UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

DONNA EMLEY, et al.,	)	
	)	
Plaintiffs,	)	
	)	
vs.	)	**Cause No. 1:17-cv-2350-WTL-TAB**
	)	
WAL-MART STORES, INC., et al.,	)	
	)	
Defendants.	)	

ENTRY ON MOTIONS FOR SUMMARY JUDGMENT

This cause is before the Court on the following motions: Defendant L. Perrigo Company's ("Perrigo") Motion for Summary Judgment on the Basis of Preemption (Dkt. No. 85) and related motions for oral argument (Dkt. Nos. 87 and 101); Defendant Wal-Mart Stores, Inc.'s ("Wal-Mart") Motion for Summary Judgment on the Basis of Preemption (Dkt. No. 88); Defendant Wal-Mart's [Second] Motion for Summary Judgment (Dkt. No. 120); Defendant Perrigo's [Second] Motion for Summary Judgment (Dkt. No. 122); and Defendant L.N.K. International, Inc.'s ("L.N.K.") Motion for Summary Judgment (Dkt. No. 124). Because the Court does not find that oral argument would be helpful, the motions for oral argument are **DENIED**. Each of the remaining motions is ripe for review and the Court, being duly advised, rules as follows.

I. SUMMARY JUDGMENT STANDARD

Federal Rule of Civil Procedure 56(a) provides that summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." In ruling on a motion for summary judgment, the properly supported facts asserted by the non-moving party must be believed, and all reasonable

inferences must be drawn in the non-movant's favor. *Zerante v. DeLuca*, 555 F.3d 582, 584 (7th Cir. 2009) ("We view the record in the light most favorable to the nonmoving party and draw all reasonable inferences in that party's favor."). However, a party who bears the burden of proof on a particular issue may not rest on his pleadings, but must show what evidence he has that there is a genuine issue of material fact that requires trial. *Johnson v. Cambridge Indus., Inc.*, 325 F.3d 892, 901 (7th Cir. 2003). The non-moving party bears the burden of specifically identifying the relevant evidence of record, and "the court is not required to scour the record in search of evidence to defeat a motion for summary judgment." *Ritchie v. Glidden Co.*, 242 F.3d 713, 723 (7th Cir. 2001).

II. BACKGROUND

The relevant background facts of record, viewed in the light most favorable to the Plaintiffs, as the non-moving parties, are as follow. Additional facts are included throughout the Entry as relevant.

On June 11, 2015, and again on June 12, 2015, Donna Emley took two pills from a bottle of Equate-brand acetaminophen because she was experiencing general muscle aches and cold symptoms. Dennis[1] had purchased a twin-back of Equate acetaminophen (the "Perrigo Product") in November 2013 from a Wal-Mart near the Plaintiffs' home in Fort Wayne, Indiana.[2] He

[1]While the Plaintiffs' Statement of Material Facts states that Donna purchased the Perrigo Product, the cited deposition testimony states unequivocally that Dennis did so.

[2]It is unclear to the Court why this case was filed in this district (or, more precisely, in a state court in this district). The Perrigo product was purchased in Fort Wayne, Indiana, which is in the Northern District of Indiana. The facts asserted by all of the parties on summary judgment indicate that none of the other relevant events occurred in Indiana. Therefore, while the Amended Complaint alleges that "[v]enue is proper in this District under 28 U.S.C. § 1391 because a substantial part of the events or omission giving rise to the claim occurred in this District," that does not appear to be true. However, [d]istrict courts should not, as a matter of

chose acetaminophen because Donna was undergoing treatment for colorectal cancer at the time and she had been advised by her oncologist to take acetaminophen for relief from headaches and other symptoms.

On June 13, 2015, the Plaintiffs travelled to Kentucky for a planned vacation, during which they were to act as caretakers of a small farm. In the late afternoon or evening after arriving at the farm, Donna noticed a mild rash. The rash worsened overnight, and her eyes became itchy and watery. Early the next morning, the Plaintiffs drove to a nearby Wal-Mart store in Tennessee to purchase medication to help alleviate Donna's symptoms. Donna believed that she was suffering an allergic reaction, perhaps to something she had been exposed to on the farm, and that Benadryl would help. Donna waited in the car while Dennis went into the store, where he purchased Equate brand Severe Allergy and Sinus Headache medication (the "L.N.K. Product"), which contains acetaminophen. Donna took one dose of the L.N.K. Product immediately, and then took another dose approximately four hours later, per the package instructions.

When her symptoms did not improve after her second dose of the L.N.K. Product, Donna went to the Gilbert Grave Urgent Care Center in Bowling Green, Kentucky on the afternoon of June 14, 2015. The physician she saw there sent her to the Bowling Green Medical Center, where she was admitted and remained hospitalized until June 19, 2015. She continued to receive acetaminophen during her treatment there.

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general practice, dismiss *sua sponte* . . . for improper venue," *Auto. Mechanics Local 701 Welfare & Pension Funds v. Vanguard Car Rental USA, Inc.*, 502 F.3d 740, 746 (7th Cir. 2007), and none of the Defendants has filed a motion to dismiss for improper venue.

On June 19, 2015, Donna was transferred to the Vanderbilt University Medical Center, where she was diagnosed with Toxic Epidermal Necrolysis ("TEN"). At that time, she was no longer given acetaminophen. Donna remained hospitalized from June 19, 2015, until July 16, 2015, for treatment of TEN and related symptoms.

III. PREEMPTION

The Plaintiffs allege, and for purposes of this ruling the Court assumes, that the acetaminophen contained in the Perrigo Product and the L.N.K. Product caused Donna to develop TEN. The Plaintiffs further allege that the Products were defective because their label did not contain the following warning regarding the risk that acetaminophen can cause severe skin reactions (hereinafter referred to as "the Warning"):

> Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:
> - skin reddening
> - blisters
> - rash
>
> If a skin reaction occurs, stop use and seek medical help right away.

Each Defendant moves for summary judgment on the ground that the Plaintiffs' claims are preempted by federal law. Specifically, the Defendants argue that the claims are preempted because it would have been impossible for them to comply with both the state-law duties upon which those claims are based and the duties imposed on them by federal law. In other words, they argue that the Plaintiffs' claims against them are barred under the doctrine of impossibility preemption.

A. Applicable Supreme Court Precedent

The Defendants' preemption defense is based upon the fact that the Food and Drug Administration ("FDA") regulates the content of warning labels on drugs pursuant to the Federal

Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.* and related regulations. The Supreme Court has instructed that determinations regarding preemption "must be guided by two cornerstones of our pre-emption jurisprudence":

> First, the purpose of Congress is the ultimate touchstone in every pre-emption case. Second, in all pre-emption cases, and particularly in those in which Congress has legislated in a field which the States have traditionally occupied, we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.

Wyeth v. Levine, 555 U.S. 555, 565 (2009) (internal quotation marks, citations, and ellipses omitted).

In *Wyeth*, the Supreme Court considered preemption as it applied to state-law failure-to-warn claims against the manufacturer of a drug being sold pursuant to an approved New Drug Application ("NDA"). Although "[t]he FDA's premarket approval of a new drug application includes the approval of the exact text in the proposed label," and "[g]enerally speaking, a manufacturer may only change a drug label after the FDA approves a supplemental application," the Court noted that the applicable regulations provided for a "changes being effected" ("CBE") process which permitted a manufacturer "to make certain changes to its label before receiving the agency's approval." *Wyeth*, 555 U.S. at 568. This includes changes made to "add or strengthen a contraindication, warning, precaution, or adverse reaction" or to "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product." 21 C.F.R. §§ 314.70(c)(6)(iii)(A), (C). Thus, the Court found that the manufacturer could have used the CBE process to add the warning in question to its label without prior approval from the FDA. And while "the FDA retains authority to reject labeling changes made pursuant to the CBE regulation in its review of the manufacturer's supplemental

application, just as it retains such authority in reviewing all supplemental applications," the Court held that "absent clear evidence that the FDA would not have approved a change to [the drug's] label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements." *Wyeth*, 555 U.S. at 571. Accordingly, impossibility preemption did not operate to bar the plaintiff's claims based on the NDA manufacturer's failure to include a particular warning on the drug's label.

The Supreme Court reached the opposite conclusion in *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011), which involved a drug being sold pursuant to an approved Abbreviated New Drug Application ("ANDA"). The ANDA process is a separate regulatory scheme that applies to generic versions of drugs that already have been approved by the FDA under the NDA process. The Supreme Court determined that the CBE process was not available to ANDA manufacturers; rather, the applicable regulations require that a generic drug being sold pursuant to an approved ANDA have the same label as the equivalent brand-name drug being sold pursuant to an NDA. *PLIVA*, 564 U.S. at 618 (citing 21 C.F.R. § 314.150(b)(10) (providing that FDA may withdraw approval of ANDA if labeling is no longer consistent with that of equivalent drug that was approved under NDA)). Because there was no mechanism for an ANDA manufacturer to change its label independently of the NDA manufacturer without violating federal law, "it was impossible for the [ANDA] Manufacturers to comply with both their state-law duty to change the label and their federal law duty to keep the label the same," *id.*, and the plaintiffs' claims were preempted. The Court recognized that it made "little sense" from the plaintiffs' perspective that the question of whether a plaintiff could pursue a failure-to-warn claim depended upon whether the plaintiff was injured by a brand-name or generic drug, but noted that "'it is not this Court's task to decide whether the statutory scheme established by Congress is unusual or even bizarre.'"

Id. at 625 (quoting *Cuomo v. Clearing House Assn., L.L.C.*, 557 U.S. 519, 556 (2009) (Thomas, J., concurring in part and dissenting in part)).

B. The Monograph System

Acetaminophen, the drug the Donna Emley took, was not approved pursuant to an NDA or an ANDA. Rather, it is manufactured and sold pursuant to the OTC Drug Monograph Review Process, which is an entirely separate regulatory system that applies to certain over-the-counter ("OTC") drugs. As Defendant Perrigo explains in its brief:

> This process was established in 1972 to address "resource challenges" facing the FDA following new legislation requiring the agency to evaluate the efficacy of all drugs on the market at the time. Rather than undertaking the impractical task of reviewing literally hundreds of thousands of individual OTC drug products already on the market, the Agency implemented a process of reviewing OTC drugs through rulemaking by therapeutic classes. In this way, the monograph process was developed to allow continued marketing of particular ingredients contained in OTC drug products already available on the market that were "generally recognized as safe and effective." *See* 21 C.F.R. § 330.1; 21 C.F.R. § 330.10(a)(1)-(9).
>
> The monograph review process involves several steps, including evaluation by FDA and independent experts of substantial data regarding the safety and efficacy of these ingredients, culminating in a determination of whether these ingredients can continue to be marketed as OTC drugs subject to the specific requirements set forth in the applicable monograph:
>
> > This process involves convening an advisory panel for each therapeutic class to review data relating to claims and active ingredients. These panel reports are then published in the Federal Register, and after FDA review, tentative final monographs for the classes of drugs are published. The final step is the publication of a final monograph for each class.

Dkt. No. 86 at 11-12 (footnotes and some citations omitted) (quoting "Draft Guidance: Marketed Unapproved Drugs – Compliance Policy Guide," § 440.100 at 12-13 (found at Dkt. No. 86-2)). The monograph establishes the conditions under which the drug(s) or category of drugs to which it applies "are generally recognized as safe and effective and not misbranded." 21 C.F.R. §

330.10(a)(9). The final monograph "constitutes final agency action from which appeal lies to the courts." 21 C.F.R. § 330.10(a)(11).

C. Acetaminophen

A tentative final monograph applicable to acetaminophen and other OTC internal analgesic products was published over thirty years ago. *See* "Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use; Tentative Final Monograph," 53 Fed. Reg. 46204 (Nov. 16, 1988). To date, no final monograph applicable to acetaminophen has been issued.

The tentative final monograph applicable to acetaminophen does not contain any warning relating to severe skin reactions such as the one suffered by Donna. In fact, in arriving at the tentative final monograph, the FDA rejected comments suggesting that such warnings be included, finding:

> The agency believes that the warnings which the comments requested are not warranted at this time because there is insufficient evidence that these adverse effects are being caused by acetaminophen. However, if sufficient evidence is presented to warrant new warnings in the future, the agency will act accordingly.

Id. On August 1, 2013, the FDA issued a Drug Safety Communication with the purpose of "informing the public that acetaminophen has been associated with a risk of rare but serious skin reactions." FDA Drug Safety Communication: FDA warns of rare but serious skin reactions with the pain reliever/fever reducer acetaminophen, found at https://www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-fda-warns-rare-serious-skin-reactions-pain-relieverfever-reducer (last visited June 26, 2019). At that time, the FDA stated its intention to

> require that a warning be added to the labels of prescription drug products containing acetaminophen to address the risk of serious skin reactions. FDA will

> also request that manufacturers add a warning about serious skin reactions to the product labels of OTC acetaminophen drug products marketed under a new drug application and will encourage manufacturers of drug products marketed under the OTC monograph do the same.

Id. In November 2014, the FDA issued a document labeled "Draft—Not for Implementation" and entitled "Guidance for Industry: Recommended Warning for Over-the-Counter Acetaminophen-Containing Drug Products and Labeling Statements Regarding Serious Skin Reactions," (found at Dkt. No. 86-9), which was finalized in January 2017 (now found at https://www.fda.gov/media/90572/download) (last visited June 26, 2019) (the final version hereinafter referred to as "the Guidance"). The Guidance stated that the FDA "does not intend to object to the marketing of products containing the following warning language":

> Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: [bullet] skin reddening [bullet] blisters [bullet] rash
> If a skin reaction occurs, stop use and seek medical help right away.

Id. at 3. The Guidance further provided:

> This guidance does not address alternative allergy warning language that may otherwise misbrand the product.
>
> The recommended allergy warning should appear under the "Warnings" heading section of the Drug Facts label under the subheading "Allergy Alert," and, when included, must directly follow the liver warning (21 C.F.R. 201.326) on acetaminophen-containing drug products. FDA recommends that this warning be included on all packaging configurations.

Id. The Guidance also contained the following disclaimer:

> This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA office responsible for this guidance as listed on the title page.

Id. at 1.

D. Preemption Principles Applied to OTC Drugs Marketed Pursuant to a Tentative Final Monograph

Given the holdings in *Wyeth* and *PLIVA*, the question of whether the Plaintiffs' claims in this case are preempted hinges on whether the Defendants had the ability to unilaterally add the Warning at issue to the labels of their products prior to the issuance of the Guidance without violating federal law.[3] *PLIVA*, 564 U.S. at 620 ("The question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it."). The Court finds that the applicable regulatory scheme did not prohibit them from doing so.

The Defendants argue that the tentative final monograph and certain regulations provide specific warnings that they are required to include on their labels and that they are not permitted to include any additional warnings without FDA approval. However, 21 C.F.R. § 330.10(b) provides that "[a]ny product which fails to conform to an applicable monograph after its effective date is liable to regulatory action," and the effective date of a monograph is set forth in the *final* monograph, *see* 21 C.F.R. § 330.10(a)(9) (providing that "[t]he monograph shall become effective as specified in" the final order containing the monograph). A tentative final monograph has no "effective date," because it is simply a proposed rule. *See* Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use; Tentative Final

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[3]The Plaintiffs assert that the Defendants must "prove by clear and convincing evidence" that federal law prohibited them from changing their labels to add the warning. *See, e.g.*, Dkt. No. 102 at 13. That is incorrect. What the law provides is not a question of fact subject to a burden of proof. It is a question of law to be determined by the Court. *See, e.g.*, *Breneisen v. Motorola, Inc.*, 656 F.3d 701, 704 (7th Cir. 2011); *Aguirre v. Turner Const. Co.*, 582 F.3d 808, 814 (7th Cir. 2009).

Monograph, 53 FR 46204-01 (Nov. 16, 1988) ("In order to conform to terminology used in the OTC drug review regulations (21 C.F.R. § 330.10), the present document is designated as a 'tentative final monograph.' Its legal status, however, is that of a proposed rule."). By its very terms, the tentative final monograph does not have the force of law; therefore, the Defendants cannot be in violation of federal law by failing to comply with it.

Not surprisingly, then, the Defendants point to no applicable provision that provides for regulatory action for the failure to conform to a tentative final monograph.[4] Perrigo does, however, cite to a document that supports the contrary position—a draft guidance document issued by the FDA that provides:

> generally products subject to an ongoing . . . OTC drug monograph proceeding (i.e., an OTC product that is part of the OTC drug review for which an effective final monograph is not yet in place) may remain on the market during the pendency of that proceeding and any additional period specifically provided in the proceeding (such as a delay in the effective date of a final OTC drug monograph). However, once the relevant . . . OTC drug monograph proceeding is completed and any additional grace period specifically provided in the proceeding has expired, all products that are not in compliance with the conditions for marketing determined in that proceeding are subject to enforcement action at any time without further notice (see, for example, 21 C.F.R. 310.6).

U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, "Draft Guidance: Marketed Unapproved Drugs – Compliance Policy Guide," Sec. 440.100, Marketed New Drugs Without Approved NDAs or ANDAs (Sept.

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[4]The Defendants cite to 21 C.F.R. § 330.10(7)(i) for the proposition that until the final monograph is issued "the applicable tentative final monograph 'establish[es] conditions under which a category of OTC drugs or specific OTC drugs are generally recognized as safe and effective and not misbranded.'" Dkt. No. 86 at 12. But that provision simply provides that the FDA "shall publish in the Federal Register a tentative order containing a monograph establishing conditions under which a category of OTC drugs or specific OTC drugs are generally recognized as safe and effective and not misbranded" and allow for a comments and objections period. It does not provide that the tentative order has any legal effect.

19, 2011) (footnotes omitted) (found at Dkt. No. 86-2). In other words, the obligation to comply with "the conditions for marketing determined in [a monograph] proceeding" does not attach until a final monograph becomes effective. Consistent with this guidance, the Court finds no statutory or regulatory authority for the proposition that the Defendants would have been subject to regulatory enforcement based upon the failure to conform to the requirements of the tentative final monograph.

Next, the Defendants argue that "[c]ontrolling regulations for monograph OTC products provide that a manufacturer is 'liable to regulatory action' for deviating from the labeling mandated by the applicable monograph or other binding regulations." *See, e.g.*, Dkt. No. 86 at 31-32. For this proposition, the Defendants point to 21 C.F.R. § 330.1, which provides that:

> An over-the-counter (OTC) drug listed in this subchapter is generally recognized as safe and effective and is not misbranded if it meets each of the conditions contained in this part and each of the conditions contained in any applicable monograph. Any product which fails to conform to each of the conditions contained in this part and in an applicable monograph is liable to regulatory action.

However, "applicable monograph" in that regulation refers to a final monograph, not a tentative final monograph; to read it otherwise would contradict 21 C.F.R. § 330.10(b), which provides for regulatory action only after the effective date of a monograph. Thus, for acetaminophen there is no "applicable monograph." The Defendants further argue that the following language in 21 C.F.R. § 330.10(c)(2) limits warnings to those set forth in the tentative final monograph:

> Any other labeling under this subchapter and subchapter C et seq. of this chapter shall be stated in the exact language where exact language has been established and identified by quotation marks in an applicable OTC drug monograph or by regulation (e.g., § 201.63 of this chapter), except as provided in paragraphs (i) and (j) of this section.

Again, however, the Court finds that "an applicable OTC drug monograph" refers to a final monograph, not a tentative one. And while certain label requirements, including warnings, applicable to acetaminophen are set forth in the regulations, the Court finds that the exact language requirement refers to the language used to convey each of the warnings required by the applicable regulations; it is not a requirement that only those warnings be included. The fact that additional warnings beyond those set forth in the regulations are permitted is, of course, demonstrated by the FDA's recommendation that the manufacturers of such products add the Warning.

The Defendants also cite to 21 C.F.R. § 330.13(b)(2), which provides:

> An OTC drug product covered by paragraph (b)(1) of this section which is marketed after the date of publication in the Federal Register of a proposed monograph but prior to the effective date of a final monograph shall be subject to the risk that the Commissioner may not accept the panel's recommendation and may instead adopt a different position that may require relabeling, recall, or other regulatory action. The Commissioner may state such position at any time by notice in the Federal Register, either separately or as part of another document; appropriate regulatory action will commence immediately and will not await publication of a final monograph. Marketing of such a product with a formulation or labeling not in accord with a proposed monograph or tentative final monograph also may result in regulatory action against the product, the marketer, or both.

But it does not appear that acetaminophen is "[a]n OTC drug product covered by paragraph (b)(1)," which is limited to OTC drug products that contain "[a]n active ingredient limited, on or after May 11, 1972, to prescription use" or "[a]n active ingredient at a dosage level higher than that available in an OTC drug product on December 4, 1975." The fact that this provision expressly states that labeling not in conformance with a tentative final monograph may result in regulatory action for these limited categories of OTC drugs is consistent with the fact that such regulatory action will not be taken with regard to other OTC drugs.

Taking into consideration the entire regulatory scheme under which the Defendants products are currently permitted to be marketed, the Court finds that, unlike the ANDA manufacturers in *PLIVA*, the Defendants would not have violated the law by the mere act of adding an additional warning to the label of their acetaminophen products. Of course, that does not mean that they could add any warning without consequence; the FDA had the ability to take regulatory action against them if it believed that the content of the warning was improper and warranted such action.[5] That, however, is no different than the situation that was present in *Wyeth*; an NDA manufacturer that utilizes the CBE process to add a warning may still be subject to regulatory action—the rejection of the new warning—if the FDA believes the new warning to be improper. That possibility is not sufficient to create preemption, however, unless the manufacturer shows by clear evidence that the FDA would not have approved the change, an argument the Defendants have chosen not to make here.

The Defendants quite reasonably argue that there are policy reasons why uniformity of labeling is preferable and why the FDA would want to limit the warnings on OTC drugs to only those specifically required by the FDA in order to avoid the risks associated with overwarning consumers. However, the Court cannot rewrite the applicable regulatory scheme, even when that

[5]The Defendants assert that "the FDA has, in fact, taken regulatory action based upon the wording of drug warnings that it found to deviate from a tentative final monograph," and cite to a warning letter sent by the FDA to Quadex Pharmaceuticals, LLC, in 2011. *See, e.g.*, Dkt. No. 86 at 32 and n.22. However, the FDA's position in that letter was not that the product at issue was misbranded simply because its label was different from that proposed in the applicable tentative final monograph; rather, the FDA found that the label contained statements that were misleading. *See* Dkt .No. 86-20.

scheme has left the Defendants and other drug makers in an unfortunate state of limbo for decades.[6]

Finally, Defendant Wal-Mart advances an additional reason why it believes the Plaintiffs' claims against it are preempted. Unlike Perrigo and L.N.K., Wal-Mart argues, it did not manufacture the drugs in question, but is merely the retailer that sold them to the Emleys. Wal-Mart asserts that "Courts have consistently held that, under the federal regulatory framework for the sale and labeling of OTC drugs, distributors, pharmacies, or others who merely sell a drug—but do not manufacture it—lack the power to change the drug's label." Dkt. No. 89 at 4. However, each of the cases cited by Wal-Mart relied upon the fact that, under the relevant regulations, the CBE process found to preclude preemption in *Wyeth* can only be undertaken by the holder of the NDA. *See In re Fosamax (Alendronate Sodium) Prod. Liab. Litig. (No. II)*, 2012 WL 181411, at *3 (D.N.J. Jan. 17, 2012) ("As a distributor of Fosamax, Watson has no power to change Fosamax labeling. That power lies with the applicant who filed the New Drug Application (NDA) seeking approval to market Fosamax. *See* 21 U.S.C. § 355(b); 21 C.F.R. § 314.70 (describing the Changes Being Effected or 'CBE' regulation, which requires that 'the *applicant* must notify FDA about each change in each condition established in an approved

[6]In making this ruling, the Court has not considered the expert opinions submitted by the Plaintiffs regarding the application of the relevant regulatory scheme to the issues in this case. *See Grussgott v. Milwaukee Jewish Day Sch., Inc.*, 882 F.3d 655, 661-62 (7th Cir.), *cert. denied*, 139 S. Ct. 456 (2018) (finding that an expert witness "overstepped his role as an 'expert'" by conveying a legal opinion because "[c]ourts do not consult legal experts; they are legal experts."); *Aguirre v. Turner Const. Co.*, 582 F.3d 808, 814 (7th Cir. 2009) ("The meaning of federal regulations is not a question of fact, to be resolved by the jury after a battle of experts. It is a question of law, to be resolved by the court.") (quoting *Bammerlin v. Navistar Int'l Transportation Corp.*, 30 F.3d 898, 900 (7th Cir.1994)); *United States v. Caputo*, 517 F.3d 935, 942 (7th Cir. 2008) (The meaning of statute and regulations is "a subject for the court, not for testimonial experts. The only legal expert in a federal courtroom is the judge.").

application.') (emphasis added)."); *Brazil v. Janssen Research & Dev. LLC*, 196 F. Supp. 3d 1351, 1364-65 (N.D. Ga. 2016) (relying on *In re Fosamax* to reach the same conclusion); *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prod. Liab. Litig.*, No. 2: 16-CV-0334, 2016 WL 7368203, at *2 (D.S.C. Nov. 1, 2016) ("As a result of the scheme set forth by the Federal Drug and Cosmetic Act (FDCA), a pharmacy also has no authority to unilaterally change a drug's label. That authority lies with the FDA and/or with Pfizer. *See* 21 C.F.R. § 314.70 (limiting label changes to those approved by the FDA and 'Changes Being Effected' or 'CBE' changes by the 'applicant,' which is the manufacturer))"; *Nelson v. Wal-Mart Stores, INC.*, No. 4:14CV4-RH/CAS, 2014 WL 12461056, at *2 (N.D. Fla. Mar. 26, 2014) ("As the seller of generic equivalents, Walmart is not free to change the labeling. *See, e.g., PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2577 (2011)."). None of these cases support Wal-Mart's claim in this case, which does not involve the CBE process.

Impossibility preemption bars the Plaintiffs' claims against Wal-Mart only if Wal-Mart could not have changed the labels of the products without violating federal law. While Wal-Mart may not, as a practical matter, have had the ability to change the labels based upon its contractual agreement with the manufacturers, Wal-Mart has not pointed to any federal law that it would have been violating by doing so. Accordingly, impossibility preemption does not apply to the Plaintiffs' claims against Wal-Mart.

For the reasons set forth above, the Defendants' motions for summary judgment on preemption grounds (Dkt. Nos. 85 and 88) and L.N.K.'s motion for summary judgment (Dkt. No. 124) as it relates to preemption are **DENIED**.

IV. PERRIGO'S SECOND MOTION FOR SUMMARY JUDGMENT

In its second motion for summary judgment (Dkt. No. 122), Perrigo asserts several reasons why it believes it is entitled to summary judgment, each of which is addressed, in turn, below.

A. Common Law Claims Governed by the Indiana Products Liability Act

Under Indiana law, which the parties agree applies to the Plaintiffs' claims against Perrigo, the Indiana Products Liability Act ("IPLA") "governs all actions that are: (1) brought by a user or consumer; (2) against a manufacturer or seller; and (3) for physical harm caused by a product . . . regardless of the substantive legal theory or theories upon which the action is brought." Ind. Code § 34-20-1-1. The Plaintiffs concede that Count VI (negligence), Count VII (gross negligence), Count IX (breach of express warranty), and Count X (implied warranty) also are governed by the IPLA, but object to summary judgment being entered on those claims and ask instead that they be "merged" with their IPLA claims. However, Perrigo is entitled to summary judgment on the Plaintiffs' claim that they are entitled to recover under those legal theories. They are not. Accordingly, Perrigo's motion for summary judgment is granted with regard to the Plaintiffs' claims for common law negligence, gross negligence, breach of express warranty, and breach of implied warranty.

Perrigo argues that the Plaintiffs' claim for negligent misrepresentation and/or fraud, asserted in Count VIII of the Amended Complaint, also is governed by the IPLA. To the extent that the Plaintiffs seek to recover for damages that arose of out the physical harm suffered by Donna, Perrigo clearly is correct. The Plaintiffs assert that they also seek "economic damages, including a full refund of the purchase price of the Perrigo product," Dkt. No. 156 at 10, because they "relied on Defendants' fraudulent misrepresentations and concealments to purchase and/or

use the products, resulting in damages." *Id.* at 9. However, the Plaintiffs' brief makes it clear that their fraud claim against Perrigo *is* based upon the physical harm that Donna suffered. The Plaintiffs argue that

> Mrs. Emley would not have continued to ingest additional acetaminophen following the outbreak of her rash, had the Equate Acetaminophen included a warning to discontinue use of acetaminophen-containing products and to seek medical attention if a rash develops. Because she did not have the benefit of an adequate warning label, Plaintiffs purchased, and Mrs. Emley ingested, yet another acetaminophen containing product from Wal-Mart, thereby suffering economic harm that they are making a claim for.

Dkt. No. 156 at 11-12. They further argue that they can satisfy the requirement of detrimental reliance: "Because the product Plaintiffs purchased never warned consumers to stop taking acetaminophen and seek medical attention if they develop a rash, Mrs. Emley kept taking acetaminophen-containing products even after she developed a rash, which both caused and exacerbated her injuries." Dkt. No. 156 at 30. In other words, the Plaintiffs do not allege that they suffered an economic injury simply because they purchased Perrigo's product; rather, they allege that they suffered injuries because Donna suffered a physical reaction to the product. Therefore, the Plaintiffs' fraud claim is one for physical injury caused by a product, and they may not maintain this as a claim separate from their IPLA claim. Accordingly, Perrigo is entitled to summary judgment as to that claim.[7]

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[7]The case relied on by the Plaintiffs, *Elward v. Electrolux Home Products, Inc.*, 264 F. Supp. 3d 877 (N.D. Ill. 2017), does not support a contrary finding. In that case, the plaintiffs alleged that "they would not have purchased [the product in question] or would have insisted on a lower price if they had been apprised of the defect." Thus, the plaintiffs alleged that the fact that they purchased or overpaid for a defective product caused them injury, even in the absence of any damage caused by the product's failure, because the product was not worth what they paid for it. Here, the Plaintiffs do not allege that they would not have purchased Perrigo's product if it had included the Warning; rather, they allege that Donna would have stopped taking acetaminophen and avoided further physical harm.

The same is true for the Plaintiffs' negligent misrepresentation claim. *See* Dkt. No. 156 at 29 ("The evidence supports Plaintiffs' claims that Perrigo inappropriately (and negligently) misrepresented to Plaintiffs that its Equate product was safe and effective, despite knowing that the product label did not warn of potentially fatal side effects associated with the product, and Plaintiff Donna Emley suffered that very side effect as a result of ingesting the product."). In addition, as Perrigo correctly points out, the tort of negligent misrepresentation has been recognized in Indiana "'in the limited circumstance of the employer-employee relationship.'" Dkt. No. 123 at 38 (quoting *Mart v. Forest River, Inc.*, 854 F. Supp. 2d 577, 595 (N.D. Ind. 2012), and citing *Darst v. Ill. Farmers Ins. Co.*, 716 N.E.2d 579, 583-84 (Ind. Ct. App. 1999)). The Plaintiffs do not respond to this argument in their brief, do not cite to any authority that suggests that the Indiana Supreme Court would recognize the tort in the factual context of this case, and, in fact, do not even delineate what they believe the elements of the tort are. "It is not this court's responsibility to research and construct the parties' arguments," *Draper v. Martin*, 664 F.3d 1110, 1114 (7th Cir. 2011), and "[p]erfunctory and undeveloped arguments are waived, as are arguments unsupported by legal authority." *Schaefer v. Universal Scaffolding & Equip., LLC*, 839 F.3d 599, 607 (7th Cir. 2016). Accordingly, the Court finds that Perrigo is entitled to summary judgment on the Plaintiffs' negligent misrepresentation claim.

B. Statute of Limitations

Remaining to be considered are Counts I and II of the Amended Complaint, which expressly assert claims under the IPLA;.[8] the Plaintiffs' claim under the Indiana Deceptive

[8]The Plaintiffs are no longer pursuing Count III, which is a defective manufacturing claim; accordingly, summary judgment is granted to all of the Defendants as to that claim. *See*

Consumer Sales Act ("IDCSA"); and Dennis Emley's claim for loss of consortium.[9] Perrigo argues that each of these claims is barred by the applicable statute of limitations.

1. IDCSA Claim

The IDCSA provides: "Any action brought under this chapter may not be brought more than two (2) years after the occurrence of the deceptive act." Ind. Code § 24-5-0.5-5(b). As Perrigo correctly argues, this is an occurrence statute of limitations to which the discovery rule does not apply. *See A.J.'s Auto. Sales, Inc. v. Freet*, 725 N.E.2d 955, 964-65 (Ind. Ct. App. 2000) ("Because the Deceptive Sales Act has an occurrence statute of limitation, rather than a discovery statute of limitation, the statutory period commences to run at the occurrence of the deceptive act."). Here, the allegedly deceptive act occurred when the Plaintiffs purchased Perrigo's product in November 2013. The Plaintiffs did not file this suit within two years of that date; their original complaint was not filed until June 8, 2017. Accordingly, the Plaintiffs' claims under the IDCSA are barred by the statute of limitations.[10]

Dkt. No. 156 at 27 n.122 ("Plaintiffs do not claim either product at issue was defective based on a manufacturing defect.").

[9]Because a loss of consortium claim is derivative of the injured spouse's personal injury claim, *Durham ex rel. Estate of Wade v. U-Haul Int'l*, 745 N.E.2d 755, 764 (Ind. 2001), the viability of Dennis's claim is dependent upon the viability of Donna's claims.

[10]The Plaintiffs do not respond to Perrigo's argument on this issue in any way; again, "[i]t is not this court's responsibility to research and construct the parties' arguments," *Draper*, 664 F.3d at 1114. In addition, the argument made by the Plaintiffs in response to Wal-Mart's motion that the statute of limitations was tolled by the doctrine of fraudulent concealment is without merit. Under Indiana law, "[t]o invoke the doctrine where no fiduciary relationship exists between the parties . . . a plaintiff must show that the wrongdoer was not simply silent but committed affirmative acts designed to conceal the cause of action." *Horn v. A.O. Smith Corp.*, 50 F.3d 1365, 1372 (7th Cir. 1995). The Plaintiffs point to no such affirmative acts taken by Perrigo or Wal-Mart.

2. IPLA and Loss of Consortium Claims

The parties agree that the Plaintiffs' IPLA and loss of consortium claims are governed by a two-year statute of limitations that accrued no earlier than June 13, 2015, when Donna first developed a rash. The Plaintiffs' original complaint was filed less than two years before that date. However, that complaint did not name Perrigo as a Defendant; Perrigo was added as a Defendant in the Plaintiffs' Amended Complaint, which was filed more than two years after that date. The Plaintiffs argue that their claims against Perrigo are nonetheless timely pursuant to the relation back rule set forth in Federal Rule of Civil Procedure 15(c). The Court agrees.

As an initial matter, Perrigo argues that the issue of relation back is governed by Indiana Trial Rule 15 rather than the Federal Rule because the original complaint was filed in Indiana state court. That argument is without merit. While "federal courts may apply state procedural rules to pre-removal conduct," *Romo v. Gulf Stream Coach, Inc.*, 250 F.3d 1119, 1122 (7th Cir. 2001), the amended complaint was filed after removal in this case. That federal court filing is subject to federal law with regard to relation back.[11]

In *Joseph v. Elan Motorsports Techs. Racing Corp.*, 638 F.3d 555, 560 (7th Cir. 2011), the court recognized that the Supreme Court's holding *Krupski v. Costa Crociere S. p. A.*, 560 U.S. 538 (2010), changed the law in this circuit with regard to relation back. Perrigo recognizes that fact, but nonetheless relies upon pre-*Krupski* cases that held that relation back does not apply to a defendant about whom the plaintiff lacked knowledge when the original complaint was filed,

[11]The case cited by Perrigo, *Clemons v. City of Hobart*, 2018 WL 1531787, at *1 (N.D. Ind. Mar. 29, 2018), does not suggest otherwise. The amended complaint in that case was filed in December 2016, before the case was removed to federal court, which occurred sometime in 2017 as demonstrated by its federal court cause number of 2:17-cv-11.

arguing that those holdings remain good law. The Court disagrees. In *Joseph*, the Seventh Circuit recognized that prior to *Krupski*, it "had thought the focus should be on what the plaintiff knew or should have known," but that

> [t]he only two inquiries that the district court is now permitted to make in deciding whether an amended complaint relates back to the date of the original one are, first, whether the defendant who is sought to be added by the amendment knew or should have known that the plaintiff, had it not been for a mistake, would have sued him instead or in addition to suing the named defendant; and second, whether, even if so, the delay in the plaintiff's discovering his mistake impaired the new defendant's ability to defend himself.

638 F.3d at 559-60. Thus, in *Joseph*, the Seventh Circuit found that the district court's ruling that there was no relation back because the plaintiff "had intended to sue Elan Corp. even though the other party to his contract was Elan Inc." had been a correct application of pre-*Krupski* law. *Id.* at 559. However, the opposite result was dictated by *Krupski*, which was decided before the appeal was heard, because "Elan Inc. knew that Waldrop meant to sue it rather than Elan Corp. He meant to sue the party to the employment contract with him and Elan Inc. was that party." *Id.* at 560.

The relevant circumstances of this case cannot be distinguished from *Joseph*. Here, there is simply no question that Perrigo knew that the Plaintiffs intended to sue the manufacturer of the product they purchased at Wal-Mart in November 2013, and Perrigo, not Wal-Mart, was that party. Therefore, Perrigo "knew or should have known that the [Pl]aintiff[s], had it not been for a mistake, would have sued [it] instead or in addition to suing the named defendant,"[12] *id.*, and,

[12]Perrigo's argument that there can be no mistake because the Plaintiffs added Perrigo as a defendant rather than substituting Perrigo for Wal-Mart is foreclosed by this plain statement by the Seventh Circuit.

since no prejudice is alleged by Perrigo, relation back applies and the Plaintiffs' claims against Perrigo are timely.

Perrigo correctly notes that, even under *Krupski*, when "the original complaint and the plaintiff's conduct compel the conclusion that the failure to name the prospective defendant in the original complaint was the result of a fully informed decision as opposed to a mistake concerning the proper defendant's identity," the requirements of relation back are not met. Dkt. No. 123 at 31 (quoting *Krupski*, 560 U.S. at 552). Perrigo argues that that is the case here, pointing to the following email sent by Plaintifs' counsel to Perrigo's counsel in response to Perrigo's suggestion that the Plaintiffs substitute Perrigo for Wal-Mart:

> At this point, we have no intention of substituting Wal-Mart out of the case since they are the labeler and retailer of the product, at a minimum. My understanding of Indiana law is that a retailer can be held liable for selling the product that caused injury, and that such claims are not limited to just the manufacturer. Additionally, we have not seen any evidence thus far of any other company's involvement in the product, which on its face only identifies Wal-Mart.

See Dkt. No. 123-4. However, that email cannot reasonably be read to support the argument that the Plaintiffs made an informed decision to sue Wal-Mart rather than Perrigo; rather, it supports a finding that the Plaintiffs were not aware that Perrigo was the manufacturer at the relevant time—that is, when they filed their original complaint[13]—and demonstrates that the Plaintiffs made a tactical decision to add Perrigo as an additional defendant instead of substituting it for Wal-Mart because they believed that Wal-Mart could be liable as a labeler and retailer even if Perrigo had manufactured the product.

[13]Indeed, Perrigo's own statement of facts contains the following: "Prior to this email, there is no evidence that Plaintiffs were aware of Perrigo's existence or role in manufacturing and labeling" the Perrigo product. Dkt. No. 123 at 12.

For the reasons set forth above, the Court finds that the Plaintiffs' claims against Perrigo under the IPLA and for loss of consortium relate back to the original complaint and therefore are not barred by the statute of limitations.[14]

C. Merits of Plaintiffs' ILPA Claims Against Perrigo

Perrigo also argues that it is entitled to summary judgment with regard to the merits of the Plaintiffs' claims under the IPLA.

> Under the [IPLA], a plaintiff must prove that a product was placed into the stream of commerce in a defective condition unreasonably dangerous to the user and that plaintiff's injuries were caused by this dangerous product. Ind. Code § 34-20-2-1. A product can be defective within the meaning of the Act because of a manufacturing flaw, a defective design or a failure to warn of dangers while using the product.

Campbell Hausfeld/Scott Fetzer Co. v. Johnson, 109 N.E.3d 953, 956 (Ind. 2018). As noted above, the Amended Complaint contains both a failure to warn claim (Count I) and a design defect claim (Count II). However, Perrigo correctly argues that the Plaintiffs do not actually assert a design defect claim, but rather simply reassert their failure to warn claim under the guise of a design defect claim. The Plaintiffs' only response to this argument is the following:

> Under Indiana law, a product can be defective (and a defendant can be strictly liable for that defect) because of a manufacturing defect, a design defect, or a lack of adequate instructions and warnings. A product is defective under the IPLA "if the seller fails to: (1) properly package or label the product to give reasonable warnings of danger about the product; or (2) give reasonably complete instructions on proper use of the product; when the seller, by exercising reasonable diligence, could have made such warnings or instructions to the user or consumer." Plaintiffs' claims that Perrigo failed to provide adequate warnings to

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[14]The parties spend much of their briefs arguing over whether Perrigo's consent to the filing of the motion for leave to file the amended complaint constituted an agreement that the amended complaint would relate back to the original complaint because of language to that effect contained in the motion for leave. The Court need not, and therefore does not, address that issue.

> consumers on its products are indeed strict liability defective design claims under Indiana law and, [sic] have proffered more than sufficient evidence to prove such claims. As such, Perrigo's motion should be denied.

Dkt. No. 156 at 27 (footnotes omitted). This is nonsensical. There is no dispute that a failure to warn claim is a claim under the IPLA; there is also no dispute that the failure to warn can render a product "defective." But that is the allegation in Count I. The Plaintiffs fail to articulate any defect in the *design* of Perrigo's product, which is what is required to succeed on the *design defect* claim asserted in Count II. Accordingly, Perrigo's motion for summary judgment is granted with regard to the Plaintiffs' design defect claim.

Perrigo also argues that it is entitled to summary judgment on the Plaintiffs' failure to warn claim.

> [A] product may be defective under the [IPLA] where the manufacturer fails in its duty to warn of a danger or instruct on the proper use of the product as to which the average consumer would not be aware. . . . This duty is twofold: (1) to provide adequate instructions for safe use and (2) to provide a warning as to dangers inherent in improper use. "[I]n an action based on . . . an alleged failure to provide adequate warnings or instructions regarding the use of the product, the party making the claim must establish that the manufacturer or seller failed to exercise reasonable care under the circumstances in . . . providing the warnings or instructions." I.C. § 34-20-2-2.

Ford Motor Co. v. Rushford, 868 N.E.2d 806, 810 (Ind. 2007).[15] "Whether a particular act or omission is a breach of duty is generally a question of fact for the jury, but can be a question of

[15]The Plaintiffs assert that "[u]nder Indiana law, a product can be defective (and a defendant can be strictly liable for that defect) because of a manufacturing defect, a design defect, or a lack of adequate instructions and warnings." Dkt. No. 156 at 27. That is incorrect. Strict liability is available only in manufacturing defect cases under the IPLA. *Johnson*, 109 N.E.3d at 957 ("In 1995, several significant amendments were made to the IPLA. *See* Ind. Code §§ 33-1-1.5-1 through 33-1-1.5-10 (1995). For instance, the 1995 Amendments eliminated joint or shared liability, limited strict liability claims to manufacturing defect claims, and provided that actions against sellers based on design defects or based on failure to provide adequate

law when the facts are undisputed and only a single inference can be drawn from those facts." *Cook v. Ford Motor Co.*, 913 N.E.2d 311, 327 (Ind. Ct. App. 2009); *see also Rushford*, 868 N.E.2d at 810 ("[T]he adequacy of warnings . . . is generally a question of fact for the trier of fact to resolve.").

Perrigo, citing *Kelso v. Bayer Corp.*, 398 F.3d 640 (7th Cir. 2005), argues that the warnings on its product were adequate as a matter of law because its labeling "complied with all mandatory labeling warnings in the applicable monograph, and other applicable federal labeling regulations." Dkt. No. 123 at 37. *Kelso* involved a drug subject to a final monograph that provided specific wording for the warning in question:

> Stop use and ask a doctor if symptoms persist. Do not use this product for more than 3 days. Use only as directed. Frequent or prolonged use may cause nasal congestion to recur or worsen.

Kelso, 398 F.3d at 641. The plaintiff in that case argued that the language of that warning

> was confusing as to whether or not the product could be used safely for more than three days, when such use was effective in relieving his congestion. As Kelso explained in his affidavit, he interpreted the warning as meaning not to exceed three days use if the product failed to relieve the congestion; he only needed to see a physician if the product did not work to relieve the congestion. Also, because the container included much more than three days' dosage, Kelso insists that he had good reason to believe that he could safely use Neo-Synephrine for more than three days.

Id. at 642. The Seventh Circuit held that the warning was adequate as a matter of law because it "complied with the FDA-required warning." *Id.* at 643.

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warnings/instructions are to be decided using a negligence standard. Ind. Code § 33-1-1.5-1 (1995); § 33-1-1.5-3 (1995)."); *Weigle v. SPX Corp.*, 729 F.3d 724, 737 (7th Cir. 2013) (same).

As discussed at length above, there is no final monograph applicable to Perrigo's product, and therefore there was no "FDA-required warning" with regard to skin reactions that Perrigo was required to follow. Unlike the defendant in *Kelso*, Perrigo had the ability under federal law to strengthen its warning label if the information available to it so warranted; it was not confined to any exact language dictated by the FDA. Perrigo cites to no authority for the proposition that a warning that conforms to non-binding warning recommendations made by the FDA is adequate as a matter of law.

Perrigo also cites *Kelso* for the proposition that where a product "contains warnings that are 'clear and unambiguous' but a plaintiff fails to follow those clear warnings, the warnings are adequate as a matter of law and summary judgment should be entered for the manufacturer." Dkt. No. 123 at 37. Indeed, the court held in *Kelso* that the warning "Do not use this product for more than 3 days" was clear and unambiguous and therefore adequate as a matter of law, despite the plaintiff's attempt to cast is as ambiguous.

Perrigo argues that the warning on its product that read as follows was similarly clear and unambiguous:

> Stop use and ask a doctor if
> - pain gets worse or lasts more than 10 days
> - fever gets worse or lasts more than 3 days
> - new symptoms occur
> - redness or swelling is present
>
> These could be signs of a serious condition

Perrigo argues that had Donna followed this warning, she would have stopped using acetaminophen and consulted a doctor once the "new symptom" of a rash occurred; thus, the warning on the product was adequate as a matter of law to prevent the injury Donna suffered. That is a reasonable argument that might, indeed, carry the day with a jury. However, the Court

cannot say that the warning was adequate as a matter of law. This case does not involve a clear and unambiguous statement like "Do not use this product for more than 3 days." Indeed, the FDA recommended that acetaminophen products also include the Warning, which reads:

> Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:
> - skin reddening
> - blisters
> - rash
>
> If a skin reaction occurs, stop use and seek medical help right away.

This suggests that, in the FDA's opinion, this more specific reference to blisters and a rash, as well as the direction to "seek medical help right away," rather than simply to "ask a doctor," is a more effective warning than that on the Perrigo Product. The Plaintiffs also have offered expert opinions that the labeling on the Perrigo Product was inadequate. Viewing the evidence of record in the light most favorable to the Plaintiffs, a reasonable jury could so find. Accordingly, Perrigo's motion for summary judgment on the Plaintiffs' failure to warn claim is denied.[16]

D. Punitive Damages

Finally, Perrigo argues that it is entitled to summary judgment on the Plaintiffs' claim for punitive damages.

> [I]n Indiana, before a court may award punitive damages, a plaintiff must demonstrate by clear and convincing evidence that the defendant acted with malice, fraud, gross negligence or oppressiveness that was not the result of mistake of fact or law, honest error of judgment, overzealousness, mere negligence, or other human failing.

[16]Perrigo does not argue that it is entitled to summary judgment on the issue of whether it exercised due care in the implementation of the Warning; rather, it argues only that its labeling at the time Donna purchased its product was adequate as a matter of law.

Juarez v. Menard, Inc., 366 F.3d 479, 482 (7th Cir. 2004) (citations omitted). "The tortfeasor must act with conscious indifference or heedless disregard of the consequences of her actions." *Id.* "Indiana courts have described this consciousness and intention as requiring a show of willful and wonton conduct or a 'quasi-criminal state of mind.'" *Id.* (citing *Stroud v. Lints*, 760 N.E.2d 1176, 1179 (Ind. App. 2002), *vacated on other grounds*, 790 N.E.2d 440 (Ind. 2003); *Mitchell v. Stevenson*, 677 N.E.2d 551, 564 (Ind. App. 1997)).

Perrigo argues that no reasonable jury could apply this high standard to the evidence of record in this case and conclude that a punitive damages award against it is warranted. The Court agrees.

The Plaintiffs' entire argument on this issue in its response to Perrigo's motion is the following:

> As an initial matter, in the months before Mrs. Emley purchased the both [sic] Equate products, Perrigo knew that: (1) acetaminophen was associated with a risk of potentially fatal serious skin reactions; (2) the FDA was encouraging manufacturers of drug products marketed under the OTC monograph to add a skin reaction warning to their product labels; (3) the FDA had specifically approved a skin reaction warning for use on NDA acetaminophen-containing products sold over the counter.
>
> In response, Perrigo did nothing. And it continued to do nothing for nearly two years. Even then, Perrigo still continued to sell older Equate Acetaminophen products without the enhanced skin reaction warning until such products were sold out. The egregious nature of this conduct is amplified by the fact that Perrigo has admitted, through its employees and in internal company documents, that it viewed the addition of a skin reaction warning as "an enhancement" to the existing labeling.
>
> But there is more. Perrigo's own employees have testified that the Company did not consider patient safety when deciding whether to change the product label. Indeed, Perrigo's Regulatory Affairs Director, Valerie Gallagher, acknowledged that Perrigo was not concerned that selling older Equate Acetaminophen without the skin reaction warning might injure consumers. Rather, the only two factors that concerned the company were FDA compliance and OTC industry backlash.

> Astonishingly, Perrigo's head of pharmacovigilance, Granine Quinn, testified that Perrigo has no obligation whatsoever to inform the public or potential consumers about potentially fatal conditions associated with its products—an opinion directly contrary to Indiana law and Supreme Court precedent. Still, the most stunning evidence supporting Plaintiffs' claims for punitive damages is that, even when Perrigo was certain that it was going to sell Equate Acetaminophen products with an updated skin reaction warning (in April 2014) or, at least by November 2014), it did not pull the older Equate Acetaminophen products without skin reaction warnings label from the shelves, but rather used a "normal flow through of a conversion process," exposing even more consumers to the risk of serious and potentially fatal skin reactions.
>
> Plaintiffs have proffered evidence that shows that Perrigo was indifferent to the consequences of its actions, including the very real risk that a consumer, like Donna Emley, might develop a life-threatening skin reaction from its product, and that Perrigo placed its profits ahead of consumer safety. Accordingly, whether Perrigo should be punished for its actions should be decided by a jury, and Perrigo's motion should be denied.

Dkt. No. 156 at 32-34 (footnotes omitted).

The problem with this argument is that it focuses on events that are unrelated to the only act for which Perrigo can be liable to Donna—the November 2013 sale of its product to the Plaintiffs. The relevant question is whether the Plaintiffs have pointed to clear and convincing evidence that Perrigo's failure to include the Warning on its product *prior to November 2013* was an act of "gross negligence . . . that was not the result of mistake of fact or law, honest error of judgment, overzealousness, mere negligence, or other human failing." The Plaintiffs have not done so. "[S]ummary judgment is the 'put up or shut up' moment in a lawsuit, *Citizens for Appropriate Rural Roads v. Foxx*, 815 F.3d 1068, 1077 (7th Cir. 2016), and on the issue of punitive damages against Perrigo, the Plaintiffs have simply failed to point to evidence that would support such a finding, and indeed have failed to articulate an argument that Perrigo's actions prior to the Plaintiffs' purchase of the Perrigo Product justify an award of punitive damages. Accordingly, Perrigo's motion for summary judgment on that issue is granted.

E. Conclusion with Regard to Perrigo

For the reasons set forth below, Perrigo's motion for summary judgment is **GRANTED** as to all claims against it except for the Plaintiffs' failure to warn claim under the IPLA (including Dennis's claim for loss of consortium that is tied to that claim).

V. REMAINDER OF L.N.K.'S MOTION FOR SUMMMARY JUDGMENT [17]

In the remainder of its motion for summary judgment, Dkt. No. 124, L.N.K. argues that it is entitled to summary judgment on all of the Plaintiffs. Each of L.N.K.'s arguments is addressed, in turn, below.

A. Choice of Law

L.N.K. argues that Tennessee law applies to the Plaintiffs' claims against it because the Plaintiffs purchased its product in Tennessee. "A federal court sitting in diversity 'applies the choice-of-law rules of the forum state to determine which state's substantive law applies.'" *Atlantic Cas. Ins. Co. v. Garcia*, 878 F.3d 566, 569 (7th Cir. 2017) (quoting *Auto–Owners Inc. Co. v. Websolv Computing, Inc.*, 580 F.3d 543, 547 (7th Cir. 2009)). Therefore, Indiana's choice-of-law rules apply in this case.

Under Indiana law, if there is a relevant conflict between the law of the states at issue,[18]

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[17]L.N.K.'s argument that the Plaintiffs' claims against it are preempted by federal law are resolved above.

[18]While the parties do not specifically address whether there are relevant differences between the substantive law of Tennessee and Indiana law, the Court has identified at least two. As noted above, failure to warn claims are subject to a negligence standard under the IPLA, while under Tennessee law such claims also can be brought under a strict liability theory. *See* Tenn. Code Ann. § 29-28-102(6) (defining "product liability action" to include actions based on "breach of or failure to discharge a duty to warn or instruct, whether negligent, or innocent"). And, as discussed below, the two laws differ with regard to when a seller can be held liable in a product liability suit.

> the presumption is that the traditional *lex loci delicti* rule (the place of the wrong) will apply. [*Hubbard Manufacturing Co. v. Greeson*, 515 N.E.2d 1071, 1073 (Ind. 1987)]. Under this rule, the court applies the substantive laws of the "the state where the last event necessary to make an actor liable for the alleged wrong takes place." *Id.*
>
> This presumption is not conclusive, however. It may be overcome if the court is persuaded that "the place of the tort 'bears little connection' to this legal action." *Id.* at 1074.

Simon v. United States, 805 N.E.2d 798, 805 (Ind. 2004); *see also Rexroad v. Greenwood Motor Lines, Inc.*, 36 N.E.3d 1181, 1183-84 (Ind. Ct. App. 2015) (same).

In this case, there is no question that Tennessee is the state in which the last act necessary to impose liability on L.N.K. occurred, as L.N.K.'s product was both purchased and used in Tennessee.[19] However, the Plaintiffs argue that Tennessee "bears little connection" to this case and therefore Indiana law should apply. The Plaintiffs' argument is premised on the fact that the Plaintiffs just happened to be traveling at the time the purchase was made, and had they not been traveling, "the purchase and/or use of the L.N.K. product would have occurred at a Wal-Mart in Indiana." Dkt. No. 141 at 7. Thus, they argue, this case is analogous to *Simon*, which the Indiana Supreme Court found to be "one of the rare cases in which the place of the tort is insignificant." *Simon*, 805 N.E.2d at 806. The Court finds that argument unpersuasive.

Simon involved a plane crash that occurred in Kentucky. The Indiana Supreme Court explained its holding as follows:

> The negligence at issue occurred in Indiana and the District of Columbia, and none of the victims or the parties are residents of Kentucky (except to the extent that the United States is a "resident" of every state). The plane flew over multiple states during the course of the flight, and the crash might have occurred anywhere. In addition, unlike in cases involving an automobile accident, the laws

[19]Donna also took a dose of L.N.K.'s product in Kentucky, but neither party argues that Kentucky law should apply in this case.

> of the state where the crash occurred did not govern the conduct of the parties at the time of the accident. Consequently, we conclude that the place of the tort was an insignificant contact in this case.

Id. In this case, the conduct of the parties *was* governed by Tennessee law at the relevant time. L.N.K. was obligated to comply with Tennessee law when it sold products in Tennessee, and consumers who make purchases in Tennessee are entitled to the protection of Tennessee laws that apply to such purchases. The unique facts present in *Simon* simply are not present in this case, and the Plaintiffs point to no other authority that would suggest that the application of *lex loci delicti* is not appropriate under the facts of this case.

Further, even if *lex loci delicti* did not apply, it would still not be appropriate to apply Indiana law to the Plaintiffs' claims against L.N.K.. *Simon* instructs that if the

> place of the tort is insignificant . . . [the Court] must consider what other contacts exist and evaluate them according to their relative importance to the litigation at hand. We apply the law of the state with the most significant relationship to the case. *Hubbard* suggests three factors that might be relevant: "1) the place [or places] where the conduct causing the injury occurred; 2) the residence or place of business of the parties; and 3) the place where the relationship is centered." *Id.* This is not a comprehensive list, of course, and other relevant factors may be considered . . . . "These factors should not be applied mechanically; rather, they are to be 'evaluated according to their relative importance to the particular issues before the court.'" *Jean v. Dugan,* 20 F.3d 255, 261 (7th Cir.1994) (quoting *Hubbard,* 515 N.E.2d at 1074).

Simon, 805 N.E.2d at 806 (some citations omitted). With regard to the Plaintiffs' claims against L.N.K., the only relationship they have to the state of Indiana is that the Plaintiffs live there. However, the court in *Simon* held that

> [t]he residence or place of business of a party, while important in cases involving family law or asset distribution, is not a particularly relevant contact in this case. People do not take the laws of their home state with them when they travel but are subject to the laws of the state in which they act. Moreover, it is the conduct of the FAA and the air traffic controllers that is at issue, not the conduct of the plaintiffs.

Id. at 807. Thus, given the lack of any other connection between Indiana and the Plaintiffs' claims against L.N.K., it would not be appropriate to apply Indiana law to those claims. Therefore, the Court determines that the substantive law of Tennessee applies to those claims.

B. Statute of Limitations

L.N.K. argues that because Tennessee substantive law applies, the Court should apply the one-year statute of limitations that applies to claims for personal injury under the Tennessee Products Liability Act ("TPLA"), rather than the two-year statute of limitations that applies to such claims in the Indiana. The Court disagrees. "A district court exercising diversity jurisdiction applies the statute of limitations of the forum state." *Orgone Capital III, LLC v. Daubenspeck*, 912 F.3d 1039, 1044 (7th Cir. 2019) (citing *Klein v. George G. Kerasotes Corp.*, 500 F.3d 669, 671 (7th Cir. 2007)). Under Indiana law, "[a] statute of limitation is a procedural constraint on when suit may be filed." *Smither v. Asset Acceptance, LLC*, 919 N.E.2d 1153, 1158 (Ind. Ct. App. 2010) (citing *Kissel v. Rosenbaum*, 579 N.E.2d 1322, 1326-27 (Ind. Ct. App. 1991)); *see also Stroud v. Stone*, 122 N.E.3d 825, 830 (Ind. Ct. App. 2019) (noting that "the law of the forum state governs procedure such as the appropriate statute of limitations"). Even when the substantive law of another state applies, "the law of the forum state where the suit is filed still governs procedure." *Smither*, 919 N.E.2d at 1157-58. Therefore, Indiana provides the relevant statute of limitations,[20] and L.N.K.'s motion for summary judgment on statute of limitations grounds on the Plaintiffs' product liability claims is denied.

[20]L.N.K. argues that "there is a clear trend moving away from treating statutes of limitations as strictly procedural." Dkt. No. 125 at 15. However, L.N.K. points to no authority that suggests that the Indiana Supreme Court would follow any such trend under the facts of this case.

C. Merits of the Plaintiffs' Claims

The TPLA applies to all "product liability actions," which it defines as:

> all actions brought for or on account of personal injury, death or property damage caused by or resulting from the manufacture, construction, design, formula, preparation, assembly, testing, service, warning, instruction, marketing, packaging or labeling of any product. "Product liability action" includes, but is not limited to, all actions based upon the following theories: strict liability in tort; negligence; breach of warranty, express or implied; breach of or failure to discharge a duty to warn or instruct, whether negligent, or innocent; misrepresentation, concealment, or nondisclosure, whether negligent, or innocent; or under any other substantive legal theory in tort or contract whatsoever.

Tenn. Code Ann. § 29-28-102(6). There is no question that, under Tennessee law, a plaintiff in a product liability action is required "to establish, at a minimum, that she would not have sustained her injuries had [the Defendant] provided proper warnings." *Whitehead v. Dycho Co.*, 775 S.W.2d 593, 599 (Tenn. 1989). L.N.K. argues that the Plaintiffs cannot make that showing in this case because it is undisputed that "Mrs. Emley did not even look at the medication label before she took two separate doses of the medication." Dkt. No. 125 at 21. However, the Plaintiffs have pointed to Dennis's deposition testimony in which he states that if the Warning had appeared on L.N.K.'s product he "wouldn't have given [Donna] this product" and that

> I would have seen the bold allergy alert next to the word "acetaminophen" and that probably would have triggered something in my head about acetaminophen. And I would have sought medical help right away and more than likely, not have gone back to the farm. I would have sought medical help right away, not consult, but seek it, go somewhere right away if I had seen that.

Dkt. No. 114 at 38. If this testimony is credited—which it must be at the summary judgment stage[21]—a reasonable jury could find that, but for the lack of the Warning, Dennis would not

[21]L.N.K.'s argument in its reply brief that "it is a stronger inference" that Dennis would have ignored the Warning if it appeared on its product because he failed to heed the warnings that were on its product misses the mark for two reasons. First, the Court may not weigh the

have purchased, and therefore Donna would not have taken, L.N.K.'s products. If the jury so finds, then it also could find that any injury that was caused by Donna taking L.N.K.'s products[22] was proximately caused by the lack of the Warning.

Next, L.N.K. argues:

> In *Kelso v. Bayer Corp.*, 398 F.3d 640, 642-43 (7th Cir. 2005), the Court found that compliance with the exact language of FDA-required warnings for an OTC drug monograph was adequate as a matter of law. As outlined above, L.N.K.'s product contained the exact warning language required of a product containing the combination OTC monograph drugs—Acetaminophen 325mg, Diphenhydramine HCl 25mg, and Phenylephrine HCl 5mg. The *Kelso* case interpreted Illinois state law. Like Illinois law, the applicable Tennessee state law does not require warnings beyond those required by the FDA for OTC monograph products. Tenn. Code Ann. 29-28-104(a).

Dkt. No. 125 at 34. This argument fails for the same reason that Perrigo's argument based on *Kelso* fails. In addition, the Court notes that the statute cited by L.N.K. does not foreclose liability when the warnings on a product comply with FDA requirements, as implied by L.N.K., but rather only creates a rebuttable presumption.

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evidence at the summary judgment stage; the question is not whether the inference urged by the moving party is stronger than that urged by the non-moving party, but whether the latter is reasonable based on the evidence of record considered in the light most favorable to the non-moving party. Second, this argument ignores the fact that a warning can be inadequate because it fails to convey the relevant information in a way that communicates to the prudent reader the "scope of the danger," the "extent or seriousness of the [possible] harm," and the "consequences that might result from the failure to follow [the warning]." *See, e.g. Pittman v. Upjohn Co.*, 890 S.W.2d 425, 429 (Tenn. 1994) (discussing criteria for determining the adequacy of a drug warning). The Plaintiffs allege that the warnings that appeared on the L.N.K. Product were inadequate because they did not properly convey the risk of a serious allergic reaction and the need to take action if signs of an allergic reaction occur, while the Warning does properly convey that information. Because reasonable minds could differ on the question of whether the label on L.N.K.'s product was adequate, it is a question for the jury to determine. *Id.*

[22]L.N.K. raises no argument with regard to whether the Plaintiffs will be able to prove that taking its product injured Donna. *See* Dkt. No. 185 at 11 n.3 (stating that that issue "is irrelevant to the issue raised on summary judgment").

L.N.K. also purports to "incorporate by reference" various arguments made in Perrigo's brief. Given that all of those arguments relate to Indiana law, and the Court has determined that Tennessee law applies (as urged by L.N.K.), none of those arguments are relevant to L.N.K.'s claims. As previously noted, "[i]t is not this court's responsibility to research and construct the parties' arguments." *Draper*, 664 F.3d at 1114. Accordingly, L.N.K. has not demonstrated that it is entitled to summary judgment on the merits of any of the Plaintiffs' claims.

D. Punitive Damages

Finally, with regard to the Plaintiffs' claim for punitive damages against it, L.N.K. argues the following:

> Tennessee law provides that punitive damages shall not be awarded in a civil action involving a drug or device if the drug or device which allegedly caused the claimant's harm:
>
> > (A) Was manufactured and labeled in relevant and material respects in accordance with the terms of an approval or license issued by the federal food and drug administration under the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040, compiled in 21 U.S.C. §§301-392, as amended, or the Public Health Service Act, 53 Stat. 682, compiled in 42 U.S.C. §§ 201-300cc-15; or
> >
> > (B) Was an over-the-counter drug or device marketed pursuant to federal regulations, was generally recognized as safe and effective and as not being misbranded pursuant to the applicable federal regulations, and satisfied in relevant and material respects each of the conditions contained in the applicable regulations and each of the conditions contained in an applicable monograph.
>
> Tenn. Code Ann. § 29-39-104(d)(1). Because L.N.K.'s product complied with federal law in the marketing of their product, Emleys' claim for punitive damages is barred.

Dkt. No. 125 at 34-35. The Court reads this argument as relying on L.N.K.'s argument, set forth at length in its preemption argument, that it was prohibited by applicable law from putting the Warning on its product's label prior to the Plaintiffs' purchase of the product. Thus, it fails for

the same reason, and L.N.K.'s motion for summary judgment on the issue of punitive damages also is denied.

E. Conclusion with Regard to L.N.K.

L.N.K.'s motion for summary judgment is **DENIED** as to all of the Plaintiffs' claims except their manufacturing defect claim, which they have indicated they are not pursuing. While some of the Plaintiffs' claims against L.N.K. might be subject to summary judgment for reasons similar to those discussed in the context of Perrigo's motion for summary judgment, L.N.K.—who argued that Tennessee law applies in this case—failed to explain how Tennessee law applies to those claims. However, the Court urges the Plaintiffs to consider whether, as a practical matter, there is any advantage to pursuing any legal theory against L.N.K. other than a strict liability failure to warn claim, and whether any such advantage might be outweighed by the risk of jury confusion at trial.

VI. WAL-MART'S SECOND MOTION FOR SUMMARY JUDGMENT

The Plaintiffs assert that Wal-Mart is liable for Donna's injuries because they purchased both the Perrigo Product and the L.N.K. Product from Wal-Mart. Wal-Mart incorporates by reference the arguments made by the two other Defendants with regard to each product, and the Plaintiffs, in turn, incorporate their responses to those other motions. Therefore, with regard to the Perrigo Product, for the reasons set forth above in the context of Perrigo's second motion for summary judgment, the Court grants Wal-Mart's second motion for summary judgment on each of the Plaintiffs' claims except the claim under the IPLA (and related loss of consortium claim) and the two claims that are unique to Wal-Mart: the claim for "retailer liability" contained in Count IV and the claim for punitive damages against Wal-Mart. The Court also denies Wal-

Mart's motion with regard to the L.N.K. Product to the extent that it relies on the unsuccessful arguments made in L.N.K.'s motion.

The additional arguments made by Wal-Mart are addressed, in turn, below.

A. IPLA Claim

Wal-Mart argues that it cannot be held liable to the Plaintiffs under the IPLA because it is not a "manufacturer" of the Perrigo Product. This argument is based on a faulty premise. Wal-Mart argues that "Plaintiffs' Wal-Mart-specific claim of 'retailer liability' (Count IV) is also premised on Mrs. Emley's alleged injuries from ingestion of the [Products]. Accordingly, it is also supplanted by the Indiana Product Liability Act, and Wal-Mart is also entitled to summary judgment as to that claim." Dkt. No. 121 at 4-5. But by its very terms, Count IV *is* a claim under the IPLA; it specifically refers to the statute in its title. And the IPLA by its express terms applies to both sellers and manufacturers. *See, e.g.*, Ind. Code Ann. § 34-20-2-2 ("[I]n an action based on an alleged design defect in the product or based on an alleged failure to provide adequate warnings or instructions regarding the use of the product, the party making the claim must establish that the manufacturer or seller failed to exercise reasonable care under the circumstances in designing the product or in providing the warnings or instructions."). The only relevant distinction that the IPLA draws between sellers and manufacturers is the following:

> A product liability action based on the doctrine of strict liability in tort may not be commenced or maintained against a seller of a product that is alleged to contain or possess a defective condition unreasonably dangerous to the user or consumer unless the seller is a manufacturer of the product or of the part of the product alleged to be defective.

Ind. Code § 34-20-2-3. But, as discussed above, there are no strict liability failure-to-warn claims under the IPLA; all failure-to-warn claims under Indiana law require a showing of negligence. Accordingly, whether Wal-Mart satisfies the definition of "manufacturer" is

irrelevant to the Plaintiffs' failure-to-warn claim under the IPLA, and Wal-Mart's motion to dismiss on that ground is denied.

Wal-Mart also argues that it is entitled to summary judgment on the Plaintiff's retailer liability claim (Count IV) because "Plaintiffs have also failed to put forth sufficient material support for liability against Wal-Mart as a retailer." Dkt. No. 121 at 8. Wal-Mart's entire argument on this issue consists of quoting Ind. Code § 34-20-2-2 and arguing:

> Here, the **only** support that Plaintiffs provide to show that Wal-Mart supposedly "failed to exercise reasonable care under the circumstances" with respect to the labeling design and/or warnings and instructions on the label are the opinions against Wal-Mart stated in Mr. Zachos' report. And, as discussed, Mr. Zachos' opinions are directly contradicted by the FDA Contract Manufacturing Guidance that he expressly incorporates and relies upon. Therefore, Wal-Mart is entitled to summary judgment as a matter of law as to Plaintiffs' retailer liability claim (Count IV) because Plaintiffs have failed to put forth sufficient material support for that claim.

Dkt. No. 121 at 9. The Court finds this argument to be too insufficient for the Court to address it. *See Schaefer*, 839 F.3d at 607 ("Perfunctory and undeveloped arguments are waived, as are arguments unsupported by legal authority."). In order to address this argument, the Court would have to research and apply the law with regard to what the "failure to exercise reasonable care under the circumstances" means in this context and what type of evidence is required to satisfy a plaintiff's burden with regard to that element of a failure-to-warn claim. As noted repeatedly above, "[i]t is not this court's responsibility to research and construct the parties' arguments," *Draper*, 664 F.3d at 1114, and the Court declines to do so in this case.

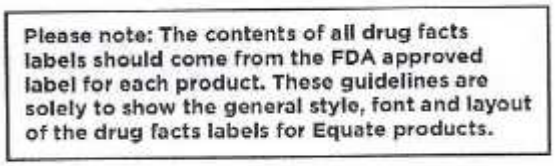
B. Punitive Damages under the IPLA

The Plaintiffs' claim for punitive damages against Wal-Mart based on the Perrigo Product fail for the same reason as their claim against Perrigo; the Plaintiffs have failed to point to evidence from which a reasonable factfinder could conclude that Wal-Mart's failure to stop

selling the Perrigo Product without the Warning *prior to November 2013* was an act of "gross negligence . . . that was not the result of mistake of fact or law, honest error of judgment, overzealousness, mere negligence, or other human failing." Accordingly, Wal-Mart's motion for summary judgment on that claim is granted.

C. TPLA Claims

The TLPA—which, as discussed above, applies to all of the Plaintiffs' claims relating to the L.N.K. Product—precludes product liability actions against a seller, other than the manufacturer, unless the seller "exercised substantial control over that aspect of the . . . labeling of the product that caused the alleged harm for which recovery of damages is sought." Tenn. Code Ann. § 29-28-106. The Plaintiffs point to various pieces of evidence that they argue demonstrate that Wal-Mart "exercised extensive control and oversight over the manufacturing of both products." Dkt. No. 136 at 4. However, the Plaintiffs do not direct the Court to any evidence that Wal-Mart actually exercised substantial control over which warnings were contained on the label of the L.N.K. product. Indeed, the documents cited by the Plaintiffs suggest the contrary, as they expressly state that it is the supplier (i.e. L.N.K.) that is responsible for complying with all laws, including state, federal, and local labeling requirements, *see*, *e.g.*, Dkt. No. 136-6 at 5, 17, and that the drugs fact label will "usually be provided by the supplier," Dkt. No. 136-7 at 50. Thus, while the Plaintiffs have provided ample evidence that Wal-Mart exercises control over the labels of its products generally—including providing very specific requirements for how each aspect of the label should look—that evidence does not show that Wal-Mart exercises control over the content of the warning labels of the drugs it sells. In fact, its Equate Branding Guidelines suggest the opposite; they set forth very specific specifications for all aspects of the labels on Equate drug products, but also note repeatedly:



See Dkt. No. 136-7 at 51-55. The evidence pointed to by the Plaintiffs would be sufficient to defeat summary judgment if their failure-to-warn claim were based on the readability of a warning or its placement on a product, as it appears that Wal-Mart exercised control over those aspects of the product's label. But the Plaintiffs have not pointed to any evidence that Wal-Mart exercised substantial control over the content of the warnings on the L.N.K. Product. Accordingly, the Plaintiffs' claims against Wal-Mart that relate to the L.N.K. Product are precluded by Tennessee law, and Wal-Mart's motion for summary judgment is granted as to those claims.

D. Conclusion with Regard to Wal-Mart

For the reasons set forth above, Wal-Mart's motion is **GRANTED** with regard to all of the Plaintiffs' claims except their failure-to-warn claim regarding the Perrigo Product.

VII. CONCLUSION

For the reasons set forth above, Defendant Perrigo's Motion for Summary Judgment on the Basis of Preemption (Dkt. No. 85), Defendant Wal-Mart's Motion for Summary Judgment on the Basis of Preemption (Dkt. No. 88), and the related motions for oral argument (Dkt. Nos. 87 and 101) are **DENIED**; Defendant Wal-Mart's [Second] Motion for Summary Judgment (Dkt. No. 120) is **GRANTED IN PART AND DENIED IN PART**; Defendant Perrigo's [Second] Motion for Summary Judgment (Dkt. No. 122) is **GRANTED IN PART AND DENIED IN PART**; and Defendant L.N.K.'s Motion for Summary Judgment (Dkt. No. 124) is **GRANTED**

with regard to the Plaintiffs' manufacturing defect claim and **DENIED** in all other respects. This case will proceed on the following claims:

- A failure to warn claim (and related loss of consortium claim) against Perrigo under the IPLA;
- A failure to warn claim (and related loss of consortium claim) against Wal-Mart under the IPLA for its sale of the Perrigo Product; and
- Claims against L.N.K. under Tennessee law for (1) failure-to-warn, under both a strict liability and negligence theory; (2) breach of express warranty; (3) breach of implied warranty; (4) negligent misrepresentation and/or fraud; (5) unfair competition or deceptive acts and practices; (6) loss of consortium; and (7) punitive damages.

SO ORDERED: 6/27/2019

Hon. William T. Lawrence, Senior Judge
United States District Court
Southern District of Indiana

Copies to all counsel of record via electronic notification