appropriate if there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law. *Id.* A genuine issue of material fact exists if reasonable minds could disagree on the conclusion of a factual issue. *Id.* at 183.

The moving party bears the initial burden of proving that there is no genuine issue of material fact. *Id.* A defendant can move for summary judgment based on the contention that there is an absence of evidence to support the plaintiff's claim. *Id.* The burden then shifts to the plaintiff to present specific facts that rebut the defendant's contention and show a genuine issue of material fact. *Id.* Summary judgment is appropriate if a plaintiff fails to present sufficient evidence on all essential elements of the claim. *Clark County Fire Dist. No. 5 v. Bullivant Houser Bailey PC*, 180 Wn. App. 689, 699, 324 P.3d 743 (2014).

2. RCW 7.72.030 – Duty to Warn

Under the WPLA, a product manufacturer can be liable for the failure to provide adequate warnings regarding the product if that product caused harm to the plaintiff. *See O'Connell v. MacNeil Wash Sys. Ltd.*, 2 Wn. App. 2d 238, 246, 409 P.3d 1107 (2017). RCW 7.72.030(1) states:

> A product manufacturer is subject to liability to a claimant if the claimant's harm was proximately caused by the negligence of the manufacturer in that the product

> was . . . not reasonably safe because adequate warnings or instructions were not provided.

The WPLA's liability standards are derived from the *Restatement (Second) of Torts* §402A (Am. Law Inst. 1965). *Taylor v. Intuitive Surgical, Inc.*, 187 Wn.2d 743, 754, 389 P.3d 517 (2017).

Although RCW 7.72.030(1) expresses a negligence liability standard, the strict liability standard established in *Restatement* §402A apparently applies to failure to warn claims. *Taylor*, 187 Wn.2d at 760, 764. Comment k to §402A provides an exception to the application of strict liability for "[u]navoidably unsafe products," including prescription drugs. However, a product is "unavoidably unsafe" and the exception applies only when the product is "accompanied by adequate warnings." *Taylor*, 187 Wn.2d at 764.

3. Learned Intermediary Doctrine

In evaluating a prescription drug manufacturer's duty to provide adequate warnings under RCW 7.72.030(1), Washington courts apply the learned intermediary doctrine. *Taylor*, 187 Wn.2d at 757-58; *Terhune v. A. H. Robins Co.*, 90 Wn.2d 9, 13-14, 577 P.2d 975 (1978).

> Under the learned intermediary doctrine, manufacturers of medical products can satisfy their duty to warn patients of the risks of their products by providing those warnings to the doctors prescribing the products. The manufacturer's duty to provide warnings to patients transfers to the doctor, who is in a better position to communicate them to the patient.

Taylor, 187 Wn.2d at 757.

The Supreme Court in *Terhune* explained the rationale behind and effect of the learned intermediary doctrine in prescription drug cases:

> Where a product is available only on prescription or through the services of a physician, the physician acts as a "learned intermediary" between the manufacturer or seller and the patient. It is his duty to inform himself of the qualities and characteristics of those products which he prescribes for or administers to or uses on his patients, and to exercise an independent judgment, taking into account his knowledge of the patient as well as the product. The patient is expected to and, it can be presumed, does place primary reliance upon that judgment. The physician

> decides what facts should be told to the patient. Thus, if the product is properly labeled and carries the necessary instructions and warnings to fully apprise the physician of the proper procedures for use and the dangers involved, the manufacturer may reasonably assume that the physician will exercise the informed judgment thereby gained in conjunction with his own independent learning, in the best interest of the patient.

90 Wn.2d at 14.

Here, the Generic Defendants had no duty under the learned intermediary doctrine to directly warn patients like Sherman who were prescribed metoclopramide. Their duty was to provide adequate warnings directed to physicians through the package inserts required under federal law. *See McKee v. Am. Home Prods. Corp.* 113 Wn.2d 701, 718, 782 P.2d 1045 (1989).

B. DUTY TO UPDATE METOCLOPRAMIDE WARNINGS

Sherman alleges that the Generic Defendants breached their duty to warn by failing to update their package inserts to reflect the strengthened warnings included in the 2004 and 2009 revisions to the Reglan package inserts. The Generic Defendants argue that even if their package inserts were inadequate, the trial court erred in denying their summary judgment motion regarding the failure to update claim based on proximate cause because Dr. Silverman testified that he did not read any package inserts and did not consider package inserts in prescribing metoclopramide for Sherman. We agree with the Generic Defendants.

1. Proximate Cause

To establish proximate cause based on a manufacturer's failure to warn, the plaintiff must show that the failure to warn was both the cause in fact and the legal cause of the harm. *Hiner v. Bridgestone/Firestone, Inc.*, 138 Wn.2d 248, 256, 978 P.2d 505 (1999). Cause in fact refers to the actual connection between an act and an injury – whether, but for the act, the injury would not have occurred. *See Dunnington v. Virginia Mason Med. Ctr.*, 187 Wn.2d 629, 636, 389 P.3d 498 (2017). The Generic Defendants focus on the cause in fact prong.

2. *Douglas v. Bussabarger*

The Generic Defendants argue that summary judgment was appropriate regarding proximate cause here under *Douglas v. Bussabarger*, 73 Wn.2d 476, 438 P.2d 829 (1968). We agree.

In *Douglas*, the plaintiff was injured by the spinal block used to anesthetize her during an operation. *Id.* at 477. She sued both the doctor who administered the spinal block and the drug company that supplied the anesthetic. *Id.* The Supreme Court summarily held that any failure to warn by the drug manufacturer could not be the proximate cause of the plaintiff's harm. *Id.* at 477-78. The court's entire analysis was as follows:

> There is no substantial basis for appeal as to defendant-drug company. . . . The only question 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. However, even if we assume such labeling should have taken place, defendant-Dr. Bussabarger testified that *he relied on his own knowledge of anesthetics and, in fact, did not read the labeling which was on the container*. Thus, if defendant-drug company was negligent in not labeling its container so as to warn of dangers, this negligence was not a proximate cause of plaintiff's disability.

Id. at 478 (emphasis added).

The only reported Washington case that has cited *Douglas* regarding a drug company's duty to warn is *Hibbs v. Abbott Laboratories*, 62 Wn. App. 451, 814 P.2d 1186 (1991). In *Hibbs*, the court noted that in *Douglas* the doctor's testimony that he did not read the drug label allowed the Supreme Court to conclusively determine that the doctor would not have seen any warnings the drug company might have provided. *Hibbs*, 62 Wn. App. at 456-57. However, the court distinguished *Douglas* because the doctor in *Hibbs* "never said that he did not or would not have read the labeling. He simply explained that it was his own knowledge of the drug that persuaded him to prescribe it . . . , not the drug company's promotional literature." *Id.* at 457.

Sherman appears to question the holding in *Douglas*, citing a New Mexico case that distinguished *Douglas* as not well reasoned. *Richards v. Upjohn Co.*, 95 N.M. 675, 680, 625 P.2d 1192 (1980). However, in *Thom v. Bristol-Myers Squibb Co.*, the Tenth Circuit Court of Appeals stated, "The majority of courts that have examined the issue have held that when a physician fails to read or rely on a drug manufacturer's warnings, such failure constitutes the 'intervening, independent and sole proximate cause' of the plaintiff's injuries, *even where the drug manufacturer's warnings were* inadequate." 353 F.3d 848, 856 (10th Cir. 2003) (quoting *Formella v. Ciba-Geigy Corp*., 100 Mich. App. 649, 300 N.W.2d 356, 358-59 (1980). The court cited to *Douglas*, 73 Wn.2d 476, and other cases for this proposition.

In any event, *Douglas* is a Washington Supreme Court case that states a clear holding regarding proximate cause. We are required to follow this binding authority. *Sluman v. State*, 3 Wn. App. 2d 656, 696, 418 P.3d 125, *rev. denied* 192 Wn.2d 1005 (2018). As a result, *Douglas* provides the controlling law in this case.

3. Analysis

Here, Dr. Silverman testified unequivocally that (1) he did not read package inserts and did not recall ever reading a package insert, (2) he had never read a package insert for Reglan or metoclopramide, and (3) any changes to the package inserts for metoclopramide did not impact his prescription decision because he did not look at them. Sherman presented no evidence that would create a genuine issue of fact regarding whether Dr. Silverman ever read the package inserts for metoclopramide.

Based on these undisputed facts, *Douglas* controls. The Generic Defendants' alleged failure to update the package inserts cannot be the proximate cause of Sherman's condition as a

matter of law because even if they had updated the package inserts, Dr. Silverman would not have read them.

Because Dr. Silverman did not read package inserts, there is no genuine issue of fact regarding whether the Generic Defendants' alleged failure to update the warnings proximately caused her condition. Accordingly, we hold that the trial court erred in denying the Generic Defendants' summary judgment motion regarding Sherman's failure to update claim.

C. DUTY TO COMMUNICATE WARNINGS IN OTHER WAYS

Sherman alleges that the Generic Defendants breached their duty to warn by failing to communicate the risks of metoclopramide to Dr. Silverman and to the physician community in ways other than in the package insert. The Generic Defendants argue that the trial court erred in denying their summary judgment motion regarding this claim because they had no such "duty to communicate" under the WPLA. We agree with the Generic Defendants.[5]

1. Nature of Sherman's Claim

The exact nature of Sherman's claimed duty to communicate claim is unclear. Sherman states that "her claims are about Generic Defendants' failures to communicate to [Dr. Silverman], 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." Br. of Resp't at 20-21. She further states that "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." Br. of Resp't at 22.

[5] The Generic Defendants also argue that Sherman cannot show there is a genuine issue of fact as to whether the failure to communicate was a proximate cause of her condition. Because we hold that the Generic Defendants had no duty to communicate under the WPLA, we do not address proximate cause.

However, she does not specifically identify in her appellate brief the "other" type of communications that she believes the Generic Defendants were required to send. In another context, Sherman discusses Dear Doctor letters. She apparently contends that the Generic Defendants at least were required to send Dear Doctor letters to Dr. Silverman and to other doctors in the physician community.

In her complaint, Sherman alleged that the Generic Defendants had a duty to (1) communicate to doctors through such means as Dear Doctor letters and advertising in medical periodicals the new warning information in the revised Reglan labels, (2) disseminate information about the risks of metoclopramide throughout the medical community in the form of reprinted publications of peer-reviewed scientific research on metoclopramide use, and (3) sponsor independently produced educational programs for doctors about metoclopramide use. But other than the Dear Doctor letters, Sherman does not mention any of these other means of communication in her brief.

2. Scope of Duty to Warn

Regardless of the type of other communication that Sherman claims the Generic Defendants were required to make, the Generic Defendants argue that they had no duty under the WPLA to make *any* communications to doctors regarding warnings other than in the package insert. We agree under the fact of this case.

As noted above, RCW 7.72.030(1) addresses the liability of a product manufacturer for the failure to provide adequate warnings. That statute states:

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

> (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.

RCW 7.72.030(1) (emphasis added).

RCW 7.72.030(1)(b) expressly states that adequate warnings must be "provided with the product." The Supreme Court in *Taylor* also stated that "the WPLA requires that warnings be *provided with products*." 187 Wn.2d at 753 (emphasis added). For prescription drugs, the package inserts are provided with the product. *See McKee*, 113 Wn.2d at 718. Nothing in RCW 7.72.030(1)(b) requires product manufacturers to provide additional warnings beyond those that are provided with the product.

In addition, comment k to *Restatement* §402A states that unavoidably unsafe products must be "*accompanied by* proper directions and warning." (Emphasis added.) And the court in *Terhune* – which applied comment k – stated that that a drug manufacturer may rely on the doctor as a learned intermediary if "the product . . . *carries* the necessary instructions and warnings." 90 Wn.2d at 14 (emphasis added). *Restatement* §402A and *Terhune* predate the adoption of the WPLA. But as the Supreme Court noted in *Taylor*, the WPLA "closely mirrors" §402A. 187 Wn.2d at 754.

The Generic Defendants also cite to cases from other jurisdictions holding that a drug manufacturer's duty to warn is limited to providing a package insert that accompanies the product. *See Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1250 (11th Cir. 2013); *Metz v. Wyeth, LLC*, 872 F. Supp. 2d 1335, 1344-45 (M.D. Fla. 2012).

Sherman disagrees with the Generic Defendants' interpretation of RCW 7.72.030(1)(b) and their reliance on *Restatement* §402A. But she does not explain why the "provided with the

product" language in RCW 7.72.030(1)(b) should be disregarded.[6] And she cites no authority for the proposition that a prescription drug manufacturer has a duty to communicate the risks of the product in any manner other than through package inserts.

Sherman suggests that the Generic Defendants had a duty to communicate by means other than the package inserts under RCW 7.72.030(1)(c). This subsection states:

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

RCW 7.72.030(1)(c).

However, RCW 7.72.030(1)(c) applies when the product manufacturer learns *after the product was manufactured* (and presumably after adequate warnings were provided with the product) about a danger connected with the product. Here, Sherman does not argue that the Generic Defendants first learned about the need for strengthened warnings for metoclopramide after their generic metoclopramide was manufactured. Sherman claims that the Generic Defendants knew about the risk of tardive dyskinesia associated with long-term use of metoclopramide when the strengthened warnings were approved in 2004 and 2009 and failed to include those warnings with their product or otherwise.

[6] Sherman primarily argues, correctly, that RCW 7.72.030(1)(b) supports her claim that the Generic Defendants had a duty to *update* their package inserts because that claim involves warnings "provided with the product." But that argument is immaterial to her "duty to communicate" claim. And as discussed above, Sherman's duty to update claim fails on proximate cause grounds.

We conclude that a prescription drug manufacturer's duty under RCW 7.72.030(1)(b) is to provide adequate warnings with the product and that there is no duty under the WPLA to communicate such warnings to doctors in ways other than through package inserts. Further, under the facts of this case, the duty to warn under RCW 7.72.030(1)(c) is inapplicable. Accordingly, we hold that the trial court erred in denying the Generic Defendants' summary judgment motion regarding Sherman's duty to communicate claim.

CONCLUSION

We reverse the trial court's ruling denying the Generic Defendants' summary judgment motion, and we remand for the trial court to dismiss Sherman's claims against the Generic Defendants.

MAXA, C.J.

We concur:

WORSWICK, J.

LEE, J.

IN THE COURT OF APPEALS OF THE STATE OF WASHINGTON

DIVISION II

DIANA SHERMAN and MARK SHERMAN,

Respondents,

v.

PFIZER, INC., WYETH LLC (formerly known as WYETH, INC); WYETH HOLDINGS CORPORATION; WYETH PHARMACEUTICALS INC., SCHWARZ PHARMA, INC.; UCB, INC; ALAVEN PHARMACEUTICAL LLC, QUALITEST PHARMACEUTICALS, INC., GENERICS BIDCO I, LLC, RANBAXY PHARMACEUTICALS, INC.; GASTROENTEROLOGY ASSOCIATES, PLLC., GRACE KIM, RPh, ROBERTA MATTHEWS, RPh, RITE AID CORPORATION,

Defendants,

BRUCE A. SILVERMAN, M.D.,

Respondent,

TEVA PHARMACEUTICALS, INC., PLIVA, INC., BARR LABORATORIES, INC.,

Appellants.

No. 50914-8-II

ORDER DENYING MOTION FOR RECONSIDERATION

Respondent Diana Sherman moves for reconsideration of the court's April 30, 2019 opinion. Upon consideration, the court denies the motion. Accordingly, it is

SO ORDERED.

FOR THE COURT:

Maxa, C.J.

MAXA, C.J.

PHILADELPHIA COURT OF COMMON PLEAS
PETITION/MOTION COVER SHEET

FOR COURT USE ONLY	
ASSIGNED TO JUDGE:	ANSWER/RESPONSE DATE:
Do not send Judge courtesy copy of Petition/Motion/Answer/Response. Status may be obtained online at http://courts.phila.gov	

CONTROL NUMBER:

(RESPONDING PARTIES MUST INCLUDE THIS NUMBER ON ALL FILINGS)

February Term, 2011
Month *Year*

No. 4100

Jannine Zitney and Steve Zitney

vs.

Wyeth, LLC, et. al.

Name of Filing Party:
PLIVA, Inc.

(Check one) ☐ Plaintiff ☒ Defendant
(Check one) ☐ Movant ☐ Respondent

INDICATE NATURE OF DOCUMENT FILED:

☐ Petition *(Attach Rule to Show Cause)* ☒ Motion
☐ Answer to Petition ☐ Response to Motion

Has another petition/motion been decided in this case? ☒ Yes ☐ No
Is another petition/motion pending? ☒ Yes ☐ No
If the answer to either question is yes, you must identify the judge(s):
Judge Arnold New

TYPE OF PETITION/MOTION *(see list on reverse side)*: Motion for Summary Judgment

PETITION/MOTION CODE *(see list on reverse side)*: MTSJD

I. CASE PROGRAM

Is this case in the *(answer all questions)*:

A. COMMERCE PROGRAM
Name of Judicial Team Leader: _____
Applicable Petition/Motion Deadline: _____
Has deadline been previously extended by the Court?
☐ Yes ☐ No

B. DAY FORWARD/MAJOR JURY PROGRAM — Year ____
Name of Judicial Team Leader: Judge Arnold New
Applicable Petition/Motion Deadline: June 3, 2019
Has deadline been previously extended by the Court?
☒ Yes ☐ No

C. NON JURY PROGRAM
Date Listed: _____

D. ARBITRATION PROGRAM
Arbitration Date: _____

E. ARBITRATION APPEAL PROGRAM
Date Listed: _____

F. OTHER PROGRAM: Mass Tort
Date Listed: _____

II. PARTIES

(Name, address and ***telephone number*** of all counsel of record and unrepresented parties. Attach a stamped addressed envelope for each attorney of record and unrepresented party.)

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III. OTHER

XV - MT - Reglan

By filing this document and signing below, the moving party certifies that this motion, petition, answer or response along with all documents filed, will be served upon all counsel and unrepresented parties as required by rules of Court (see Pa.R.C.P. 206.6, Note to 208.2(a), and 440). Furthermore, moving party verifies that the answers made herein are true and correct and understands that sanctions may be imposed for inaccurate or incomplete answers.

(Attorney/Signature/Unrepresented Party) — 6/3/19 *(Date)* — Walter H. Swayze III *(Print Name)* — 59101 *(Attorney I.D. No.)*

This Petition, Motion and Answer or Response, if any, will be forwarded to the Court after the Answer/Response Date. No extension of the Answer/Response Date will be granted even if the parties so stipulate.

30-1061 (Rev. 7/04)

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JANNINE ZITNEY and STEVE ZITNEY, Plaintiffs, v. WYETH, LLC, et al., Defendants.	:	**PHILADELPHIA COURT OF COMMON PLEAS** **FEBRUARY TERM, 2011** **CASE NO. 4100**

DEFENDANT, PLIVA INC.'S
MOTION FOR SUMMARY JUDGMENT

Filing Date: June 3, 2019
Response Date: July 3, 2019
Reply Date: July 18, 2019

Control Number: _____

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JANNINE ZITNEY and STEVE ZITNEY, Plaintiffs, v. WYETH, LLC, et al., Defendants.	:	**PHILADELPHIA COURT OF COMMON PLEAS** **FEBRUARY TERM, 2011** **CASE NO. 4100**

ORDER

AND NOW, this _____ day of _____2019, upon consideration of defendant PLIVA, Inc.'s Motion for Summary Judgment, and the response of plaintiff, if any, it is **ORDERED** that the motion is **GRANTED,** and defendant PLIVA, Inc., is **DISMISSED** from the case **WITH PREJUDICE**.

By the Court:

_____
Arnold L. New, J.

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VIA ELECTRONIC FILING AND HAND DELIVERY

The Honorable Arnold L. New
Court of Common Pleas
Philadelphia County
Complex Litigation Center
City Hall, Room 622
Philadelphia, PA 19107

Re: ***Jannine Zitney, et al. vs. Wyeth, LLC, et al.***
Philadelphia County Court of Common Pleas Feb. Term 2011, Case No. 4100

Dear Judge New:

In accordance with the Case Management Order issued in this case, and Mass Tort Motion Procedure, please accept the following motion for summary judgment, filed by defendant PLIVA, Inc.

SUMMARY OF THE ARGUMENT

Based on statements plaintiffs made in papers filed in this Court, plaintiffs have made it clear that they are proceeding in this case on a limited claim based on a purported failure to communicate changes made to the label of the brand drug Reglan to Mrs. Zitney's prescribing physician, Dr. Karen Tobin, through a Dear Health Care Provider letter (also known as a Dear Doctor letter). Although plaintiffs' admissions were made in filings on motions filed by or against co-defendant, Teva Pharmaceuticals USA, Inc., there is no reason why plaintiffs' claims could or should be different against PLIVA. Nevertheless, because plaintiffs have included in their short-form complaint other Counts, PLIVA also has addressed those Counts in demonstrating why summary judgment for PLIVA is proper.

As discussed below there is no duty under Pennsylvania law to communicate as alleged by plaintiffs. Without a duty, there can be no breach entitling PLIVA to summary judgment on plaintiffs' negligence claim.

In addition, plaintiffs have not presented any evidence to establish PLIVA did not exercise reasonable care, another requirement of plaintiffs' negligence claim. The only evidence demonstrates that PLIVA complied with the applicable standard of care, again warranting entry of judgment in its favor.

In addition to the lack of duty and breach, plaintiffs have not produced evidence (including the necessary expert testimony) of any inadequacy in PLIVA's metoclopramide package insert. Aside from that, plaintiffs' attempt to fashion their claim as an adequacy attack runs them straight into preemption under *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011). Like in *Mensing*, an assertion that additional warnings are required by state law conflicts with federal law, preempting plaintiffs' claim.

Plaintiffs' claim that PLIVA should have sent a DHCP letter is preempted for additional reasons, as numerous courts have held. As explained below, PLIVA could not send out a DHCP letter about the Sentences when the Reglan brand manufacturer did not, and there is no dispute that did not occur.

Next, there is a total lack of evidence to establish proximate cause. Dr. Tobin never saw or relied on a PLIVA metoclopramide label when prescribing branded Reglan to plaintiff. As a result, any alleged inadequacy in PLIVA's metoclopramide warnings cannot be the proximate cause of plaintiffs' alleged injuries.

Dr. Tobin made a clinical decision to prescribe Reglan off-label[1] on an as needed, intermittent basis over a five-year period because Mrs. Zitney was not taking pills every day. As a result, Dr. Tobin believed the sentences added in 2004 to the INDICATIONS AND USAGE and DOSAGE AND ADMINISTRATION sections of the Reglan label ("**Therapy should not exceed 12 weeks in duration**" and "**Therapy with reglan® tablets should not exceed 12 weeks in duration**") (the "Sentences") were not applicable to plaintiff. A manufacturer's alleged failure to include a purported warning that does not apply to the plaintiff cannot be the proximate cause of plaintiff's injury. Therefore, any alleged failure by PLIVA to send a Dear Health Care Provider ("DHCP") letter about the Sentences or include the Sentences in its generic metoclopramide label cannot be the proximate cause of any injuries alleged by plaintiffs.

Plaintiffs also cannot prove proximate cause because the label for Reglan, the medication prescribed by Dr. Tobin, included the Sentences and the plaintiffs' allegations essentially are that the Reglan labeling was adequate. An alleged failure to provide a warning that was in the label of the drug which Dr. Tobin actually prescribed cannot be the proximate cause of any injury to plaintiff.

Finally, plaintiffs cannot establish proximate cause because they do not have evidence that the outcome would have differed if PLIVA had sent a DHCP letter to Dr. Tobin, or included the Sentences in its metoclopramide label.

Just as plaintiffs are unable to prove proximate cause, they also cannot establish that PLIVA's metoclopramide was the cause-in-fact of her alleged injuries.

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[1] "Off-label" refers to physicians' practice of prescribing a prescription drug to treat a condition for which FDA has not approved the drug. (*See* Deposition of Karen Tobin, M.D., pp. 73-75, Ex. 13.) Reglan and its generic equivalents are approved for the treatment of symptoms associated with acute and recurrent diabetic gastroparesis and for the short-term treatment of gastroesophageal reflux ("GERD") in adults who fail to respond to conventional therapy.

Plaintiffs' negligence per se count is not a distinct cause of action. Negligence per se is merely a shortcut, an evidentiary presumption that might supply the duty and breach elements of a negligence claim where there is a violation of a statute or ordinance. Here, however, there is neither an allegation nor proof of any violation of any statute or ordinance with respect to plaintiffs' assertion that PLIVA should have communicated warnings through a DHCP letter. Further, to the extent plaintiffs are attempting to pursue negligence per se based on the absence of the Sentences from the PLIVA metoclopramide label, they cannot establish the required elements of negligence per se, nor can they prove proximate causation for the same reasons they cannot prove proximate cause on their negligence claim. For all these reasons, that count must be dismissed.

Plaintiffs have disclaimed that they are pursuing a negligent design claim, as they must because it is not available to them under state law and it is preempted by federal law. Plaintiffs have not dismissed the claim, notwithstanding their disclaimer. Accordingly, summary judgment for PLIVA is required on that claim.

PLIVA is entitled to summary judgment on plaintiffs' non-negligence claims as well.

Plaintiffs' strict liability claims are barred under Pennsylvania law because plaintiffs allege injury from a prescription drug. Plaintiffs' fraud, misrepresentation and suppression claims are barred because they are not proper claims for personal injury allegedly resulting from a prescription drug, because there is no evidence of any representation by PLIVA to Mrs. Zitney or Dr. Tobin and because plaintiffs also cannot prove the required element of reliance. In fact, neither Mrs. Zitney nor Dr. Tobin had ever heard of PLIVA prior to this lawsuit.

Similarly, Pennsylvania does not recognize a cause of action for breach of implied warranty in prescription drug cases. Further, plaintiffs' implied and express warranty claims are

barred by the statute of limitations, plaintiffs have not identified any statement made by PLIVA that could be an express warranty, and plaintiffs' failure to give the required notice. Plaintiffs' breach of warranty claims should be dismissed with prejudice.

Plaintiffs' Unfair and Deceptive Trade Practices claim should be dismissed because the act upon which it is based is not applicable to personal injury claims made by a prescription drug user against a prescription drug manufacturer and plaintiffs cannot demonstrate any justifiable reliance by Mrs. Zitney upon PLIVA's conduct. Plaintiffs' unjust enrichment claim is barred by the statute of limitations, has no application to the prescription drug personal injury claim of plaintiffs, and, in any event, they cannot satisfy their burden of proof on that claim. Plaintiffs' civil conspiracy claim also fails because plaintiffs have no evidence that PLIVA combined or agreed with any other defendant drug manufacturer to not send a DHCP letter to Dr. Tobin, to any other physician, or to the "medical community" about the addition of the Sentences to the 2004 Reglan label. Plaintiffs' "Conscious or Negligent Misrepresentation Involving Physical Harm" Count contains only allegations directed at brand manufacturer defendants, which does not include PLIVA.

PLIVA is entitled to summary judgment on plaintiffs' claim that PLIVA's acts or omissions constitute gross negligence because there is no independent cause of action for gross negligence. Plaintiffs' loss of consortium claim is derivative of the previously discussed claims. Having shown those claims have no merit, the consortium claim fails as well. Plaintiffs' request for punitive damages is barred by applicable law. Finally, plaintiffs have not produced evidence to support a request for punitive damages.

In summary, due to a multitude of reasons, plaintiffs' claims against PLIVA fail and should be dismissed in their entirety.

STATEMENT OF THE QUESTIONS INVOLVED

Question 1: Is there a duty under Pennsylvania law to send DHCP letters directly to physicians to apprise them of a label change to another entity's product?

Proposed Answer: No

Question 2: Did PLIVA breach any duty under Pennsylvania law?

Proposed Answer: No

Question 3: Have plaintiffs produced evidence that PLIVA did not exercise reasonable care?

Proposed Answer: No

Question 4: Was PLIVA's metoclopramide label adequate as a matter of law?

Proposed Answer: Yes

Question 5: Is any claim based on an alleged inadequacy in PLIVA's metoclopramide package insert preempted?

Proposed Answer: Yes

Question 6: Is any claim based on an alleged failure by PLIVA to send a DHCP letter preempted?

Proposed Answer: Yes

Question 7: Have plaintiffs produced evidence to satisfy their burden of proving proximate cause?

Proposed Answer: No.

Question 8: Have plaintiffs produced evidence to satisfy their burden of proving cause in fact?

Proposed Answer: No.

Question 9: Do plaintiffs have a viable negligence per se claim?

Proposed Answer: No.

Question 10: Is PLIVA entitled to summary judgment on plaintiffs' negligent design claim?

Proposed Answer: Yes

Question 11: Is PLIVA entitled to summary judgment on plaintiffs' strict liability claim?

Proposed Answer: Yes

Question 12: Is PLIVA entitled to summary judgment on plaintiffs' fraud, misrepresentation and suppression claims?

Proposed Answer: Yes

Question 13: Is PLIVA entitled to summary judgment on plaintiffs' breach of express and implied warranty claim?

Proposed Answer: Yes

Question 14: Is PLIVA entitled to summary judgment on plaintiffs' Unfair and Deceptive Trade Practices claim?

Proposed Answer: Yes

Question 15: Is PLIVA entitled to summary judgment on plaintiffs' unjust enrichment and civil conspiracy claims?

Proposed Answer: Yes.

Question 16: Is PLIVA entitled to summary judgment on plaintiffs' "Conscious of Negligent Misrepresentation Involving Physical Harm" Count

Proposed Answer: Yes

Question 17: Have plaintiffs stated a viable claim for gross negligence/malice?

Proposed Answer: No.

Question 18: Is plaintiff's request for punitive damages barred?

Proposed Answer: Yes.

STATEMENT OF FACTS

A. PROCEDURAL HISTORY AND PLAINTIFFS' ALLEGATIONS

In 2009, plaintiffs from across the United States began filing personal injury actions related to their ingestion of the brand-name drug Reglan® and/or its generic bioequivalent, metoclopramide, in the Philadelphia Court of Common Pleas. The cases were coordinated under a mass tort program before Judge Sandra Mazer Moss. *In re Reglan/Metoclopramide Litigation*, January Term 2010, No. 01997 (the "Litigation"). In January 2010, in a case management order, Judge Moss ordered that plaintiffs file a "Master Long Form Complaint" that would supersede all prior individual complaints and state all potential claims of any plaintiff in the Litigation. The case management order also required that each plaintiff serve a Short Form Complaint ("SFC"), indicating the defendant(s) and the causes of action from among those pled in the Master Long-Form Complaint that he or she chose to pursue.

Plaintiffs collectively filed their Master Long-Form Complaint ("MLFC") on March 18, 2010, setting forth causes of action based on various theories of liability. (Ex. 1.) In the Litigation, plaintiffs' claims initially were based on allegations that both the labels of the brand-name drug Reglan and the generic versions understated the risk of developing tardive dyskinesia. But, after the United States Supreme Court issued its decision in *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011), *reh'g denied* 564 U.S. 1058 (Aug. 15, 2011), plaintiffs could no longer pursue those claims against the generic metoclopramide manufacturer defendants ("Generic Manufacturer Defendants"), and plaintiffs sought and obtained leave to file another amended complaint to assert new and novel theories, which gained the monikers "failure to

update" and "failure to communicate." Plaintiffs' Third Amended Master Long-Form Complaint ("TAMLFC")[2] was filed on August 1, 2011, in the Reglan mass tort docket. (Ex. 2.)

PLIVA and other Generic Manufacturer Defendants in the Litigation filed preliminary objections to the TAMLFC asserting that the claims of all plaintiffs in the Litigation against the Generic Manufacturer Defendants were preempted. Judge Moss overruled the preliminary objections holding that blanket preemption was premature absent a state-by-state analysis. *See In re Reglan/Metoclopramide Litigation*, 81 A.3d 80, 85 (Pa. Super. 2013). An appeal was taken. The Superior Court ruled that all pre-FDAAA (2007) failure-to-warn claims are preempted to the extent the label for a generic drug manufacturer's metoclopramide matched the label of the brand-name drug Reglan. *Id.*, 81 A.3d at 96. The remaining claims were left to be decided on a case-by-case basis. *Id.*

B. REGLAN'S APPROVAL AND THE CHANGES TO ITS PACKAGE INSERT

The brand-name drug Reglan, (chemical name metoclopramide), was approved on December 30, 1980.[3] Reglan was and is approved and "indicated" for the treatment of symptoms associated with acute and recurrent diabetic gastroparesis and for the short-term (4 to 12 weeks) treatment of gastroesophageal reflux ("GERD") in adults who fail to respond to conventional therapy. In the DOSAGE AND ADMINISTRATION section of the Reglan label, physicians are advised that Reglan is indicated for short-term treatment of diabetic gastroparesis: "Administer 10 mg of metoclopramide 30 minutes before each meal and at bedtime for two to eight weeks, depending upon response and the likelihood of continued well-being upon drug discontinuation."

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[3] *See* https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=017854.

Since at least 1984, the Reglan labeling has advised under its DOSAGE AND ADMINISTRATION section that "[t]herapy longer than 12 weeks has not been evaluated and cannot be recommended." (*See, e.g.*, 1989 Physician Desk Reference (PDR) Reglan label, p. 1704, Ex. 3.[4])

In March 1985, the Reglan label was updated to include in the "Warnings" section of the label a specific, detailed warning regarding the risk of developing tardive dyskinesia:

> ***Tardive Dyskinesia***: Tardive dyskinesia, a syndrome consisting of potentially irreversible, involuntary, dyskinetic movements may develop in patients treated with metoclopramide. Although the prevalence of the syndrome appears to be highest among the elderly, especially elderly women, it is impossible to predict which patients are likely to develop the syndrome. Both the risk of developing the syndrome and the likelihood that it will become irreversible are believed to increase with the duration of treatment and the total cumulative dose.
>
> Less commonly, the syndrome can develop after relatively brief treatment periods at low doses; in those cases, symptoms appear more likely to be reversible.

[4] Courts in Pennsylvania routinely take judicial notice of the authoritativeness and veracity of information found on FDA's website as well as information found in the Physician's Desk Reference (PDR). *See In re Egalet Corp. Sec. Litig*., 340 F. Supp. 3d 479, 497 (E.D. Pa. 2018) (noting that federal courts have taken "'judicial notice of the veracity of' FDA website documents") (citations omitted); *In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751, 755 n.2 (E.D. Pa. 2003) (taking judicial notice of information found on FDA's website); *Kielar v Salko*, No. 97CV6056, 2007 WL 4357099 at n.2 (Pa. Com. Pl. Jan. 29, 2007) (taking judicial notice of the PDR as an authoritative publication); *Carroll v. Ayallone*, 869 A.2d 522, 526 (Pa. Super. 2005) (noting that the "...the Physician's Desk Reference, [is] a recognized authority in the medical profession."), *reversed on other grounds*, 595 Pa. 676 (2007); *Trach v. Fellin*, 817 A.2d 1102, 1106-07 (Pa. Super. 2003) (observing that the PDR "is considered authoritative and is relied on regularly by physicians in prescribing drugs to patients."). Pennsylvania courts may rely on case law construing the Federal Rules of Evidence to the extent they do not contradict the Pennsylvania Rules of Evidence because the Pennsylvania Rules of Evidence closely follow their federal counterparts. *See Maley v. Shell W. Expl. & Prod., LP*, No. 874 MDA 2017, 2018 WL 6616855, *5 (Pa. Super. Dec. 18, 2018) (interpreting federal case law in regard to case involving application of Pa. R. Evid. 801); *NASDAQ OMX PHLX, Inc. v. PennMont Secs.*, 52 A.3d 296, 303 (Pa. Super. 2012) (noting that Pennsylvania state courts will follow federal case law whenever possible) (citations omitted). Pa. R. Evid. 201 is virtually identical to Fed. R. Evid. 201 and to the extent they are different is a matter of wording; there is no conflict between the two rules.

> There is no known treatment for established cases of tardive dyskinesia although the symptoms may remit, partially or completely, within several weeks-to-months after metoclopramide is withdrawn. Metoclopramide itself, however, may suppress (or partially suppress) the signs of tardive dyskinesia, thereby masking the underlying disease process. The effect of this symptomatic suppression on the long-term course of the syndrome is unknown. Therefore, the use of metoclopramide for the symptomatic control of tardive dyskinesia is not recommended.

Id.

In February 2004, the Reglan manufacturer submitted to FDA proposed changes to the Reglan package insert to reiterate the product was approved only for short-term use. The changes were the inclusion of the Sentences: "**The use of reglan® tablets is recommended for adults only. Therapy should not exceed 12 weeks in duration"** directly under the heading in the INDICATIONS AND USAGE section of the package insert and the sentence "**Therapy with reglan® tablets should not exceed 12 weeks in duration"** directly under the heading of the DOSAGE AND ADMINISTRATION section of the package insert (bolding in original). The 2004 changes, which did not add any new warnings about tardive dyskinesia, were approved by FDA on July 26, 2004. (FDA Letter to Donna K. Multhauf, Ex. 4.)

Reglan has never been approved by FDA for treatment of migraine associated symptoms.

C. PLIVA'S GENERIC METOCLOPRAMIDE

PLIVA's Abbreviated New Drug Application (ANDA) A71-250 for 10 mg metoclopramide tablets was approved on February 3, 1988.[5] At all times, PLIVA's label for its generic metoclopramide included the Tardive Dyskinesia warning described above. It also included the language described above regarding the short-term use of its generic

[5] *See* https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=071250.

metoclopramide for treatment of GERD and gastroparesis that had been in the INDICATIONS AND USAGE and DOSAGE AND ADMINISTRATION sections of the Reglan label since its approval in 1980 and the language in the DOSAGE AND ADMINISTRATION section that "[t]herapy longer than 12 weeks has not been evaluated and cannot be recommended." Between the February 3, 1988, approval and through March 2002, PLIVA made changes to the label for its 10 mg generic metoclopramide as instructed by FDA. At all times, PLIVA had in place proper procedures for monitoring changes to the labeling for Reglan, and PLIVA followed FDA's instructions for checking changes to the Reglan label and making changes to the label for its generic metoclopramide products. (Report of David Feigal, M.D., M.P.H., pp. 30-31, Ex. 6.)

D. THE ZITNEY PLAINTIFFS

On February 28, 2011, the Zitney plaintiffs commenced this individual lawsuit by filing their SFC.[6] (Ex. 7.) Plaintiffs named 50 entities as defendants, i.e., numerous brand-name and generic drug manufacturers or sellers, among others, as well as Mrs. Zitney's prescribing physician, Karen Tobin, M.D. Plaintiffs' SFC asserted that Dr. Tobin's prescribing of "metoclopramide to the plaintiff … for a period of time that deviated from the standard of care of a reasonably prudent physicians acting under the same or similar circumstances" "in excess of 12 weeks duration" caused her damages. (SFC, ¶¶9 D and E.) As to the other 50 entities, plaintiffs adopted and incorporated by reference 14 claims for relief from the MLFC "and as amended."

E. MRS. ZITNEY'S MEDICAL HISTORY AND USE OF METOCLOPRAMIDE

In this product liability action, plaintiffs allege Mrs. Zitney developed mild tardive dystonia and blepharospasm and tardive dyskinesia as a result of her use of metoclopramide.

[6]Plaintiffs reinstated their SFC on April 4, 2011; April 28, 2011; May 28, 2011; and August 26, 2011.

Plaintiff Jeannine Zitney was born in 1970. (Deposition of Jeannine Zitney, 2/14/19 ("Zitney Dep."), pp. 13-14, Ex. 10.) Mrs. Zitney has experienced numerous medical problems during her life, including chronic migraine headaches which began when she was 11 years old. (*Id.*, p. 89:6-16.) During a typical migraine, Mrs. Zitney experiences "horrible pain" often accompanied by vision issues, nausea, vomiting, sound sensitivity, and dizzy spells. (*Id.*, pp. 93:4-9; 71:11-23.) Her migraines varied; at times, they occurred once or twice a month, at other times a couple times a week, and might last a day or several days. (*Id.*, pp. 94:25-95:2.) She was granted disability in 2004 in part due to her migraines. (*Id.*, p. 50:11-16.) Plaintiff tried to return to work following her first pregnancy, but was unable to due to her migraines. (*Id*., pp. 55:22-56:9.)

Over the years, she has been treated with "countless medications" to alleviate not only the migraines, but also the effects of her migraines, such as nausea. (*Id*., pp. 95:7-10; 101:10-14.) Those medications include Migranal, Stadol, Imitrex, Propranolol, , Gabapentin, Topamax, Maxalt, Compazine, Fioricet, Zomig, Vicodin, Percocet, and Reglan. (*Id*., pp. 95:8-19; 147:9-14; 84:23-85:3; 86:3-13; 95:18-21; 100:10-11; 167:22-168:1; Centerville Clinic Records ("Centerville Rec."), 2ZITNEY000394, 000390-391, 0000388, Ex. 11.)

In addition to migraines, Mrs. Zitney had other medical conditions, including three types of breast cancer diagnosed in 2013. (Zitney Dep., pp. 76:21-25, 111:19-24.) Following a bilateral mastectomy in February 2013, she had radiation treatment. (*Id*., pp. 110:19-21; 114:3-7.) After her treatment Mrs. Zitney no longer has active cancer in her breasts, but continues to take daily medications and vitamins in response to her breast cancer as well as having regular oncology visits. (*Id*., pp. 77:1-12; 115:14-21, 116:1-5.) Mrs. Zitney also has had her gallbladder removed, a tonsillectomy, surgery on her knee, and abdominal hernia surgery. (*Id*., pp. 132:12-19; 133:15; 133:18-22.)

Mrs. Zitney admits to having allergic reactions to at least 21 different medications. (*Id*., p. 143:1-6; Uniontown Hospital records ("Uniontown Rec."), 3ZITNEY010360, Ex. 12.) One is to the drug Compazine, which she was prescribed for migraine symptoms. (Zitney Dep., pp. 149:23-150:3.) She also is allergic to avocadoes. (*Id*., p. 154:9-10.) Her reaction was so severe she almost died due to asphyxiation. (*Id*., pp. 154:19-155-4.)

Mrs. Zitney was prescribed Reglan off-label by her neurologist Karen Tobin, M.D., to take as needed to alleviate the nausea that accompanied plaintiff's migraine headaches. (Zitney Dep., p. 165:9-14; Tobin Dep., p. 90:19-22, Ex. 13.)

Mrs. Zitney's first documented Reglan use was an intravenous administration during a hospitalization for a migraine on October 25, 2004. (Uniontown Rec., 3ZITNEY000070, Ex. 12.) Earlier that year, she first saw neurologist Dr. Karen Tobin to treat her migraines and a pituitary microadenoma. (Tobin Dep., p. 101:9-17, Ex. 13.) Shortly thereafter, Dr. Tobin began writing prescriptions for Reglan to alleviate the effects of nausea caused by Mrs. Zitney's migraines. (Zitney Dep., pp. 165:12-14; 167:7-16; 170:6-8; 172:3-4.) The entire time Dr. Tobin prescribed Reglan for Mrs. Zitney, the prescriptions were for 10 mg, *as needed*. (*Id.*, pp. 171:25-172:7; Tobin Dep., pp. 114:11-115:8; 120:9-121:11.) Dr. Tobin told Mrs. Zitney that she should only take Reglan for severe migraines and only if her symptoms were severe enough to interfere with her ability to function. (Tobin Dep, pp. 114:11-22; 120:9-121:1.) Mrs. Zitney testified she did not take metoclopramide for every bout of nausea. (Zitney Dep., pp. 172:5-12; 172:21-173:7.) When she did take it, metoclopramide helped her nausea. (*Id*., p. 188:2-6.)

Mrs. Zitney received nine Reglan prescriptions sporadically during an approximate five-year period, from October 2004 through December 2009. (*Id*., p. 178:10-18; Rite Aid Records ("Rite Aid Recs."), ZITNEY PLA00014, 00039-43, Ex. 14.) Plaintiff's Reglan prescriptions

were filled with metoclopramide manufactured by three different companies: PLIVA, Inc. (4 prescriptions), Teva (4 prescriptions), and Ranbaxy (1 prescription). (*Id.*)[7] :

Date	Dosage	# of Tablets	Days	Manufacturer	Prescribing Physician
10/31/2004	10mg	30	7	PLIVA 50111	Karen Tobin
6/10/2005	10mg	60	30	PLIVA 50111	Karen Tobin
2/6/2006	10mg	30	10	PLIVA 50111	Karen Tobin
12/4/2006	10mg	30	10	PLIVA 50111	Karen Tobin
12/28/2007	10mg	30	10	Teva 00093	Karen Tobin
4/14/2008	10mg	50	16	Teva 00093	Karen Tobin
7/30/2008	10mg	30	10	Teva 00093	Karen Tobin
11/21/2008	10mg	30	10	Teva 00093	Karen Tobin
12/23/2009	10mg	40	13	Ranbaxy 63304	Karen Tobin

(Rite Aid Recs., ZITNEY PLA00014, 00039-43, Ex. 14.)

In June 2005, Mrs. Zitney was having only one headache per week and did not need to take Reglan with every headache. (Zitney Dep., p. 186:9-20.) As of January 2008, she had the same exact headache pattern and Reglan use as she did in June of 2005. (Centerville Rec., 2ZITNEY000375, Ex. 11.) As of April 2008, she was using Reglan ONLY once or twice a month to treat migraine-induced nausea. (Centerville Rec., 2ZITNEY000374.) On December 23, 2009, she told Dr. Tobin that "she ran out of ... Reglan some time ago." (Centerville Rec., 2ZITNEY000359.) Before her final Reglan prescription fill on December 23, 2009, her last

[7] PLIVA and the manufacturers of the brand-name drug Reglan with which plaintiff has settled, also were named as defendants; Ranbaxy was not named as a defendant.

Reglan prescription fill was over 13 months earlier, on November 21, 2008. (Rite Aid Recs., ZITNEY PLA00039, Ex. 14.)

When Mrs. Zitney was asked if she would have taken Reglan if advised by Dr. Tobin of certain information in the Reglan label prior to the addition of the Sentences, Mrs. Zitney, in each instance, answered no:

> Q. So if Dr. Tobin told you that therapy longer than 12 weeks has not been evaluated and cannot be recommended, would you have taken Reglan?
>
> A. I would say no.
>
> Q. Okay. If Dr. Tobin told you that tardive dyskinesia may develop in patients treated with Metoclopramide, would you have taken the medication?
>
> A. No.
>
> Q. If Dr. Tobin told you that tardive dyskinesia was a syndrome consisting of potentially irreversible dyskinetic movements, would you have taken the medication?
>
> A. No.
>
> Q. If Dr. Tobin told you that both the risk for developing tardive dyskinesia and the likelihood that it would become irreversible were believed to increase with the duration of treatment and the total cumulative dose, would you have taken the medication?
>
> A. No.
>
> Q. If Dr. Tobin told you that side effects of Reglan were involuntary movements of the eyes, face, limbs and muscle spasms, would you have taken Reglan?
>
> A. No.

(Zitney Dep, pp. 207:4-208:5.)

Mrs. Zitney never heard of PLIVA before filing her lawsuit, never saw any type of advertisement, and has no knowledge of ever speaking to anyone at PLIVA. (*Id.*, p. 214:3-25.)

In all her neurological examinations of Mrs. Zitney during multiple office visits, Dr. Tobin never witnessed any jaw movements, clenching, chewing, or grinding, no arm jerking, leg contractions, truncal pulling, foot twisting, or leg twisting. (*Id.*, pp. 188:17-189:14.) On December 23, 2009, Mrs. Zitney complained of an eye twitch, which improved with a Botox treatment. (*Id.*, pp. 162:8-163:11, 165:21-167:11; 169:1-11.) Dr. Tobin noted that Mrs. Zitney had mild hemifacial spasm during that visit and that her eye twitching was consistent with that condition. (*Id.*, p. 166:10-23; Centerville Rec., 2Zitney000359; Southwestern Pennsylvania Neurology Associates Records ("Southwestern Rec."), 9Zitney000022.) Hemifacial spasm occurs independent of any use of metoclopramide. (Report of John Wald, M.D. ("Wald Rpt."), p. 5, Ex. 15.) Dr. Tobin also noted that Mrs. Zitney's eye twitching can be brought on with stress and is a common complaint of many of her patients. (Tobin Dep., p. 163:3-23.)

Mrs. Zitney also complained of muscle spasms in her back. (*Id.*, pp. 168:20-24-171:4-11.) In fact, Mrs. Zitney presented on numerous occasions over the years with spasms of her back and spine muscles, specifically the trapezius and paraspinal muscles. Records indicate treatment for spasms of those muscles on November 19, 2009; March 17, 2010; March 26, 2010; June 28, 2010; September 22, 2010; August 8, 2011; December 10, 2012; December 12, 2013; June 22, 2016; and November 3, 2016. (Centerville Rec., 2ZITNEY000344, 000346, 000349, 000350, 000355; Uniontown Rec., 3ZITNEY000591-593, 007649-53, 007654-55, 007656-57; Southwestern Rec.), 9ZITNEY000006-10, Ex. 16.) Dr. Tobin testified that spasms of the trapezius muscles and paraspinal muscles are "very common" in individuals with migraine headaches. (Tobin Dep., pp. 181:23-182:4.)

At her visit on March 17, 2010, Dr. Tobin, reviewed an extensive EMG performed on Mrs. Zitney's left arm which revealed findings consistent with chronic left C6 and C7

radiculopathies. (Southwestern Rec., 9ZITNEY000028, Ex. 16.) Radiculopathies are associated with cervical and paraspinal spasms, and related shoulder movements, of the type Mrs. Zitney reportedly experienced. (Wald Rpt., p. 4.) Dr. Tobin agreed that the radiculopathies could be the cause of Mrs. Zitney's shoulder and arm symptoms. (Tobin Dep., p. 177:15-25.) Dr. Tobin recommended an MRI that revealed mild spondylotic changes and arthrosis at the C5-6 level and mild bilateral foraminal stenosis. (Centerville Rec., 2ZITNEY000346.) The MRI results confirmed the EMG findings. (Tobin Dep., pp. 196:19-197:9.) In addition, Dr. David Hinkle, another neurologist who examined Mrs. Zitney, told her that her shoulder and arm symptoms could be related to her radiculopathy. (Centerville Rec., 2ZITNEY000353.) As late as 2017, Mrs. Zitney's radiculopathies have resulted in medical treatment for dizziness, chest pain, and paresthesias. (Uniontown Rec., 3ZITNEY010346; 3ZITNEY010359-361.)

Mrs. Zitney last saw Dr. Tobin on November 3, 2016. (Tobin Dep., pp. 211:3-8, 213:25-214:2.)

F. PLAINTIFF'S PRESCRIBING PHYSICIAN

Dr. Tobin is a board-certified neurologist. (Tobin Dep., p. 27:6-11.) She considers staying abreast of the pharmaceuticals she prescribes her obligation as a physician. (*Id.*, pp. 56:13-58:12.) Toward that end, she obtains information relating to the drugs she prescribes from a variety of sources, including, *inter alia*, her medical training, medical journals, colleagues, neurology meetings, her own clinical experience, online data sources, product package inserts and pharmaceutical sales representatives, who she rates as "pretty low on the list." (*Id.*, pp. 45:23-52:19, 56:7-12; 63:25-65:9.) Dr. Tobin has signed up to receive notices from FDA, like safety alerts. (*Id.*, p. 50:1-8.) She reads notices she receives from FDA and recalls seeing public health advisories from FDA, but not for the drugs at issue. (*Id.*, pp. 75:20-76:13.)

Dr. Tobin does not recall ever receiving a Dear Health Care Professional letter from a generic company. (*Id.*, pp. 54:2-55:21.) She does not think it would be helpful if she received a notice from a branded company and also receive notices from generic drug companies. And, she does not expect to receive notices from generic drug companies, or otherwise communicate with generic drug companies. (*Id.*, pp. 55:22-56:4.) She does not expect to be detailed by a generic drug company. (*Id.*, p. 63:14-16.)

Dr. Tobin prescribes Reglan for some of her patients who suffer from migraines to alleviate the nausea that accompanies the headaches. (*Id.*, pp. 33:24-34:1, 89:14-90:11.) Dr. Tobin understands that her Reglan prescriptions for that purpose are an "off-label" use of the drug. (*Id.*, pp. 77:25-78:13.)

Dr. Tobin first learned about Reglan and that it was indicated to treat diabetic gastroparesis in the late 1980s while in medical school. (*Id.*, pp. 76:14-77:11.) From the time of her medical residency in the late 1980s, Dr. Tobin was aware of the possible risks associated with Reglan use, including involuntary movement disorders. (*Id.*, pp. 80:14-85:2.) Dr. Tobin's understanding was that extrapyramidal reactions, in particular tardive dyskinesia, from metoclopramide use was comparatively rare. (*Id.*, p. 219:13-17.) The patients she saw that developed extrapyramidal symptoms were "from using the medications on a daily basis." (*Id.*, p. 226:1-13 ("I mean, they were always from using the medications on a daily basis.").)

She also was aware that Reglan was not approved for use beyond 12 weeks and understood that to mean continuous days of therapy. (*Id.*, pp. 86:10-87:13, 227:19-228:1 (she interpreted the statement that "Therapy longer than 12 weeks has not been evaluated and cannot be recommended" as referring to daily use, as she did the sentence "Therapy should not exceed 12 weeks in duration).)

When Dr. Tobin prescribed Reglan to Mrs. Zitney, she made the medical determination that the benefits of taking the drug outweighed any risk; a determination she made based on her past education about Reglan and her clinical experience. (*Id.*, p. 91:3-13.) She did not believe the statements limiting use to 12 weeks applied to Mrs. Zitney because Mrs. Zitney was not supposed to take the product daily. (*Id.*, p. 228:1-7.) Finally, Dr. Tobin testified that if she had known about the Sentences, she still would have prescribed Reglan to Mrs. Zitney. (*Id.*, pp. 228:16-229:2.)

Dr. Tobin never heard of PLIVA, never reviewed any materials authored by PLIVA, never reviewed a PLIVA metoclopramide label, never saw any advertisements by PLIVA, never saw any document promoting metoclopramide for use longer than 12 weeks, did not rely on PLIVA's label in prescribing Reglan, and never had any relationship with PLIVA. (*Id.*, pp. 34:18-21, 35:4-23, 37:21-38:11.)

ARGUMENT

A. STANDARD FOR SUMMARY JUDGMENT

The standard for granting summary judgment is well settled. Pursuant to Pennsylvania Rule of Civil Procedure 1035.2, summary judgment must be granted:

> (1) Whenever there is no genuine issue of any material fact as to a necessary element of a cause of action or defense which could be established by additional discovery or expert testimony, or
>
> (2) If, after the completion of discovery relevant to the Motion, including the production of expert reports, an adverse party who will bear the burden of proof at trial has failed to produce evidence of facts essential to the cause of action or defense which, in a jury trial, would require the issues to be submitted to a jury.

Pa. R. Civ. P. 1035.2. Summary judgment is merited "in whole or in part" when "there is no genuine issue of any material fact as to a necessary element of the cause of action or defense,"

and the moving party is entitled to relief as a matter of law. Pa. R. Civ. P. 1035.2; *see also A.B. v. Ortho-McNeil-Janssen Pharms.*, No. 100100649, 2013 WL 2917651, *4 (Phila. Cty. Ct. Com. Pl. Apr. 5, 2013) (New, J.) (quoting *Bell v. Dean*, 5 A.3d 266, 268 (Pa. Super. 2010)).

Although "the court must examine the record in the light most favorable to the nonmoving party," if "the non-moving party bears the burden of proof on an issue, [she] may not merely rely on [her] pleadings or answers in order to survive summary judgment." *A.B.*, 2013 WL 2917651, at *4 (quoting *Bell*, 5 A.3d at 268) (internal quotation marks omitted). Moreover, the non-moving party's failure "to adduce sufficient evidence on an issue essential to [her] case on which [she] bears the burden of proof … establishes the entitlement of the moving party to judgment as a matter of law." *Id*. (quoting *Bell*, 5 A.3d at 268). *See also Zurich Am. Ins. Co. v. O'Hanlon*, 968 A.2d 765, 767-68 (Pa. Super. 2009).

B. PLAINTIFFS HAVE LIMITED THEIR CLAIMS AGAINST PLIVA TO AN ALLEGED FAILURE TO COMMUNICATE

Through admissions made in papers plaintiffs filed in this Court, they have made it clear that their claim against PLIVA is limited to an alleged failure to communicate the addition of the Sentences directly to Dr. Tobin, plaintiff's prescribing physician, by sending Dr. Tobin a Dear Healthcare Provider (DHCP) letter. (*See* Plaintiffs' Motion for Partial Summary Judgment, Ex. 9.) Although plaintiffs' admissions were made in filings on motions filed by or against co-defendant, Teva Pharmaceuticals USA, Inc., there is no reason why plaintiffs' claims should be different as to PLIVA. PLIVA's generic metoclopramide label did not include the Sentences about which plaintiffs contends a DHCP letter should have been sent to Dr. Tobin. But Teva's generic metoclopramide label did include the Sentences and plaintiffs have admitted that it is inconsequential to their claim because Dr. Tobin never saw Teva's label. The same is true of

PLIVA. Accordingly, just as with Teva, plaintiffs do not take issue with the content of the warnings in PLIVA's metoclopramide package insert, rather they take issue with PLIVA's alleged failure to provide those warnings to Mrs. Zitney's physicians. Plaintiffs have described that as the "the heart" of their claims.[8]

The Court and other litigants are entitled to rely on a party's representation to the Court. Under the doctrine of judicial estoppel, "a party to an action is estopped from assuming a position inconsistent with his or her assertion in a previous action, if his or her contention was successfully maintained." It "appl[ies] with equal if not greater force when a party switches positions within the same action." *See, e.g., Bienert v. Bienert*, 168 A.3d 248, 255 (Pa. Super. 2017) citing *Ligon v. Middletown Area School Dist.*, 584 A.2d 376, 380 (Pa. Commw. 1990).

Accordingly, any remaining claim which plaintiffs assert against PLIVA should be limited to a purported negligent failure-to-communicate theory. However, plaintiffs have not dismissed the other Counts they incorporated from the TAMLFC, and plaintiffs' negligence Count based on the absence of the Sentences from the label for PLIVA's generic metoclopramide technically remain. Consequently, PLIVA has moved for summary judgment on those Counts and briefed them below, in addition to briefing the dismissal of plaintiffs negligence claim based on the alleged failure of PLIVA to send a DHCP letter about the addition of the Sentences to the Reglan label.

C. PLAINTIFFS CANNOT SHOW A DUTY OR BREACH – ESSENTIAL ELEMENTS OF THEIR NEGLIGENCE CLAIM

1. Duties Regarding Prescription Pharmaceutical Products in Pennsylvania

[8] Plaintiffs also argued that a purported "duty to provide warnings directly to physicians is central to the Pennsylvania law on which plaintiff's claims rest." (*Id*., pp. 18-19.)

When the Pennsylvania Supreme Court first considered the potential liability of drug manufacturers for injuries caused by allegedly inadequate warnings accompanying prescription pharmaceuticals, it was mindful of the necessary interplay between physician, patient, and drug manufacturer. That interaction led the Court to adopt the learned intermediary doctrine. *See Incollingo v. Ewing*, 282 A.2d 206, 220 (Pa. 1971), *abrogated on other grounds by Kaczkowski .v Bolubasz*, 421 A.2d 1027 (Pa. 1980). Because prescription pharmaceuticals are available only through the prescription from a duly-licensed physician, the court held that a drug manufacturer's duty is to provide warnings to the prescribing physician. *Id.* at 220. The rule was formulated with reference to comment k to Section 402A of the Restatement (Second) of Torts, which provides that unavoidably unsafe products, such a prescription pharmaceuticals, that are properly prepared and accompanied by proper directions and warnings are not defective or unreasonably dangerous. *See Coyle v. Richardson-Merrell, Inc.*, 584 A.2d 1383, 1385 (Pa. 1991); *see also Makripodis v. Merrell-Dow Pharms., Inc.*, 523 A.2d 374, 377 (Pa. Super. 1987) ("Where a prescription drug is accompanied by proper warnings, the manufacturer 'is not strictly liable for unfortunate consequences attending the use of otherwise useful and desirable products which are attended with a known but apparently reasonable risk. Rather, such a manufacturer is liable only if he fails to exercise reasonable care to inform those for whose use the article is supplied of the facts which make it likely to be dangerous.' *Baldino v. Castagna*, 478 A.2d 807, 810 (Pa. 1984).") In short, in the case of prescription drugs, the warning required is not to the general public or to the consumer but rather to the prescribing doctor. *See Makripodis*, 523 A.2d at 377 (citing *Baldino*, 478 A.2d at 810; *Incollingo*, 282 A.2d at 220; *Leibowitz v. Ortho Pharm. Corp.*, 307 A.2d 449, 457 (Pa. Super. 1973)).

Along with the duty of a pharmaceutical manufacturer to provide warnings to prescribing physicians, the court recognized the physicians' duty:

> "[I]t is the duty of the prescribing physician to be fully aware of (1) the characteristics of the drug he is prescribing, (2) the amount of the drug which can be safely administered, and (3) the different medications the patient is taking. It is also the duty of the physician to advise the patient of any dangers or side effects associated with the use of the drug as well as how and when to take the drug. The warnings which must accompany such drugs are directed to the physician rather than to the patient-consumer as '[i]t is for the prescribing physician to use his independent medical judgment, taking into account the data supplied to him by the manufacturer, other medical literature, and any other source available to him, and weighing that knowledge against the personal medical history of his patient, whether to prescribe a given drug.' *Makripodis v. Merrell Dow Pharmaceuticals, Inc*., 361 Pa. Super. 589, 596-97, 523 A.2d 374, 378 (1987) *quoting Leibowitz v. Ortho Pharm. Corp.*, 224 Pa. Super. 418, 431, 307 A.2d 449, 457 (1973)."

Coyle, 584 A.2d at 1385-86.

2. There Is No Duty Under Pennsylvania Law for a Drug Manufacturer to Provide Warnings to Prescribing Physicians in some Manner Apart from the Package Insert Shipped with Its Prescription Drug Product

Plaintiffs' negligence claim is premised on a duty that does not exist; i.e., that PLIVA was required to send *all* physicians, including Mrs. Zitney's prescribing physician, a DHCP letter (also known as a Dear Doctor letter) about the 2004 label change. There are several problems with plaintiffs' attempt to impose liability here, not the least of which is that there is no legal duty, which is an initial element in any negligence cause of action. *See R.W. v. Manzek*, 888 A.2d 740, 746 (Pa. 2005). Moreover, a duty depends on the existence of a relationship that exists at the relevant time. *See Dumanski v. City of Erie*, 34 A.2d 508, 509 (Pa. 1943). Notably, plaintiffs identify neither a duty nor a relationship.

In essence, plaintiffs assert that PLIVA was not prohibited from providing warnings relating to the risks of long-term use of metoclopramide to learned intermediaries (physicians) through a DHCP letter and seek to transform that into a duty to warn that PLIVA breached. Yet,

the fact an action is not "prohibited" does not create a "duty" to act. There is absolutely no authority that PLIVA had a duty to send a DHCP letter to Dr. Tobin. Nor have plaintiffs provided evidence that PLIVA had any knowledge relating to Dr. Tobin's Reglan prescriptions in general, or Mrs. Zitney's specifically. Likewise, there is no evidence PLIVA knew or should have known Mrs. Zitney received any of PLIVA's metoclopramide when her Reglan prescriptions were filled. In reality, what plaintiffs are postulating is that like Teva PLIVA was required to alert the public at large that FDA had approved changes to the Reglan label in 2004. (*See, e.g.,* Plaintiffs' Motion for Partial Summary Judgment, p. 4, ("Teva did not communicate information in the updated label for metoclopramide to the general public or the healthcare community …."), Ex. 9.) But, the Pennsylvania Supreme Court unequivocally has held that there is no duty to warn the general public. Likewise, there is no authority to support the suggestion that some manner of disseminating information regarding the benefits and risks of a pharmaceutical product outside the product's FDA-approved package insert is required. Pennsylvania case law is replete that the duty is for warnings *to accompany* the product. *See, e.g., Coyle*, 584 A.2d at 1385-86; *Mazur v. Merck & Co.*, 964 F.2d 1348, 1356 (3d Cir. 1992); *Rowland v. Novartis Pharm. Corp.*, 9 F. Supp. 3d 553, 569 (W.D. Pa. 2014).

Indeed, that same assertion was outright rejected by the Court of Appeals of the State of Washington about one month ago. *See Sherman v. Pfizer, Inc.*, No. 50914-8-II, --- P.3d ---, 2019 WL 1923583 (April 30, 2019), *reconsideration denied* Order, May 31, 2019, Ex. 20. In *Sherman*, the same attorney who represents plaintiffs here argued that PLIVA had a duty to send a DHCP letter about the 2004 Reglan label update. The court disagreed. It held that PLIVA did not have a duty to "make any communication to doctors regarding warnings other than in the package insert." *Id.*, *7. Quoting the Washington Supreme Court, the *Sherman* Court reiterated

the rationale for the learned intermediary doctrine in prescription drug cases, which notably is identical to the rationale stated by Pennsylvania courts:

> Where a product is available only on prescription or through the services of a physician, the physician acts as a "learned intermediary" between the manufacturer or seller and the patient. It is his duty to inform himself of the qualities and characteristics of those products which he prescribes for or administers to or uses on his patients, and to exercise an independent judgment, taking into account his knowledge of the patient as well as the product. The patient is expected to and, it can be presumed, does place primary reliance upon that judgment. The physician decides what facts should be told to the patient. Thus, if the product is properly labeled and carries the necessary instructions and warnings to fully apprise the physician of the proper procedures for use and the dangers involved, the manufacturer may reasonably assume that the physician will exercise the informed judgment thereby gained in conjunction with his own independent learning, in the best interest of the patient.

Id., *4, *quoting Terhune v. A. H. Robins Co.*, 90 Wn. 2d 9, 14, 577 P.2d 975 (1978). Washington, like Pennsylvania, follows comment k to Section 402A of the Restatement (Second) of Torts. In holding that PLIVA did not have a duty to send a DHCP letter, the *Sherman* Court pointed to comment k which provides that unavoidably unsafe products must be "*accompanied by* proper directions and warning." *Sherman*, 2019 WL 1923583, *7 (emphasis in original). The court further explained that the "court in *Terhune* – which applied comment k – stated that that a drug manufacturer may rely on the doctor as a learned intermediary if 'the product ... carries the necessary instructions and warnings.' 90 Wn. 2d at 14 (emphasis added)." *Id.*

The *Sherman* Court also referenced language in the Washington Product Liability Act (WPLA), Rev. Code Wash. 7.72.030(1)(b), that "adequate warnings must be 'provided with the product"' and pointed out that "for prescription drugs, the package inserts are provided with the product." *Id.* That too is on point with Pennsylvania law because "the WPLA's liability standards are derived from" §402A and "the WPLA 'closely mirrors' §402A." *Id.*, *4, 7, *citing Taylor v. Intuitive Surgical, Inc.*, 187 Wn. 2d 743, 754, 389 P. 3d 517 (2017).

As the court in *Sherman* noted, its holding is consistent with other courts that have held that a drug manufacturer's duty to warn is limited to providing a package insert that accompanies the product. *Id.*, *7, *citing Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1250 (11th Cir. 2013); *Metz v. Wyeth, LLC*, 872 F. Supp. 2d 1335, 1344-45 (M.D. Fla. 2012).

In addition, it must be remembered that Dr. Tobin prescribed Reglan, not PLIVA's metoclopramide. There is no duty for one drug company to notify doctors (or anyone else) of another drug company's package inserts. *See Colacicco v. Apotex, Inc*., 432 F. Supp. 2d 514, 543 (E.D. Pa. 2006) (holding drug company does not owe duty regarding competitor's product), *aff'd*, 521 F.3d 253 (3d Cir. 2008) *vacated and remanded on other grounds*, 556 U.S. 1101 (2009); *In re Darvocet, Darvon, & Propoxyphene Prod. Liab. Litig.*, 756 F.3d 917, 951 (6th Cir. 2014) (same). Plaintiffs do not identify any legal authority otherwise.

Similarly, plaintiffs do not provide any support (in fact, they did not even allege, nor could they), that any relationship existed between PLIVA and Dr. Tobin that created a duty for PLIVA to communicate information. It is undisputed that PLIVA never had any relationship with Dr. Tobin, who prescribed Reglan. Absent such a relationship, PLIVA had no legal duty to notify Dr. Tobin of any revisions to the labeling. *See Dumanski*, 34 A.2d. at 509 (duty depends on existence of relationship); *Prohias v. Pfizer*, 490 F. Supp. 2d 1228, 1237-38 (S.D. Fla. 2007) (recognizing there is no duty to speak absent a relationship).

Finally, Pennsylvania law does not even support a suggestion that any drug company, much less a generic drug manufacturer, has an obligation to do more to disseminate drug warnings than distribute them, in accordance with uniform FDA and industry practice, via the product labeling. In sum, without a state-law duty, there can be no claim.

3. There Is No Evidence PLIVA Did Not Satisfy the Standard of Care

To prove their negligence claim, plaintiffs also must demonstrate that PLIVA did not satisfy the standard of care. A drug manufacturer's standard of care is that set out in §388 of the Restatement (Second) of Torts. Specifically, plaintiffs must provide admissible evidence that PLIVA did not act as a reasonable generic drug manufacturer. That burden includes demonstrating that PLIVA (1) knew or had reason to know that its metoclopramide is or is likely to be dangerous for the use for which it is supplied (to treat GERD or diabetic gastroparesis); (2) had no reason to believe that those for whose use the metoclopramide was supplied would realize its dangerous condition (allegedly to cause tardive dyskinesia when used on a continuous, daily basis for longer than 12 weeks); and (3) failed to exercise reasonable care to inform the prescribing physician of the product's dangerous condition or of the facts which make it likely to be dangerous. *See Incollingo*, 282 A.2d at 220 n.8 (holding standard in §388 Restatement (Second) of Torts applies to failure-to-warn claims involving pharmaceuticals); *Hahn v. Richter*, 673 A.2d 888, 891 (Pa. 1996) ("[W]here the adequacy of warnings associated with prescription drugs is at issue, the failure of the manufacturer to exercise reasonable care to warn of dangers, i.e., the manufacturer's negligence, is the only recognized basis of liability.").

There are several relevant facts to keep in mind. First, Mrs. Zitney did not use the product to treat those indications for which Reglan is approved. Rather, Dr. Tobin prescribed Reglan "off-label" to treat a condition for which Reglan is not approved. Plaintiffs have not provided any evidence that PLIVA knew or had reason to know of that off-label use. As a result, plaintiffs cannot establish the first prong necessary to demonstrate that PLIVA did not exercise reasonable care.

Second, Dr. Tobin was fully apprised of the potential risks of Reglan use alleged by plaintiffs—tardive dyskinesia. She testified she was aware at least since her residency of the

possibility to develop tardive dyskinesia when used on a continuous, daily basis for longer than 12 weeks. The fact that Dr. Tobin did not think that possibility applied to plaintiff's intermittent use for treatment of migraine symptoms is consistent with the fact that the intermittent use of Reglan (approximately 300 pills over a more than 5-year period covering 1928 days) is not associated with a risk of developing tardive dyskinesia.[9] Further, there is no evidence that PLIVA had any reason to know of Mrs. Zitney's off-label use of the product.

Third, it is undisputed that the Reglan label included all the warnings at the time Mrs. Zitney's Reglan prescription was filled with PLIVA's product. The determination of reasonable care requires an examination of the relevant circumstances. *See Martin v. Evans*, 711 A.2d 458, 461 (Pa. 1998). Here, that determination requires an examination of what is reasonable care for a generic drug manufacturer under the same circumstances. More specifically, plaintiffs must prove that PLIVA failed to exercise reasonable care by not sending a DHCP letter about the 2004 label change. And, consideration of whether PLIVA exercised reasonable care requires expert testimony. *See, e.g., In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 172, 191 (S.D.N.Y. 2009) ("lay jury cannot be expected to understand the complex regulatory framework that informs the standard of care in the pharmaceutical industry"). Plaintiffs have none.

In contrast, PLIVA disclosed two experts to testify about those matters. One is Dr. David Feigal, a physician and a regulatory and industry expert who worked at FDA for 13 years, including work with DHCP letters. Dr. Feigal also has worked in the pharmaceutical industry including as the Senior Vice President for Global Regulatory Affairs and Global Safety for Élan Pharmaceuticals and Vice President of Global Regulatory Affairs at Amgen, Inc. (Feigal Rpt., p.

[9] *See* Wald Rpt., p. 4. Ex. 3.

3, Ex. 6..) The second is Peter Lankau who has more than 40 years of experience in the pharmaceutical industry including extensive experience in commercial matters involving brand and generic drug products and the significant differences between the two. (Report of Peter Lankau, pp. 1, 5 ("Lankau Rpt."), Ex. 21.)

Dr. Feigal and Mr. Lankau make clear that reasonably careful generic drug manufacturers have not, cannot, and should not send out DHCP letters about label changes, and that PLIVA acted consistent with federal regulations and industry practice, and as a reasonably careful generic drug manufacturer in not sending out a DHCP letter about the 2004 label change. (Feigal Rpt., p. 29; Lankau Rpt., p. 13.) There are multiple reasons that is true:

- DHCP letters are a regulatory mechanism created by FDA consisting of letters that brand-name drug manufacturers (NDA holders) may send out in certain circumstances, usually to announce significant new safety finding resulting in labeling changes. (Feigal Rpt., p. 26.)
- A generic drug manufacturer (ANDA holder) does not have access to the communications between the NDA holder and FDA about any label changes, past or future, that may impact the decision of whether a DHCP letter is appropriate for a specific label change. (Feigal Rpt., p. 27.)
- Only the Office of New Drugs, which regulates NDA products, reviews DHCP letters "that concern information about a significant hazard to health and/or important changes to drug package labeling." The Office of New Drugs has a specific procedure (MAPP 6020.10) in place for DHCP letters. The Office of Generic Drugs, which regulates generic drugs like PLIVA's metoclopramide, does not have a process or the personnel or data to conduct that review. (Feigal Rpt., p. 27.)
- The purpose of a DHCP letter is to advise healthcare professionals about important new safety information. The Guidance for Dear Healthcare Provider letters issued by FDA in January 2014 confirmed FDA's view that DHCP letters are to be sent selectively so as to avoid dilution of their intended effect, and only for truly new information. *See Guidance for Industry and FDA Staff*, Dear Health Care Provider Letters: Improving Communication of Important Safety Information, Jan. 2014, Ex. 22; Feigal Rpt., p. 27.
- By the time a generic drug manufacturer could submit a label change to match the brand-name drug's label, the information is no longer new. The change to the brand-name drug's label may precede the approval date of that label by many

months and, in some cases, a year or more. (Feigal Rpt., p. 27.) The approval date of the brand-name drug's label is the earliest date on which the generic drug manufacturer could change its label to match. Further, even under plaintiffs' view that a generic drug manufacturer can send a DHCP letter when the brand-name drug manufacturer does not, a generic drug manufacturer could not do so until FDA approves the generic drug manufacturer's label, further prolonging the period between the "new" label information and when plaintiffs assert a generic drug manufacturer could send a DHCP letter. (Feigal Rpt., p. 32.)

- In terms of dilution, FDA has estimated that less than 30 DHCP letters are sent each year across all products, a small number compared to the total number of labeling changes. Generic drug manufacturers do not have the data to determine when a DHCP letter should be sent and to which healthcare professionals. (Feigal Rpt., p. 28). Under plaintiff's theory, at a minimum, each generic drug manufacturer would have to send out a DHCP letter for every label change. Dr. Feigal has researched and analyzed the number of NDA label changes approved by FDA, including the years 2004 and 2005. Even if there were just three generic drug manufacturers for each drug for which there was a label change, and each sent a DHCP letter for each change, the number of DHCP letters sent to physicians would have been over 1500 for those two years alone. And, that is assuming the brand-name drug manufacturer did not send a DHCP letter. Not only would that be inconsistent with the selective purpose of the DHCP letters, but also it would create a cacophony of labeling messages, potentially conflicting, from the multiple manufacturers. (Feigal Rpt., pp. 28-29.)

- When there are significant changes to package inserts, FDA widely disseminates the information by, *inter alia*, issuing Safety Alerts and press releases, requesting a DHCP letter from the NDA holder, utilizing its MedWatch Partners program, or other measures. None of those available mechanisms were used by FDA for the 2004 Reglan label change, though they were available. (Feigal Rpt., p. 29.)

- The infrastructure and customer base for generic drug manufacturers and brand drug manufacturers are very different because of the very different roles they play. Generic drug manufacturers do not have the infrastructure or processes in place to determine if a DHCP letter is appropriate nor do they have the data or the relationships with FDA or physicians with respect to a generic product like metoclopramide to make that determination. (Feigal Rpt., pp. 27-28; Lankau Rpt., pp. 10-12.)

- Generic drug manufacturers do not have sales representatives to visit doctors about generic drug products like metoclopramide. They do not have relationships with the doctors who may prescribe Reglan that are filled at the pharmacy with generic metoclopramide. The customers for generic drug manufacturers for drugs like metoclopramide are a relatively small number of trade customers including wholesalers, distributors, drug store chains, and group purchasing organizations. (Lankau Rpt., pp. 11-12.) "The small number of customers are extremely savvy, and purchase products through aggressive negotiation based on specific contract

terms, scale, relationships, bundles of products, and ultimately, the best price." (Lankau Rpt., p. 11)

- There is no mechanism for a generic drug manufacturer to be alerted whether the brand-name drug product manufacturer did or did not send out a DHCP letter for a label change. The generic drug manufacturer also would have no information why a brand product manufacturer might choose not to send out a DHCP letter, whether it ever considered a letter, whether a DHCP letter was discussed with FDA, or whether FDA vetoed a DHCP letter. (Feigal Rpt., pp. 26-27; Lankau Rpt., p. 12.)
- Over the course of their combined 70-plus years of experience with FDA and the pharmaceutical industry, Dr. Feigal and Mr. Lankau have never heard of a generic drug manufacturer sending out a DHCP letter about a change to the label of its generic product to match the label of the branded product or the change to the label of that brand-name product (Feigal Rpt., pp. 26, 28-29; Lankau Rpt., p. 13.)

PLIVA's evidence negates an underlying assumption in plaintiffs' claim – that the circumstances of the brand-name drug manufacturer and a generic drug manufacturer like PLIVA are the same, including with respect to DHCP letters. But that assumption is wrong. The differences have been described by courts, which recognize that unlike brand-name drug manufacturers who may do so, generic drug manufacturers do not promote or advertise their generic medications to doctors or consumers, nor do they employ sales representatives to detail physicians about their generic pharmaceutical drugs. *See, e.g., New York v. Actavis, PLC*, 2014 WL 7015198, *27 (S.D.N.Y. Dec. 11, 2014), *aff'd sub nom. N.Y. ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638 (2d Cir. 2015), *cert. denied sub nom. Allergan PLC v. N.Y. ex. rel. Schneiderman*, 136 S. Ct. 581 (2015). The generic version(s) of a medication available at a given pharmacy for dispensation to patients is a result of a contract, or series of contracts, among generic drug manufacturers, distributors and/or wholesalers and pharmacies. Accordingly, generic products are not marketed to prescribers, and in fact, marketing to prescribing doctors would be contrary to the generic business model. *See Actavis, PLC*, 2014 WL 7015198, *27. "Generics compete on price and avoid marketing to physicians because the costs of such

marketing severely impact their ability to offer the significantly lower prices upon which they compete." *Id.* Further, "because the generic [firm] promoting the product would have no way to ensure that its generic product, rather than an AB-rated generic made by one of its competitors, would be substituted for the brand by pharmacists, a substantial investment in marketing a generic product to physicians would not make sense as a practical matter." *Id.* (citations omitted).

Plaintiffs also rely on another premise that is contrary to Pennsylvania law; specifically, that PLIVA should have assumed that doctors prescribing Reglan were not reading the Reglan labels, requiring PLIVA to send DHCP letters with its metoclopramide labels to those doctors. Pennsylvania law says exactly the opposite: It is presumed that doctors prescribing Reglan read and heed the warnings in the Reglan label. *See, e.g.*, *Hahn*, 673 A.2d at 890 ("it can be assumed that where warnings are given they will be heeded"); *Baldino*, 478 A.2d at 811 (presumption that doctors will read and heed warnings in package insert). Therefore, and contrary to plaintiffs' premise, under Pennsylvania law, a reasonably careful generic drug manufacturer may presume doctors were reading the Reglan package insert.

In like vein, plaintiffs do not have evidence that PLIVA did not exercise reasonable care with respect to the updating of the label for its generic metoclopramide. Lack of reasonable care cannot be presumed based simply on the fact that PLIVA did not update its label to include the Sentences. *Martin*, 711 A.2d at 461. Plaintiffs bear the burden of proving lack of reasonable care. *Id.*

As noted above, plaintiffs did not name an expert to provide any opinions relative to PLIVA's reasonable care. That includes PLIVA's reasonable care relative to the 2004 addition of the Sentences to the Reglan label. Dr. David Feigal, PLIVA's regulatory and industry expert,

analyzed the history of the Office of Generic Drugs (OGD) of FDA and its instructions to ANDA holders for label changes to match the brand drug (RLD) label. (*See* Feigal Rpt., pp. 19-26.) He also analyzed the history of PLIVA's other metoclopramide label change submissions to FDA, and the history of other generic drug manufacturers relative to the 2004 label change. (*Id*., pp 30-31.) Based on those analyses, his knowledge of the applicable regulations, his experience with FDA, and his experience with industry, Dr. Feigal opined that PLIVA "had in place proper procedures for monitoring changes to the labeling for Reglan, and PLIVA followed FDA's instructions for checking changes to the Reglan label and making changes to the label for its generic metoclopramide products." (*Id*., p. 30.) Dr. Feigal also opined that PLIVA acted, at all times, as a reasonably prudent manufacturer of generic metoclopramide tablets in monitoring FDA's website for approved label changes. (*Id*., pp. 30-31.) Among other bases for his opinions, Dr. Feigal reported the following:

- Starting in 2000 and continuing through 2004, OGD repeatedly changed links, webpages and instructions for generic drug manufacturers relative to monitoring changes to labels for brand products. At times, OGD's instructions directed generic drug manufacturers to two different options for monitoring, which had different information. Approved labeling for the brand product was not reliably available through the webpages identified by the OGD. (Feigal Rpt., pp. 20-21___.)
- There were changes to the Reglan label in May 2001. FDA approved changes on November 7, 2001, but the way in which FDA handled the approval created a question as to what was the approved label that should be followed by generic drug manufacturers. OGD also posted the wrong Reglan label at the webpage it instructed generic drug manufacturers to check and on January 31, 2002, had to contact generic drug manufacturers to alert them to the fact that the posted Reglan label was wrong and fax them the correct label. Nevertheless, the wrong label remained posted at the OGD website. (*Id*., pp. 25-26.)
- On April 22, 2003, FDA approved changes to the Reglan labeling. The approved Reglan label incorporating the 2003 changes was not found at the place where OGD instructed generic drug manufacturers to look. At least three generic drug manufacturers in 2003 (Actavis/Purepac, PLIVA and Teva), all of which were

experienced with metoclopramide and other generic products, did not make the 2003 label changes in 2003, and it is likely a fourth (Mutual) did not, because the approved Reglan label was never posted where OGD instructed generic drug manufacturers to look. It is unknown when approved Reglan label containing the Sentences became available at the webpage where OGD instructed generic drug manufacturers to look for approved changes to the Reglan label. It was not before November 12, 2004. (*Id*., pp. 22-23, 31.)

- Three metoclopramide generic drug manufacturers (Mutual, PLIVA, and Teva) did not add the Sentences to their labels in 2004. Teva submitted a revised label to OGD in June 2005 and Mutual submitted revised label to OGD in January 2006. The only generic drug manufacturer that submitted its revised labeling to match the Reglan label in 2004 was Actavis, which submitted revised labeling on November 12, 2004. However, Actavis did not find the Reglan label at the place where OGD instructed generic drug manufacturers to look for updated FDA-approved Reglan labels. (*Id*., pp. 24-25.)

- The implementation of web-based systems for managing documents and other information was a new challenge for FDA and there was trial and error involved. Any assessment of ANDA labeling must include the regulatory environment in which generic drug companies like PLIVA and Teva operated, particularly in 2003 and 2004. Any evaluation of their conduct should be made in the context of the OGD instructions they received about monitoring for label changes, the limitations of the FDA data sources at that time, and what posted RLD labeling an ANDA holder was permitted to use for purposes of updating its labeling. (*Id*., p. 26.)

- From its approval on February 3, 1988, through March 2002, PLIVA made all changes to the label for its 10 mg generic metoclopramide as instructed by FDA. That included two label changes after the FDA webpages were launched, demonstrating that PLIVA was checking for label changes as instructed by the OGD, and making those changes. (*Id*., p. 30.)

- Before and after July 26, 2004 (when FDA approved the addition of the Sentences to the Reglan label), PLIVA submitted annual reports to FDA. In those annual reports, PLIVA reported about label changes it had made and provided copies of the current labeling to FDA. There had been situations where after receipt of an annual report, FDA communicated with PLIVA about label issues. There were no communications of that kind about the 2004 changes to the Reglan label and FDA never advised PLIVA that it had failed to make the changes. (*Id*., p. 31.)

In short, plaintiffs have no evidence that PLIVA did not exercise reasonable care, as they are required to present to prove their negligence claim. In fact, the only evidence demonstrates

that PLIVA satisfied the applicable standard of care. Summary judgment is proper for PLIVA because plaintiffs cannot prove that required element of their claim.

D. ANY CLAIM OF INADEQUACY IS BARRED UNDER STATE AND FEDERAL LAW

In addition to the lack of duty and breach, there is no evidence of any inadequacy in PLIVA's metoclopramide package insert. Nor is there authority to support an argument that the determination of the adequacy of prescription drug warnings under Pennsylvania law involves considerations other than the content of the warning.

Initially, it is worth noting that PLIVA's warnings (even without the Sentences) were adequate as a matter of law because (1) they warn of the exact injury of which plaintiffs complain, *see Demmler v. SmithKline Beecham Corp.*, 671 A.2d 1151, 1155 (Pa. Super. 1996); and (2) they were adequate as to Mrs. Zitney who testified she would not have taken the product if her physician had apprised her of other information included in the package insert (*see* Zitney Dep., p. 207:4-8; Tobin Dep., p. 121:12-16).

Moreover, Pennsylvania law is clear that plaintiffs are required to submit expert testimony to prove any alleged inadequacy in a prescription drug warning. *See Demmler*, 671 A.2d at 1154 (citing *Dion v. Graduate Hosp. of Univ. of Pa.*, 520 A.2d 876, 879 (Pa. Super. 1987) (noting expert medical testimony required to determine whether drug manufacturer's warning is adequate because prescription drugs are complex medicines, esoteric in formula and varied in effect). That requirement flows from a recognition that the issues about prescription drug warnings are not within the ken of the lay juror. Thus, any assertion by plaintiffs that PLIVA was required to send a DHCP letter about the 2004 label change, or that PLIVA's label without the Sentences inadequately warned, must be supported by expert testimony. Plaintiffs do not have that testimony.

Plaintiffs have named one expert – Vernon Neppe M.D., Ph.D. The only opinion Dr. Neppe has to offer is that Mrs. Zitney "has tardive dystonia and blepharospasms and also tardive dyskinesia as a result of her long-term intermittent use of metoclopramide." (*See* Dr. Neppe's report, p. 1, Ex. D to Plaintiffs' motion for partial summary judgment.)[10] Critically, Dr. Neppe does not attempt to offer any admissible opinion (nor could he) about the adequacy of PLIVA's generic metoclopramide package insert. Consequently, plaintiffs cannot prove the warnings were inadequate and for that reason, in addition to the others, PLIVA is entitled to summary judgment.

Moreover, plaintiffs' attempt to fashion their claim as an adequacy attack runs them headlong into another bar to their claim—preemption. The plaintiffs in *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 612 (2011), alleged that the generic drug manufacturer's metoclopramide package inserts (including PLIVA's) did not adequately warn under state law standards, just as plaintiffs assert here, that additional warnings, in the form of additional communication, were required to meet the adequacy requirements of state law. The Court held that federal law preempts a state-law claim that seeks to require a generic drug manufacturer to provide different labeling (here a DHCP letter) than the brand-name drug manufacturer to satisfy state-law adequacy. *Id*. at 625. That holding applies here.

E. PLIVA Is Entitled to Summary Judgment on All Plaintiffs' Claims Because Plaintiff's Alleged Injuries Were Not Proximately Caused By Any Alleged Inadequacy in the PLIVA Metoclopramide Package Insert

1. Plaintiff's Physician Did Not Read or Rely on PLIVA's Package Insert in Prescribing Reglan for Plaintiff

[10] Defendants are filing their motion to preclude Dr. Neppe from testifying, concurrently with their summary judgment motions.

PLIVA is entitled to judgment as a matter of law because any alleged inadequacy in PLIVA's warnings cannot be the proximate cause of plaintiffs' injuries where plaintiff's prescribing physician, Dr. Tobin, never saw or relied on a PLIVA metoclopramide label when prescribing branded Reglan for plaintiff or at any time thereafter.[11] (*See generally,* Tobin Dep. 34:18-21, 35:4-23, 37:21-38:11.) Indeed, Dr. Tobin never heard of PLIVA, Inc., never reviewed any materials authored by PLIVA, never reviewed a PLIVA metoclopramide label, never saw any advertisements by PLIVA, never saw any document promoting metoclopramide for use longer than 12 weeks, did not rely on PLIVA's label in prescribing Reglan, and never had any relationship with PLIVA. (*Id*., pp. 34:18-21, 35:4-23, 37:21-38:11.) The law requires that "there must be some reasonable connection between the act or omission of the defendant and the injury suffered by the plaintiff." *Burnside v. Abbott Labs.*, 505 A.2d 973, 978 (Pa. Super. 1985).

Pennsylvania applies the learned intermediary doctrine, under which a prescription drug manufacturer's duty to warn is satisfied by warning the prescribing physician rather than the patient who uses the drug. *See Incollingo*, 282 A.2d 206. "In the event that a warning is inadequate, proximate cause is not presumed." *Demmler*, 671 A.2d at 1155. "A plaintiff … cannot establish causation if the record lacks evidence to indicate the prescribing physician reviewed or relied upon information furnished by the defendant in prescribing the drug." *A.B.*, 2013 WL 2917651, *16; *see also Demmler*, 671 A.2d at 1155-56 (holding claims cannot stand where prescribing physician did not rely on information supplied by defendant).

Moreover, to succeed, plaintiffs must establish that Mrs. Zitney's prescribing physician

[11]As set forth above, the fact that plaintiff's prescribing physician never relied on or even saw a PLIVA label is consistent with the fact that generic products are not marketed to physicians and physicians do not get sales call from manufacturers for generic non-branded products like metoclopramide. (*See* pp. 29-30, above.)

would not have prescribed the medication. *See* Pa. SSJI (Civ) 23.20 (noting plaintiff must establish that the prescribing physician would not have prescribed the drug if a different warning had been provided (emphasis added).) Plaintiffs do not have any testimony from Dr. Tobin that she would not have prescribed Reglan if a different warning had been provided. Quite the contrary. First, Dr. Tobin testified that the label change would not apply to Mrs. Zitney as prescribed and that "I would have probably, with the new indication, I probably would have reiterated to her that she had to be very careful with how much she used." (Tobin Dep., p. 228:18-228:23.) She did not say she would have stopped prescribing it.

At best, Dr. Tobin testified that had she been provided information about the label changes, she would have been inclined to tell her patients that "it was not to exceed 12 weeks in duration." (Tobin Dep., p. 224:9-24.) Even then, she admitted that her response was speculative:

> Q. Okay. All right. So we're in this setting here in 2019, and you're being asked what you would have done in 2004, with the addition of a sentence, for a situation that doesn't really describe your treatment of Mrs. Zitney; is that right?
>
> A. That's correct.
>
> Q. And so would you agree that what you're being asked to do to is speculate as to what you would have done because it really doesn't fit the facts of the case that you had?
>
> A. I would say that's a true statement.

(Tobin Dep., pp. 236:20 - 237:6.)

Dr. Tobin did not rely on PLIVA's metoclopramide package insert when prescribing Reglan for plaintiff, and plaintiffs lack evidence that Dr. Tobin would have changed her

prescribing decision. As a result, plaintiffs cannot satisfy their burden to show a causal link exists between any alleged inadequacy in PLIVA's metoclopramide labeling – whether from an alleged failure to send a DHCP letter or otherwise – and plaintiffs' injuries. That causal link is an essential element of all claims, no matter how characterized, so PLIVA is entitled to summary judgment on all claims. Indeed, summary judgment has been granted in other metoclopramide cases for that very reason. *See, e.g.*, *Fulgenzi v. PLIVA, Inc.*, 140 F. Supp. 3d 637, 648-652 (N.D. Ohio 2015) (summary judgment granted where physician did not read PLIVA label).

2. Failure to Include a Warning that Does Not Apply to the Plaintiff Cannot Be the Proximate Cause of a Plaintiff's Injuries

The crux of plaintiffs' claim is that the Sentences added to the 2004 Reglan[12] package insert were not sent to plaintiff's physician. However, those Sentences are inapplicable to plaintiff who used Reglan only intermittently. Dr. Tobin learned in her neurology residency that Reglan was used for nausea associated with migraines, which is not an approved indication. (Tobin Dep., p. 78:6-13.) Dr. Tobin prescribed Reglan for Mrs. Zitney for her migraines, but did not prescribe it on a chronic or even daily basis. (Tobin Dep., pp. 90:19-21, 18:16-21, 225:5-17; *see also* Zitney Dep., p. 165:9-14.[13]) Instead, Dr. Tobin prescribed Reglan for Mrs. Zitney to use on an "as needed" basis, and recommended that Mrs. Zitney reserve it only for severe migraines, significant enough to interfere with her ability to function. (Tobin Dep., pp. 114:11-22; 120:19-121:1.)

Dr. Tobin made a clinical decision to prescribe Reglan on an as needed, intermittent basis over a five-year period because Mrs. Zitney was not taking pills every day. (Tobin Dep., p.

[12] Dr. Tobin prescribed Reglan to Mrs. Zitney; she did not prescribe metoclopramide. (Tobin Dep., p. 33:14-18.)

[13] In doing so, Dr. Tobin did not tell Mrs. Zitney she was prescribing Reglan off-label. (Tobin Dep., pp. 90:19-91:2; 121:2-8.)

227:13-17.) Mrs. Zitney's prescription history, as well as her deposition testimony cited above, bears that out. For example, Mrs. Zitney's first prescription of Reglan was filled with PLIVA metoclopramide on October 31, 2004, with 30 tablets. That prescription lasted approximately seven months. (*See generally,* Tobin Dep., pp. 126:17-129-1.)

Because Mrs. Zitney used Reglan only intermittently, Dr. Tobin believes the Sentences were inapplicable to her. (Tobin Dep., pp. 227:19-228:23.) A manufacturer's alleged failure to include a warning that does not apply to the plaintiff cannot be the proximate cause of plaintiff's injury, and plaintiff's claim based on such a warning fails as a matter of law. *See Cochran v. Wyeth, Inc*., 3 A.3d 673, 681 (Pa. Super. 2010). Here, the Sentences did not pertain to plaintiff. Accordingly, any alleged failure by PLIVA to include those Sentences or communicate them in the form of a DHCP letter or otherwise, cannot be the proximate cause of plaintiff's injuries.

3. An Alleged Failure to Provide a Warning that Was in the Label of the Drug Actually Prescribed Cannot Be the Proximate Cause of Any Injury to Plaintiff

Plaintiffs also cannot establish proximate cause because Reglan, the medication prescribed by Dr. Tobin, included the Sentences and the upshot of plaintiffs' allegations is that the Reglan labeling was adequate. An alleged failure to provide a warning that was in the label of the drug which Dr. Tobin actually prescribed cannot be the proximate cause of any injury to plaintiff. Consequently, for that additional reason, PLIVA is entitled to summary judgment. In fact, summary judgment in other metoclopramide cases has been granted for just that reason. *See, e.g.*, *Fullington v. Pfizer, Inc.*, 720 F.3d 739, 747 (8th Cir. 2013) (dismissal affirmed on proximate cause ground where plaintiff admitted doctor relied on branded Reglan labeling, which contained updated language); *Bell v. Pfizer, Inc.*, 716 F.3d 1087, 1097-1098 (8th Cir. 2013) (same).

4. There Is No Evidence the Outcome Would Have Differed If PLIVA Had Updated Its Label or Sent a DHCP Letter

Plaintiffs cannot prove proximate cause for another reason: They have no evidence that had PLIVA updated its label or sent a DHCP letter about the Sentences to Dr. Tobin, and had Mrs. Zitney stopped using metoclopramide immediately after Dr. Tobin's receipt of such a letter that the injuries plaintiffs allege would have been prevented. Any contention otherwise is sheer speculation.

Plaintiffs' only expert is Dr. Neppe. Putting aside for the moment whether he would have the qualifications to do so, Dr. Neppe provides no opinion about when PLIVA should have updated its label or sent a DHCP letter. His report also does not include any opinion that if metoclopramide had been discontinued on that unknown date, that Mrs. Zitney would not have experienced the conditions plaintiffs allege. Thus, plaintiffs have no admissible evidence an updated label or a DHCP letter they allege PLIVA was not prohibited from sending to Dr. Tobin about the 2004 Reglan label change would have made a difference in Mrs. Zitney's conditions. *See Conti v. Ford Motor Co*., 743 F.2d 195, 199 (3d Cir. 1984) (*citing Sherk v. Daisy–Heddon, A Div. of Victor Comptometer Corp*., 498 Pa. 594 (1982) (a defendant may be liable in a failure to warn case "only when there is sufficient evidence that additional warnings or reminders may have made a difference")).

Any claim by plaintiffs against PLIVA based on an alleged failure to include the Sentences in the label for its generic metoclopramide is barred for an additional reason. Mrs. Zitney's Reglan prescriptions were filled with PLIVA's generic metoclopramide four times – on October 31, 2004; June 10, 2005; February 6, 2006; and December 4, 2006. Mrs. Zitney's next Reglan prescription fill, over one year later on December 28, 2007, was filled with Teva's

generic metoclopramide. Teva had updated the label for its generic metoclopramide more than two years before December 28, 2007. (*See* Teva Labeling Supplement submission letter to Gary Buehler, Director, FDA Office of Generic Drugs, dated June 24, 2005, submitting Teva metoclopramide package insert Rev.I (5/2005), Ex. 5.[14]**)** Further, there is no evidence, or even an allegation, that Mrs. Zitney had any of the movements plaintiffs attempt to attribute to Mrs. Zitney's use of metoclopramide before December 28, 2007. Accordingly, the absence of the Sentences from the label could not be the proximate cause of plaintiffs' alleged injuries. Under plaintiffs' theory of their case, the presence of the Sentences in the Teva label did not make any difference. In the same way, the absence of the Sentences from the PLIVA did not make any difference, and plaintiffs are required to show that any allegedly absent warning would have made a difference. *See Conti*, 743 F.2d at 199. For that additional reason, summary judgment for PLIVA should be granted on any claim based on the absence of the Sentences from PLIVA's generic metoclopramide label.

F. PLAINTIFFS HAVE FAILED TO PROVE THAT PLIVA'S METOCLOPRAMIDE WAS THE CAUSE-IN-FACT OF PLAINTIFFS' INJURIES

Plaintiffs also are required to prove that Mrs. Zitney's use of PLIVA's generic metoclopramide was a cause-in-fact of the injuries alleged by plaintiffs in order to recover. *See Straw v. Fair*, 187 A.3d 966, 993 (Pa. Super. 2018) (plaintiff must prove both cause-in-fact and legal or proximate cause in order to establish a prima facie case of liability). Plaintiffs cannot

[14] There was a further amendment to the Reglan label regarding the risk of tardive dyskinesia and duration of therapy, in the form of a so-called "black box," the strongest form of warning permitted in drug labeling. The FDA directed the Reglan manufacturer to add a black box warning in February 2009, and the Reglan labeling including the black box was not approved by FDA until June 30, 2009. As plaintiff's last Reglan prescription filled with PLIVA metoclopramide was dispensed in December 2006, the black box label change is not implicated with respect to PLIVA in this action.

make that showing or show there is a genuine issue of material fact on that required element of their claims. Plaintiffs' expert, Dr. Vernon Neppe, wrote in his report that Mrs. Zitney has "mild dystonia and blepharospasm" and "mild dyskinetic movements" "as a result of her long-term intermittent use of metoclopramide." (*See* Neppe Rpt., pp. 1-2, Ex. 23.) PLIVA has moved to exclude Dr. Neppe because his opinions about the conditions and causation relative to Mrs. Zitney are based on a novel theory and he did not employ a generally accepted methodology in arriving at his made-for-litigation conclusions. (*See* June 3, 2019, Motion to Exclude Vernon Neppe, M.D., Ph.D.) As PLIVA explains in that motion, Dr. Neppe's opinion that tardive injuries can be caused by intermittent use of metoclopramide like that reported for Mrs. Zitney is a novel opinion that is not based on any scientific methodology. Further, Dr. Neppe's opinions that Mrs. Zitney has tardive dystonia and blepharospasm and tardive dyskinesia resulting from her use of metoclopramide are not derived from a proper methodology, and are not admissible.

If PLIVA's motion to exclude is granted, plaintiffs will have no admissible evidence that Mrs. Zitney's use of PLIVA's metoclopramide was a cause-in-fact of the injuries alleged by plaintiffs, and PLIVA's motion for summary judgment should be granted.

G. PLIVA IS ENTITLED TO SUMMARY JUDGMENT ON PLAINTIFFS' NEGLIGENCE *PER SE* "CLAIM"

Plaintiffs' negligence *per se* "claim" must be dismissed for multiple reasons. First, negligence *per se* is not a distinct cause of action. Rather, it is an evidentiary presumption that may supply the first two elements of negligence (duty and breach). *See Schemberg v. Smicherko*, 85 A.3d 1071, 1074 (Pa. Super. 2014). Negligence *per se* is based on the violation of a statute or ordinance. *See Wagner v. Anzon, Inc.*, 684 A.2d 570, 574 (Pa. Super. 1996). But, plaintiffs

never assert that PLIVA violated any statute or ordinance by not sending a DHCP letter. Plaintiff asserts only that PLIVA was not prohibited from sending a DHCP letter under the FDCA and the regulations promulgated under the Act (an assertion PLIVA disputes). Accordingly, plaintiffs cannot possibly pursue negligence *per se* with respect to their negligence claim because the fundamental predicate for negligence *per se* is absent.

To the extent, notwithstanding their multiple statements to the contrary, plaintiffs may be asserting a negligence claim against PLIVA based on a so-called failure-to-update theory (i.e., the absence of the Sentences from PLIVA's metoclopramide label), negligence *per se* is not available to them for the same reason they cannot pursue a negligence claim. Specifically, plaintiffs' negligence *per se* claim must be dismissed because plaintiffs cannot prove proximate cause. As demonstrated above, Dr. Tobin never saw PLIVA's label for its generic metoclopramide. Consequently, any alleged omission from PLIVA's label could not be the proximate cause of plaintiffs' injuries. *Demmler*, 671 A.2d at 1155-56. Plaintiffs' inability to prove a required element of negligence *per se* means that summary judgment for PLIVA is proper. *Wagner*, 684 A.2d at 574.

Further, an alleged violation of the FDCA and any regulation promulgated under the Act requiring PLIVA's label to be the "same as" the Reglan label could not be the basis of negligence *per se*. In order to prove a claim based on negligence *per se* in Pennsylvania, the purpose of the statutory provision relied on by a plaintiff must be, at least in part, the protection of the interest of a group of individuals, as opposed to the public generally. *Id*.

FDA's approval of PLIVA's ANDA for generic metoclopramide tablets was pursuant to the Hatch-Waxman Amendments to the FDCA. The Hatch-Waxman Amendments were passed in 1984 to address the need of individuals and state and federal governments for low-cost

versions of previously-approved drug products. To that end, the requirement to demonstrate that a generic drug is a copy of the brand drug in every significant respect, including its labeling, was to ensure that the lower cost generic version could be freely substituted for the brand drug at the pharmacy. *See* FDA, Approved Drug Products with Therapeutic Equivalence Evaluations, p. iv (30th ed. 2010). Achieving the goals of free substitution and lower-cost drugs also required confidence on the part of the physicians, health professionals, and consumers that generic drugs were as effective and safe as the brand drug. During the rulemaking process for adoption of regulations implementing Hatch-Waxman in 1992, FDA commented, "[c]onsistent labeling will assure physicians, health professionals, and consumers that a generic drug is as safe and effective as its brand-name counterpart." *See Abbreviated New Drug Application Regulations – Final Rule* ("ANDA Regs"), 57 Fed. Reg. 17950, 17961 (April 28, 1992). In furtherance of that goal, FDA promulgated 21 C.F.R. §314.150(b)(10) that allows FDA to withdraw approval of a generic drug if the labeling is no longer consistent with the brand label.

In other words, the purpose of "same as" labeling for generic drugs was not to protect the interests of any particular group of individuals. Rather, those provisions are in place to support a regulatory system for the benefit of the public generally in the form of lower cost drugs and the resultant benefit to the health care system. As such, the "same as" provisions do not come within the ambit of negligence *per se*. *See Wagner*, 684 A.2d at 574; *see also Talley v. Danek Medical, Inc.*, 179 F.3d 154, 159 (4th Cir. 1999)(where statutory provision does not establish a specific standard of care, violation of the provision does not support a negligence *per se* claim). That is true even if other parts of the statute or the regulatory scheme can be viewed as protecting individuals. *Id*. Plaintiffs agree. Their DHCP letter theory is based on the assertion that the federal regulatory system for generic drug labels is not in place to protect individuals.

Finally, by its express terms, 21 U.S.C. §337(a) prohibits any private right of action for alleged violations of the FDCA and FDA regulations. At a minimum, that is an indicator that enforcement of the "same as" provision for individual harms was not the purpose of those provisions. *Wagner*, 684 A.2d at 575. Other courts have pointed out that allowing a plaintiff to bring a negligence *per se* claim based on an alleged violation of the FDCA would be improper and impermissible. *See, e.g., Patton v. Forest Laboratories, LLC*, 2018 WL 5270476 at *20 (C.D. Cal May 10, 2018) (plain language of §337(a) indicates that where the FDA is concerned negligence *per se* claims fail) (citations omitted).

For all the foregoing reasons, PLIVA should be awarded summary judgment on plaintiffs' negligence *per se* "claim."

H. PLAINTIFFS' CLAIMS ARE PREEMPTED

Plaintiff's "failure to communicate" theory is fundamentally inconsistent with federal regulations on drug labeling and is preempted.[15] Federal law strictly controls what information generic drug manufacturers may convey in their "labeling"—a category that extends far beyond a drug's package insert to include "nearly every conceivable form of communication with medical professionals." *Holmes v. Hospira, Inc.*, 2013 WL 12132046, at *10 (C.D. Cal. Jan. 10, 2013) (quotation marks omitted); *see* 21 U.S.C. § 321(m); 21 C.F.R. §§ 1.3, 202.1(l)(2). Under FDA regulations, any communications with doctors (such as DHCP letters) regarding a product's "warnings, hazards, contraindications, side effects, and precautions" must be "the same in language and emphasis" as "the approved ... labeling" for the brand. 21 C.F.R. § 201.100(d)(1).

[15] PLIVA maintains that plaintiffs' failure-to-update theory is likewise preempted for the reasons stated in the preliminary objections filed by the Generic Manufacturing Defendants.

In *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 131 S. Ct. 2567 (2011), the Supreme Court applied those federal regulatory requirements to bar precisely the sort of attempted end-run around preemption that plaintiffs argue for here with their "failure to communicate" theory. In *Mensing*, the plaintiffs argued that even if generic drug manufacturers could not unilaterally change their product labels to strengthen their warnings, they still "could have used 'Dear Doctor' letters to send additional warnings to prescribing physicians and other healthcare professionals." 564 U.S. at 615. But the Supreme Court rejected that argument, explaining that it would violate FDA regulations for the generic manufacturers to send their own "Dear Doctor" letters that were not "consistent with the drug's approved labeling." *Id.* (citing 21 C.F.R. § 201.100(d)(1)).

Plaintiffs try to distinguish *Mensing* on the grounds that even if PLIVA could not have communicated warnings to doctors that differed in content from the brand label, it could have disseminated DHCP letters to publicize the 2004 change to the warning label for Reglan. But such a claim is still preempted because federal law simply does not allow generic drug manufacturers to send DHCP letters and similar warnings "unless their brand counterparts do so first." *In re Darvocet, Darvon & Propoxphene Prods. Liability Litig.*, 756 F.3d 917, 932-33 (6th Cir. 2014). Indeed, the vast majority of courts to address the issue, including every federal circuit court, have held that federal law bars generic drug manufacturers from sending DHCP letters "unless their brand counterparts do so first[.]" *In re Darvocet*, 756 F.3d at 932-33; *see also Johnson v. Teva Pharm. USA, Inc.*, 758 F.3d 605, 612 (5th Cir. 2014) ("[Plaintiff] acknowledges that no brand-name manufacturer sent a warning based on the 2004 label change. Accordingly, Generic Defendants were not at liberty to do so."); *Lashley v. Pfizer, Inc.*, 750 F.3d 470, 475 (5th Cir. 2014); *Brinkley v. Pfizer, Inc.*, 772 F.3d 1133, 1139 (8th Cir. 2014); *Moretti v.*

PLIVA, Inc., 2012 WL 628502, *5 (D. Nev. Feb. 27, 2012) *motion to alter and/or amend denied* (D. Nev. May 8, 2012) *aff'd* 579 Fed. App'x 563 (9th Cir. 2014); *Strayhorn v. Wyeth Pharms., Inc.*, 737 F.3d 378, 398 (6th Cir. 2013); *Moretti v. Mutual Pharm. Co.*, 518 Fed. Appx. 486 (8th Cir. 2013); *Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1288 (10th Cir. 2013) (noting "the same federal regulatory scheme that prevented generic manufacturers from unilaterally issuing label changes and "DHCP letters" at issue in *Mensing* applies to a broad array of communications"); *Morris v. PLIVA, Inc.*, 713 F.3d 774, 777 (5th Cir. 2013); *Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1249 (11th Cir. 2013).[16]

Plaintiffs' allegations that PLIVA can, and should, be held liable for failing to send a DHCP letter apprising Dr. Tobin of the warning language is tantamount to an allegation that PLIVA failed to "strengthen the warnings" and, therefore, is preempted. DHCP letters are

[16]In addition, the following federal district courts and state courts have held DHCP letter theory-based claims preempted: *In re Fosamax Prods. Liab. Litig.*, 965 F. Supp. 2d 413, 418-19 (S.D.N.Y. 2013) (noting that it joins the majority of other courts in rejecting the DHCP letter theory); *Woods v. Wyeth, LLC*, 2016 WL 1719550, *6 (N.D. Ala. Apr. 29, 2016); *Weeks v. Wyeth, Inc.*, 121 F. Supp. 3d 1278, 1285-86 (M.D. Ala. Aug. 3, 2015); *Fulgenzi v. PLIVA, Inc.*, 140 F. Supp. 3d 637, 650-653 (N.D. Ohio 2015); *Davis v. Teva Pharm. USA, Inc.*, 2014 WL 4450423, *3 (E.D. La. Sept. 10, 2014); *Cooper v. Wyeth, Inc.*, 2013 WL 6502554, *3-4 (M.D. La. Dec. 11, 2013); *Stephens v. Teva Pharms. USA, Inc.*, 2013 WL 12149265, *9 (N.D. Ala. Oct. 31, 2013); *In re Fosamax Prods. Liab. Litig.*, 2013 WL 4306434, *5 (S.D.N.Y. Aug. 15, 2013); *Chatman v. Pfizer, Inc.*, 960 F. Supp. 2d 641, 647 (S.D. Miss. Mar. 28, 2013); *Arters v. Sandoz, Inc.*, 912 F. Supp. 2d 813, 819 (S.D. Ohio 2013); *Gardley-Starks v. Pfizer, Inc.*, 917 F. Supp. 2d 597, 608-09 (N.D. Miss. 2013); *Harris v. Pharmaceutical Associates, Inc.*, 2012 WL 6025954, *3 (E.D. La. Dec. 4, 2012); *Purvis v. Teva Pharms. USA, Inc.*, 901 F. Supp. 2d 716, 720 (M.D. La. 2012); *Fullington v. PLIVA, Inc.*, 2012 WL 1893749 (E.D. Ark. May 23, 2012) *aff'd on other grounds* 720 F.3d 739 (8th Cir. 2013); *Pirello v. Qualitest Pharms., Inc.*, 2012 WL 5363243, *3 (M.D. La. Oct. 30, 2012); *Hogue v. Pfizer, Inc.*, 2012 WL 11944897, *6 (S.D. Ohio Sept. 27, 2012); *Jacobsen v. Wyeth, LLC*, 2012 WL 3575293 (E.D. La. Aug. 20, 2012); *Phelps v. Wyeth, Inc.*, 857 F. Supp. 2d 1114, 1126 (D. Or. 2012); *Del Valle v. PLIVA, Inc.*, 2011 WL 7168620, *6 (S.D. Tex. Dec. 21, 2011); *Kellogg v. Wyeth*, 2012 WL 368658, *4-5 (D. Vt. Feb. 3, 2012); *Grinage v. Mylan Pharms., Inc.*, 840 F. Supp. 2d 862, 868-869 (D. Md. 2011); *Pliva, Inc. v. Dement*, 780 S.E. 2d 735, 740-41 (Ga. App. 2014); *Dietrich v. Actavis Elizabeth, LLC*, 138 So.3d 1163, at *1 (Fla. Ct. App. 2014); *In Re Isotretinoin Litig.*, 2013 WL 3483813, at *6 (N.J. Sup. Ct. June 28, 2013).

labeling under the FDCA and FDA's regulations. *See* 21 C.F.R. §202.1(k)(2) (defining "labeling" to include, inter alia, letters containing drug information supplied by the manufacturer for use by medical professionals).

Plaintiffs cannot dispute that the manufacturer of brand Reglan did not send a DHCP letter following the FDA's July 2004 revision to the Reglan label or thereafter. Indeed, the underlying premise of plaintiffs' theory of liability must depend on the contention the brand manufacturer did not adequately communicate the contents of the July 2004 Reglan labeling to the medical community. But federal law and the "duty of sameness" forbid generics manufacturers from acting unilaterally in that manner; "they are dependent on brand-names taking the lead." *Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1249 (11th Cir. 2013) (quotation marks omitted). For that reason, every federal court of appeals that has addressed a "failure to communicate" theory like plaintiff's has held that such claims against generic drug manufacturers are preempted, and dozens of federal district and state courts have reached the same result.

For example, in *Harris v. Pharm. Assocs., Inc.*, No. 10-cv-3159, 2012 WL 6025954, at *3 (E.D. La. Dec. 4, 2012), plaintiff proposed precisely the same mechanisms of communication plaintiffs argue for in this case. In its carefully reasoned opinion, the court held:

> Harris claims that the Defendants should have widely disseminated information about the risks of the drug independent of their brand-name counterparts. (Rec. Doc. No. 27 at 16). Harris' interpretation of the Supreme Court's holding is misguided. It is precisely this kind of independent action that *Mensing* prohibits.
>
> Under the federal duty of "sameness" imposed by the FDA regulations on generic drug manufacturers, Defendants are prohibited from taking actions which imply any differences between their generic drug and the brand-name drug originally approved by the FDA. *Mensing*, 131 S. Ct. at 2581. Therefore, the proposed avenues which Harris cites in her briefs to this Court, including but not limited to "Dear Doctor" letters and informational sessions for physicians and healthcare

> professionals, are unavailable to generic drug manufacturers such as the Defendants.

Id.

Plaintiffs' argument is irreconcilable with the Supreme Court's reasoning in *Mensing*, with the Superior Court, and with controlling federal regulations. A generic manufacturer cannot unilaterally send a DHCP letter (or other similar warning) without violating FDA's prohibition on warnings that depart in content or emphasis from the brand's labeling. 21 C.F.R. § 201.100(d)(1). This follows because sending such a letter communicates significant information about a warning's "emphasis." DHCP letters are not issued routinely for every labeling update—a practice that would quickly dilute their efficacy. Rather, FDA guidance provides that they should be used "to convey important new safety information that concerns a significant hazard to health," and agency regulations specify that "such mail should be distinctive in appearance so that it will be promptly recognized and read." 21 C.F.R. § 200.5. But because DHCP letters are used to indicate that a new warning is "important," *id.*, it would create undesirable confusion if a generic manufacturer were to trumpet a label update's significance while the brand stays silent. As the Supreme Court recognized in *Mensing*, "if generic drug manufacturers, but not the brand-name manufacturer," were to send DHCP letters to communicate a warning, the letters "would inaccurately imply a therapeutic difference between the brand and generic drugs." 564 U.S. at 615. And, the Superior Court recognized in *In re Reglan/Metoclopramide Litigation*, 81 A.3d 80, 85 (Pa. Super. 2013) and *Hassett v. Dafoe*, 74 A.2d 302, 307 (Pa. Super. 2013), that the Supreme Court in *Mensing* "rejected the plaintiffs' assertions that generic manufacturers could … issue warnings to doctors via Dear Doctor letters."

Further, to require PLIVA to send a Dear Doctor letter, whatever the form, would be an undue obstacle to executing the full purposes and objectives of FDA's enforcement of drug warning laws set forth in the FDCA. FDA has emphasized that DHCP letters are intended for only the most important safety labeling changes. *See* Guidance for Industry and FDA Staff: Dear Healthcare Provider Letters: Improving Communication of Important Safety Information (Jan. 2014) ("[A] DHCP letter is used to notify health care providers about important new or updated information about a drug."). According to FDA, those types of changes would require approximately 30 letters per year. *See* Agency Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Draft Guidance for Industry and Food and Drug Administration Staff on Dear Health Care Provider Letters; Improving Communication of Important Safety Information, 78 Fed. Reg. 41064, 41065 (July 9, 2013). If generic drug manufacturers were required by state law to send a DHCP letter about label changes, the number of those letters sent would increase several hundred-fold, turning what FDA directs should be an exceptional warning into an everyday occurrence—in essence, junk mail. Indeed, seen in this light, plaintiffs' theory would present "'an obstacle to the accomplishment and execution of'" important federal objectives for drug warnings," and would constitute an entirely independent basis of federal preemption. *Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 881-83 (2000)(*quoting Hines v. Davidowitz,* 312 U.S. 52, 67 (1941)).

It is not open to dispute that the FDA considers approved drug product labeling in the form of package inserts to be the established means by which drug companies are to communicate with physicians, and the "primary source of information [for medical professionals] about a drug's safety and effectiveness." FDA Guidance for Industry, Drug Safety Information – FDA's Communication to the Public, at 7 (March 2007). There is no

contention in the instant case that PLIVA was not in compliance with regulatory requirements to disseminate its package inserts with its metoclopramide products.

In short, plaintiffs' "failure to communicate" claim is preempted under *Mensing*, and any argument that PLIVA could have delivered or driven home a message to the medical community about metoclopramide's alleged risks even though the brand manufacturer did not both conflicts with federal law, and leads to an absurd conclusion.

I. PLIVA IS ENTITLED TO SUMMARY JUDGMENT ON PLAINTIFFS' NEGLIGENCE BASED DESIGN DEFECT CLAIM

Plaintiffs' allegations of design defect are not cognizable under Pennsylvania law. In addition, design defect claims aimed at pharmaceutical products are preempted pursuant to *Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. 472 (2013).[17] Finally, the theory that PLIVA can be held liable for not stopping sales or withdrawing its metoclopramide from the market equates to asserting that PLIVA should have recalled its product, but there is no duty to recall under Pennsylvania law.

1. Plaintiffs' Design Defect Claim Is Not Cognizable under Pennsylvania Law

PLIVA is entitled to summary judgment on the design defect claims because the allegations do not fall within the parameters of a design defect claim involving pharmaceutical products set out in *Lance v. Wyeth*, 85 A.3d 434 (Pa. 2014). In *Lance*, the Pennsylvania Supreme Court recognized that plaintiffs may pursue negligent design defect claims where a product is too dangerous for anyone's use. *Id.* That is not the case here. Neither plaintiffs nor FDA consider Reglan/metoclopramide "dangerous" if used as recommended. Plaintiffs have

[17] In plaintiffs' Response to Teva's Motion for Summary Judgment based on federal preemption, they discussed the applicability of the *Bartlett* decision. They nonetheless, wrote "Plaintiff Zitney does not assert a design defect case here." Ex. 17, p. 12, n.5.

never made that allegation and, in fact, has conceded the opposite. (Short Form Complaint ("SFC"), ¶ 9 D and E, Ex. 7 (alleging Dr. Tobin was negligent for prescribing metoclopramide "for a period of time that deviated from the standard of care of reasonably prudent physicians acting under the same or similar circumstances" and that plaintiff's ingestion as prescribed "in excess of 12 weeks duration" caused her injuries). And, FDA has not taken any action to have Reglan and its generic equivalents withdrawn from the market.

2. Plaintiff's Design Defect Claim Is Preempted

In *Bartlett*, the Supreme Court held that where plaintiffs argue that a generic drug's design is defective that claim too is preempted by federal law. That is because a generic drug cannot be designed differently; it must include the "same" active ingredient as the brand-name drug. *See* 21 U.S.C. § 355(j)(2)(A). The only other way to change the safety profile of a generic drug is to change the labeling, which, as the Supreme Court held in *Mensing* and again in *Bartlett*, is a claim preempted by federal law. *See Mensing*, 564 U.S. at 614; *Bartlett*, 570 U.S. at 475. Asserting that the generic drug company should simply have stopped selling the drug does not change the result and was rejected in *Bartlett* as no more than an attempted end-run around federal law. *Bartlett*, 570 U.S. at 475.

To prove design defect in this case, plaintiffs would have to prove that PLIVA could both change the design of metoclopramide and comply with federal law. But federal law does not permit PLIVA to unilaterally alter a drug's design. *See Bartlett*, 570 U.S. at 482-485. As a result, plaintiff's design defect claim is preempted.

The Superior Court's decision supports that conclusion. The Superior Court recognized only that a design defect claim to the extent the allegations "suggest that the drug, even when used as recommended and with appropriate warnings, was defective and unreasonably

dangerous," *In re Reglan/Metoclopramide Litig.*, 81 A.3d at 90, are not preempted. That is not true here. Plaintiff does not, and never has alleged, that metoclopramide is defective or unreasonably dangerous when used as recommended, which is for short-term use only. In fact, as noted above plaintiff acknowledges that fact. (SFC, ¶¶ 9 D and E, Ex. 7.)

FDA's action in 2009 adding warnings to the Reglan package insert further buttresses that conclusion. In 2009, FDA did not declare Reglan or any metoclopramide product misbranded and it did not withdraw the products from the market. Instead, in recognition that the product is safe and effective for its intended short-term use, it added warnings in a black box to further emphasize to physicians that the medication is not intended for long-term use.

Accordingly, PLIVA is entitled to judgment as a matter of law on plaintiffs' design defect allegations.

J. PLIVA IS ENTITLED TO SUMMARY JUDGMENT ON ALL PLAINTIFFS' NON-NEGLIGENCE CLAIMS

As described above, plaintiffs have advised the Court in prior filings that their sole claim is a negligence claim based on an alleged failure to communicate via a DHCP letter the addition of the Sentences to the Reglan label. Plaintiffs' statements were made in briefing on motions filed by or against Teva, PLIVA's co-defendant. However, in light of the statements plaintiffs have made in describing their sole remaining claim and the reasons they stated, there is no reason to think they would or could be pursuing any other claim against PLIVA.

Nevertheless, in their SFC, plaintiffs incorporate various Counts of the TAMLFC. As matters stand, those Counts technically remain pending against PLIVA. Accordingly, it is necessary for PLIVA to move for summary judgment on them as well. Plaintiffs attempt to assert strict liability failure to warn and strict liability design defect. (TAMLFC Counts I and II,

¶¶ 127-151.) Plaintiffs have also attempted to assert claims for fraud, misrepresentation, and suppression (Count V; TAMLFC ¶¶ 169-183), constructive fraud (Count VI; TAMLFC ¶¶ 184-190), breach of express and implied warranties (Count VII; TAMLFC ¶¶ 191-196); unfair and deceptive trade practices (Count VII; TAMLFC ¶¶ 197-205); unjust enrichment (Count IX; TAMLFC ¶¶ 206-209); conscious or negligent misrepresentation (Count X; TAMLFC ¶¶ 210-221); and civil conspiracy (Count XI; TAMLFC ¶¶ 222-226); gross negligence/malice (Count XV) and punitive damages (Count XVI).[18]

PLIVA is entitled to summary judgment on those Counts on a global basis because, first, those claims were limited by the Superior Court's ruling to allegations premised on PLIVA's advertising or promotional materials, which the Superior Court contended "arguably do not fall within the definition of labeling under the Act." *In re Reglan/Metolcopramide Litig.*, 81 A.3d at 93. Putting aside for the moment issues with the Superior Court's contention, the testimony is undisputed that neither plaintiff nor Dr. Tobin ever saw, read, or relied on any information from PLIVA. In fact, neither plaintiff nor Dr. Tobin ever had heard of PLIVA before this lawsuit. (Zitney Dep., p. 214:23-25; Tobin Dep., p. 34:18-21.)

Additionally, each is barred under Pennsylvania law, which only recognizes a negligence cause of action against a manufacturer of pharmaceutical products. *See Hahn*, 673 A.2d at 891. A pharmaceutical company's "negligence is the only recognized basis for liability." *Gronniger v. American Home Products*, No. 3584, 2005 WL 3766685, *3 (Pa. Ct. Com. Pl. Oct. 21, 2005); *see also Leonard v. Taro Pharm. USA, Inc.*, No. 10CV1341, 2010 WL 4961674 (W.D. Pa. Dec.

[18] The cover page of the TAMLFC and the SFC lists gross negligence/malice (Count XV) and punitive damages (Count XVI) as Counts in the complaint, but the TAMLFC does not have those Counts set forth in the actual complaint. Instead, the TAMLFC asserts "Basis for Punitive Damages Remedy" and "Punitive Damages Remedy." (*See* TAMLFC ¶¶ 245-258.)

2, 2010); *Kline v. Pfizer, Inc.*, No. 08-3238, 2008 WL 4781577 (E.D. Pa. Oct. 31, 2008). As a result, plaintiffs' non-negligence claims fail for that reason alone. *Kline*, 2008 WL 4787577 (unjust enrichment barred by the holding of *Hahn*).

Plaintiffs' remaining claims fail for the following additional reasons:

1. Strict Liability

PLIVA is entitled to summary judgment on plaintiffs' strict liability claims (Counts I and II). Under Pennsylvania law, strict liability claims may not be brought for injuries allegedly arising from use of a prescription drug. *Hahn*, 673 A.2d at 889-91 (applying Restatement (Second) of Torts § 402 A cmt. k (1965) to preclude strict liability claims for prescription drugs); *Lance v. Wyeth*, 85 A.3d 434, 451-60 (Pa. 2014) (reaffirming *Hahn's* bar on strict liability claims); *A.H. Jr. v. Janssen Pharms., Inc.*, No. 130401995, 2015 WL 6407529, *7 (Pa. Ct. Com. Pl. Oct. 1, 2015) ("A review of Pennsylvania law shows that … Pennsylvania prohibits strict liability claims against drug manufacturers, albeit for different reasons." (citing *Hahn v. Richter*, 673 A.2d 888, 889 (Pa. 1996))).

The Pennsylvania Supreme Court has expressly "declined to extend strict liability into the prescription drug arena." *Lance*, 85 A.3d at 453. Accordingly, under Pennsylvania law, no cause of action lies in strict products liability for the design, manufacture, or sale of prescription drugs. "[U]nlike the duty imposed on most product manufacturers, Pennsylvania courts have repeatedly refused to impose strict liability on manufacturers of prescription drugs." *Berry v. Wyeth*, 2005 WL 1431742, at *2 (Pa. Com. Pl. June 13, 2005) (citing *Hahn*, 673 A.2d at 891).

2. Fraud, Misrepresentation, and Suppression

Plaintiffs' claims for fraud, misrepresentation, and suppression (Count V) also are barred. The TAMLFC alleges "willful, intentional and fraudulent misrepresentations" as well as

"passive assent and indirect cooperation … uniformly and deliberately or recklessly with willfulness, [and] wantonness in order to induce doctors to prescribe, and their patients to consume, Reglan or generic metoclopramide." (TAMLFC ¶¶170-171, 182.) Because common law fraud is an intentional tort, *see Reis v. Curtis*, No. 13-400, 2013 WL 3196429, *5 (E.D. Pa. June 25, 2013), and plaintiffs have pled their fraud claim in terms of intentional conduct, the fraud claim is not a negligence-based claim, which fails under *Hahn* and its progeny. *Hahn*, 673 A.2d 888. Any negligent misrepresentation claim fares no better. *See Luke v. Amer. Home Prods. Corp.*, No. 1998-C-01977, 1998 WL 1781624, *4-5 (Pa. Ct. Com. Pl. Nov. 18, 1998); *Howell v. Mylan Pharmaceuticals Inc.*, No. 090801947, 2010 WL 8453520 (Pa. Ct. Com. Pl. Apr. 30, 2010) ("negligent misrepresentation must be dismissed as negligent failure to warn is the only recognized basis for the liability of a manufacturer of prescription drugs" (citing *Hahn*, 673 A.2d 888, 891)).

Moreover, plaintiff has no proof of any representation by PLIVA (let alone a misrepresentation) or a fraudulent statement to plaintiffs or Dr. Tobin, a necessary predicate for such claims. Mrs. Zitney never saw any type of advertisement; she never saw a document that promoted the use of any PLIVA metoclopramide product (let alone one that promoted for a period longer than 12 weeks); is unaware of ever speaking or having written communications with anyone at PLIVA, and she does not know if anyone acting on her behalf ever spoke to, or had any written communications with, PLIVA. (Zitney Dep., p. 214:3-25.)

Dr. Tobin testified similarly. She never reviewed any written materials regarding any PLIVA metoclopramide product; never reviewed any label or package insert for any PLIVA metoclopramide product; never saw any type of advertisement or other document that she considered to be marketing material for any PLIVA metoclopramide product; and never saw any

PLIVA document that promoted the use of any metoclopramide product (again, let alone for a period of longer than 12 weeks). (Tobin Dep., pp. 34:18-21, 35:4-23, 37:21-38:11.) In fact, neither Dr. Tobin nor Mrs. Zitney ever heard PLIVA prior to the lawsuit. (Zitney Dep., p. 214:23-25; Tobin Dep., p. 34:18-21.)

Plaintiffs' claims for fraud, misrepresentation, and suppression (Count V), should be dismissed.

3. Breach of Express and Implied Warranties

Pennsylvania also does not recognize a cause of action for breach of implied warranty in prescription drug cases. *See Walker v. Bracco Research USA, Inc.*, Mar. Term 2009 No. 2041, Control No. 09060003 (Phila. C.C.P. Jan. 14, 2010) (Moss, J.) (sustaining preliminary objections alleging legal insufficiency and striking plaintiff's implied warranty claims); *Makripodis*, 523 A.2d at 377 ("Thus, we find the very nature of prescription drugs themselves precludes the imposition of a warranty of fitness for 'ordinary purposes.'"). *See also Aaron v. Wyeth*, No. 07–927, 2010 WL 653984, *11 (W.D. Pa. Feb. 19, 2010) (dismissing breach of express and implied warranty claims under *Hahn*); *Kline*, 2008 WL 4787577, *3 (dismissing breach of express and implied warranty claims under *Hahn*)). PLIVA is entitled to summary judgment on these claims.

Plaintiffs' breach of warranty claims fail for the additional reason that they are barred by the statute of limitations. The statute of limitations for a breach of warranty claim is four years. *See* 13 Pa. Cons. Stat. Ann. § 2725(a). Pennsylvania law is very clear that the statute of limitations begins to run on breach of warranty claims on the date of sale. *See*, 13 Pa. Cons. Stat. Ann. § 2725 (b). ("A cause of action accrues when the breach occurs, regardless of the aggrieved party's lack of knowledge of the breach. A breach of warranty occurs when tender of delivery is made … *Id.* [emphasis added]). Plaintiff allegedly had her Reglan prescriptions filled with

PLIVA's generic metoclopramide between October 31, 2004, and December 4, 2006; as such, the last sale of any PLIVA metoclopramide product was December 4, 2006.

Accordingly, plaintiffs would have had to commence any breach of warranty cause of action no later than December 4, 2010. Plaintiffs commenced this action by SFC filed on February 28, 2011, beyond the limitations period. Accordingly, any claim for breach of warranty is time barred. *Accord, Patton v. Mack Trucks, Inc*. 519 A.2d. 959 (Pa. Super. 1986); *Rufo v. Bastian-Blessing Co.*, 207 A.2d 823, 826 (Pa. 1965) (holding an action for breach of implied warranties of fitness and merchantability accrued upon tender of delivery).

Plaintiffs cannot prove their express warranty claim for another straightforward reason. Plaintiffs cannot point to any statement by PLIVA that could possibly constitute an express warranty. As noted several times in this Motion, Mrs. Zitney had never heard of PLIVA prior to this lawsuit.

Yet another independent reason for granting summary judgment on plaintiffs' breach of warranty claims is plaintiffs' failure to give notice to PLIVA of the alleged breach of warranties and to plead such notice. Pennsylvania law requires notice of a breach of warranty to the seller:

"Where a tender has been accepted:

> (1) the buyer must within a reasonable time after he discovers or should have discovered any breach notify the seller of breach or be barred from any remedy."

13 Pa. Stat. Ann. § 2607(c)(1).

Reasonable notice is a condition precedent to recovery and plaintiff has the burden of pleading compliance with § 2607(c). *See Beneficial Commercial Corp. v. Brueck*, 23 Pa. D. & C.3d 34, 40 (Pa. Ct. Com. Pl. 1982); *Vanalt Electrical Construction Inc. v. Selco Manufacturing Corp.*, 233 Fed. Appx. 105 (3d Cir. 2007) ("reasonable notice is a precondition to

the buyer's recovery for the breach" and determining the Pennsylvania Supreme Court would place the burden of reasonable notice on the buyer).

Failure to plead facts showing that notice was given within a reasonable time is fatal to plaintiffs' claims. *See Beneficial Commercial Corp.*, 23 Pa. D. & C. 3d at 40 (failure to plead is grounds for sustaining demurrer). Plaintiffs did not plead any facts that if proven would show that plaintiffs gave notice to any defendant of the alleged breach of warranty within a reasonable time after that alleged breach. Further, and consistent with their lack of pleading, there will be no evidence that plaintiffs provided notice within a reasonable time to PLIVA of any alleged breach of warranty.

Plaintiffs' causes of action for breach of implied and express warranties should, therefore, be dismissed, with prejudice.

4. Unfair and Deceptive Trade Practices Claim

PLIVA is entitled to summary judgment on plaintiffs' unfair trade practices act claim because it does not apply to claims made by a prescription drug user against a prescription drug manufacturer. To prove a violation of the unfair trade practices act, plaintiffs must prove causation. Specifically, Mrs. Zitney must demonstrate that she justifiably relied on the PLIVA's conduct. *See Weinberg v. Sun Co., Inc.*, 565 Pa. 612 (Pa. 2001); *Hunt v. U.S. Tobacco Co.*, 538 F.3d 217, 221 (3d Cir. 2008). "Under the 'learned intermediary doctrine,' a manufacturer of prescription drugs must direct information and warnings to *prescribing physicians*, not the patient. *See Taurino v. Ellen*, 579 A.2d 925 (Pa. Super. Ct. 1990)." *Albertson v. Wyeth Inc.*, 63 Pa. D. & C. 4th at 538 (*citing Luke v. Amer. Home Prods. Corp.*, 1998 WL 1781624 (Pa. Com. Pl., Nov. 18, 2008)). There can be no cause of action based on PLIVA's alleged omissions because PLIVA had no duty to disclose any information directly to plaintiff. *See Luke*, 1998 WL

1781624, at *9 ("we hold that Plaintiffs' have no cause of action under the UTPCPL against a manufacturer of prescription drugs.") Moreover, plaintiffs cannot prove justifiable reliance when, as shown above, no information was provided by PLIVA to her and she had never even heard of PLIVA.

Plaintiffs' unfair trade practices act claim should, therefore, be dismissed, with prejudice.

5. Unjust Enrichment

PLIVA is entitled to summary judgment on plaintiffs' claims for unjust enrichment for four separate reasons. First, the statute of limitations for unjust enrichment is four years. *See* 42 Pa. Cons. Stat. Ann. § 5525(a)(4); *Sevast v. Kakouras* (Appeal of Sunday), 915 A.2d 1147 (2007). It begins to run at the time the action accrues, which is as of the date the relationship between the parties terminated. *See Colonial Assur. Co. v. Mercantile & Gen. Reassurance Co.*, 297 F. Supp. 2d 764 (E.D. Pa. 2003), *aff'd* 130 Fed. Appx. 607 (3d Cir. 2005). There was never any relationship between plaintiff and PLIVA. Nonetheless, to the extent there was a connection, it terminated in December, 2006, when plaintiff's last Reglan prescription was filled with PLIVA's metoclopramide. Plaintiffs' assertion of an unjust enrichment claim for the first time in her SFC filed on February 28, 2011, is well after the four year limitation period.

Secondly, plaintiffs cannot satisfy their burden of proof on their unjust enrichment claim. To recover on a claim for unjust enrichment, plaintiff must prove she conferred a benefit on the defendant, that defendant appreciated the benefit under the circumstances, and that the defendant accepted and retained the benefit without payment for value. *See Stutzle v. Rhone-Poulenc S.A.*, No. 002768, 2003 WL 2250424 (Pa. Com. Pl. Sept. 26, 2003) (*citing BurgettstownSmith Twp. Joint Sewage Auth. v. Langeloth Townsite Co.*, 588 A.2d 43, 45 (Pa. Super. 1991)). Here, Mrs. Zitney did not confer a benefit on PLIVA. Mrs. Zitney is an indirect purchaser (she had her

prescriptions filled, and paid for them, at Rite Aid. (Plaintiff Fact Sheet, p. 4, Ex. 24; Zitney Dep., p. 169:9-12.) Mrs. Zitney had no direct dealings with PLIVA. In fact, Mrs. Zitney never heard of PLIVA before pursuing this lawsuit.

Moreover, plaintiffs cannot prove any unjust benefit PLIVA received resulting from Mrs. Zitney's pharmacy's purchases of PLIVA's metoclopramide. Plaintiff received the product she sought, a medication to help her with the nausea and vomiting she had with her migraines. And it did help. (Zitney Dep., 188:2-15.) *See Albertson v. Wyeth Inc.*, 63 Pa. D. & C. 4th 514, 536 (Phil. Ct. Com. Pl., July 8, 2003) ("Here, … plaintiffs did receive the product they sought, a hormone replacement therapy. Plaintiffs merely allege that Prempro was not safe, and that Wyeth knew it was unsafe but promoted the drug anyway. These allegations are insufficient to state a claim for unjust enrichment.").

Finally, as shown earlier, the only recognized causes of action against a manufacturer of pharmaceutical products is in negligence. *Hahn*, 673 A.2d at 891. As a result, plaintiff's unjust enrichment claim fails. *Kline*, 2008 WL 4787577 (unjust enrichment barred by the holding of *Hahn*).

6. Conscious or Negligent Misrepresentation Involving Physical Harm

PLIVA is entitled to summary judgment on plaintiffs' claim for conscious or negligent misrepresentation involving physical harm (Count X in the TAMLFC and described as "Negligent Misrepresentation" in plaintiffs' SFC) for the simple reason that all allegations of that claim are directed to the "Brand Name Defendants" which does not include PLIVA.

7. Civil Conspiracy

PLIVA is entitled to summary judgement on plaintiffs' claim of civil conspiracy (Count XI). Plaintiffs allege that PLIVA conspired with other defendant drug manufacturers to "violate

safety standards established by the FDCA, FDA regulations, and parallel state statutes and regulations …." TAMLFC ¶ 223. To recover on a cause of action for civil conspiracy, plaintiffs must show that two or more persons combined or agreed with intent to do an unlawful act or to do an otherwise lawful act by unlawful means, and actual damage. *See Slaybaugh v. Newman*, 479 A.2d 517, 519 (1984). There is no evidence that PLIVA combined or agreed with any other defendant drug manufacturers to do any act. Plaintiffs cannot prove their civil conspiracy count, so it too should be dismissed.

8. Gross Negligence

There is no independent cause of action for gross negligence under Pennsylvania law. See Jordan v. City of Philadelphia, 66 F. Supp. 2d 638, 644-45 (E.D. Pa. 1999); Kline v. Pfizer, Inc., C.A. No. 08-3238, 2008 WL 4787577, at *3 (E.D. Pa. Oct. 31, 2008) (dismissing the plaintiff's claims for gross negligence because "Pennsylvania courts do not recognize degrees of negligence"). Plaintiffs' independent claim for gross negligence is barred as a matter of law and Teva is entitled to summary judgment.

K. PLIVA IS ENTITLED TO SUMMARY JUDGMENT ON PLAINTIFF'S REQUEST FOR PUNITIVE DAMAGES

Finally, PLIVA is entitled to summary judgment on plaintiffs' request for punitive damages. Aside from the fact that no evidence exists to support that request, punitive damages are not recoverable under applicable law. Here, under the doctrine of dépecage, which provides that different issues within the same lawsuit can be decided by the laws of different states, New Jersey's law on punitive damages should be applied. *See* Restatement (Second) of Conflicts of Law § 145 cmt. d ("courts have long recognized that they are not bound to decide all issues under the local law of a single state"). Pennsylvania courts have applied the doctrine of

dépecage. *See, e.g., McDonald v. Whitewater Challengers, Inc.*, 116 A.3d 99, 107 n.16 (Pa. Super. 2015) (noting if there is more than one issue, Pennsylvania applies dépecage). Generally, to determine which state's law to apply, the court uses the forum state's choice-of-law analysis.

Pennsylvania's choice of law analysis is a hybrid that combines the approach of the Restatement (Second) on Conflicts of Law and the interests of the state analysis. *See Griffith v. United Air Lines, Inc.*, 203 A.2d 796 (Pa. 1964)). Pennsylvania's analysis involves a two-prong test. First, the court must determine whether there is a conflict between the states' laws. See *Cipolla v. Shaposka*, 267 A.2d 854, 855 (Pa. 1970)). If there is no conflict, the forum's law applies. *See TIG Specialty Ins. Co. v. Koken*, 855 A.2d 900, 908 n.12 (Pa. Com. Pl. 2004)). If a conflict does exist, then the Court must determine which state has the greater interest in applying its law. *See Cipolla*, 267 A.2d at 855-856). The same is true if there is a "false conflict"; i.e., where the result would be the same. *See Titeflex Corp. v. National Union Fire Ins. Co. of Pittsburgh, PA*, 88 A.3d 970, 979 (Pa. Super. 2014)).

Here, a conflict exists between Pennsylvania and New Jersey law as Pennsylvania law permits the recovery of punitive damages in pharmaceutical products liability cases while the New Jersey Products Liability Act, N.J. Stat. Ann. § 2A:58C-5(c), does not if a product was approved by FDA. Because there is a conflict the Court must determine whether Pennsylvania or New Jersey has a greater interest in the application of its law.

Determining which state has the greater interest requires a qualitative analysis, rather than a "mere counting of contacts." *Troxel v. A.I. DuPont Inst.*, 636 A.2d 1179, 1181 (Pa. Super. 1994). "The relevant inquiry is 'the extent to which one state rather than another has demonstrated, by reason of its policies and their connection and relevance to the matter in dispute, a priority of interest in the application of its rule of law.'" *Troxel*, 636 A.2d at 1181.

To determine which state has the greater interest in applying its law, a methodology that combines the governmental interest analysis and the significant relationship approach of § 145 of the Restatement (Second) of Conflicts is employed. *Marks v. Redner's Warehouse Markets*, 136 A.3d 984, 987 (Pa. Super. 2016) (citing *Griffith*, 203 A.2d at 801-06). The relevant governmental considerations include:

(1) The needs of the interstate and international systems;

(2) The relevant policies of the forum;

(3) The relevant policies of other interested states and the relative interest of those states in the determination of the particular issue;

(4) The protection of justified expectations;

(5) The basic policies underlying the particular field of law;

(6) Certainty, predictability and uniformity of result; and

(7) Ease in the determination and application of the law to be applied.

Restatement (Second) of Conflicts §(6)(2)(1971). In applying those principles, a number of contacts are considered including (a) the place where the injury occurred, (b) the place where the conduct causing the injury occurred, (c) the domicile, residence, nationality, place of incorporation and place of business of the parties, and (d) the place where the relationship, if any, between the parties is centered. *Id.* at § 145(2). In *Daniel v. Wyeth Pharms., Inc.*, 15 A.3d 909, 935 (Pa. Super. 2011), the court held that with respect to punitive damages, the most critical contacts include the place where the alleged punitive conduct occurred and, if dealing with a corporate defendant, the state of incorporation, and its principal place of business.

Here, plaintiff concedes that PLIVA is incorporated and has a principal place of business in New Jersey. (TAMLFC Ex. 2, ¶18.) New Jersey law disfavors the award of punitive damages.

In fact, in 1995, the New Jersey legislature enacted the Punitive Damages Act expressly for the purpose of establishing stricter standards for imposing punitive damages. *See Pavlova v. Mint Management Corp.*, 868 A.2d 322, 325 (N.J. Super. App. Div. 2005) (citing N.J. Stat. Ann. 2A:15-5.9 *et seq).* In New Jersey, punitive damages cannot be awarded unless there is an award of compensatory damages; nominal damages cannot serve as a basis for the award of punitive damages. *Id*. Furthermore, New Jersey law caps punitive damages at the greater of $350,000 or five times the compensatory damages award. N.J. Stat. Ann. § 2A:15-5.14(b). In suits involving pharmaceutical products, New Jersey law prohibits punitive damages if the drug that allegedly caused the plaintiff's injury "was subject to premarket approval or licensure by the federal Food and Drug Administration under the 'Federal Food, Drug, and Cosmetic Act' … and was approved or licensed; or is generally recognized as safe and effective pursuant to conditions established by the federal Food and Drug Administration and applicable regulations, including packaging and labeling regulations." N.J. Stat. Ann. § 2A:58C-5(c).

In contrast, Pennsylvania law does not cap punitive damages, require compensatory damages as a prerequisite to an award of punitive damages, or prohibit punitive damages in pharmaceutical cases.

Applying Pennsylvania's choice of law analysis results in the conclusion that New Jersey has the stronger stated interest in the application of its laws and its law should be applied to the issue of punitive damages. PLIVA's metoclopramide was subject to FDA's pre-market approval and at all times was approved by FDA as was the package insert accompanying its product. Thus, under New Jersey's statute, plaintiff cannot recover punitive damages.

In addition to the fact that punitive damages are prohibited in this case by statute, plaintiffs cannot present any evidence that would support an award of punitive damages. In

order to recover for punitive damages under New Jersey law, the plaintiff must prove, by clear and convincing evidence, actual malice or a wanton and willful disregard of persons who foreseeably might be harmed. N.J.S.A. § 2A:15–5.12; *Herman v. Sunshine Chem. Specialties, Inc.*, 133 N.J. 329 (1993).

Plaintiffs cannot make that showing. PLIVA did not act with the requisite intent for the award of punitive damages. Nor is there evidence that PLIVA acted with malice or a wanton and willful disregard of persons who foreseeably might be harmed. Thus, PLIVA is entitled to judgment as a matter of law on plaintiffs' punitive damage request.[19]

Finally, in *State Farm v. Campbell* (2003) 538 U.S. 408, the United States Supreme Court addressed the issue of what conduct could constitutionally be considered as the basis of a punitive damage award and the proper limits or extent of such an award. The *Campbell* Court

[19] PLIVA also is entitled to summary judgment on plaintiffs' punitive damage request under Pennsylvania law. Punitive damages are only available in the "most exceptional matters," because they are designed to punish and deter truly egregious conduct. *Phillips v. Cricket Lighters*, 883 A.2d 439, 445, 446 (2005). When assessing the viability of a punitive damages claim, "the state of mind of the actor is vital," and the tortfeasor's act or failure to act "must be intentional, reckless or malicious," not merely negligent, or even grossly negligent. *Hutchison ex rel. Hutchison v. Luddy*, 870 A.2d 766, 770-71 (2005); *see Feld v. Merriam*, 485 A.2d 742, 747 (1984) (quoting Restatement (Second) of Torts § 908(2) (1979)); *see also Chambers v. Montgomery*, 192 A.2d 355, 358 (1963). Here, plaintiffs cannot show, and do not purport to show, that PLIVA maliciously or willfully wished them harm, nor have plaintiffs produced evidence of recklessness.

Under Pennsylvania punitive damages law, recklessness requires that the defendant acted or failed to act with "an appreciation of the risk" of harm. *Martin v. Johns-Manville Corp.*, 494 A.2d 1088, 1097 n.12 (1985) (plurality opinion), *abrogated on other ground by Kirkbride v. Lisbon Contractors, Inc.*, 521 Pa. 97, 555 A.2d 800 (1989). "If the defendant actually does not realize the high degree of risk involved, even though a reasonable man in his position would, the mental state required for the imposition of punitive damages under Pennsylvania law is *not* present." *Field v. Philadelphia Elec. Co.*, 565 A.2d 1170, 1182-83 (Pa. Super. 1989). Thus, "a punitive damages claim must be supported by evidence sufficient to establish that (1) a defendant had a subjective appreciation of the risk of harm to which the plaintiff was exposed and (2) the defendant acted, or failed to act, in conscious disregard of that risk." *Luddy*, 870 A.2d at 772. Plaintiffs cannot make either showing.

found that punitive damages may be assessed only for "conduct directed toward the [plaintiff in this case]." *Id.* at 420. The alleged misconduct "must have a nexus to the specific harm suffered by the plaintiff." *Id.* at 409-410. In other words, "[a] defendant should be punished for the conduct that harmed the plaintiff, not for being an unsavory ... business." *Id.* at 423. Here, plaintiffs have no evidence that PLIVA acted with actual malice or with a wanton and willful disregard of plaintiffs. There has been no evidence that PLIVA directed any of its conduct specifically towards plaintiffs. And, there is no evidence from which a reasonable fact finder could conclude that PLIVA acted with actual malice. Therefore, plaintiffs' request for punitive damages should be dismissed.

CONCLUSION

Based on the foregoing, PLIVA is entitled to judgment as a matter of law on all plaintiffs' claims and PLIVA requests dismissal of those claims in their entirety.

*****

The undersigned verifies that a true and correct copy of all Exhibits referenced in this motion have been attached for the Court's convenience, except for Exhibits 11, 12, 14, and 16, which have been filed as a Confidential Document/Exhibit pursuant to 204 Pa. Code § 213.81.

Respectfully submitted,

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Dated: June 3, 2019

CERTIFICATE OF SERVICE

It is hereby certified that I filed the foregoing Motion for Summary Judgment on behalf of Defendant, PLIVA, Inc., with the Prothonotary and it is being sent via hand delivery to The Honorable Arnold L. New and served this day on all counsel of via *electronic mail* to the parties below:

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