IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
BEAUMONT DIVISION

KATHERINE MILLS, individually and on behalf of all others similarly situated, and VERONICA EVANS, individually and on behalf of all others similarly situated,	§	
Plaintiffs,	§	
v.	§	**CIVIL ACTION NO.1:07-CV-264-TH**
	§	**JURY**
WARNER-LAMBERT COMPANY, PFIZER, INC., BAYER CORPORATION, DEL PHARMACEUTICALS, INC., DEL LABORATORIES INC., AND CARE TECHNOLOGIES, INC., and INSIGHT PHARMACEUTICAL CORPORATION,	§	
Defendants.	§	

MEMORANDUM OPINION & ORDER
GRANTING DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

Before the Court is the *Motion for Summary Judgment and Supporting Memorandum of Defendants Warner-Lambert Company LLC, Pfizer Inc., Bayer Corporation, Del Pharmaceuticals, Inc., Del Laboratories, Inc. and Insight Pharmaceuticals Corporation* [Clerk's Docket No. 41], filed September 28, 2007. Having considered the motion, the responsive pleadings, and the applicable law, the Court is of the opinion that the motion should be granted.

I. INTRODUCTION

Plaintiffs Katherine Mills and Veronica Evans (collectively "Plaintiffs") bring this putative class action against the manufacturers of various lice treatment medications. Plaintiffs

challenge the effectiveness of those medications, and seek recovery of the money they spent purchasing them. This opinion considers whether federal law preempts such a challenge to a drug when it has previously been approved by the FDA. The Court concludes that it does. Because this is not a products liability action (under Texas law), Plaintiffs' claims are expressly barred by Section 379r of the Federal Food, Drug and Cosmetic Act, (21 U.S.C. § 301 *et. seq.*) (the " FDCA"), the preemption clause of the statute that relates to nonprescription drugs.

II. BACKGROUND

A. Plaintiffs' Lawsuit

Plaintiffs purchased lice treatment medications manufactured by the defendants in this case, and now claim that they are ineffective–that they do not kill lice. Plaintiffs do not just claim that these medications failed in specific instances, or for specific individuals. Rather, they claim that lice are resistant to the products, and that the medications do not work for anyone at any time.

This suit specifically concerns three nonprescription lice treatment medications: (1) NIX Lice Treatment, sold by defendant Insight Pharmaceuticals Corporation[1] (" Insight"), and previously sold by defendant Warner-Lambert Company LLC[2] (" Warner-Lambert"); (2) RID Lice Killing Shampoo, sold by defendant Bayer Corporation (" Bayer"), and previously sold by defendant Pfizer, Inc. (" Pfizer"); and (3) PRONTO Lice Treatment, sold by

[1]Any reference in this order to " Insight" includes Insight Pharmaceuticals LLC, which is also named as a defendant.

[2]Warner-Lambert Company LLC is incorrectly named in the caption of this case as Warner-Lambert Company.

defendant Del Pharmaceuticals, Inc.[3] (" Del").[4] All of these products are generically known by the scientific name " pediculicides."[5]

To be clear about the nature of this suit: Plaintiffs do not allege a negligent manufacturing defect, a design defect sounding in strict liability, or a failure to warn. They do not claim that the lice treatments have caused any personal injury or any damage to property. And, they do not claim that the treatments are potentially unsafe. Their sole contention is that the products are ineffective. In Plaintiffs' own words:

> The plaintiffs are contending that defendants' products amount to snake oil. The products are inherently useless and worthless. They do not kill lice. They do not cure lice infestations.

Mills v. Warner Lambert, 2005 Tex. App. LEXIS 7105, *3-4 (Tex. App. - Beaumont, August 31, 2005) (quoting Plaintiffs' briefs).

On this basis, Plaintiffs assert two causes of action under Texas law. First, Plaintiffs claim that by selling ineffective medications Defendants breached the implied warranty of merchantability codified by the Texas UCC, Tex. Bus. & Comm. Code § 2.314. Under Texas law, a warranty of merchantability is implied in every contract for the sale of goods by a merchant, unless the warranty is properly excluded or modified. Tex. Bus. & Comm. Code § 2.314(a) (Vernon 2007); *Hininger v. Case Corp.*, 23 F.3d 124, 128 (5th Cir. 1994). Second, Plaintiffs claim that by selling ineffective medications, Defendants violated the Texas

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[3]Any reference in this order to " Del" includes, Del Laboratories, Inc., which Plaintiffs have also named as a defendant.

[4]For purposes of clarity and simplicity, defendants Insight, Warner-Lambert, Pfizer and Insight will be referred to collectively in this order as " Defendants."

[5]The term " pediculicide" is a combination of two Latin words: " pediculi," meaning " lice;" and " cide," which means " killer" or " killing." WEBSTER' S NEW TWENTIETH CENTURY DICTIONARY OF THE ENGLISH LANGUAGE, UNABRIDGED, 1321 (2d ed. 1980). " Pediculicide is defined by the Code of Federal Regulations as " [a] drug product for the treatment of head, pubic (crab) and body lice." 21 C.F.R. § 358.603.

Deceptive Trade Practices Act, Tex. Bus. & Comm. Code § 17.50(a)(2) (the " DTPA"). While this DTPA claim is a distinct cause of action, the DTPA does not actually create an independent claim for breach of warranty. *See Hininger*, 23 F.3d at 129 (citing *La Sara Grain Co. V. First Nat' l Bank of Mercedes*, 673 S.W.2d 558, 565 (Tex. 1984) (the DTPA " does not create any warranties")); *Parkway Co v. Woodruff*, 901 S.W.2d 434, 438 (Tex. 1995). Instead, the DTPA simply provides additional monetary remedies for a breach of the implied warranty of merchantability. *Id.* So, the two claims are substantively the same.

Rather than attack the merits of these allegations, Defendants argue that all of Plaintiffs' claims are preempted by federal law; and, therefore, must be dismissed.

B. Federal Preemption

The doctrine of federal preemption is based on the Supremacy Clause of the United States Constitution. *Fid. Fed. Sav. & Loan Ass' n v. de la Cuesta*, 458 U.S. 141, 152, 102 S.Ct. 3014, 73 L.Ed.2d 664 (1982). The Supremacy Clause provides that United States law is " the supreme Law of the Land;...any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. CONST. Art VI, Cl. 2. As such, any State law that conflicts with the exercise of federal power is preempted and has no effect. *Maryland v. Louisiana*, 451 U.S. 725, 747, 101 S.Ct. 2114, 68 L.Ed.2d 576 (1981); *See McCulloch v. Maryland*, 17 U.S. 316, 4 L.Ed. 579 (1819).

Supreme Court case law has established that State law is preempted under the Supremacy Clause in three circumstances. *English v. General Electric Co.*, 496 U.S. 72, 78-79, 110 S.Ct. 2270, 110 L.Ed.2d 65 (1990). First, Congress may expressly preempt State law. *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516, 112 S.Ct. 2608, 120 L.Ed.2d 407 (1992); *English,* 496 U.S. at 79. Second, in the absence of explicit statutory language, " state law is preempted where it regulates conduct in a field that Congress intended the Federal

Government to occupy exclusively." *English*, 496 U.S. at 79; *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287, 115 S.Ct. 1483; 131 L.Ed.2d 385 (1995). Finally, preemption may also be implied to the extent that State law actually conflicts with federal law. *English*, 496 U.S. at 79. The Supreme Court has found such implied conflict preemption where " (1) it is impossible for a private party to comply with both State and federal requirements; or (2) State law obstructs accomplishing and executing Congress' full purposes and objectives." *Freightliner*, 514 U.S. at 287.

C. FDCA Preemption

In this case, Defendants argue that Plaintiffs' claims are preempted for two reasons: (1) they are expressly preempted by Section 379r of the Federal Food, Drug and Cosmetic Act (" FDCA") (21 U.S.C. § 301 *et. seq.*); and (2) they are impliedly preempted because they conflict with the FDCA and the Food and Drug Administration (" FDA") regulations governing the sale of Defendants' Medications. (Def.s' Mot. for Summ. J. at 9). This opinion only addresses Defendants' first argument: express preemption under Section 379r.

Section 379r is the preemption provision of the FDCA that applies to nonprescription drugs. 21 U.S.C. § 379r.[6] It provides that any State requirement relating to drug regulation that is not identical to a federal requirement under the FDCA is expressly preempted. 21 U.S.C. § 379r(a). Here, Defendants argue that Plaintiffs' claims are preempted by Section 379r because they would impose a drug labeling " requirement" different from that required by the FDA. Essentially (the argument goes), the FDCA specifies that Defendants' drug labels must state that they are effective in the treatment of head lice. However, Plaintiffs' suit is based on the notion that the medications are *not effective*. It would punish Defendants for selling their products with the labeling language required by the FDCA. So according to

[6]The FDCA contains another preemption provision in 21 U.S.C. § 360k(a), which is quite similar to Section 379r but applies to medical devices.

Defendants, Plaintiffs' claims would impose a requirement on the marketing and sale of their products that differs from the FDCA's. Plaintiffs admit that a jury verdict in this lawsuit "might effect or induce" Defendants to change their conduct. Nevertheless, Plaintiff maintain that their claims do not constitute a "requirement," under the meaning of the statute.

Alternatively, Plaintiffs argue that their claims are 'saved' from preemption by Section 379(e), the FDCA's 'saving clause.' Section 379(e) provides that nothing in the preemption provision "shall be construed to modify or otherwise affect any action or the liability of any person under the *product liability law* of any State." 21 U.S.C. § 379r(e). As such, Plaintiffs argue that their claims brought under the product liability law of Texas and are therefore exempt from preemption.

These preemption arguments have been part of this case for more than seven years.

D. Procedural History

Plaintiffs originally filed this suit as a potential class action in the 163rd Judicial District Court of Orange County, Texas on January 24, 2001. Over the next six years, the case traveled up and down the Texas court system, stopping twice at the Beaumont Court of Appeals–and visiting the Texas Supreme Court–before returning to Orange County.[7] Essentially back where they started, the Parties renewed their wrangling over federal preemption and class certification.

Then, in March 2007, Plaintiffs filed their Sixth Amended Petition, adding Insight as a

[7] *Warner-Lambert Company v. Mills*, 117 S.W.3d 488, 494 (Tex. App. - Beaumont 2003) (citation omitted); *Warner-Lambert Company v. Mills*, 2005 Tex. App. LEXIS 7105, 2005 WL 2088366 (Tex. App. - Beaumont Aug. 31, 2005, *no pet.*). *Mills v. Warner Lambert Co.*, 157 S.W.3d 424 (Tex. 2005).

defendant. Insight had purchased Warner-Lambert's lice eradication business in 2003, and was selling NIX lice treatment. Insight promptly removed the case to federal court citing the Class Action Fairness Act ("CAFA") as the source of federal jurisdiction. By order dated August 13, 2007, this Court found that such jurisdiction was proper.

Despite this lengthy history, the question now before this Court is the same one the Parties first tackled in the Spring of 2001: are Plaintiffs' claims preempted by federal law.

In answering this question, this Court will not be blazing new trails. The Beaumont Court of Appeals previously considered the issue. *See generally, Warner-Lambert v. Mills*, 117 S.W.3d 488 (Tex. App. - Beaumont 2003). And, State courts in California and Florida have considered preemption in two cases nearly identical to this one. *See generally Kanter v. Warner-Lamber Company*, 99 Cal. App. 4th 780 (Cal. Ct. App. 2002); *see generally Berenguer v. Warner-Lambert Co.*, 2003 WL 24299241 (Fla. Cir. Ct. July 31, 2003). Both the California and Florida cases involved claims that the lice medications RID and NIX were ineffective. *Id.* And, like the Beaumont Court of Appeals, both the California and Florida courts held that those claims were preempted.

As discussed below, this Court likewise reaches the conclusion that Plaintiffs' claims are expressly preempted by Section 379r of the FDCA. However, the Court does not reach the issue of implied conflict preemption.[8]

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[8]Earlier this year, the Supreme Court granted certiorari in *Wyeth v. Levine,* 128 S.Ct. 1118, 169 L.Ed.2d 845 (Jan. 18, 2008), a case involving implied preemption. The specific question at issue in *Levine* is whether Congress has impliedly preempted tort actions related to pharmaceuticals through the FDA regulations. *See Levine v. Wyeth*, 2006 VT 107 (Vt. 2006). The Supreme Court will hear argument in *Levine* in November. Adam Liptak, *Drug Label, Maimed Patient and Crucial Test for Justices*, N.Y. Times, September 18, 2008, at www.nytimes.com/2008/09/19/us/19scotus.html; *see* Gardiner Harris, *Justices Add Legal Complications to Debate on F.D.A.'s Competence*, N.Y. Times, February 21, 2008, at www.nytimes.com/2008/02/21/washington/21fda.html. However, because the case before this Court is not a product liability action, and because it is decided based on express (rather than implied) preemption, this Court does not anticipate that *Levine* will change the outcome of this decision.

II. LEGAL STANDARD

Summary judgment is proper when, after viewing the evidence in the light most favorable to the non-movant, "there is no genuine issue as to any material fact and . . . the moving party is entitled to judgment as a matter of law." *Amburgey v. Corhart Refractories Corp.*, 936 F.2d 805, 809 (5th Cir. 1991); Fed. R. Civ. P. 56(c). If the moving party establishes the absence of any genuine issue, the burden shifts to the non-moving party to produce evidence of the existence of a genuine issue for trial. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). Conclusory allegations, unsubstantiated assertions, and mere scintillas of evidence do not satisfy this burden. *Little v. Liquid Air Corp.*, 37 F.3d 1069, 1075 (5th Cir. 1994). Summary judgment is proper where a party fails to establish the existence of an element essential to his case and on which he bears the burden of proof. A complete failure of proof on an essential element renders all other facts immaterial because there is no longer a genuine issue of material fact. *Washington v. Armstrong World Industries*, 839 F.2d 1121, 1122 (5th Cir. 1988).

Fed. R. Civ. P. 56(c) requires the court to look at the full record, including the pleadings, depositions, answers to interrogatories, admissions, and affidavits. But the court is not obligated to " sift through the record in search of evidence to support a party' s opposition to summary judgment." *Doddy v. Oxy USA, Inc.*, 101 F.3d 448, 463 (5th Cir. 1996). All reasonable inferences to be drawn from the underlying facts must be viewed in the light most favorable to the party opposing the motion, and any doubt must be resolved in its favor. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587, 106 S.Ct. 1348, 89 L.Ed.2d 538 (1986). However, only reasonable inferences in favor of the nonmoving party can be drawn from the evidence. *Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 112 S.Ct. 2072, 119 L.Ed.2d 265 (1992).

III. DISCUSSION

Defendants argue that Plaintiffs' claims are expressly preempted by Section 379r of the FDCA. For the reasons given below, the Court agrees.

A. Express Preemption under FDCA § 379r

In 1997, Congress passed the Food and Drug Administration Modernization and Accountability Act (the FDA Modernization Act"), legislation that was intended " [t]o amend the [FDCA] and the Public Health Service Act to improve the regulation of food, drugs, devices, and biological products, and for other purposes." 105 P.L. 115, 111 Stat. 2296 (Nov. 21, 1997). Among other things, the FDA Modernization Act added Section 379r to the FDCA–a provision that expressly preempts State requirements relating to drug regulation. Section 379r was included under the heading " National uniformity for nonprescription drugs." 21 U.S.C. § 379r.

Section 379r(a) states that:

> (a) ...no State or political subdivision of a State may establish or continue in effect any *requirement*—
>
> (1) that relates to the regulation of a [nonprescription] drug...; and
>
> (2) that is different from or in addition to, or that is otherwise not identical with, a *requirement* under [the FDCA]...(emphasis added).

21 U.S.C. § 379r(a).

However, the FDA Modernization Act also included a " saving clause" in Section

379r(e), that provides an exception to preemption under Section 379r(a). The saving clause states that " [n]othing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the *product liability law* of any State." 21 U.S.C. § 379r(e). (emphasis added).

The Court's present task is to analyze the preemptive scope of this statute. Its plain language makes clear that Congress intended the FDCA to preempt at least *some* State law. *Medtronic v. Lohr*, 518 U.S. 470, 484, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996). But, the Court must still " identify the domain expressly preempted by that language." *Id.* (quoting *Cipollone*, 505 U.S. at 517) (internal quotations omitted). To do so, the Court clearly must begin with the statute's text. *Lohr*, 518 U.S. at 484 (stating that analyzing the scope of a preemption statute must begin with its text). When a statute contains an express preemption clause–as is the case here–" the task of statutory construction must in the first instance focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' preemptive intent." *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664, 113 S.Ct. 1732, 123 L.Ed.2d 387 (1993) (*superseded by statute on other grounds*).

However, if it is not clear from the text that Congress intended to supersede State law (including State common law duties) there is a presumption against preemption. *Lohr*, 518 U.S. at 485. This presumption is rooted in the concept of federalism. *Geier v. American Honda Motor Co., Inc.*, 529 U.S. 861, 907, 120 S.Ct. 1913, 146 L.Ed.2d 914 (2000). As the Supreme Court has stated, " [i]n areas of traditional State regulation, we assume that a federal statute has not supplanted State law unless Congress has made such intention 'clear and manifest.' " *Bates v. Dow AgroSciences, LLC*, 544 U.S. 431, 449, 125 S.Ct. 1788, 161 L.Ed.2d 687 (2005). And, regulating health and safety is primarily and historically such a matter of local concern. *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 719, 105 S.Ct. 2371, 85 L.Ed.2d 714 (1985) (citing *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 213, 230, 67 S.Ct. 1146, 91 L.Ed. 1447 (1947)).

Additionally, the Court's analysis is guided by the notion that " the purpose of Congress is the ultimate touchstone in every preemption case." *Frank v. Delta Airlines, Inc.*, 314 F.3d 195, 197 (5th Cir. 2002) (*quoting Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996)). " Congress' intent, of course, primarily is discerned from the language of the preemption statute and the 'statutory framework' surrounding it." *Lohr*, 518 U.S. at 486 (quoting *Gade v. National Solid Wastes Management Assn.,* 505 U.S. 88, 111, 112 S.Ct. 2374, 120 L.Ed.2d 73 (1992)); *Cipollone*, 505 U.S. at 516 (" Congress' intent may be explicitly stated in the statute's language or implicitly contained in its structure and purpose." (quoting *Jones v. Rath Packing Co.*, 430 U.S. 519, 525, 97 S.Ct. 1305, 51 L.Ed.2d 604 (1977))).

With these principles of interpretation in mind, the Court now turns to the text of Section 379r to interpret its preemptive scope.

Given the language of the statute, it is clear that the Court's analysis must proceed in four steps. First, the Court must determine whether the FDA's drug-approval and labeling regulations constitute a *federal requirement* under Section 379r(a). Second, the Court must consider whether Plaintiffs' claims based on Texas law would establish a *State requirement* relating to the regulation of a drug. If these questions are both affirmatively answered, the Court must then decide whether the State requirement is *different from or in addition to, or otherwise not identical with* the federal requirement. If it is, the final step in the Court's analysis is to determine whether Plaintiffs' action is brought under the product liability law of Texas, and therefore exempted from preemption by Section 379r's saving clause.

(1) The FDA Regulations Relating to the Content, Labeling and Sale of Defendants' Medications Constitute Federal Requirements

Taking the first step in the preemption analysis, the Court considers whether the

FDCA's drug-approval and labeling regulations constitute a *federal requirement* under Section 379r(a). This consideration obviously requires a threshold review of the FDA's drug-approval process and the applicable regulations.

(a) Background: FDA Drug Approval & Labeling Regulations

The FDA has two systems for evaluating the safety and effectiveness of drugs that are relevant to this case: (1) the new drug application ("NDA") process for approving drugs before they are put on the market; and (2) the monograph system for evaluating over-the-counter ("OTC") drugs that are already on the market. Both are relevant to this case. The lice treatment Nix was approved by the FDA as a new drug after completing the NDA process. RID and PRONTO were approved as part of the monograph system.

(i) The NDA Process

Congress first established a pre-marketing drug-approval system when it enacted the FDCA in 1938. *Cutler v. Kennedy*, 475 F.Supp. 838, 840 (D.D.C. 1979) *overruled on other grounds in Chaney v. Heckler*, 718 F.2d 1174, 1188 n.35 (D.C. Cir. 1983). Under the FDCA, a drug manufacturer may not sell a new drug until the FDA has approved it as safe and effective for its intended use. 21 U.S.C. § 355(a); *Cartwright v. Pfizer,* 369 F.Supp.2d 876, 878 (E.D. Tex. 2005) (Steger, J.); *Kanter,* 99 Cal. App. 4th at 784 (citing *Weinberger v. Hynson, Westcott & Dunning* 412 U.S. 609, 612-13, 93 S.Ct. 2469, 37 L.Ed.2d 207 (1973)).

A manufacturer seeking approval of a new drug must submit a detailed NDA in accordance with the requirements of the FDCA and related regulations promulgated by the FDA. *Kanter*, 99 Cal.App. 4th at 784 (citing 21 U.S.C. § 355(b)(1); 21 C.R.F. §§ 314.1-314.3, 314.50 (2001)). Among other information, the application must include "substantial evidence" that the drug is safe and effective. *Id.* "Substantial evidence" means "evidence

consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed recommended or suggested in the labeling or proposed labeling thereof." *Id.* (citing 21 U.S.C. § 355(d)); *Weinberger v. Hynson*, 412 U.S. at 613 n.3); *see* 21 C.F.R.d § 314.126 (2001) (detailing the characteristics of an " adequate and well-controlled study").

The FDA specifically regulates all drug labeling, including " all written, printed, or graphic matter" used in marketing the drug. 21 C.F.R. §1.3(a); *Cartwright*, 369 F.Supp.2d at 879. So, an NDA must also include " specimens of the labeling proposed for the drug. *Kanter*, 99 Cal.App. 4th at 785 (citing 21 U.S.C. § 355(b)(1)(F); 21 C.F.R. §§ 314.50(c)(2)(I) (2001) (application must include proposed text of labeling), and 201 *et seq.* (2001) (general labeling provisions)). The FDA will only approve an NDA if it " determines that the drug meets the statutory standards for safety...and labeling." 21 C.F.R. § 314.105(c); *Cartwright*, 369 F.Supp.2d at 879.

If it determines that the drug meets these standards, the FDA sends an " approvable" letter to the drug manufacturer, which includes its product-specific labeling requirements. *Cartwright*, at 879 (citing 21 C.F.R. § 314.110(a)). *Id.* What' s more," [a]pproval of the NDA is 'conditioned upon the applicant incorporating the specified labeling changes exactly as directed, and upon the applicant submitting to FDA a copy of the final printed labeling prior to marketing.' " *Id.* (quoting 21 C.F.R. § 314.105(b)).

On the other hand, if the FDA determines that the labeling of a new drug is false or misleading in any particular, the drug is deemed " misbranded." *Kanter*, 99 Cal.App. 4th at 785. Whether labeling is false or misleading depends on its stated or suggested representations–and the extent to which it fails to reveal any material facts. *Id.* (citing 21

U.S.C. §§ 352(a), 321(n)). The application will be refused: (1) if the FDA determines that the labeling is false or misleading in any particular; (2) if the application contains an untrue statement of material fact; or (3) if the proposed labeling does not comply with the requirements established in the regulations. *Id.* (citing 21 U.S.C. § 355(d)(7); 21 C.R.F. §§ 314.125(b)(6), (7), (8) (2001)).

Once a new drug application has been approved, any change in the labeling requires a supplement to an application and approval by the FDA, either before or after the change. *Kanter*, 99 Cal.App. 4th at 785 (citing 21 C.F.R. §§ 314.70(b), (c), 314. 17 (2001)) Furthermore, the FDA must withdraw its approval of a drug, if it finds on the basis of new evidence that the drug is unsafe, the drug does not have the effect represented or suggested on its labeling, or that the labeling is false and misleading in any particular. *Id.* (citing 21 U.S.C. § 355(e); 21 C.R.F. §§ 314.150(a)(2)(iii), (iv), (b)(3) (2001)); *Cartwright*, 369 F.Supp.2d at 878.

In short, FDA regulations mandate the format and content of all labeling sections. *Cartwright*, 369 F.Supp.2d at 879 (citing 21 C.F.R. § 314.110(a)). And, the manufacture and distribution of any misbranded drug is expressly prohibited by the FDCA. *Kanter*, 99 Cal.App. 4th at 785 (citing 21 U.S.C. § 331(a), (b), (c), (g), (k)).

(ii) FDA Approval of the NIX NDA

The FDA approved an NDA for the lice medication NIX in 1986, allowing it to be sold as a prescription drug. *Kanter*, 99 Cal. App. 4th at 787. The approved labeling described NIX as " a topical pediculicide and ovicide for the treatment of infestation with *Pediculus humanus var capitis* (the head louse) and its nits (eggs)." *Id.* In the indications and usage section, the label stated " NIX is indicated for the single-application treatment of infestation with *Pediculus humanus var capitis* (the head louse) and its nits (eggs)." *Id.*

Four years later, the FDA approved another NDA that allowed NIX to be sold as an OTC drug. *Id.* Again, the indications section of the newly-approved labeling stated that NIX was " [f]or the treatment of head lice."

In summary, at all times relevant to this lawsuit, the FDA-approved labeling for NIX stated that the product was " [f]or the treatment of head lice," and that it " [k]ills lice and their eggs." *Kanter*, 99 Cal. App. 4th 787.

Unlike NIX, Defendants' medications RID and PRONTO were not required to go through the NDA process. Instead, they were subject to another FDA method of evaluating drugs: the monograph system.

(iii) The Monograph System for Over-the-Counter Drugs

The FDCA, as enacted in 1938, established the original application procedures for premarket drug approval. But, the NDA process did not take the form described above until Congress passed the Drug Amendments of 1962. *See generally Cutler v. Kennedy*, 475 F.Supp. at 840-846 (D.D.C. 1979). The 1962 amendments first added the requirement that a drug be effective, and that the labeling of a drug not be false or misleading. *Cutler v. Kennedy*, 475 F.Supp. at 841. The amendments placed these new requirements on any " new drug," while defining a " new drug" as one not generally recognized among experts as safe and effective for its intended use. 21 U.S.C. § 321(p)(1); *Weinberger v. Hynson,* 412 U.S. at 613. Any drug not defined as a " new drug" was exempt from the requirement of providing substantial evidence of its effectiveness. *Smithkline Corp. V. Food & Drug Administration,* 587 F.2d 1107, 1110, 190 U.S. App. D.C. 210 (D.C. Cir. 1978). Nevertheless, the Drug Amendments of 1962 required the FDA to review *all* marketed drugs for their efficacy, whether or not they had previously been approved. *Weinberger v. Hynson,* 412 U.S. at 614. Clearly, this review represented a " massive task." *Smithkline*, 587 F.2d at 1112.

The FDA quickly realized that it would be impossible to conduct a case-by-case appraisal of the thousands of prescription and OTC drugs already on the market. *Weinberger v. Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 651, 93 S.Ct. 2488, 37 L.Ed.2d 235 (1973) (noting that in 1973 there were between 100,000 and 500,000 OTC drugs on the market, few of which were previously approved by the FDA). Accordingly, the FDA retained the National Academy of Sciences-National Research Council to create expert panels to assist with the task. *Weinberger v. Hynson,* 412 U.S. at 614. The Academy put together seventeen advisory panels of outside experts to review twenty-six categories of OTC drugs, which were grouped by intended effect (e.g., antacids, cold remedies, contraceptives, pediculicides). *Cutler v. Kennedy,* 475 F.Supp. at 844. These categories were then divided into 88 subgroups. Mark B. Gelbert, *State Statutes Affecting the Labeling of OTC Drugs: Constitutionality Based on Commerce Clause and Preemption Theories,* 46 Food Drug Cosm. L.J. 629, 631 (1991). This approach seems fairly prudent, given that " there are hundreds of thousands of OTC drugs," but that those drugs are " composed of a relatively small number of active ingredients." *Cutler v. Kennedy*, 475 F.Supp. at 845.

The FDA then determined that the OTC drug review would be conducted in four phases. *Cutler v. Hayes*, 818 F.2d 879, 882-884, 260 U.S. App. D.C. 230 (D.C. Cir. 1987). This review is known as the monograph process.[9] Its four steps are summarized as follows:

> First, advisory review panels of qualified experts are appointed to analyze existing test data and make recommendations in the form of monographs establishing the conditions under which each OTC drug could be marketed without an NDA. In Phase II, FDA reviews these monographs and publishes them in the Federal Register for public comment on the safety and effectiveness of the products under examination. The third stage of the program obligates FDA to review comments, to publish a tentative final monograph, and to offer

[9]"Monograph" is defined as "a learned detailed thoroughly documented treatise covering exhaustively a small area of a field of learning." *Kanter*, 99 Cal. App. 4th at 786 n.2 (quoting Webster's 3d New International Dictionary (1986) p. 1462.

> the public the opportunity to object formally, either in writing or at a hearing, to the findings made with respect to individual drugs. In the fourth and final part of the OTC review, FDA promulgates a final monograph containing the agency's conclusive and legally binding determinations on the conditions under which a drug is considered [generally safe and effective for use].

Cutler v. Hayes, 818 F.2d at 884.

Once the final monograph is approved, the FDA publishes it in the form of an agency regulation in the Code of Federal Regulations. *Id.* " Those regulations establish conditions under which a category of over-the-counter drug is recognized as safe and effective and not misbranded." *Kanter*, 99 Cal. App. 4th at 786 (citing 21 C.F.R. § 330.10 (2001); *Cutler v. Hayes*, 818 F.2d at 884. " Any product which fails to conform" to " each of the conditions contained in the monograph and 21 C.F.R. 330.1 is " liable to regulatory action." 21 C.F.R. 330.1, 330.10(b). The final monograph " constitutes final agency action from which appeal lies to the courts." 21 C.F.R. 330.10(a)(11).

As with the regulations for new prescription drugs (described above), the monograph regulations for a class of OTC drugs include labeling requirements. *Kanter*, 99 Cal. App. 4th at 786. " Under the heading 'Uses,' the label must 'contain the labeling describing the 'Indications' that have been established in an applicable [OTC] drug monograph or alternative truthful and nonmisleading statements describing only those indications for use that have been established in an applicable monograph...' " *Id.* (quoting 21 C.F.R. § 330.1(c)(2) (2001)).

(iv) RID, PRONTO & the Pediculicide Monograph

The FDA issued the final monograph for OTC pediculicides in 1993. The monograph specified the active ingredients for such products and established the conditions under which they are " generally recognized as safe and effective and not misbranded." *Kanter*, 99 Cal.

App. 4th at 787. (citing 58 Fed.Reg. 65452-01 (Dec. 14, 1993)). The pediculicide monograph appears in 21 C.F.R. §§ 358.601-3158.650. *Id.* It provides that an OTC pediculicide like RID and PRONTO is generally recognized as safe and effective and is not misbranded if it meets each condition in the monograph and each general condition in 21 C.F.R. § 330.1. *Id.* One of the conditions of the monograph relates to labeling. *Id.* Specifically, the monograph requires that an OTC pediculicide state, under the heading " Indications:" " [f]or the treatment of head, pubic (crab), and body lice.' " *Id.* at 787-88. It also requires that under the heading " Directions," the label must state: " [a] fine-toothed comb or a special lice/ nit removing comb may be used to help remove dead lice or their nits from hair. A second treatment must be done in 7 to 10 days to kill any newly hatched lice." *Id.* at 788 (citing 21 C.R.R. § 358.650(b), (d)(2), (3) (2001).

At all times relevant to this lawsuit, the labels for RID and PRONTO include the foregoing statements required by the monograph.

(b) The Existence of Federal Requirements

Section 379r(a) preempts only State requirements that are different from, in addition to, or otherwise not identical with a federal requirement under the FDCA. Therefore, the Court must determine whether the NDA and monograph regulations described above amount to *requirements* applicable to Defendants' medications. The Court finds that they do.

(i) The NDA regulations establish a federal requirement with respect to the marketing and sale of Defendants drugs

This case is about drug regulation and the preemptive scope of Section 379r. And, the NDA approval process described above applies to only drugs. However, the FDA's regulation of medical devices–and the courts' interpretation of them–are relevant to the

analysis here.

The FDA established a separate premarket approval process for medical devices through the 1976 Medical Device Amendments to the FDCA, 21 U.S.C. § 360k (the " MDA"). Furthermore, the MDA contains its own express preemption provision in 21 U.S.C. § 360k(a), which is quite similar to Section 379r. The MDA' s express preemption provision provides that " no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any *requirement* (1) which is different from, or in addition to, any requirement applicable under [the FDCA] to the device, and (2) which regulates the safety or effectiveness of the device. 21 U.S.C. § 360k(a).

A number of courts, including the United States Supreme Court and the Fifth Circuit, have interpreted this MDA preemption clause. *See, e.g., Riegel v. Medtronic, Inc.*, —U.S.—, 128 S.Ct. 999, 169 L.Ed.2d 892 (2008); *Gomez v. St. Jude Medical Daig Division Inc.,* 442 F.3d 919 (5th Cir. 2006); *Martin v. Medtronic, Inc.*, 254 F.3d 573, (5th Cir. 2001); *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1420-22 (5th Cir. 1993). In doing so, those courts have concluded that the premarket approval process for Class III medical devices constitutes a federal *requirement*.[10] *Id.* The similarities between the approval process for medical devices and the approval process for drugs make the reasoning of those cases relevant here. Based on that reasoning, the NDA approval process establishes a federal requirement for drug labeling under Section 379r.

As the California Court of Appeals wrote in *Kanter*, " [t]he parallels between the

[10]The MDA has three levels of oversight for medical devices. *Riegel*, 128 S.Ct. At 1003-04. Class I includes devices like elastic bandages and examination gloves. *Id.* Class I devices are subject to the lowest level of federal oversight: "general controls." *Id.* Those in Class II, which include devices such as powered wheelchairs and surgical drapes, are additionally subject to "special controls" such as performance standards and post-market surveillance measures. *Id.* Medical Devices in Class III receive the most federal oversight. *Id.* A device is assigned to Class III if a less stringent classification would not provide a reasonable assurance of safety and effectiveness. *Id.* Class III devices must then submit to the "rigorous" premarket approval process. *Id.*

premarket approval process for medical devices and the new drug application process with respect to product labeling are striking." *Kanter,* 99 Cal.App. 4th at 793-94. For example, the MDA's premarketing approval process (" PMA") requires a manufacturer to " submit detailed information regarding the safety and efficacy of their devices;" *Gomez*, 442 F.3d at 928 (quoting *Lohr*, 518 U.S. at 477), which typically amounts to " a multivolume application." *Riegel*, 128 S.Ct. at 1004. Among other things, this application includes " full reports of all studies and investigations of the devices' s safety and effectiveness...a 'full statement' of the device' s 'components, ingredients, and properties' ...and a specimen of the proposed labeling." *Riegel*, 128 S.Ct. At 1004 (quoting 21 U.S.C. § 360e(c)(1)). Likewise, as explained in Section III(1)(a)(I) *supra*, as part of an NDA, a drug manufacturer must submit a detailed application that includes substantial evidence of the drug' s safety and efficacy (e.g., investigations and clinical studies), and a specimen of the proposed drug label. *See* Section III(1)(a)(I) *supra* (citing 21 U.S.C. § 355(b)(1)(F). Further, the PMA process includes a review of the proposed labeling for a medical device; just as the NDA process does for drugs. *Compare Riegel*, 128 S.Ct. at 1004. (citing § 360c(a)(2)(B), 360e(d)(1)(A)); *with Kanter*, 99 Cal.App. 4th at 794 (citing § 352(a), 321(n). Under both review processes, the FDA will reject the application if the labeling is false or misleading in any particular. *Id.* Then, once a medical device has received premarket approval, the MDA prohibits a manufacturer from making any change in the device labeling without prior FDA approval. *Riegel*, 128 S.Ct. At 1005 (citing § 360e(d)(6)(A)(I). Equally, FDA permission is required if a manufacturer wishes to make changes to a drug label after its NDA is approved. *Kanter*, 99 Cal.App. 4th at 785 (citing 21 C.F.R. § 314.70(b), (c), 314.71). And finally, " [t]he FDA has the power to withdraw approval of a new medical device or drug permanently or temporarily if it determines on the basis of new evidence that the device or drug is not effective as represented on its labeling." *Kanter,* at 794 (citing 21 U.S.C. §§ 360(e), 355(e)); *see also Riegel*, 128 S.Ct. At 1005.

In addition to being procedurally similar, the PMA and NDA processes are also alike in the level of scrutiny which they apply. Justice Ginsburg, while dissenting from the

majority's holding in *Riegel*, wrote that " [t]he process for approving new drugs is at least as rigorous as the premarket approval process for medical devices." *Riegel*, 128 S.Ct. at 1018 (Ginsburg, J., dissenting).

Given the equally rigorous review, and the substantial similarities in the PMA and NDA processes described above, the Court concludes that the NDA process establishes a requirement with respect to drug labeling under the FDCA. *Accord*, *Kanter*, 99 Cal.App. 4th at 794, *Warner-Lambert v. Mills*, 117 S.W.3d 488 (Tex. App. - Beaumont 2003); *Berenguer v. Warner-Lambert Co.*, 2003 WL 24299241 (Fla. Cir. Ct. July 31, 2003).

(ii) The monograph system establishes a federal requirement with respect to the marketing and sale of Defendants' drugs

While the monograph system for OTC drugs involves labeling regulation for classes of drugs rather than for one drug in particular, the Court likewise concludes that it establishes a federal requirement for drug labeling. *Accord Kanter*, at 794.

OTC drugs reviewed under the monograph system are not required to submit an NDA. *See* III(1)(A)(iii). As such, the similarities between the premarket application processes for medical devices and new drugs, described above, are not directly applicable to the Court's analysis of whether the monograph system establishes requirements. Nevertheless, there are parallels to be drawn from that discussion, given that the monograph system does involve FDA review of an OTC drug's safety and efficacy, and mandates particular labeling.

To begin with, the labeling regulations of the monograph system are not like the general requirements considered by the Supreme Court in *Lohr*, 518 U.S. 470. As in *Riegel*, the Supreme Court in *Lohr* was interpreting the MDA's preemption provision. *See generally Riegel,* 128 S.Ct. 999, *Lohr*, 518 U.S. 470. However, in *Lohr,* the Court examined the MDA's

" substantially equivalent" review procedure–an exception to the rigorous procedure for premarket approval. *Id.* at 1006-1007. Substantial equivalence review 'grandfathered' medical devices already on the market when Congress passed the MDA. *Lohr*, 518 U.S. at 477-79. Such devices were not required to go through the PMA process if the manufacturer could show that the device was " substantially equivalent" to a pre-existing device. *Lohr*, at 478; 21 U.S.C. § 360e(b)(1)(A); 21 C.F.R. § 814.1(c)(1). However, the review focused only on *equivalence*–not safety or efficacy. *Riegel*, 128 S.Ct. At 1007. The Court in *Lohr* ultimately concluded that the " substantially equivalent" procedure was not a federal requirement with respect to manufacturing and labeling of medical devices. *Id.* at 1106.

However, while the monograph review system also, in some sense, 'grandfathered' existing OTC drugs from the NDA process, it is not at all like the review process for substantial equivalence. Under the monograph system, the FDA used a panel of experts to review the efficacy of OTC drugs–specifically, pediculicides. At the end of a multi-step process, the FDA then published regulations under which pediculicides are recognized as safe, effective and not misbranded. *See* Section III(1)(A)(iii), (iv). Those regulations include content-specific labeling requirements which apply only to pediculicides. *Id.*

Noting these specific labeling requirements, the California Court of Appeals in *Kanter* compared the requirements of the monograph system to the MDA's regulations of Class II medical devices. These regulations are less stringent than the requirements of the PMA process for Class III devices discussed above (and in *Riegel*). But, they are *more* stringent than the requirements of substantial equivalence examined in *Lohr*. *Kanter*, 99 Cal.App. 4th at 794. *Kanter* cited *Papike v. Tambrands, Inc.*, 107 F.3d 737 (9th Cir. 1997), *cert denied* (full citation omitted), a case that found the Class II regulations were 'requirements' under the MDA preemption provision. The Court in *Papike* found the Class II regulations to be unlike the general requirements at issue in *Lohr*. *Ibid.* Instead, the court found that the Class II regulations " reflected the sort of concerns regarding a specific device or field of device

regulation which the regulations were designed to protect from potentially contradictory State requirements." *Kanter*, at 794 (quoting *Papike*, 107 F.3d at 740-41) (internal quotations omitted). The *Papike* court relied on the fact that Class II regulations " mandated the specific substantive content of the warning on the labeling," to conclude that such regulations constituted a *requirement* under the MDA preemption statute. *Id. Kanter* applied the same analysis, concluding that the monograph established a federal requirement under Section 379r because it " sets forth explicit and detailed federal requirements" regarding the content of the pediculicide labels. *Kanter,* at 794. The Court finds this reasoning persuasive.

It is undisputed that the approved monograph for pediculicides contains labeling standards applicable to Defendants' medications RID and PRONTO. (Pl.'s Resp. at 29, stating that " Plaintiffs do not dispute that an actual monograph contains certain labeling requirements for OTC drugs."). Defendants' medications must conform to the conditions contained in the monograph, including the labeling requirements, or be subject to FDA action. 21 C.F.R. 330.10(b). As such, the Court concludes that the monograph establishes a federal requirement with respect to drug labeling under the FDCA. *Accord*, *Kanter*, 99 Cal.App. 4th at 794, *Warner-Lambert v. Mills*, 117 S.W.3d 488 (Tex. App. - Beaumont 2003); *Berenguer v. Warner-Lambert Co.*, 2003 WL 24299241 (Fla. Cir. Ct. July 31, 2003).

Having concluded that Defendants' medications are subject to federal requirements that regulate drugs, the Court must now consider whether Plaintiffs' lawsuit would establish a conflicting State requirement.

(2) Plaintiffs' Lawsuit Would Establish a State Requirement Relating to Defendants' Medications

The Supreme Court's recent decision in *Riegel* compels this Court's determination that Plaintiffs' claims would establish a State requirement that relates to the marketing and

sale of Defendants' lice treatments. In *Riegel,* the majority concluded that the MDA provision that expressly preempts State 'requirements' preempts common-law duties. *Riegel*, 128 S.Ct. at 1008. (finding that plaintiff' s common-law claims, *including a claim for breach of implied warranty* were State requirements). The Supreme Court had previously reached similar conclusions with respect to other preemption statutes. *Id.* For example, in *Bates v. Dow Agrosciences, LLC,* 554 U.S. 431, 125 S.Ct. 1788, 161 L.Ed.2d 687 (2005), the court found that common-law actions were preempted by a provision of the Federal Insecticide, Fungicide, and Rodenticide Act that prohibited States from imposing " any requirements for labeling or packaging in addition to or different from those required under this subchapter." *Riegel,* 128 S.Ct. at 1008 (citing *Bates* at 443 (discussing 7 U.S.C. § 136v(b). Additionally, when examining a similar preemption provision in the Public Health Cigarette Smoking Act of 1969 in *Cipollone*, 505 U.S. 504, the Supreme Court held that common-law actions constituted a preempted " requirement" under State law. *Id.* (citing *Cipollone* at 504 (discussing 15 U.S.C. § 1334(b)). Given this consistent interpretation of the term " requirement" across three different statutes, the *Riegel* Court went beyond its specific construction of the MDA preemption provision to make a general statement about the meaning of State " requirements":

> " Congress is entitled to know what meaning this Court will assign to terms regularly used in its enactments. Absent other indication, reference to a State' s requirements" includes its common-law duties."

Riegel, 128 S.Ct. at 1008.

This definition of " requirements" applies to Plaintiffs' claims under both the UCC and the DTPA for breach of the implied warranty of merchantability–despite the fact that Plaintiffs' cause of action under the DTPA is a statutory claim, as opposed to a common-law claim. In *Worthy v. Collagen Corp.*, 967 S.W.2d 360 (Tex. 1998), the Texas Supreme Court considered whether a DTPA claim was preempted by the MDA' s express preemption

provision. *Worthy* at 376. The court considered whether the United States Supreme Court's statement in *Lohr* (that State common-law claims could impose State 'requirements') could also apply to the plaintiff's statutory DTPA claim. *Id.* The Texas Supreme Court concluded that with respect to the establishment of a State requirement, there was no substantive difference between State common law claims and claims for violation of a consumer statute. *Id.* As such, both Plaintiffs' UCC and DTPA claims constitute State requirements under *Riegel*.

Furthermore, apart from *Riegel*, the text of Section 379r also indicates that the term 'requirements' includes State law claims. Section 379r(e), the statute's 'saving clause,' exempts " any action...under the product liability law of any State." 21 U.S.C. § 379r(e). There would be no reason to exempt only product liability actions, unless Congress intended to encompass State law claims within the term " requirement," in Section 379r(a). As the Beaumont Court of Appeals recognized in *Mills*, 117 S.W.3d at 494, by excluding only product liability actions, Congress made clear that the term 'requirement' includes all other State law claims.

Given the text of Section 379r, and the Supreme Court's clear pronouncement in *Riegel*, the Court concludes that the claims brought by Plaintiffs in this case are State requirements that relate to the FDCA's regulation of drugs. *Accord, Gomez,* 442 F.3d 919; *Martin*, 254 F.3d 573; *Stamps*, 984 F.2d 1416.

(3) <u>The State Requirement Established by Plaintiffs' Lawsuit is Different From, in Addition to, or Otherwise Not Identical With the Requirements of the FDCA</u>

Having determined that Plaintiffs' claims would establish State requirements related to Defendants' drugs, it is fairly clear that such requirements are different from or not identical with the federal requirements for those drugs that were established by the FDA. The

FDA has approved NIX, RID and PRONTO as being effective for the treatment of lice–and has required that they be labeled as such. On the other hand, Plaintiffs' breach of warranty and DTPA claims are based solely on the ideas that Defendants' drugs are *not* effective for the treatment of lice, and that Defendants are liable for representing that they *are* effective. The two positions are diametrically opposed.

When this case made its first visit to the Beaumont Court of Appeals, the Court described the effect of this conflict in detail:

> The trial court's certification order would permit lay and expert testimony, anecdotal evidence, and documentary evidence as proof that the products were or were not properly formulated as an effective treatment for head lice infestation...[Plaintiffs] would attempt to prove that [Defendants'] products were chemically and scientifically ineffective for the cure of Texas head-lice infestations. It appears [Plaintiffs] would attempt to prove the FDA regulation–which specifies the active ingredients that must be included if the product is to be considered effective–is simply incorrect, and that [Defendants'] products should not contain the active ingredients specified by the FDA if they are to be marketed in Texas as a treatment for head-lice infestation. In practical effect, the State lawsuit would make unlawful the sale of a product formulated to comply with a federal requirement.

Mills, 117 S.W.3d at 493-94 (internal quotations omitted)

As discussed above, the FDA specifically reviewed the safety and effectiveness of NIX during the NDA process. The FDA determined that NIX was "effective" for the "treatment of head lice" (now "treats head lice"); and, required that such language appear on the NIX label. Similarly, during monograph process, the FDA tested the active ingredients in RID and PRONTO and determined that they were "safe and effective" for the "treatment of head lice." The FDA then issued a final monograph for OTC pediculicides, specifying the terms upon which they may be sold without being misbranded. If Defendants sell NIX, RID or PRONTO without the FDA-required language on the drug's label, they are subject to

regulatory action. However, if they sell the drugs *with* the FDA-required label (and Plaintiffs prevail in this suit), Defendants will be subject to liability. The two requirements are clearly different.

The defendants in *Worthy v. Collagen Corp.*, 967 S.W.2d 360 (Tex. 1998) faced a similar dilemma. In *Worthy* the Texas Supreme Court considered whether a DTPA claim would impose a labeling requirement on a medical device that was different from the requirement established by the FDA. The Court described the difference between the two requirements as follows:

> To prevail, therefore, Worthy must prove that Zyderm as approved by the FDA is not safe. This contradicts not only the FDA's specific finding to the contrary but also the manufacturing, distribution, and labeling protocols approved by the FDA. [Defendant] cannot both market Zyderm in compliance with the FDA requirements and not market Zyderm because it is unsafe.

Worthy, 967 S.W.2d at 376.

The same reasoning is applicable in this case. Defendants can market their products in compliance with the FDA requirements, or they can refrain from marketing their products in order to comply with the requirements (and avoid the liability) imposed by Plaintiffs' lawsuit. They cannot do both.

As such, it is clear that the requirements that Plaintiffs' suit would impose on Defendants' drugs are " different from or in addition to, or otherwise not identical with the requirements imposed by the FDA. *Accord Kanter*, 99 Cal.App. 4th at 794, *Mills*, 117 S.W.3d 488; *Berenguer*, 2003 WL 24299241; *Gomez,* 442 F.3d 919.

(4) Plaintiffs' Claims are not 'Saved' by Section 379r(e)

Based on the foregoing conclusions, Plaintiffs' claims will be expressly preempted by Section 379r(a)–unless they are exempted by the statute's 'saving clause.' Again, that saving clause states that the preemption provision shall not " be construed to modify or otherwise affect any action or the liability of any person under the *product liability law* of any State." 21 U.S.C. § 379r(e). (emphasis added). The Court must then determine whether Plaintiffs' causes of action arise under Texas product liability law.

Plaintiffs, however, assert that " [t]he question...is not whether [State law] considers this claim to be one of products liability, but whether Congress intended for a claim arising out of a defective product to be exempted from the preemption provision." (Pl.'s Resp. at 15). They argue that Congress intended " product liability law," as the term is used in Section 379r(e), to have a broad meaning that would encompass any action that would impose liability on the manufacturer or seller of a defective product–whether it arises in tort or contract. (Pl.'s Resp. at 15 (citing Black's Law Dictionary (8th ed. 2004) and 72A C.J.S. Products Liability, § 1). This Court respectfully disagrees. Section 379r(e) indicates that Congress did not intend to attribute any particular meaning to " product liability law." Rather, the statute's language reflects an intent to defer to each State's interpretation of " product liability," and thereby avoid interfering with the State's product liability regime. Despite Plaintiffs' attempt to frame the issue differently, the relevant question for this Court is whether Texas considers Plaintiffs' claims to be product liability actions.

Chapter 82 of the Texas Civil Practice and Remedies Code applies to " Products Liability." Tex. Civ. Prac. & Rem. Code § 82.001 *et seq.* It defines a " products liability action" as:

> " ...any action against a manufacturer or seller for recovery of damages arising out of personal injury, death, or property damage allegedly caused by a defective product whether the action is based in strict tort liability, strict

> products liability, negligence, misrepresentation, breach of express or implied warranty, or any other theory or combination of theories."

Tex. Civ. Prac. & Rem. Code § 82.001(2).

It is beyond dispute that Plaintiffs' claims in this lawsuit do not " aris[e] out of personal injury, death, or property damage." Their claims seek only recovery of the purchase price for the lice medications. As such, they are not products liability actions, as defined by Section 82.001(2).

On this basis alone, the Beaumont Court of Appeals in *Mills* concluded that Plaintiffs' claims were not " product liability actions" under Texas law–and, therefore, were not 'saved' from preemption by Section 379r(e). *Accord Kanter*, 99 Cal. App. 4th at 790. The court did not look beyond the definition set forth in Section 82.001(2).

Similarly, in *Sanchez v. Liggett & Myers, Inc.*, 187 F.3d 486 (5th Cir. 1999), the Fifth Circuit relied solely on Section 82.001(2)' s definition to determine the meaning of " products liability action" under Texas law. In that case, the court found that the plaintiffs' claims were " products liability actions" because they arose " out of personal injury, death, or property damage allegedly caused by a defective product." *Sanchez*, at 491 (quoting Tex. Civ. Prac. & Rem. Code § 82.001(2).

Nevertheless, Plaintiffs argue that the definition of " products liability action" that appears in Section 82.001(2) does not conclusively establish the meaning of " products liability" under Texas law. In support of their position, Plaintiffs cite a separate provision of the Civil Practice & Remedies Code which *does* include suits for economic loss under its definition of products liability actions. That provision, Section 16.012, is a statute of repose for products liability claims. Tex. Civ. Prac. & Rem. Code. § 16.012 (Vernon 2007). It defines " products liability action" as " any action against a manufacturer or seller for recovery of damages or other relief allegedly caused by a defective product...including a suit

for...economic loss." *Id.* § 16.012(a)(2)(D). However, this statute of repose is only applicable to claims filed on or after July 1, 2003. *Vaughn v. Fedders Corp.*, 239 Fed.Appx. 27, 29 (5th Cir. 2007). So, technically, it would not apply to Plaintiffs' claims. Still, Section 16.012(a)(2)'s definition of "products liability action" is incongruous with the definition in Section 82.001(2). Texas case law, however, erases any doubt created by the difference in these two definitions.

Decisions from Texas courts and the Fifth Circuit establish that Plaintiffs' claims under the UCC and the DTPA for breach of the implied warranty of merchantability are not products liability actions under Texas law. The cases show that Plaintiffs' claims are grounded in contract (rather than tort); and contract claims are distinguished from product liability actions.

Under Texas law, breach of implied warranty can certainly be a cause of action based on tort. *JCW Electronics, Inc. v. Garza*, 257 S.W.3d 701, 704 (Tex. 2008). In fact, the Texas Supreme Court has "often recognized that 'implied warranties are created by operation of law and are grounded more in tort than in contract.'" *Id.* at 704 (quoting *La Sara Grain Co. v. First Nat'l Bank*, 673 S.W.2d 558, 565 (Tex. 1984); and citing other authorities for the same proposition). However, whether the breach of an implied warranty is a contract or a tort depends on the circumstances. *Id.* More specifically, the Texas Supreme Court explains that the damages alleged ordinarily determine the precise nature of the claim:

> when the damages are purely economic, the claim sounds in contract, *Sw. Bell Tel. Co. V. DeLanney*, 809 S.W.2d 493, 495 (Tex. 1991); *Jim Walter Homes, Inc. v. Reed*, 711 S.W.2d 617, 618 (Tex. 1986); but a breach of implied warranty claim alleging damages for death or personal injury sounds in tort, *see Hyundai Motor Co. v. Rodriguez*, 995 S.W.2d 661, 664 (Tex. 1999); WILLIAM POWERS, JR., TEXAS PRODUCTS LIABILITY LAW § 1.02, at 1-1 (2d ed. 1994).

JCW Electronics, 257 S.W.3d at 705.

In this case, Plaintiffs have alleged purely economic damages. *See* William Powers, Jr. & Margaret Niver, *Negligence, Breach of Contract, and the "Economic Loss" Rule,* 23 Tex. Tech. L. Rev. 477, 478 (1992) ("Pure economic loss is loss that is not itself a consequence of personal injury or property damage."). They seek return of the purchase price for the lice treatments. They stipulate that they are not suing to recover for personal injuries, and are not claiming that Defendants' products damaged some other property. (Pl.'s Compl. at 11). Accordingly, based on the Texas Supreme Court's reasoning stated above, Plaintiffs' breach of warranty claim sounds in contract.

Plaintiffs' DTPA claim is based in contract law as well. As previously stated, Plaintiffs' DTPA claim is derivative of their claim for breach of warranty. Section II(A) *supra* (citing *Hininger*, 23 F.3d at 129 n.4). The DTPA "does not create any warranties." *Id.*; *Parkway Co v. Woodruff*, 901 S.W.2d 434, 438 (Tex. 1995). "Any warranty must be established independently of the [DTPA]." *Hininger*, 23 F.3d at 129 n.4 (quoting *La Sara Grain Co.*, 673 S.W.2d at 565; *Parkway*, 901 S.W.2d at 438. Instead, it simply provides additional monetary remedies for a breach of the implied warranty of merchantability. *Parkway*, 901 S.W.2d at 438. Therefore, the DTPA claim is rooted in the same ground as Plaintiffs' breach of warranty claim: contract.

Plaintiffs advance a definition of product liability that would encompass actions in both tort and contract–as long as a product defect was involved. However, it is generally acknowledged that claims based in contract law are different from product liability claims. *See East River S.S. Corp. v. Transamerica Delaval, Inc.*, 476 U.S. 858, 106 S.Ct. 2295, 90 L.Ed.2d 865 (recognizing "the need to keep products liability and contract law in separate spheres"). This distinction is reflected in Texas cases that have prevented recovery for economic losses in certain products liability cases. *See, e.g., Mid Continent Aircraft Corp. v. Curry County Spraying Service, Inc.*, 572 S.W.2d 308 (Tex. 1978) (applying the "economic loss" rule in strict product liability case); *Nobility Homes of Texas, Inc. v. Shivers*, 557 S.W.2d 77 (Tex. 1977) (same). The

Fifth Circuit has commented that " the principal policy" exhibited by Texas in those cases " is a desire to separate products liability from contracts and the law of sales."[11] *James v. Bell Helicopter*, 715 F.2d 166, 171 (5th Cir. 1983). Similarly, in several cases bringing claims under Texas law, the Fifth Circuit has distinguished between " no-injury product liability claims" and product-defect claims that seek contract law damages. *See, e.g.*, *Rivera v. Wyeth-Ayerst Laboratories*, 283 F.3d 315, 320 (5th Cir. 2002); *Coghlan v. Wellcraft Marine Corp.*, 240 F.3d 449, 455 n.4 (5th Cir. 2001); *Ryan v. Brookdale Intern. Systems, Inc.*, 230 Fed.Appx. 366 (5th Cir. 2007). The key distinction noted in these cases was that the " no-injury" product liability claim are rooted in product liability, while the others are rooted in basic contract law. *Id.* All of these cases suggest that Texas law does not define product liability to encompass contract-based claims.

Based on the definition of " product liability action" in Section 82.001(a)(2) of the Texas Civil Practice and Remedies Code and the case law cited above, the Court concludes that Plaintiffs' claims under the UCC and the DTPA for breach of the implied warranty of merchantability are not products liability actions under Texas law. Accordingly, they are not 'saved' from preemption by Section 379r(e) of the FDA Modernization Act.

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[11]Plaintiff has suggested that the term " products liability" should not be defined by Texas' s adherence to the economic loss doctrine. (Pl.' s Resp. at 15). And, to clarify the above reference to the doctrine, the Court notes that the economic loss rule, in and of itself, does *not* determine whether Plaintiffs' claims are product liability actions.

Texas' s application of the economic loss rule reflects " a desire to separate products liability from contracts and the law of sales." *James v. Bell Helicopter*, 715 F.2d 166, 171. However, the economic loss rule does not determine whether the nature of a claim lies in products liability. Rather, " the 'economic loss' rule has life in Texas jurisprudence *as an internal element of tort doctrine*."William Powers, Jr. & Margaret Niver, *Negligence, Breach of Contract, and the " Economic Loss" Rule,* 23 Tex. Tech. L. Rev. 477, 498 (1992). Further, the " economic loss" rule has never been a general rule of *tort* law; it is a rule in *negligence* and *strict product liability*." *Id.* at 492. In other words, the economic loss rule does not define whether a cause of action arises under products liability law. Instead, in certain products liability cases, the economic loss rule acts as an internal limitation that may prevent recovery.

B. Conclusion: Plaintiffs' Claims Are Expressly Preempted by Section 379r

In summary, the Court finds: (1) that the FDCA regulations relating to the content, labeling and sale of Defendants' Medications constitute Federal requirements; (2) that Plaintiffs' claims brought in this lawsuit would establish a State requirements relating to Defendants' medications; (3) that those State requirements are different from, in addition to, or otherwise not identical with the requirements of the FDCA; and (4) that Plaintiffs' claims are not 'saved' by Section 379r(e). Accordingly, Plaintiffs' claims are expressly preempted by Section 379r.

IV. CONCLUSION

For the reasons given above, the Court concludes that Plaintiffs' claims fail as a matter of law. Summary judgment is appropriate.

IT IS THEREFORE ORDERED that the *Motion for Summary Judgment and Supporting Memorandum of Defendants Warner-Lambert Company LLC, Pfizer Inc., Bayer Corporation, Del Pharmaceuticals, Inc., Del Laboratories, Inc. and Insight Pharmaceuticals Corporation* [Clerk's Docket No. 41] is in all things **GRANTED**.

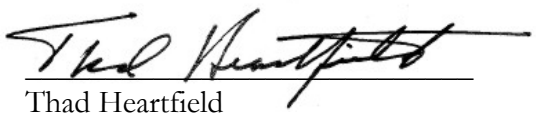
IT IS FURTHER ORDER that all pending motions in this civil action are **DENIED AS MOOT**.

IT IS FURTHER ORDERED that Plaintiff's claims are hereby **DISMISSED WITH PREJUDICE**. A final judgment on these claims will be entered separately in accordance with Fed. R. Civ. P. 58.

IT IS FURTHER ORDERED that the clerk is **DIRECTED** to close this file.

SO ORDERED.

SIGNED this the **30** day of **September, 2008.**



Thad Heartfield
United States District Judge