IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

TARA VITATOE, individually and as next friend and natural mother of Jacobie Vitatoe, a minor,

Plaintiff,

v. // CIVIL ACTION NO. 1:08CV85
(Judge Keeley)

MYLAN PHARMACEUTICALS, INC., MYLAN, INC., and MYLAN LABORATORIES, INC.,

Defendants.

ORDER GRANTING-IN-PART AND DENYING-IN-PART DEFENDANTS' MOTION FOR SUMMARY JUDGMENT [DKT. NO. 67]

I. PROCEDURAL BACKGROUND

Tara Vitatoe ("Vitatoe"), the plaintiff in this civil action, lives in Louisiana with Jacobie, her African-American special needs son. On February 12, 2008, she sued the defendants, Mylan Pharmaceuticals, Inc., and Mylan, Inc. ("Mylan"), in the Circuit Court of Monongalia County, West Virginia, seeking damages for injuries she claims Jacobie suffered from ingesting Phenytoin, a phenytoin sodium-based product that is a generic anti-epileptic drug ("AED") manufactured by Mylan. On February 29, 2008, Mylan removed the case to this Court based on its original jurisdiction under 28 U.S.C. § 1332.

Mylan has moved for summary judgment as to all of Vitatoe's claims, arguing that Louisiana law and federal preemption preclude them. (dkt. no. 67). That motion is now fully briefed and ripe for review. For the reasons that follow, the Court concludes that 1) the Louisiana Products Liability Act ("LPLA") governs Vitatoe's claims; 2) the affirmative defense of the learned intermediary doctrine available under Louisiana law violates the public policy of West Virginia; and 3) Vitatoe's state law claims are not preempted by federal law. Consequently, it **GRANTS** summary judgment to Mylan as to those claims in Vitatoe's complaint barred by the LPLA, and **DENIES** the remainder of Mylan's motion.

II. FACTUAL BACKGROUND

When Jacobie Vitatoe was sixteen years old, he developed Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis ("SJS/TEN") after ingesting Phenytoin, an AED prescribed by his neurologist, Joseph Nadell, M.D. ("Dr. Nadell"), to control his seizure disorder. SJS/TEN are variations of a severe hypersensitive reaction to an external stimulus, such as medication. Experts in the field of epileptology and dermatology recognize that AEDs such as Phenytoin can cause SJS/TEN.

The hallmark symptom of SJS/TEN is the blistering of the mucous membranes and sloughing of the surface of the skin. In cases of TEN, the more serious and sometimes fatal variation of the hypersensitive reaction, necrosis of at least 30% or more of the epidermis occurs. See Pierre-Dominique Ghislain M.D., Jean-Claude Roujeau, M.D., 8(1) Dermatology Online Journal 5, Treatment of Severe Drug Reactions: Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis and Hypersensitivity Syndrome, available at http://dermatology.cdlib.org/DOJvol8num1/reviews/drugrxn/ghislain.html (last accessed Feb. 11, 2010).

Jacobie, who suffers from autism as well as a seizure disorder, was born on October 11, 1990, and lives with his mother. On January 12, 2007, he was admitted to Lake Charles Memorial Hospital suffering from seizures. After Jacobie's discharge from the hospital, Dr. Nadell attempted to control his seizures by prescribing Dilantin®, a name brand AED.

Vitatoe filled Jacobie's prescription at a local Walgreens pharmacy, where the pharmacist substituted Phenytoin, Mylan's generic brand of Dilantin®, and also provided an instructional pamphlet about the drug for her information.[1] Although she admits

[1] Under Louisiana law, pharmacists may substitute a generic version, unless the prescription specifically indicates that the

that she never reviewed Mylan's drug label before administering Phenytoin to Jacobie, Vitatoe contends she consulted the pamphlet provided by Walgreens. That pamphlet, in pertinent part, advised:

> POSSIBLE SIDE EFFECTS:
> . . .
> CONTACT YOUR DOCTOR IMMEDIATELY if you experience skin rash; swollen glands; bleeding, swollen, or tender gums; . . . AN ALLERGIC REACTION to this medicine is unlikely, but seek immediate medical attention if it occurs. Symptoms of an allergic reaction include rash, itching, swelling, dizziness, or trouble breathing. . . .

After taking Phenytoin for three or four weeks, Jacobie developed a rash on the evening of March 4, 2007. By the next day, his condition was severe enough to warrant his readmission to the hospital, where he was diagnosed with SJS. To avert a more serious allergic reaction, Jacobie's physicians withdrew the Phenytoin, but his condition continued to worsen. Finally, on March 7, 2007, three days after he first developed symptoms of SJS, Jacobie was transferred to the Shriners Burn Hospital in Galveston, Texas, suffering from TEN. Despite a month-long hospitalization, during which he developed contractures of his limbs, underwent numerous surgeries, and more than 80% of his skin was debrided, Jacobie

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brand name drug should be "dispensed as written." See, e.g., La. Rev. Stat. § 37:1241(A)(17) (West 2010); La. Admin. Code tit. 46, § 2511(B)(6) (2010).

tragically lost approximately 99% of his epidermal skin and suffered severe damage to his eyes.

Vitatoe attributes Jacobie's injuries to his use of Phenytoin. She argues that Mylan, as the manufacturer of Phenytoin, failed to adequately warn her that Jacobie, an African-American patient, faced an increased risk of developing SJS/TEN by using Phenytoin. She claims that Jacobie's injuries from his use of Phenytoin are severe and life-changing. They include pain and anguish, severe disfigurement and scarring, the inability to perform his normal and usual activities, huge medical bills, diminished earning capacity, loss of the enjoyment of life, embarrassment, and humiliation. Mylan, however, counters that the warning on its Phenytoin label fully complied with the requirements of federal law and adequately disclosed the drug's possible side-effects, including the risk of SJS/TEN.

III. SUMMARY JUDGMENT STANDARD

Under Fed. R. Civ. P. 56, "summary judgment is proper 'if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.'" Celotex Corp. v.

Catrett, 477 U.S. 317, 322 (1986). When ruling on a motion for summary judgment, a court reviews all evidence in the light most favorable to the nonmoving party. Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986).

IV. DISCUSSION

A. Applicability of Louisiana Law

This case raises a difficult choice-of-law issue. Despite the fact that Vitatoe filed her lawsuit in West Virginia, where Mylan's manufacturing plant is located, Mylan argues that, under West Virginia's choice of law rules, the substantive law of Louisiana governs all of Vitatoe's claims because Jacobie's injuries occurred there. It also contends that, under the correct application of the LPLA, the Court should grant it summary judgment and dismiss all of Vitatoe's claims.

In Vest v. St. Albans Psychiatric Hosp., Inc., 387 S.E.2d 282, 283 (W. Va. 1989), the West Virginia Supreme Court of Appeals recognized that, under the rule of lex loci delicti, "[i]n tort cases . . . the substantive rights between the parties are determined by the law of the place of injury." Mylan contends that, as there is no dispute in this case that Jacobie's injuries occurred in Louisiana, Vitatoe's claims are subject to the

provisions of the LPLA, under which the only possible claim against it could be one of inadequate warning about the risk of SJS/TEN.

Pursuant to Erie R. Co. v. Tompkins, 304 U.S. 64, 78 (1938), the applicable law in a diversity case such as this is determined by the substantive law of the state in which a district court sits. This includes the forum state's prevailing choice of law rules. Klaxon Co. v. Stentor Electic Mfg. Co., 313 U.S. 487, 496-97 (1941). Thus, under West Virginia's rule of lex loci delicti, because Jacobie's injuries occurred in Louisiana, that state's substantive law will govern Vitatoe's claims unless the public policy of West Virginia would bar application of that state's law. Vest, 387 S.E.2d at 283.

In considering the applicability of the LPLA to Vitatoe's claims, the Court must first consider which of her claims survive under the LPLA. It must next determine whether any part of the LPLA violates West Virginia public policy.[2]

Under Nadler v. Liberty Mutual Fire Ins. Co., 424 S.E.2d 256, 265 (W. Va. 1992) (quoting 16 Am. Jur.2d Conflict of Laws § 18), a court in West Virginia should decline to apply foreign laws that

[2] Vitatoe does not argue that the LPLA in its entirety violates the public policy of West Virginia, but only that the affirmative defense of the learned intermediary doctrine does so.

are "'contrary to pure morals or abstract justice, or unless enforcement would be of evil example and harmful to its own people.'" Importantly, not every differing foreign law offends West Virginia public policy. See Howe v. Howe, 625 S.E.2d 716, 724 (W. Va. 2005).

B. The Louisiana Products Liability Act

The LPLA "establishes the exclusive theories of liability for manufacturers for damage caused by their products." La. Rev. Stat. Ann. § 2800.52. "[A] claimant may not recover from a manufacturer for damage caused by a product on the basis of any theory of liability that is not set forth in this Chapter." Id. This language "limits a plaintiff's theories of recovery against a manufacturer of an allegedly defective product to those established by the LPLA." Stahl v. Novartis Pharma. Corp., 283 F.3d 254, 261-62 (5th Cir. 2002); and Broussard v. Procter & Gamble Co., 463 F. Supp.2d 596, 603 (W.D. La. 2006). These exclusive theories, for example, preclude products liability claims for intentional torts. Stahl, 283 F.3d at 262 ("There is no language in the LPLA indicating that its exclusive remedy provision does not preclude intentional tort claims, and both federal and Louisiana courts have read the Act's exclusive remedy provision to prevent plaintiffs

from bringing intentional tort claims." (citing Grenier v. Med. Eng'g Corp., 243 F.3d 200, 202-06 (5th Cir. 2001); and Arabie v. R.J. Reynolds Tobacco Co., 698 So.2d 423, 424-25 (La. App. 5 Cir. 1997)).

To state a cause of action under the LPLA, a claimant must allege "1) that the defendant is a manufacturer of the product; 2) that the claimant's damage was proximately caused by a characteristic of the product; 3) that the characteristic made the product unreasonably dangerous in one of the four ways provided in the statute; and 4) that the claimant's damage arose from a reasonably anticipated use of the product by the claimant or someone else." Jefferson v. Lead Indus. Ass'n, 106 F.3d 1245, 1251 (5th Cir. 1997) (citing La. Rev. Stat. Ann. § 2800.54 (West 1988)). A claimant such as Vitatoe may prove that a product is "unreasonably dangerous under one or more of four theories of liability, including (1) construction or composition, (2) design, (3) adequacy of warning, or (4) failure to conform to an express warranty." Broussard, 463 F. Supp.2d at 603 (citing La. Rev. Stat. § 9:2800.54(B)).

1. Vitatoe's Complaint

Vitatoe's complaint asserts that Mylan markets, manufactures, and designs Phenytoin for the purpose of treating seizures. Pl.'s Compl. at ¶ 27. It further asserts that Dr. Nadell prescribed Phenytoin to control Jacobie's seizures, id. at ¶ 16, that Jacobie ingested Phenytoin for this purpose, id. at ¶ 17, and that, subsequent to doing so, he developed SJS/TEN. Id. at ¶ 19.

The complaint alleges that Mylan "designed, manufactured, marketed and sold" Phenytoin, id. at ¶ 27, and that "Phenytoin Sodium, as designed, manufactured, and/or marketed by [Mylan], was defective and/or hazardous in design, manufacture, and/or marketing; the defect existed at the time the Phenytoin Sodium left [Mylan's] possession; Phenytoin Sodium is unreasonably dangerous as a result of the design, manufacturing and/or marketing defect(s); and said defect(s) was(were) the producing cause of [Jacobie's] injuries and damages." Id. at ¶ 29. It also alleges that "Phenytoin Sodium, as distributed, manufactured, marketed and/or supplied by [Mylan], has been and continues to be unaccompanied by adequate warnings regarding the fact that the drug can and does cause or contribute to the development of TEN and SJS." Id. at ¶ 30.

Additionally, Vitatoe's complaint alleges that Mylan's marketing and labeling of Phenytoin was unreasonably dangerous and defective because it failed to warn both her and Jacobie's physician about the dangers of SJS/TEN, and that Mylan failed to exercise reasonable care in testing for, and failing to warn of, these symptoms. Id. at ¶¶ 34-36. It also alleges that Mylan was "negligent in the design, manufacture, testing, advertising, warning, marketing, and sale of Phenytoin Sodium . . .", id. at ¶ 42, and that all of Mylan's actions and inactions proximately caused Jacobie's injuries.

The complaint's remaining allegations assert that Mylan breached implied warranties that its Phenytoin was "of merchantable quality and safe and fit for [its] intended use," id. at ¶ 46, that "Mylan misrepresented the character and quality of Phenytoin," id. at ¶ 50, that Mylan's conduct was intentional, reckless, indifferent and justifies punitive damages, id. at 57, and that Vitatoe has suffered emotional distress from witnessing Jacobie's injuries. Id. at ¶ 59. It also seeks recovery for loss of consortium.

2. Mylan's Contentions

Mylan claims that its warnings sufficiently advised both Vitatoe and Dr. Nadell of the known risks of using Phenytoin, including the rare reaction of SJS/TEN. It also contends that Dr. Nadell knew that SJS/TEN could occur with the use of Phenytoin, and that, in any case, neither he nor Vitatoe read Mylan's labeling prior to giving the drug to Jacobie. Mylan also asserts that there is no legitimate scientific or medical basis for including on its Phenytoin label a warning that Phenytoin poses a unique risk and danger of developing SJS/TEN to African-Americans. Moreover, it claims that, because Dr. Nadell was aware that SJS/TEN was a rare side-effect and prescribed Phenytoin to Jacobie anyway, it discharged its duty under Louisiana law to warn Vitatoe of the rare risk of developing SJS/TEN from Phenytoin use. Mylan therefore concludes that Vitatoe cannot meet her burden under the LPLA of showing that it failed to adequately warn her of the risk of SJS/TEN, or that such failure was the proximate cause of Jacobie's injuries. Stahl, 283 F.3d at 264.

3. Claims Not Recognized By the LPLA

Under the LPLA, Vitatoe's claims for strict liability, negligence, breach of implied warranty, § 402B misrepresentation, intentional conduct, reckless indifference, and malice, emotional distress, and loss of consortium do not survive. In Jefferson v. Lead Indus. Ass'n, the Fifth Circuit held that claims for negligence, fraud by misrepresentation, market share liability, breach of implied warranty of fitness and civil conspiracy are not independently recognized theories of liability under the LPLA. 106 F.3d at 1251. See also Carter v. Louisville Ladder Group, LLC, No. 3:04CV1324, 2005 WL 3088613, at *7 (W.D. La. Nov. 17, 2005) (unpublished) (holding that the LPLA bars claims for general negligence).[3] Vitatoe does not contest this conclusion, nor does she argue that the loss of these claims in any way violates West Virginia public policy.

[3] While not an independent cause of action under the LPLA, loss of consortium may serve as a derivative basis for recovering damages under theories such as a failure-to-warn that are recognized under the Act. See De Atley v. Victoria's Secret Catalogue, LLC, 876 So.2d 112, 116 (La. App. 4 Cir. 2004) (holding that "[d]amages recoverable under the LPLA include pain and suffering, medical expenses, damage to property, other than to the product itself, and loss of consortium").

4. Claims Recognized By the LPLA

a. Claim of Unreasonably Dangerous Construction or Composition

Under the LPLA, Vitatoe may demonstrate that Phenytoin is unreasonably dangerous in its construction or composition. La. Rev. Stat. Ann. § 9:2800.54(B)(1). Section 9:2800.55 of the LPLA recognizes that "[a] product is unreasonably dangerous in construction or composition if, at the time the product left its manufacturer's control, the product deviated in a material way from the manufacturer's specifications or performance standards for the product or from otherwise identical products manufactured by the same manufacturer."

To pursue such a theory, however, Vitatoe must make a prima facie showing that the characteristic of Phenytoin that rendered it unreasonably dangerous deviated "from the manufacturer's production standards or from the manufacturer's otherwise identical products." Stahl, 283 F.3d at 263. Vitatoe's complaint is devoid of any allegation that the tablets of Phenytoin Jacobie ingested deviated in a material way from other Phenytoin tablets manufactured by Mylan. Nor has she attempted to pursue such a claim through discovery. The hallmark of her complaint is that Mylan's labeling

failed to adequately warn her of the particular dangers Phenytoin posed to Jacobie.

b. Claim of Unreasonably Dangerous Design

Under the LPLA, Vitatoe may pursue a claim that the design of Phenytoin is unreasonably dangerous. La. Rev. Stat. Ann. § 9:2800.54(B)(2). Section 9:2800.56 of the LPLA states:

> A product is unreasonably dangerous in design if, at the time the product left its manufacturer's control: (1) There existed an alternative design for the product that was capable of preventing the claimant's damage; and (2) The likelihood that the product's design would cause the claimant's damage and the gravity of that damage outweighed the burden on the manufacturer of adopting such alternative design and the adverse effect, if any, of such alternative design on the utility of the product. An adequate warning about a product shall be considered in evaluating the likelihood of damage when the manufacturer has used reasonable care to provide the adequate warning to users and handlers of the product.

Even assuming there is evidence that a pharmaceutical product such as Phenytoin can cause a harmful reaction like SJS/TEN, under the LPLA, absent "any reasonable inference that there existed an alternative design for [the product] that was capable of preventing the plaintiff's damage," such evidence is insufficient to demonstrate that the product was unreasonably dangerous in design. Guidry v. Aventis Pharma., Inc., 418 F. Supp.2d 835, 842 (M.D. La.

2006). Although Vitatoe's complaint alleges that Phenytoin was defectively designed, it makes no claim that an alternative design was available and would have prevented Jacobie's injuries.

c. Claim of Failure to Conform to an Express Warranty

Under the LPLA, Vitatoe may also pursue a claim that a product is unreasonably dangerous by alleging that it does not conform to an express warranty of the manufacturer. La. Rev. Stat. Ann. § 9:2800.54(B)(4). Section 9:2800.58 of the LPLA explains that "[a] product is unreasonably dangerous when it does not conform to an express warranty made at any time by the manufacturer about the product if the express warranty has induced the claimant or another person or entity to use the product and the claimant's damage was proximately caused because the express warranty was untrue." Vitatoe's complaint, however, includes no allegation that Jacobie's injuries resulted from Mylan's breach of an express warranty.

d. Claim of Unreasonable Dangerousness Due to Inadequate Warning

Vitatoe's claim that the Phenytoin manufactured by Mylan was unreasonably dangerous because its labeling failed to adequately warn her about the risks the drug posed to users like Jacobie is recognized under Louisiana law. At section 9:2800.57(A), the LPLA states:

> A product is unreasonably dangerous because an adequate warning about the product has not been provided if, at the time the product left its manufacturer's control, the product possessed a characteristic that may cause damage and the manufacturer failed to use reasonable care to provide an adequate warning of such characteristic and its danger to users and handlers of the product.

Under Louisiana law, moreover, a manufacturer's duty to warn is a continuing obligation. Am. Cent. Ins. Co. v. Terex Crane, 861 So.2d 228, 231 (La. App. 1 Cir. 2003). Thus, "[t]o successfully maintain a failure-to-warn claim under the LPLA, a plaintiff must demonstrate [1] that the product in question has a potentially damage-causing characteristic, and [2] that the manufacturer failed to use reasonable care to provide an adequate warning about this characteristic." Stahl, 283 F.3d at 264.

Vitatoe's complaint alleges that Phenytoin was unreasonably dangerous because Mylan failed to adequately warn that Jacobie could develop SJS/TEN. She alleges that Mylan was the manufacturer of Phenytoin; that Jacobie's injuries were proximately caused by Mylan's failure to warn of its dangers; that his damages arose from ingesting Phenytoin to treat his seizures; and that the product was intended and marketed by Mylan for such use. See Jefferson, 106 F.3d at 1251 (listing the elements of a cause of action under the

LPLA). Thus, her cause of action for inadequate warning under the LPLA is adequately pleaded.

C. Louisiana's Learned Intermediary Doctrine and West Virginia Public Policy

Mylan contends that the learned intermediary doctrine, a defense under the LPLA to a failure-to-warn claim, bars Vitatoe's inadequate warning claim. In Stahl, the Fifth Circuit held that, under Louisiana law, "a drug manufacturer discharges its duty to consumers by reasonably informing prescribing physicians of the dangers of harm from a drug." 283 F.3d at 265.

Louisiana courts employ a two-prong test to determine whether a manufacturer adequately warned a learned intermediary of a drug's risks. "First, the plaintiff must show that the defendant failed to warn (or inadequately warned) the physician of a risk associated with the product that was not otherwise known to the physician;" and "[s]econd, the plaintiff must show that this failure-to-warn the physician was both a cause in fact and the proximate cause of the plaintiff's injury." Stahl, 283 F.3d at 265-66 (citations omitted).

Vitatoe, however, contends that Louisiana's learned intermediary doctrine violates the public policy of West Virginia. Relying on State ex rel. Johnson & Johnson Corp. v. Karl, 647

S.E.2d 899 (W. Va. 2007), and a recent decision from the Southern District of West Virginia, Woodcock v. Mylan, Inc., 661 F. Supp.2d 602, 607-08 (S.D.W. Va. 2009) (Goodwin, CJ), she argues that West Virginia law should govern her claim of inadequate labeling/warning.[4]

The West Virginia Supreme Court of Appeals has never directly decided whether the learned intermediary doctrine violates West Virginia's public policy. In Karl, however, it did consider whether to adopt the doctrine as substantive law. 647 S.E.2d at 900. After comprehensively surveying the availability of the doctrine in the United States, and finding it available in only twenty-two states, West Virginia's highest court rejected it as largely antiquated and outdated in the day of direct-to-consumer advertising.

Mylan contends that the absence of any evidence that it engaged in direct-to-consumer advertising in marketing Phenytoin

[4] Vitatoe contends, alternatively, that, under the Restatement (Second) of Conflicts "significant relationship" analysis, West Virginia's substantive law should govern her claims because of the significant relationship that exists between West Virginia and Mylan. See Oakes v. Oxygen Therapy Servs., 363 S.E.2d 130, 131-32 (W. Va. 1987) (sanctioning application of the Restatement (Second) Conflicts of Law analysis "to resolve particularly thorny conflicts problems."). Given the Court's conclusions infra, it need not address this issue.

cuts against this Court's reliance on Karl to determine whether Louisiana's learned intermediary doctrine violates the public policy of West Virginia. Although direct-to-consumer advertising may have served as a practical reason for West Virginia's highest court to reject the doctrine, that court, in dicta, was strongly critical of the doctrine on public policy grounds:

> [B]ecause it is the prescription drug manufacturers who benefit financially from the sales of prescription drugs and possess the knowledge regarding potential harms, and the ultimate consumers who bear the significant health risks of using those drugs, it is not unreasonable that prescription drug manufacturers should provide appropriate warnings to the ultimate users of their products.

Id. at 913. Karl also observed that, "under West Virginia products liability law, manufacturers of prescription drugs are subject to the same duty to warn consumers about the risks of their products as other manufacturers." Id. at 914. Thus, under the public policy of West Virginia, a pharmaceutical manufacturer has a duty to inform consumers directly of the risks its product poses or face being sued for failing to meet this obligation.

In Woodcock, Judge Goodwin concluded that this duty is not one that the manufacturer may discharge merely by informing a learned intermediary of the product's risks. Rather, in West Virginia, a

manufacturer's duty runs directly to the consumer. 661 F. Supp.2d at 609. In reaching this conclusion, Judge Goodwin weighed the public policy implications of applying Alabama's learned intermediary doctrine in a case involving a drug manufacturer's alleged failure to warn an Alabama consumer of its drug's risks. Id. at 602. Based on his understanding of Karl, he concluded that Alabama's learned intermediary doctrine contravened the public policy of West Virginia: "Because West Virginia has rejected the learned-intermediary doctrine on public-policy grounds and applying Alabama law to the marketing defect claim would violate that public policy, West Virginia law applies to that claim." Id. at 609.[5]

Both Karl's strong criticism of the doctrine's shift of a drug manufacturer's responsibility to warn of a drug's harms from the ultimate consumer to a physician, as well as Woodcock's helpful public policy analysis, lead this Court to conclude that the public policy of West Virginia bars the application of Louisiana's learned intermediary doctrine as a defense in this case. Mylan therefore

[5] Prior to Karl, federal district courts in West Virginia had speculated, albeit incorrectly, that West Virginia would likely adopt the learned intermediary doctrine. See Ashworth v. Albers Med., Inc., 395 F. Supp.2d 395, 407 (S.D.W. Va. 2005); Pumphrey v. C.R. Bard, Inc., 906 F. Supp. 334, 338 (N.D.W. Va. 1995); and Rohrbough v. Wyeth Labs., Inc., 719 F. Supp. 470, 478 (N.D.W. Va. 1989).

may not raise the defense as a bar to Vitatoe's inadequate warning claim. Moreover, as the duty to warn under Louisiana law runs to a learned intermediary, such as a physician, rather than the consumer, West Virginia law governs Vitatoe's inadequate warning claim. This is because, absent this defense, it is impossible to apply the substantive law of Louisiana to Vitatoe's inadequate warning claim without violating West Virginia public policy.

D. No Implied Federal Preemption

Mylan's next contention is that Vitatoe's inadequate warning claim is impliedly preempted under the doctrine of conflict preemption because it was unable to alter its Phenytoin labeling from that of Dilantin®, the name brand version of the drug. According to Mylan, the Changes Being Effected ("CBE") process of the Food and Drug Administration ("FDA"), 21 C.F.R. § 314.70(c)(6)(iii), which permits a drug manufacturer to implement label changes without prior FDA approval for the purpose of strengthening a warning based on newly acquired information, is unavailable to generic drug manufacturers. Mylan argues that FDA regulations compel generic drug labels to mirror their branded counterparts, and it is therefore impossible for it, as a generic

drug manufacturer, to simultaneously conform to the requirements of both federal law and state tort law.

When Dr. Nadell prescribed Phenytoin to Jacobie in January 2007, the sections of Mylan's labeling concerning adverse reactions and precautions stated as follows:

> . . .
> PRECAUTIONS: . . .
> **Phenytoin should be discontinued if a skin rash appears** (see WARNINGS section regarding discontinuation). If the rash is exfoliative, purpuric, or bullous, or **if** lupus erythematosus, **Stevens-Johnson Syndrome**, or **toxic epidermal necrolysis is suspected**, **use of this drug should not be resumed and alternative therapy should be considered**. (See ADVERSE REACTIONS.) If the rash is of a milder type (measeals-like or scarlatiniform), therapy may be resumed after the rash has completely disappeared. If the rash recurs upon reinstitution of therapy, further phenytoin medication is contraindicated.
>
> Phenytoin and other hydantoins are contraindicated in patients who have experienced phenytoin hypersensitivity. . . .
> . . .
> ADVERSE REACTIONS: . . .
> . . .
> Integumentary System: **Dermatological manifestations sometimes accompanied by fever have included** scarlatiniform or morbilliform rashes. A morbilliform rash (measels-like) is the most common; **other types of dermatitis are seen more rarely**. **Other more serious fatal forms have included** bullous, exfoliative or purpuric dermatitis, lupus erythematosus, **Stevens-Johnson syndrome**, and **toxic epidermal necrolysis** (see PRECAUTIONS).

. . .

Mylan Pharmaceuticals, Inc., Extended Phenytoin Sodium Capsules, USP 100 mg (revised September 1998) (dkt. no. 67-6) (emphasis added). Moreover, in the warnings section of its label Mylan cautioned:

> WARNINGS: Abrupt withdrawal of phenytoin in epileptic persons may precipitate status epilepticus. When, in the judgment of the clinician, the need for dosage reduction, discontinuation, or substitution of alternative antiepileptic medication arises, this should be done gradually. **[In] [t]he event of an allergic or hypersensitivity reaction**, **more rapid substitution of alternative therapy may be necessary**, in this case, alternative therapy should be an antiepileptic drug not belonging to the hydantoin chemical class.
> . . .

Id. (emphasis added).

Vitatoe contends that Mylan's failure to warn specifically about the risk of SJS/TEN in its "Warnings" section, its failure to emphasize these risks more prominently, as well as its failure to communicate information about a possible increased risk to African-Americans of developing SJS/TEN, constitutes a breach of its duty to warn under state tort law that proximately caused Jacobie's injuries. To support her argument, she relies heavily on the holding of the Supreme Court of the United States in Wyeth v.

Levine, 129 S. Ct. 1187, 1204 (2009), that held state failure-to-warn claims against name brand drug manufacturers are not preempted by federal law.

Levine undoubtedly undercuts the strength of Mylan's claim of conflict preemption. Mylan, however, contends that, because the Supreme Court was not called upon to consider the historically unique relationship between the FDA and generic drug manufacturers, Levine is inapplicable to this case. In support of this argument, it relies heavily on a post-Levine decision, Gaeta v. Perrigo Pharma. Co., __ F. Supp.2d __, 2009 WL 4250690 (N.D. Cal. 2009), in which the district court found that Levine's holding of non-preemption did not apply to generic drug manufacturers. Mylan also points to a number of other district court decisions decided before Levine that hold the same. See Mensing v. Wyeth, Inc., 562 F. Supp.2d 1056 (D. Minn. 2008), overruled by 588 F.3d 603 (8th Cir. 2009); Smith v. Wyeth, Inc., No. 5:07CV18, 2008 WL 4697002 (W.D. Ky. Oct. 24, 2008), aff'd on reh'g 2009 WL 736208 (reconsidering and affirming prior decision in light of Wyeth v. Levine); Masterson v. Apotex Corp., No. 07-61665CIV, 2008 WL 3262690 (S.D. Fla. Aug. 7, 2008); Bolin v. SmithKline Beecham Corp., No. 08-60523CIV, 2008 WL 3286973 (S.D. Fla. Aug. 7, 2008); and Valerio v.

SmithKline Beecham Corp., No. 08-60522CIV, 2008 WL 3286976 (S.D. Fla. Aug. 7, 2008).[6]

Vitatoe's argument, in contrast, is based primarily on two circuit court cases which rely on the reasoning of Levine and conclude that state failure-to-warn claims against generic drug manufacturers are not preempted. See Demahy v. Actavis, Inc., 593 F.3d 428 (5th Cir. 2010); and Mensing v. Wyeth, Inc., 588 F.3d 603 (8th Cir. 2009).

In determining whether Vitatoe's inadequate warning claim against Mylan is impliedly preempted, this Court is mindful of the caution of Justice Stevens, the author of Levine, that there is a presumption against preemption, especially in areas such as drug regulation, where "Congress has 'legislated . . . in a field which the States have traditionally occupied.'" 129 S. Ct. 1187, 1194-95 (2009) (quoting Lohr, 518 U.S. at 485 (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947)); see also Demahy, 593 F.3d 428 at 434-37. Furthermore, "'[t]he purpose of Congress is the ultimate touchstone' in every pre-emption case." Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996) (quoting Retail Clerks

[6] After Mylan cited to the district court's decision in Mensing v. Wyeth, Inc., the Eighth Circuit reversed that decision, holding that federal law does not preempt state-law failure-to-warn claims. See 588 F.3d 603, 608 (8th Cir. 2009).

Intern. Ass'n, Local 1625, AFL-CIO v. Schermerhorn, 375 U.S. 96, 103 (1963)).

Federal preemption of state law generally takes one of three forms: 1) express congressional preemption; 2) field preemption; and 3) conflict preemption. See English v. Gen. Elec. Co., 496 U.S. 72, 79 (1990) (citations omitted). Mylan's argument here sounds entirely in conflict preemption, which arises either "where compliance with both federal and state regulations is a physical impossibility," Florida Lime & Advocado Growers, Inc. v. Paul, 373 U.S. 132, 142-43 (1963), or where state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Hines v. Davidowitz, 312 U.S. 52, 67 (1941). Federal regulations and statutes may serve as sources of state law preemption. Hillsborough County, Fla. v. Automated Med. Labs., Inc., 471 U.S. 707, 713 (1985). Relying on this framework for its analysis, the Court turns first to Mylan's impossibility preemption argument.

1. Impossibility Preemption

Despite the presumption against preemption, Mylan contends it is an impossibility for it to comply with both federal and state labeling requirements. There is no question that federal law

preempts state law "where compliance with both federal and state regulations is a physical impossibility." Paul, 373 U.S. at 142-43. Levine, however, observed that "[i]mpossibility pre-emption is a demanding defense." 129 S. Ct. at 1199. Thus, to determine the merits of Mylan's impossibility preemption argument, the statutory history of federal regulation of pharmaceuticals generally, and of generic drug manufacturers in particular, provides helpful insight.

Congress first entered the arena of drug regulation in 1906, when it enacted the Federal Food and Drugs Act. Id. at 1195 (citing 34 Stat. 768). It expanded federal regulation of drugs in the 1930s, when it enacted the Federal Food, Drug, and Cosmetic Act ("FDCA"), which provided for pre-market approval of new drugs. Id. (citing 52 Stat. 1040, as amended, 21 U.S.C. § 301 et seq.). In 1962, Congress amended the FDCA's premarket approval process by requiring drug manufacturers "to demonstrate that its drug was 'safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling' before it could distribute the drug." Id. (quoting 76 Stat. 781, 784). In 1976, Congress expressly preempted medical devices from state regulations, but declined to do so for prescription drugs. Id. at 1196 (citing 90 Stat. 574 (codified at 21 U.S.C. § 360k(a)).

Significant changes to federal regulation of generic drug manufacturing occurred in 1984 when Congress enacted the Hatch-Waxman Amendments to the FDCA ("Hatch-Waxman"). Under Hatch-Waxman, generic drug manufacturers can participate in an abbreviated new drug application procedure ("ANDA") by demonstrating that a proposed generic drug is the "same as" or bioequivalent to a pioneer or name brand drug already approved by the FDA. Demahy,593 F.3d at 432 (citing 21 U.S.C. § 355(j)(2)(A)(iii), (iv)).

Congress designed the ANDA process to encourage generic drug manufacturers to bring low cost generic drugs to market by permitting them to bypass the rigorous clinical trials and tests with which pioneer manufacturers must comply. It intended that this process should make lower-priced drugs available more rapidly to consumers. Id. at 432 (citing H.R. Rep. No. 98-857, pt. 1, at 16, 1984 U.S.C.C.A.N. at 2649; 54 Fed. Reg. 28872, 28874 (proposed Jul. 10, 1989); and Mead Johnson Pharm. Group v. Bowen, 838 F.2d 1332, 1333 (D.C. Cir. 1988) (stating the purpose of the Hatch-Waxman Act)). Of significance to this case is the fact that the ANDA process also requires generic drug manufacturers to demonstrate "that the labeling proposed for the new drug is the same as the labeling approved for the listed drug." 21 U.S.C. § 355(j)(2)(A)(v).

Neither Mylan nor Vitatoe disputes that during the ANDA process a generic drug's label must remain identical to the label of its name brand counterpart. However, they vigorously dispute whether a generic drug manufacturer may modify its labeling after the drug enters the marketplace. Although Mylan properly notes that the unique history of the ANDA process and federal regulation of generic drug manufacturers were not at issue in Levine, to meet its burden here it nevertheless must establish that, as a generic drug manufacturer, it was foreclosed from using the CBE and the prior approval processes, and also could not have urged the FDA to send out "Dear Doctor" letters to health care providers.

Prior to Levine, in Foster v. American Home Products Corp., 29 F.3d 165 (4th Cir. 1994), the Fourth Circuit concluded that a generic drug manufacturer could change its label without obtaining prior approval from the FDA:

> Although generic manufacturers must include the same labeling information as the equivalent name brand drug, they are also permitted to add or strengthen warnings and delete misleading statements on labels, even without prior FDA approval. 21 C.F.R. § 314.70 (1993). The statutory scheme governing premarketing approval for drugs simply does not evidence Congressional intent to insulate generic drug manufacturers from liability for misrepresentations made regarding their products, or to otherwise alter state products liability law. Manufacturers of generic drugs,

> like all other manufacturers, are responsible for the representations they make regarding their products.

Id. at 170.

Foster, which was decided under Maryland law, did not discuss the doctrine of impossibility preemption. Its analysis is pertinent, however, because, in concluding that a generic drug manufacturer could be held liable under Maryland law for negligent misrepresentations on its label, Foster categorically rejected the argument that, because the generic manufacturer did not initially formulate the warning and representations on a drug's label, it could not be liable for a label's flawed warnings and representations: "We do not accept the assertion that a generic manufacturer is not responsible for negligent misrepresentations on its product labels if it did not initially formulate the warnings and representations itself." Id. at 169.

After the decision in Levine, the Eighth and Fifth Circuits considered whether state claims of inadequate labeling were preempted by federal laws regulating generic drug manufacturers. Mensing, 588 F.3d 603; and Demahy, 593 F.3d 428. In Mensing and Demahy, both circuits made clear that, at the very least, generic drug manufacturers may utilize the FDA's prior approval process to initiate changes to drug labels, and also may urge that agency to

send out "Dear Doctor" letters on their behalf. Consequently, they concluded that generic drug manufacturers may not invoke impossibility preemption to avoid state law claims of inadequate warning.

a. Mensing v. Wyeth, Inc.

In Mensing, the Eighth Circuit reversed the district court's holding that generic drug manufacturers of metoclopramide, the generic version of the brand drug Reglan®, had met their burden of establishing impossibility preemption. 588 F.3d at 611-12. The circuit court's analysis noted that the contention of the generic drug manufacturers, that they were prohibited from using the CBE process to modify or alter drug labels without FDA approval, was in direct conflict with 21 C.F.R. § 314.97, which requires them to "'comply with the requirements of §[ ] 314.70.'" Id. at 608 (quoting 21 C.F.R. § 314.97). Mensing pointed out that § 314.70 "includes the CBE process and the prior approval supplement process,"[7] Id. (emphasis in original).

[7] The "prior approval" process is one of several ways by which a drug manufacturer may initiate a change to its labeling. A drug manufacturer may only make "major changes" through using the prior approval process by obtaining "the FDA's prior approval through a prior approval supplement." Mensing, 588 F.3d at 606 (citing 21 C.F.R. § 314.70(b)).

Mensing also observed that generic drug manufacturers have a regulatory duty to alert the FDA to dangers and hazards associated with their products, and, at the very least, to propose changes through the prior approval process. Id. at 608-10 (citing 21 C.F.R. § 201.57(e)). It determined that, once generic drug manufacturers have notice of dangers arising from the use of their drugs, they may ask the FDA to send out warning letters to health care professionals.[8] Id. at 610. In light of these options, Mensing concluded that the defendants could not demonstrate that compliance with federal and state law was a physical impossibility. Id. at 611.

Mensing also noted that the defendants were not compelled to sell their product, and, indeed, could have ceased sales after recognizing that their labels contained inadequate warnings. The Eighth Circuit pointedly commented that by continuing to sell products with the knowledge that the warning on their labels was inadequate, the generic drug manufacturers profited from sales and assumed the risk of being sued for inadequate labeling. Id.

[8] Mensing found that "Dear Doctor" letters are regulated labeling, and noted that "Congress did not intend that generic manufacturers send out 'Dear Healthcare Provider' letters uncoordinated with other manufacturers of the drug." Id. at 610 n.5.

b. Demahy v. Actavis, Inc.

In Demahy, the Fifth Circuit explicitly held "that the federal regulatory regime governing generics is . . . without preemptive effect." 593 F.3d at 430. The defendant in Demahy also manufactured a generic version of Reglan®, and had argued that federal law prohibited it from modifying its label from that of its name brand counterpart. As the defendants in Mensing had done, it argued it was an impossibility for it to comply with both federal regulations and state law. Id. at 436.

Noting Levine's admonition that physical impossibility is a "demanding defense," 129 S. Ct. at 1193, the Fifth Circuit reviewed the statutory framework governing generic drug manufacturers and concluded that, although the Hatch-Waxman Amendments require a generic drug manufacturer to maintain labeling "identical to- or, the 'same as' - the brand name drug when seeking ANDA approval, the statutory scheme 'is silent as to the manufacturer's obligations after the ANDA is granted.'" Demahy, 593 F.3d at 436 (citing Bartlett v. Mutual Pharma. Co., Inc., 659 F. Supp.2d 279 (D.N.H. 2009) (quoting Stacel v. Teva Pharms., USA, 620 F. Supp.2d 899, 907 (N.D. Ill. 2009))).

Finding no statutory basis for preemption, the Fifth Circuit looked next to whether any of the FDA's regulations might preempt state law. It specifically considered whether such regulations prohibit generic manufacturers from using the CBE process, the prior approval process, or from sending warnings directly to healthcare providers. Id. at 439. Reasoning that "[a] finding of preemption would require that all [three options] be foreclosed to generic manufacturers," it thoroughly analyzed both the regulations and the regulatory history governing generic drug manufacturers, and also the CBE process, id., and declined to hold that generics are barred from using the CBE process. Id. at 444. In reaching its conclusion, the circuit court found persuasive the fact that the FDA's commentary to regulations, which clearly requires generic drug labels to mirror the labeling of brand name counterparts during the ANDA process, is silent as to such labeling constraints post-ANDA approval. Id. at 440 (citing 57 Fed. Reg. at 17955).

Demahy also acknowledged that all ANDA applicants must comply with the requirements of 21 CFR §§ 314.70 and 314.71, which "include, of course, the CBE process." Id. at 440. It therefore rejected any contention that generic drug manufacturers may only participate in the CBE process after following the lead of a name brand manufacturer. Id. at 442-44. In reaching this conclusion,

it found significant the fact that, after the Supreme Court decided Levine, the FDA withdrew amicus briefs it had previously filed with both the district court and the Third Circuit in the case of Colacicco v. Apotex Corp.. 521 F.3d 253 (3d Cir. 2008); and 432 F.Supp.2d 514 (E.D. Pa. 2006). In those briefs, the FDA had argued that the Hatch-Waxman Amendments and regulations preempted state failure-to-warn claims against both brand name and generic drug manufacturers.[9] Id. at 442-43.

Demahy also weighed carefully the fact that, although the FDA had proposed regulatory language barring generics from utilizing the CBE process, it had never included such language in the final version of the rule. Id. at 443 (citing 73 Fed. Reg. at 49604). That discussion in Demahy severely undercuts Mylan's reliance on Gaeta, 2009 WL 4250690, at *3-*5, where the district court relied, in part, on the proposed regulatory language explicitly barring generic drug manufacturers from using the CBE process to modify drug labels in a way that differed from their brand name counterparts.

[9] The Third Circuit's decision in Colacicco was vacated in the wake of Wyeth v. Levine. See Colacicco v. Apotex, Inc.,129 S. Ct. 1578, 1579 (2009).

In declining to hold that generic drug manufacturers are prohibited from using the CBE process, the Fifth Circuit specifically observed that, because the FDA's regulations neither explicitly refer to nor exclude generic drug manufacturers from using that process, any contention that the CBE process was unavailable to generic drug manufacturers was, at best, only as strong as the contrary position. Id. at 444-45. Given Levine, such "equivocation falls short of the 'clear and manifest purpose of Congress' required for a finding of preemption." Id. (quoting Levine, 129 S. Ct. at 1195 (citation omitted)).

The Fifth Circuit also observed that there are no congressional or regulatory indications that generic drug manufacturers may not propose labeling changes to the FDA "- no matter the significance of the change- through the prior approval process." Id. at 444. It also pointed out that, although generic drug manufacturers may only send out "Dear Doctor" letters with FDA approval, nothing prohibits those manufacturers from suggesting that the FDA do so on their behalf. Id. at 444-45 (citing 21 U.S.C. § 355-1(i)(2)).

Finally, the Fifth Circuit noted that the deeper principle of Levine, "'that the manufacturer bears responsibility for the content of its label at all times,'" applies within the context of

a generic drug manufacturer's responsibilities in "full force." Id. at 445-46 (quoting Levine, 129 S. Ct. at 1197-98). Therefore, having no indication that the FDA would have rejected a labeling proposal from the defendant generic drug manufacturer, the circuit court held that the defendant had failed to meet its burden of establishing conflict preemption through impossibility of compliance with both federal and state laws. Id.

Demahy recognized that whether the CBE process is available to generic drug manufacturers raises a difficult question of regulatory interpretation. Nevertheless, it declined to find that the CBE process was unavailable to the defendant: "Without explicit reference to the use of the CBE process by generic manufacturers, we decline to read in a bar to its use." Id. at 444.

Mensing and Demahy both stand for the proposition that generic drug manufacturers are not precluded by either statute or regulation from utilizing the prior approval process or requesting that the FDA send out "Dear Doctor" letters. Mensing, 588 F.3d 603; and Demahy, 593 F.3d 428. For this reason alone, Mylan's attempt in this case to establish that it was an impossibility for

it to comply with its obligations under federal law, as well as its duties under state law, fails.[10]

After Levine other district courts have concluded that federal law does not preempt state failure-to-warn claims against generic drug manufacturers. See Bartlett, 659 F. Supp.2d 279 (holding that federal law does not preempt a generic drug manufacture's duty to warn consumers of a drug's dangers under state law); Kellogg v. Wyeth, 612 F. Supp.2d 437, 442 (D. Vt. 2009) (same); Stacel, 620 F. Supp.2d at 907 (same); Munroe v. Barr Labs., Inc., __ F. Supp.2d __, 2009 WL 4047949 (N.D. Fla. 2009) (same); and Schrock v. Wyeth, Inc., 601 F. Supp.2d 1262, 1265 (W.D. Okla. 2009) (same). Moreover, as discussed previously, the decision of the Fourth Circuit in Foster supports the conclusion that FDA regulations do not bar generic drug manufacturers from using the CBE process to enhance and strengthen the warnings on their drug labels. 29 F.3d at 169-70. The Court therefore concludes that, without "clear

[10] On this basis, the Eighth Circuit in Mensing found that the availability of the CBE process to generic manufacturers was "immaterial" to the question of impossibility preemption, and therefore declined to determine its availability to a generic drug manufacturer. 588 F.3d at 609 (holding that "[t]he availability of one particular procedure (the CBE process, on which the district court expended the majority of its discussion) is immaterial to the preemption analysis in light of this clear directive to generic manufacturers and the availability of the prior approval process.").

evidence" that the FDA would not have approved a change to Mylan's Phenytoin label, there is no basis for finding impossibility of compliance preemption in this case. Levine, 129 S. Ct. at 1198. Mylan thus may not invoke impossibility preemption as a bar to Vitatoe's state law inadequate warning claim.

2. Implied Preemption Based on the Obstruction of the Accomplishment and Execution of the Full Purposes and Objectives of Congress

Mylan also argues that Vitatoe's inadequate warning claim is preempted because that claim "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Hines, 312 U.S. at 67. The Supreme Court has previously recognized that "one of the [FDCA's] core objectives is to ensure that any product regulated by the FDA is 'safe' and 'effective' for its intended use." Food and Drug Admin. v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 133 (2000) (citing 21 U.S.C. § 393(b)(2) (1994 ed., Supp. III)). In Demahy, the Fifth Circuit considered the FDCA's safety objectives alongside the goals of the Hatch-Waxman Amendments. Building on the reasoning of the Supreme Court in Levine,[11] it concluded that "nothing about the

[11] In Levine, the Supreme Court recognized that

> [t]he FDA has limited resources to monitor the

Hatch-Waxman Amendments and their goal of cheaper drugs[] obviates the concomitant prescription that all drugs, even cheaper ones, remain safe." Demahy, 593 F.3d at 448. See also Mensing, 588 F.3d at 612. It further observed that the Hatch-Waxman Amendments do not change state policies regarding the duty of generic drug manufacturers to adequately warn consumers of their products' dangers. Demahy, 593 F.3d at 448-49. Accord Mensing, 588 F.3d at 612.

Mylan nevertheless contends that, if generic drug manufacturers are required to comply with state tort laws,

> 11,000 drugs on the market, and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge. **State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly**. They also serve a distinct compensatory function that may motivate injured persons to come forward with information. **Failure-to-warn actions, in particular, lend force to the FDCA's premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times**. Thus, the FDA long maintained that state law offers an additional, and important, layer of consumer protection that **complements** FDA regulation.

129 S. Ct. at 1202 (emphasis added).

physicians will lose the benefit of uniform labeling and could no longer confidently prescribe generic medications that are the therapeutic equivalent of brand name drugs. The need for uniform labeling notwithstanding, the purpose of the FDCA is to enhance consumer safety. Levine, 129 S. Ct. at 1194-95. Mylan's argument offers no indication that the FDA's primary responsibility for drug labeling would be frustrated or obstructed should a state action alleging that a generic drug manufacturer had failed to adequately disclose known safety risks of its drugs be allowed to proceed.

V. CONCLUSION

For the reasons discussed, the Court:

1) **GRANTS** Mylan's motion for summary judgment as to Vitatoe's claims excluded under the Louisiana Products Liability Act;

2) **DENIES** Mylan's motion for summary judgment based on the availability of the affirmative defense of the learned intermediary doctrine; and

3) **DENIES** Mylan's motion for summary judgment on the issue of conflict preemption.

See (dkt. no. 67).

It is so **ORDERED**.

The Clerk is directed to transmit copies of this Order to counsel of record.

DATED: March 5, 2010.

/s/ Irene M. Keeley
IRENE M. KEELEY
UNITED STATES DISTRICT JUDGE