IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

Margarita Gaeta, as guardian ad litem for A.G., a minor child, et al.,

Plaintiffs,

v.

Perrigo Pharmaceuticals Company, et al.,

Defendants.
_____/

NO. C 05-04115 JW

ORDER GRANTING DEFENDANT PERRIGO'S MOTION FOR SUMMARY JUDGMENT

I. INTRODUCTION

Margarita Gaeta and Augustine Gaeta (collectively, "Plaintiffs"), bring this diversity action on behalf of their son, A.G., against Perrigo Pharmaceuticals Company ("Perrigo"), PAR Pharmaceutical Inc. ("PAR"), and BASF Corporation ("BASF") (collectively, "Defendants"), alleging, *inter alia*, strict products liability, breach of warranty, and negligence. Plaintiffs allege A.G. suffered liver failure as a result of his consumption of ibuprofen manufactured and distributed by Defendants.

Presently before the Court is Defendant Perrigo's Motion for Summary Judgment. (hereafter, "Motion," Docket Item No. 156.) The Court conducted a hearing on April 14, 2008. Based on the papers submitted to date and oral arguments of counsel, the Court GRANTS Defendant Perrigo's Motion for Summary Judgment.

II. BACKGROUND

A. Factual History

On June 3, 2004, A.G. had two benign moles removed in a surgical procedure. (Second Amended Complaint ¶ 21, hereafter, "SAC," Docket Item No. 29.) During the procedure, A.G.'s anaesthesiologist administered Halothane, an anesthetic known to cause liver failure in certain circumstances. NEIL KAPLOWITZ & LAURIE D. DELEVE, DRUG-INDUCED LIVER DISEASE 406-07 (Inferma Health Care 2003). After the surgery, A.G. was discharged with instruction to take 400mg of ibuprofen once every six hours as needed for pain. (Declaration of Kelly J. Savage, hereafter, "Savage Decl." Ex. B at 116:15-117:7, Docket Item No. 158.)

Plaintiffs purchased a bottle of Perrigo's generic over-the-counter ("OTC") ibuprofen at 200mg per tablet. (SAC ¶ 22.) From June 3 to June 6, 2004, A.G. took 400mg of the ibuprofen every six to eight hours.[1] On June 11, 2004, A.G. developed a fever, and he was seen by his pediatrician. A.G.'s pediatrician prescribed prescription-strength ibuprofen (400mg) to him. (Savage Decl., Ex. D 109:20-111:20.) However, A.G's condition continued to worsen: on June 13, 2004, he was referred to the emergency room with a diagnosis of septic shock, dehydration, and liver failure. (Id., Ex. A at 4.) He was later transferred to Stanford University Hospital for a liver transplant, which took place on June 15, 2004. (Id., Ex. A at 4-6.) A.G. developed other complications, and he eventually had to have necrotic tissue on his fingers and toes amputated. (Id., Ex. A at 7.)

B. The Food and Drug Administration's Role in Regulating Drugs

Under the Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, a drug manufacturer must obtain Food and Drug Administration ("FDA") approval before a new drug may be marketed and sold to the public. See 21 U.S.C. § 355. The process for approval requires

[1] (Plaintiffs' Response to Perrigo's Motion for Summary Judgment, Ex. A at 3, hereafter, "Opposition," Docket Item No. 165.) Plaintiffs have moved for leave to file a supplemental reply. (Docket Item No. 221.) However, since the proffered supplemental reply is entirely duplicative of previous briefing, this motion is DENIED.

submission of a new drug application ("NDA") to demonstrate that the drug is "safe and effective." 21 U.S.C. § 355(a)-(i). The proof of the efficacy and safety of the drug must be based on extensive laboratory testing. 21 U.S.C. § 355(b). Drug manufacturers also must submit to the FDA "specimens of the labeling proposed to be used for such drug." 21 U.S.C. § 355(b)(1). The label must contain a "warnings" section which describes "clinically significant adverse reactions (including any that are potentially fatal, are serious even if infrequent, or can be prevented or mitigated through appropriate use of the drug)." 21 C.F.R. § 201.57(c)(6)(I). When the drug is approved, the FDA includes it in its published list of approved drugs. See 21 U.S.C. § 355(j)(7). The drug is then referred to as a "listed drug." Id. § 355(j)(2)(A)(i). A listed drug may also be referred to as an "innovator" or "pioneer" drug. See, e.g., Bristol-Myers Squibb Co. v. Shalala, 91 F.3d 1493, 1494, 1497-98 (D.C. Cir. 1996).

Before 1984, generic drug manufacturers were required to submit their own NDA. See Tri-Bio Labs., Inc. v. United States, 836 F.2d 135, 138-39 (3d Cir. 1987). With the Drug Price Competition and Patent Term Restoration Act of 1984, Congress relaxed the procedure for obtaining approval from the FDA to market and sell a generic drug, allowing the generic maker to submit an abbreviated NDA ("ANDA"). Id.; see 21 U.S.C. § 355(j), 35 U.S.C. §§ 156, 271, 281. The ANDA must certify that the generic manufacturer will produce a bio-equivalent of the listed drug and that the labeling and warnings of the generic drug are the same as those of the listed drug. 21 U.S.C. § 355(j)(2)(A).

C. Procedural History

On October 12, 2005, Plaintiff Margarita Gaeta filed a Complaint, as guardian ad litem for her son, A.G., against Perrigo and Longs Drug Stores Corporation. (Complaint, Docket Item No. 1.) The Complaint has been amended twice, adding Augustine Gaeta as a Plaintiff and PAR and BASF as Defendants. (See Docket Item Nos. 6, 29.) On February 28, 2006, Plaintiffs filed a Second Amended Complaint, which remains the operative complaint. In the Second Amended Complaint,

Plaintiffs allege that Defendants are liable for injuries A.G. sustained as a result of ingesting ibuprofen manufactured and distributed by Defendants. (Id.)

Plaintiffs allege the following causes of action against Defendants: (1) Defective Design; (2) Marketing Defect; (3) Breach of Express Warranty; (4) Breach of Implied Warranty; (5) Negligence and Gross Negligence; and (6) Deceit by Concealment pursuant to Cal. Civ. Code §§ 1709-1710. (SAC ¶¶ 33-53.)

Presently before the Court is Perrigo's motion for summary judgment.

III. STANDARDS

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 judgment as a matter of law." Fed. R. Civ. P. 56(c). The purpose of summary judgment "is to isolate and dispose of factually unsupported claims or defenses." Celotex v. Catrett, 477 U.S. 317, 323-24 (1986).

The moving party "always bears the initial responsibility of informing the district court of the basis for its motion, and identifying the evidence which it believes demonstrates the absence of a genuine issue of material fact." Id. at 323. The non-moving party must then identify specific facts "that might affect the outcome of the suit under the governing law," thus establishing that there is a genuine issue for trial. Fed. R. Civ. P. 56(e).

When evaluating a motion for summary judgment, the court views the evidence through the prism of the evidentiary standard of proof that would pertain at trial. Anderson v. Liberty Lobby Inc., 477 U.S. 242, 255 (1986). The court draws all reasonable inferences in favor of the non-moving party, including questions of credibility and of the weight that particular evidence is accorded. See, e.g., Masson v. New Yorker Magazine, Inc., 501 U.S. 496, 520 (1992). The court determines whether the non-moving party's "specific facts," coupled with disputed background or contextual facts, are such that a reasonable jury might return a verdict for the non-moving party. T.W. Elec. Serv. v. Pac. Elec. Contractors, 809 F.2d 626, 631 (9th Cir. 1987). In such a case,

summary judgment is inappropriate. Anderson, 477 U.S. at 248. However, where a rational trier of fact could not find for the non-moving party based on the record as a whole, there is no "genuine issue for trial." Matsushita Elec. Indus. Co. v. Zenith Radio, 475 U.S. 574, 587 (1986).

IV. DISCUSSION

Perrigo moves for summary judgment on the ground that all of Plaintiffs' claims are preempted by the FDCA. (Motion at 7.)

The Supremacy Clause of United States Constitution provides that federal laws and treaties "shall be the supreme law of the land." U.S. Const. Art. VI, Cl. 2. The United States Supreme Court has recognized three types of federal preemption of state law under the Supremacy Clause: (1) express preemption, where Congress states explicitly the preemptive effect of its legislation on state law; (2) field preemption, where Congress intends for federal law to occupy exclusively an entire field of regulation; and (3) conflicts preemption, where it is impossible for a private party to comply with both state and federal requirements. English v. General Electric Co., 496 U.S. 72, 78-79 (1990).

The Food and Drug Modernization Act of 1997 ("Modernization Act") amended the FDCA to provide for express preemption of state laws regarding non-prescription, "OTC" drugs. 21 U.S.C. § 379r(a). However, § 379 has a savings clause, which provides that preemption provision does not affect "the liability of any person under the product liability law of any State." § 379r(e). The scope of the term "product liability law" as used in the statute is not exactly clear. The California Court of Appeal has found that the § 379r savings clause does not cover all "common law and statutory actions imposing liability on commercial sellers of products." Kanter v. Warner-Lambert Co., 99 Cal. App. 4th 780, 790-91 (2002). Regardless, the savings clause "does not bar the ordinary working of conflict pre-emption principles." Geier v. Am. Honda Motor Co., Inc., 529 U.S. 861, 869 (2000). Under such principles, a court should "decline to give broad effect to savings clauses where doing so would upset the careful regulatory scheme established by federal law." United

States v. Locke, 529 U.S. 89, 106-07 (2000). Thus, the Court proceeds to consider whether conflicts between common law and federal law upset the regulatory scheme of the FDA.

Consideration of conflicts preemption under the Supremacy Clause "starts with the basic assumption that Congress did not intend to displace state law." Building and Const. Trades Council of Metro. Dist. v. Assoc. Builders and Contractors of Mass./RI, Inc., 507 U.S. 218, 224 (1993). In order for a court to find conflicts preemptions, there must be "clear evidence of a conflict." Geier, 529 U.S. at 885. Conflicts preemption can occur with respect to the regulations of a federal agency because regulations promulgated pursuant to federal statutory authority "have no less pre-emptive effect than federal statutes." Fidelity Federal Savings and Loan Ass'n v. de la Cuesta, 458 U.S. 141, 153 (1982). The preemption of such regulations may be challenged only to determine whether they exceed statutory authority or were made arbitrarily. Id.

In approving an ANDA for a generic drug, the FDA requires the drug's manufacturer "to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug referred to in the [ANDA]." 21 C.F.R. § 314.127; 21 U.S.C. § 355(j)(2)(A)(v). "Labeling" is defined by statute as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C § 321(m). Thus, labeling "embraces advertising or descriptive matter that goes with the package in which the articles are transported," in addition to any label that may be placed directly on a pill bottle. Kordel v. United States, 335 U.S. 345, 350 (1948). The FDA will allow certain changes to the label in an approved petition under § 314.93, which provides:

> A person who wants to submit an abbreviated new drug application for a drug product which is not identical to a listed drug in route of administration, dosage form, and strength, or in which one active ingredient is substituted for one of the active ingredients in a listed combination drug, must first obtain permission from FDA to submit such an abbreviated application.

21 C.F.R. § 314.93.

The FDA may withdraw approval for an ANDA if the agency finds that "the labeling for the drug product . . . is no longer consistent with that for the listed drug" or that the label "is false or

misleading in any particular." 21 C.F.R. § 314.150(b)(3), (b)(10). For a non-generic drug, a Changes Being Effected ("CBE") supplement to a label "is appropriate to amend the labeling for an approved product . . . to add or strengthen a contraindication, warning, precaution, or adverse reaction only if there is sufficient evidence of a causal association with the drug." 73 Fed. Reg. 2848, 2849 n.1 (background to proposed rule). However, "CBE changes are not available for generic drugs approved under an [ANDA] . . . . To the contrary, a generic drug manufacturer is required to conform to the approved labeling for the listed drug." Id.; see 21 CFR 314.150(b)(10); 57 Fed. Reg. 17950, 17953, and 17961. Under these regulations, a generic drug manufacturer cannot change its label to add a warning or contraindication without FDA approval.[2]

In 2006, the FDA amended its regulations and set forth its position that "under existing preemption principles, FDA approval of labeling under the act . . . preempts conflicting or contrary State law." 71 Fed. Reg. 3922, 3934. The FDA's reasons for this position are as follows:

> State law actions can rely on and propagate interpretations of the act and FDA regulations that conflict with the agency's own interpretations and frustrate the agency's implementation of its statutory mandate. For example, courts have rejected preemption in State law failure-to-warn cases on the ground that a manufacturer has latitude under FDA regulations to revise labeling by adding or strengthening warning statements without first obtaining permission from FDA. In fact, the determination whether labeling revisions are necessary is, in the end, squarely and solely FDA's under the act.
> . . .
>
> According to many courts, State law serves as an appropriate source of supplementary safety regulation for drugs by encouraging or requiring manufacturers to disseminate risk information beyond that required by FDA under the act. In fact, FDA interprets the act to establish both a "floor" and a "ceiling," such that additional disclosures of risk information can expose a manufacturer to liability under the act if the additional statement is unsubstantiated or otherwise false or misleading. Given the comprehensiveness of FDA regulation of drug safety, effectiveness, and labeling under the act, additional requirements for the disclosure of risk information are not necessarily more protective of patients. Instead, they can erode and disrupt the careful and truthful representation of benefits and risks that prescribers need to make appropriate judgments about drug use. Exaggeration of risk could discourage appropriate use of a beneficial drug.
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[2] Id. The manufacturer of the generic drug may only unilaterally change its label to reflect "differences in expiration date . . . or omission of an indication or other aspect of labeling protected by patent." 21 C.F.R. § 314.127(a)(8).

> FDA has previously found that labeling that includes theoretical hazards not well-grounded in scientific evidence can cause meaningful risk information to "lose its significance." Overwarning, just like underwarning, can similarly have a negative effect on patient safety and public health. Similarly, State-law attempts to impose additional warnings can lead to labeling that does not accurately portray a product's risks, thereby potentially discouraging safe and effective use of approved products or encouraging inappropriate use and undermining the objectives of the act.

Id. at 3934-35 (citations ommitted).

In the absence of clear authority to the contrary, a court is to give deference to an agency's interpretation of the scope of its authority to regulate. Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 843-44 (1984); see Medtronic, Inc. v. Lohr, 518 U.S. 470, 505-06 (1996) (Breyer, J., concurring) (considering preemptive effect of FDA regulations, in light of the FDA's position that certain claims were not preempted). Under this principle, "state tort law which would hold a generic drug manufacturer liable for failing to modify a label . . . conflict[s] with the FDCA," and any such claims are preempted by FDA regulations to the extent they seek to do so. Colacicco v. Apotex, Inc., 432 F. Supp. 2d 514, 537-38 (E.D. Pa. 2006) aff'd, Colacicco v. Apotex Inc., 2008 WL 927848 (3d Cir. 2008); cf. Papike v. Tambrands Inc., 107 F.3d 737, 742 (9th Cir. 1997).

In this case, Plaintiffs allege causes of action for: (1) Defective Design; (2) Marketing Defect; (3) Breach of Express Warranty; (4) Breach of Implied Warranty; (5) Negligence and Gross Negligence; and (6) Deceit by Concealment. (SAC ¶¶ 33-53.) With respect to each of these causes of action, Plaintiffs allege, at least in part, that Defendants failed to warn individuals with appropriate materials. (Id.) Specifically, in pleading their Defective Design cause of action, Plaintiffs allege that Perrigo "failed to adequately and completely inform or warn of the risks of liver injury and renal failure associated with the use of OTC ibuprofen to treat children for pain or fever." (Id. ¶ 35.) In their Marketing Defect cause of action, Plaintiffs allege that "[t]he warnings and instructions that accompanied the defendants' drugs provided inadequate warning to the consumer and/or healthcare provider about the risk of acute liver failure." (Id. ¶ 40.) Similar allegations are made in Plaintiffs' Breach of Warranty, Negligence, and Deceit causes of action. (Id. ¶¶ 42-53.)

Perrigo's OTC ibuprofen was approved by the FDA under the ANDA process in 1987, which indicates that the FDA found it safe and effective. (Declaration of Robert Pinco in Support of Motion for Summary Judgment ¶ 7, hereafter, "Pinco Decl.," Docket Item No. 159.) In 2002, the FDA engaged in a comprehensive review regarding the safety of ibuprofen. (Id. ¶ 8.) The FDA concluded that warning for risk of liver injury was not scientifically supported by the available data. 67 Fed. Reg. 54139, 54145-56. The FDA also considered warning for risk of kidney injury and found that "the consumer labeling for OTC ibuprofen should have a warning directed [to] those at risk for the development of acute renal failure associated with the use of the product." Id. at 54144-45. However, the FDA has not yet approved inclusion of the warning. 71 Fed. Reg. 77314, 77316.

At the time it was administered to A.G., Perrigo's ibuprofen followed the labeling for the listed drug, which contained the warnings mandated by the FDA. (Pinco Decl. ¶¶ 7, 8.) Thus, the Court finds that Perrigo has complied with the labeling requirements that the FDA has set for OTC ibuprofen. Plaintiffs' causes of action seek to hold Perrigo liable for, in part, failing to warn of risks on the labeling for its drug. Since including these warning would put the Perrigo's ANDA in jeopardy for failing to conform with the FDA's approved labeling for the listed drug, Plaintiffs' state law causes of action conflict with Perrigo's obligations under federal law.

Accordingly, the Court GRANTS in part Perrigo's Motion for Summary Judgment. The Court finds that Plaintiffs' causes of action are preempted to the extent that they allow for liability based on a lack of adequate warning on the company's OTC generic drug labeling for its 200mg ibuprofen product.

V. CONCLUSION

The Court GRANTS Perrigo's Motion for Summary Judgment. Perrigo's Motion to Strike the Testimony of Randall Tackett,[3] an expert designated to testify about warning labels, is DENIED as moot.

[3] (Docket Item No. 188.) Plaintiffs have also moved for an extension of time to respond to Perrigo's motion to strike. (Docket Item No. 225.)

The Court defers entering judgment in favor of Perrigo. The Court sets a Further Case Management Conference for **June 30, 2008 at 10 a.m.** The parties shall meet and confer and file a Joint Case Management Statement on or before **June 20, 2008.** The Statement shall address what claims, if any, remain at issue in this case. Specifically, whether any of Plaintiffs' claims are based on another non-preempted theory of recovery, such as, design defect for failure to conform to the specification of the FDA approved form of the drug.

This Order terminates Docket Item Nos. 156, 188, 221, and 225.

Dated: June 13, 2008

JAMES WARE
United States District Judge

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Dated: June 13, 2008

Richard W. Wieking, Clerk

By: /s/ JW Chambers
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