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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

MARGARITA GAETA, as Guardian ad litem for A.G. a minor, et al.,

Plaintiffs,

vs.

PERRIGO PHARMACEUTICALS COMPANY, et al.,

Defendants.

Case No.: C 05-04115 JW

PLAINTIFF'S NOTICE OF MOTION AND MOTION FOR RECONSIDERATION IN LIGHT OF WYETH V. LEVINE; MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT THEREOF

[Fed. R. Civ P. Rule 60(b)]

Hearing Date: November 4, 2009
Time: 9:00 a.m.
Ctrm: 8

TO ALL PARTIES AND THEIR RESPECTIVE ATTORNEYS OF RECORD:

NOTICE IS HEREBY GIVEN THAT on November 4, 2009 at 9:00 a.m., or as soon thereafter as the matter may be heard, in Courtroom 8 of the above-entitled Court, Plaintiffs Margarita Gaeta as guardian ad litem for A.G., a minor, et al., will move this Court to reconsider its Order granting summary judgment to Defendant Perrigo Pharmaceuticals Company based on the United States Supreme Court's decision in *Wyeth v. Levine,* 129 S. Ct. 1187 (2009) which was decided after this Court's Order. Plaintiffs also base this Motion on other federal and California case law that were decided after this Court's Order.

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This Motion for Reconsideration is based on the following grounds:

1. Plaintiffs' state-law failure-to-warn claims are not preempted by federal law.

2. A generic drug manufacturer has an independent obligation under "Changes Being Effected" (CBE) federal regulations to revise its label and add or strengthen its warnings whenever it becomes aware of an association of a serious hazard with its drug, without prior FDA approval.

This Motion will be based on grounds set forth in this Notice, the grounds set forth in the attached Memorandum of Points and Authorities; all papers, pleadings and records in this action, all matters of which this Court is requested to take judicial notice, and on such argument and evidence as may be presented at the hearing on the Motion.

DATED: August 25, 2009 **LAW OFFICES OF BRIAN D. WITZER, INC.**

By: /s/ Rowena J. Dizon

Brian D. Witzer, Esq.
Rowena J. Dizon, Esq.
Attorneys for Plaintiffs

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MEMORANDUM OF POINTS AND AUTHORITIES

I

INTRODUCTION

Plaintiff A.G. Gaeta was an eleven-year-old minor who sustained acute liver failure resulting from the ingestion of generic ibuprofen prescribed by his physicians after he was administered Halothane during surgery to remove two benign moles. In addition to suffering other painful and horrific injuries, A.G. required an emergency liver transplant to survive. Plaintiffs allege that Defendant Perrigo Phamaceuticals ("Defendant" or "Perrigo") manufactured the generic ibuprofen and that it failed to warn of the increased risk of acute liver injury when ibuprofen is ingested in combination with other hepatotoxic drugs, such as Halothane.

This Court granted summary judgment to Defendant because it found that all of Plaintiffs' causes of action alleged lack of adequate warning and are preempted by federal law.

This Court entered the Amended Judgment on its Order granting the Motion on December 15, 2008. In its Order, the Court explained that it found conflict preemption between applicable federal regulations and the plaintiffs' state-law failure-to-warn claims. The Court gave *Chevron* deference to the 2006 FDA Preamble and thus found FDA intent to preempt state-law failure-to-warn claims. This Court also cited *Colacicco v. Apotex, Inc.*, *infra*, to support its conclusion that claims against generic drug manufacturers for failure to modify a label is preempted by federal regulations. (Order, page 8 lines 10-14.)

This Court also found that the Changes Being Effected regulation is not available to generic drug manufacturers such that a generic drug manufacturer cannot change its label to add a warning without prior FDA approval. This Court also held that Plaintiffs' state law claims conflicted with Perrigo's obligations under federal law because including the warnings sought by Plaintiffs "would put the Perrigo's [sic] ANDA in jeopardy for failing to conform with the FDA's approved labeling for the listed drug" and thus conflicted with Perrigo's obligations under federal law. (Order, page 9 line 14-16.)

Finally, this Court also held that while some information relating to risk of liver injury had been provided to FDA, it "has not yet" approved inclusion of the warning. (Order, page 9, line 9.) This Court should note that Perrigo presented no competent evidence that FDA "considered and rejected" a warning of liver toxicity concomitant with use of other hepatotoxic drugs, as required by *Wyeth v. Levine*, *infra*.

II

THE COURT SHOULD RECONSIDER AND DENY SUMMARY JUDGMENT TO PERRIGO IN LIGHT OF *WYETH V. LEVINE*

Reconsideration is proper where there has been an intervening change in controlling law since the date this Court granted summary judgment. *See School Dist. No. 1J, Multnomah County, Or. v. AcandS, Inc.*, 5 F.3d 1255, 1263 (9th Cir. 1993). Here, Plaintiff presents case law that were decided after this Court's Order granting summary judgment to Defendant Perrigo.

A. No Congressional Intent to Preempt

Since the time this Court granted summary judgment in favor of Defendant Perrigo Pharmaceuticals, the United States Supreme Court issued its opinion in *Wyeth v. Levine,* 129 S.Ct. 1187 (2009), which held that drug manufacturers have an independent obligation to add or strengthen the warnings on its drug labels and that federal law does not preempt state-law failure-to-warn claims.

In *Levine*, the Court began its analysis of the preemption issue by emphasizing the importance of congressional intent and the strong presumption against preemption of state law. *Id.* at 1194-95. The Court then reviewed the history of federal regulation of pharmaceuticals, emphasizing the ways in which federal law "supplemented" and "preserve[d]" the consumer protections that already existed under state law. *Id.* at 1195-96. The Court also deemed it significant that Congress had declined to adopt an express presumption provision for prescription drugs at the time it enacted one for medical devices. *Id.* at 1196.

The Court ruled first, that it would not have been impossible for the drug

manufacturer to strengthen its label warnings. The Court stressed that it is " a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times. It is charged both with crafting an adequate label and with ensuring its warnings remain adequate as long as the drug is on the market." *Id.* at 1197-98. '[A]bsent clear evidence that the FDA would not have approved a change to [the drug's] label, we will not conclude that it was impossible for [the manufacturer] to comply with both federal and state requirements." *Id.* at 1198.

The Supreme Court next turned to Wyeth's argument that state tort liability posed an obstacle to congressional objectives. The Court rejected the argument, finding that it "relies on an untenable interpretation of congressional intent." *Id.* at 1199. The Court took note of the absence of a federal remedy for persons injured by unsafe drugs and the of the 70-year coexistence of state tort remedies and federal regulation of prescription drugs.:

> "If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70-year history. But despite its 1976 enactment of an express pre-emption provision for medical devices, Congress has not enacted such a provision for prescription drugs. Its silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness. As Justice O'Connor explained in her opinion for a unanimous Court: 'The case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts and to tolerate whatever tension there [is]

between them."

Id. at 1200 (quoting *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.* 489 U.S. 141, 166-167 (1989)) (other citations omitted). The Court concluded: "In short, Wyeth has not persuaded us that failure-to-warn claims like Levine's obstruct the federal regulation of drug labeling." *Id.* at 1204.

In finding no intent to preempt based on the legislative history of the FDCA, the Supreme Court gave no deference whatsoever to the FDA's 2006 Preamble to 71 Fed. Reg. 3922 governing the content and format of prescription drug labels. The Court found that the Preamble "is at odds with what evidence have of Congress' purposes, and it reverses the FDA's own longstanding position without providing a reasoned explanation, including any discussion of how state law has interfered with the FDA's regulation of drug labeling during decades of coexistence." *Id.* at 1201. The Court found that "Congress has not authorized the FDA to pre-empt state law directly." *Id.*

> "While agencies have no special authority to pronounce on pre-emption absent delegation by Congress, they do have a unique understanding of the statutes they administer and an attendant ability to make informed determinations about how state requirements may pose an 'obstacle to the accomplishment and execution of the full purposes and objectives of Congress.' (Citations omitted.) The weight we accord the agency's explanation of state law's impact on the federal scheme depends on its thoroughness, consistency, and persuasiveness. (Citations omitted.)
>
> Under this standard, the FDA's 2006 preamble does not merit deference."

Id. at 1201 *citing Skidmore v. Swift & Co.* 323 U.S. 134,140 (1944).

The Supreme Court's holding that the 2006 Preamble is entitled to "no weight," *id.* at 1204, is controlling in this action. Thus, where this Court had previously given

"considerable weight" to the FDA's 2006 Preamble, pursuant to *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.* 467 U.S. 837, 843-44 (1984), this Court now must follow *Levine*, and find that there is no preemption of Plaintiff's state action against Perrigo.

This Court should note that the FDA has now withdrawn the position it had previously taken in these preemption arguments. After the Supreme Court vacated the judgment in *Colacicco v. Apotex, Inc.,* 129 S.Ct. 1578 (Mar. 9, 2009), and remanded it for further consideration consistent with *Levine*, the FDA withdrew the *amicus* briefs it had previously filed in the *Colacicco* litigation, stating that "the United States does not take a position on whether plaintiffs-appellants' claims ... are preempted." Letter from Sharon Swingle, U.S. Dept. of Justice to Clerk, U.S. Court of Appeals for the Third Circuit (Apr. 28, 2009). **See Exhibit A to Request for Judicial Notice.**

Furthermore, the President of the United States, Barack Obama, issued a Memorandum for the Heads of Executive Departments and Agencies on May 20, 2009 instructing that "Heads of departments and agencies should not include in regulatory preambles that the department or agency intends to preempt State law through the regulation except where preemption provisions are also included in the codified regulation." 74 Fed. Reg. 24693-24694. **See Exhibit B to Request for Judicial Notice.**

Plaintiffs' state-law claims are not preempted by federal law. The Court should reconsider its previous order and deny summary judgment to Perrigo.

III

THE SUPREME COURT INTENDS *LEVINE* OPINION TO APPLY TO CLAIMS AGAINST GENERIC MANUFACTURERS

A. Broad and Sweeping Language of Opinion

This Court should note that nowhere in the *Levine* opinion did the Supreme Court limit its application to "brand-name" drugs or to manufacturers of such drugs. "Had the Supreme Court issued the sort of opinion that merely narrowly parsed the terms and applicability of the CBE provision to brand name manufacturers, [the generic

manufacturers'] point would carry more weight. That is not what the Supreme Court did, however." *Kellogg v. Wyeth* 612 F. Supp. 2d 437 (D.Vt. Apr. 10, 2009). "Given the sweeping language and overall conclusions of the Supreme Court in *Levine*, this court concludes that [claims against generic manufacturers] should not be preempted as a matter of law." *Stacel v. Teva Pharmaceuticals, USA*, 620 F. Supp. 2d 899,(N.D. Ill. Mar. 16, 2009).

B. U.S. Supreme Court Vacated the Judgment in Colaccico v. Apotex, Inc.

On March 9, 2009, the U.S. Supreme Court granted certiorari, vacated and remanded the case of *Colacicco v. Apotex, Inc.* to the U.S. Court of Appeal for the Third Circuit, for reconsideration in light of *Levine*. *See Colacicco v. Apotex Inc.*, 129 S. Ct. 1578 (2009). The Third Circuit had previously affirmed dismissal of claims against both brand-name and generic drug companies on preemption grounds.

In turn, the Third Circuit vacated its judgment in *Colacicco v. Apotex Inc.* 521 F. 2d 253 (3d Cir. 2008), and remanded the case to the district court for further proceedings consistent with Levine. *See Colacicco v. Apotex Inc.*, No. 06-3107, Orders dated Apr. 15, 2009 and April 28, 2009 (vacating judgment and remanding to district court). **See Exhibits C and D to Request for Judicial Notice.**

This Court relied on the Third Circuit's opinion in *Colacicco* when it granted Perrigo summary judgment, and stated that holding "'a generic drug manufacturer liable for failing to modify a label conflicts with the FDCA,' and any such claims are preempted by FDA regulations to the extent they seek to do so." (Order, page 8, lines 10-14.) The *Levine* court used broad and sweeping language to apply its ruling to "drug manufacturers" and not just "brand-name manufacturers." By vacating *Colacicco* and remanding it for further decision consistent with its opinion in *Levine*, the Supreme Court has indicated that its ruling must also be applied to failure-to-warn claims against generic manufacturers.

Federal courts have applied *Levine* to reject preemption defenses made in similar cases by generic drug manufacturers. To date, at least three federal courts have issued

rulings against preemption claims by generic drug companies on the basis of *Levine*. *See Kellogg v. Wyeth* 612 F. Supp. 2d 437, (D. Vt. Apr. 10, 2009) (denying motion to certify ruling denying preemption for immediate appeal); *Stacel v. Teva Pharmaceuticals., U.S.A.*, 620 F. Supp. 2d 899 (N.D. Ill. Mar. 16, 2009) (denying motion to dismiss on preemption grounds); *Schrock v. Wyeth, Inc.* 601 F. Supp. 2d 1262 (W.D. Okla. Mar. 11, 2009) (same).

Stacel involves a state-law action for products liability against a generic drug manufacturer after the plaintiff sustained drug-induced lupus. The defendant generic drug manufacturer moved to dismiss on the ground that the claim is preempted. The district court denied the motion based on a complete application of *Levine*.

Citing the *Levine* Court's finding that Congress was aware of state tort litigation yet decided not to foreclose them in any of the amendments to the FDCA, the *Stacel* court said:

> "There is no reason to conclude that Congress felt differently about generic drugs. Although it is clear that the Hatch-Waxman Amendment was devised to allow generic drug manufacturers to get their drugs to market both cheaply and quickly, this purpose was to be achieved by permitting manufacturers to forego duplicative clinical trials. It was *not* to be achieved by permitting manufacturers to engage in negligent activities. (Citations omitted.) Although Congress intended for ANDA applicants to submit identical labeling to the FDA when seeking ANDA approval - *see* 21 U.S.C. § 355(j)(2)(A) (v) - the statute is silent as to the manufacturer's obligation after the ANDA is granted. But 21 C.F.R. § 314.97 is not silent - it states that generic drug manufacturers are obligated to comply with the same CBE provisions as brand-listed manufacturers are.

> Nor, from this history and the Court's analysis in *Levine*, can the court agree that permitting state law tort actions would necessarily frustrate the purpose of Congress in passing the Hatch-Waxman Amendment. The underlying purpose of the FDCA is not making sure that drugs can be quickly and cheaply brought to market, but rather to assure that the drugs are safe when they are brought to market."

Stacel at 907 *citing Levine,* 129 S.Ct. at 1195-98 (italics in original). *See also Schrock v. Wyeth, Inc.* 601 F. Supp. 2d at 1264-1265 (determining, on the basis of *Levine*, that it was not impossible for generic drug companies to comply with both state and federal requirements and that plaintiff's state-law action did not "obstruct the purposes and objectives of Congress").

In the post-*Levine* opinion of *Kellogg v. Wyeth* 612 F.Supp. 2d 437 (D. Vt. Apr. 10, 2009), the Vermont district court was confronted with a motion to certify its ruling denying preemption for interlocutory review. The court denied the motion because *Levine* "reduces substantially the grounds for difference of opinion concerning whether federal law preempts state law failure-to-warn cases against drug manufacturers." *Id.* at 439. While the court acknowledged that *Levine* involved a brand-name drug, it continued to reject the generic manufacturers' preemption arguments based on the 1984 Hatch-Waxman Amendment to the FDCA. "[A]lthough the *Levine* decision did not definitively dispose of the issues in this case, its statement that '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 does not appear to permit the caveat, "except for generic drug manufacturers." *Id.* at 441 *citing Levine*, 129 S. Ct. at 1202. Mirroring the *Levine* analysis of legislative history and intent, the court held:

> "To be sure, one primary purpose of the Hatch-Waxman Amendments was to facilitate the availability of lower cost generic drugs. But the Hatch-Waxman Amendments to the

> FDCA were enacted in 1984, against the backdrop of decades of federal drug labeling regulation coexisting with state tort litigation. Only eight years earlier, Congress enacted an express preemption provision for medical devices. (Citation omitted.) ... Given that Congress could and did insert an express preemption provision when it amended the FDCA in 1976 to provide for the safety and effectiveness of medical devices, it is telling that Congress did not make any express provision when it amended the FDCA in 1984 to authorize abbreviated new drug applications. Evidently, in the Congressional view, *creating a streamlined process for generic drugs to reach the market did not preclude the manufacturers' duty to ensure the safety and effectiveness of their products*."

Kellogg at 440-441 [italics added].

There is no suggestion anywhere in the legislative history of the Hatch-Waxman Amendments that Congress was unconcerned with the safety of generic drugs or the adequacy of the warnings they carried. Indeed, in balancing the interests of generic drug manufacturers and pioneer drug companies, Congress remained "mindful of the public need for safe commercial drugs." *Tri-Bio Laboratories, Inc. v. United States*, 836 F.2d 135 (3d Cir. 1987).

IV

A GENERIC DRUG MANUFACTURER IS REQUIRED BY FDA REGULATIONS TO UNILATERALLY ADD OR STRENGTHEN ITS WARNINGS WITHOUT PRIOR FDA APPROVAL

A. "Changes Being Effected" (CBE) Regulation

Previously this Court granted granted Perrigo's summary judgment motion because it found that the Changes Being Effected ("CBE") regulation is not available to generic

drug manufacturers purportedly because it cannot change its label to add a warning without prior FDA approval. In *Levine,* the Supreme Court rejected this argument. It held that the CBE regulations authorized a manufacturer to make unilateral labeling changes that add or strengthen a warning to improve its drug's safety ahead of FDA approval. *See Levine* at 1197-1199.

As the FDA has recognized, "drug labeling does not always contain the most current information and opinion available to physicians about a drug because advances in medical knowledge and practice inevitably precede formal submission of proposed new labeling by the manufacturer and approval by the FDA." 44 Fed. Reg. 37434, 37435 (Jun. 26, 1979). Therefore, FDA regulations place the onus on drug manufacturers – both brand-name and generic – to strengthen label warnings as soon as possible: "the labeling *shall be revised* to include a warning *as soon as there is reasonable evidence of an association of a serious hazard with a drug*; a causal relationship need not have been proved." 21 C.F.R. § 201.57 (e) (2005) (emphasis added). There can be no question that this obligation to strengthen warning labels applies to manufacturers of generic drugs. In the 1992 rulemaking notice promulgating final rules to implement the Hatch-Waxman Amendments, the FDA explicitly stated: "An ANDA applicant who believes the labeling for a proposed drug product should differ from that approved for the reference listed drug should contact the FDA to discuss whether labeling for both generic and listed drugs should be revised." 57 Fed. Reg. 17950, 17957 cmt. 20 (Apr. 28 1992) . This obligation to strengthen warnings continues after an ANDA is approved. *See* 57 Fed. Reg. at 17961 cmt. 40; *see also Kellogg v. Wyeth,* 612 F. Supp. 421 (D. Vt. Dec. 17, 2008).

B. Kellogg v. Wyeth (Pre-Levine)

In *Kellogg v. Wyeth*, 612 F. Supp. 2d 421 (D.Vt. Dec. 17, 2008), the Hon. William K. Sessions III denied various motions to dismiss and for summary judgment filed by the defendants, brand-name and generic manufacturers of the drug Reglan (metoclopramide). The manufacturers argued that plaintiff's state-law failure-to-warn claims were preempted. *Kellogg* was decided on December 17, 2008, presaging the Supreme Court's

reasoning in *Levine*.

The *Kellogg* court found that a generic manufacturer is required by the express and unambiguous language of the federal regulations to "revise its label whenever it becomes aware of an association of a serious hazard with the drug." *Id.* at p. 436. The court rejected the generic manufacturers' argument that the CBE regulation does not apply to them: "There is no ambiguity in the regulations at issue. [21 C.F.R.] Section 314.97 plainly instructs ANDA holders to comply with § 314.70 'regarding the submission of supplemental applications and other changes to an approved abbreviated application.' ... Title 21 C.F.R. § 201.80(e) requires that an ANDA holder revise its label whenever it becomes aware of an association of a serious hazard with the drug." *Id.* at 436.

> "To defer to FDA's interpretation 'would be to permit the agency, under the guise of interpreting a regulation, to create *de facto* a new regulation,' (citation omitted), that would essentially eliminate any incentive for a generic drug manufacturer to ensure that its product continues to be safe and effective once it obtains its ANDA approval. Accordingly the Court does not defer to the FDA interpretation as argued by the defendants, as it is inconsistent with the unambiguous language of the regulations." *Id.* at 436.

In response to the generic manufacturers' claim that its labeling must be the "same as" the listed drug, the *Kellogg* court stated that this did not mean that the generic manufacturer could never seek to revise its label. The court cited 57 Fed. Reg. 17950, 17961, Final Rule, Abbreviated New Drug Application Regulations:

> "If an ANDA applicant believes new safety information should be added to a product's labeling, it should contact FDA, and FDA will determine whether the labeling for the generic and listed drugs should be revised. After approval of

> an ANDA, if an ANDA holder believes that new safety information should be added, it should provide adequate supporting information to FDA, and FDA will determine whether the labeling for the generic and listed drugs should be revised." *Id.* at 435.

In the post-*Levine* decision, the *Kellogg* court found that its earlier opinion regarding the generic drug manufacturer's independent obligation was confirmed by *Levine*.

> "Section 314.70 includes the CBE provisions. *See* 21 C.F.R. § 314.70 (c) (6). The plain language of FDA's regulations communicates the obligation borne by name brand and generic manufacturers alike to revise a label to add or strengthen a warning in light of newly acquired information. *See id.* § 314.70 (c)(6)(iii)(A). This makes sense in light of the fact that brand name manufacturers may elect to manufacture and distribute a generic version of their own brand name drug – as Wyeth has done with Reglan – once the brand name drug loses patent protection. According to the defendants' logic, the same company that would have a duty to strengthen a warning or add a contraindication to its label as an NDA holder could argue that as a manufacturer of the generic form it escaped that same duty."

Kellogg v. Wyeth, 612 F. Supp. 2d 437 at 441 (D.Vt. Apr. 10, 2009).

A generic manufacturer cannot sit idly back and claim that it cannot change its label even when it becomes aware of an association of a serious hazard with the drug. The regulations allow an ANDA holder to act unilaterally and seek to change the approved label, even if the brand-name manufacturer has not yet done so. Generic manufacturers cannot have their cake and eat it too – by permitting them to rely on the

listed drug label for commercial purposes and then rely on preemption arguments for legal purposes. The Hatch-Waxman Act was not intended to absolve generic manufacturers of responsibility for their labeling. *Foster v. American Home Products Corp.* 29 F.3d 165, 169 (4th Cir. 1994). The listed drug label *is* the generic drug label, and the listed drug warnings *are* the generic drug's warnings. If a plaintiff relies on the generic drug's warnings and the warnings are proven inadequate, the generic manufacturer should be held responsible. Perrigo had this Court accept that it can continue to market a dangerous drug even though they know it poses serious un-warned side effects and do nothing -- and hide behind the excuse that the brand-name manufacturer did nothing to change the label.

> "[T]he FDA traditionally regarded state law as a complementary form of drug regulation. The FDA has limited resources to monitor the 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. ..."

Wyeth v. Levine, *supra* at 1202.

C. Misbranding Arguments Are Speculative

To the extent this Court held that Plaintiffs' failure-to-warn claims conflicted with Perrigo's obligations under federal law and that including the warnings "would put the Perrigo's [sic] ANDA in jeopardy for failing to conform with the FDA's approved

labeling for the listed drug," the *Levine* Court rejected this argument as speculative. The Supreme Court rejected the manufacturer's arguments that making unilateral changes to its drug label would have violated federal law governing unauthorized distribution and misbranding. The Court found it "difficult to accept" the manufacturer's arguments that "the FDA would bring an enforcement action against a manufacturer for strengthening a warning pursuant to the CBE regulation" *Id.* at 1196-1197. The Court found that the FDA retains authority to reject labeling changes made pursuant to the CBE regulation in its review of the manufacturer's supplemental application. The Court held that "absent clear evidence that the FDA would not have approved a change to [the drug's] label, we will not conclude that it was impossible for [the manufacturer] to comply with both federal and state requirements." *Id.* at 1198.

Perrigo did not provide evidence, beyond speculation, of what the FDA "might" or "would" do were Perrigo to make unilateral changes to its ibuprofen label to warn about the increased risks of serious liver injury when ibuprofen is used in combination with other hepatotoxic drugs. Both in *Levine* and in this case, the drug manufacturer showed no evidence that the FDA would have ultimately rejected such a labeling change. *See id.* at 1198-1199. The Court held that the drug manufacturer is always responsible for the content of its label – to craft an adequate label and to ensure that the label remains adequate. *Id.* at 1198. Perrigo submitted no evidence that the FDA would have rejected a stronger warning had it submitted a supplemental application pursuant to the CBE regulation. Indeed, Perrigo never made such an application, and there is no evidence that the FDA ever rejected a proposed warning that serious liver injury could occur with concomitant use of ibuprofen and other hepatotoxic drugs. Thus, any arguments based on what the FDA "would do" or "would have done" is mere speculation.

V

CALIFORNIA HOLDS THAT FAILURE-TO-WARN CLAIMS AGAINST GENERIC MANUFACTURERS ARE NOT PREEMPTED

In *McKenney v. Purepac Pharmaceutical Company,* 167 Cal. App. 4th 72 (2008)

review denied (Jan. 14, 2009), the Fifth District of the California Court of Appeal found that a plaintiff's state-law failure-to-warn claim against a generic drug manufacturer is not preempted by federal law. In an opinion consistent with the Supreme Court's reasoning in *Levine*, the Fifth District found that preemption principles apply equally to brand-name and generic manufacturers and stated:

> "The FDA has stated that its mechanism for compelling labeling revisions 'applies to both ANDA and NDA drug products' ... We therefore see no reason to distinguish between original or 'listed' drugs and their generic equivalents for federal preemption purposes. Nor do we see any indication that the FDA itself has ever taken the position that its labeling requirements for generics would invoke federal preemption principles so as to exempt manufacturers of generic drugs from tort liability." Id. at 83.

This Court should reconsider its Order and deny summary judgment. There is no legal or logical distinction to exempt Perrigo from liability for failure-to-warn, if the brand-name manufacturer would be held liable on the basis of the same drug label, for a bioequivalent drug.

VI

CONCLUSION

Based on the intervening change in the law as cited and discussed above, Plaintiffs respectfully request the Court to reconsider its previous Order and deny Perrigo's motion for summary judgment.

Respectfully submitted,

DATED: August 25, 2009

LAW OFFICES OF BRIAN D. WITZER, INC.

By: /s/ Rowena J. Dizon

Brian D. Witzer, Esq.
Rowena J. Dizon, Esq.
Attorneys for Plaintiffs

PROOF OF SERVICE
STATE OF CALIFORNIA, COUNTY OF LOS ANGELES
(CCP SECTION 1013A(3), 2030, 2301)

I am employed in the County of Los Angeles, State of California, I am over the age of 18 years and not a party to the within action; my business address is Witzer Law Building,8752 Holloway Drive, West Hollywood, CA 90069-2327.

On August 26, 2009, I served the foregoing document described as:

PLAINTIFF'S NOTICE OF MOTION AND MOTION FOR RECONSIDERATION IN LIGHT OF WYETH V. LEVINE; MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT THEREOF

on the interested parties in this action by placing a true copy thereof in a sealed envelope addressed as set forth below:

See Service List

[ ] MAIL:. I am "readily familiar" with the firm's practice of collection and processing correspondence for mailing with the United States Postal Service, and that correspondence shall be deposited with the United States Postal Service on that same day with postage thereon fully pre-paid in the ordinary course of business.

[ ] BY PERSONAL SERVICE I delivered such envelope(s) by hand to the offices of the addressee(s).

[X] ELECTRONIC FILING - by electronic transmission via the internet for uploading onto the District Court website/docket.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct. Executed on **August 26, 2009**, at West Hollywood, California.

Marcela Sanchez-Orozco /s/

Service List

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