IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: BUDEPRION XL MARKETING & SALES LITIGATION	:	**MDL No. 2107**
THIS DOCUMENT APPLIES TO: ALL ACTIONS	:	**09-md-2107**

MEMORANDUM

Schiller, J. **May 26, 2010**

In this putative nationwide class action brought under California state consumer protection laws, Plaintiffs claim that Defendants failed to warn them about differences between their generic anti-depressant medication and the name brand medication. Class members experienced adverse side effects after switching to the generic anti-depressants offered by Defendants. Plaintiffs suggest that they never would have purchased Defendants' products had they been made aware of the risks attached to the medication. Defendants believe that Plaintiffs' claims are preempted and have moved to dismiss the Complaint. The Court concludes that the Supreme Court's recent decision in *Wyeth v. Levine*, and subsequent cases interpreting that decision, have foreclosed Defendants' preemption argument. Their motion, therefore, is denied.

I. BACKGROUND

A. Factual and Procedural Background

Bupropion Hydrochloride ("Bupropion") is the active ingredient in the prescription anti-depressant Wellbutrin and several generic antidepressants. (Admin. Class Compl. ¶¶ 11-12.) By 2007, Buproprion was the fourth-most prescribed anti-depressant in this country, with over 20

million retail prescriptions written annually. (*Id*. ¶ 13.) Its side effects include headaches, migraines, agitation, tremors, nervousness, dizziness, decreased memory, insomnia, abdominal pain, nausea, diarrhea, vomiting, chest pains, and seizures. (*Id*. ¶ 20.)

GlaxoSmithKline (Glaxo) first brought Bupropion to the market in the late 1980s under the name Wellbutrin. (*Id*. ¶ 21.) It was originally available only in an immediate-release form (Wellbutrin IR) that the patient was required to take three times per day. (*Id*. ¶ 22.) It used a matrix release mechanism and was metabolized in the upper gastrointestinal tract. (*Id*.) The concentration of Bupropion in the blood peaked two hours after taking Wellbutrin IR. (*Id*. ¶ 23.) The initial sale of Wellbutrin IR, however, was delayed due to the possibility of serious side effects. (*Id*. ¶ 24.)

In 1996, Glaxo introduced Wellbutrin SR, a sustained-release formulation of Wellbutrin, which also used a matrix release mechanism; concentrations of Buproprion in the blood peaked three hours after taking Wellbutrin SR. (*Id*. ¶¶25-26.) Wellbutrin SR users often took two 150 mg pills per day. (*Id*. ¶ 26.) This iteration of the drug was prone to "dose dumping," meaning the drug was absorbed quicker when the pill was taken with food. (*Id*. ¶ 28.) Glaxo, as well as the generic makers of Wellbutrin SR, disclosed the possibility of dose dumping on their labels though they considered it clinically insignificant. (*Id*. ¶¶ 28-29.) The Food & Drug Administration ("FDA") did not require a New Drug Application ("NDA") for this formulation; instead, Glaxo was permitted to rely on the data submitted along with the immediate-release formulation. (*Id*. ¶ 25.)

In 2003, Glaxo released Wellbutrin XL, an extended-release formulation that only needed to be taken once per day. (*Id*. ¶ 30.) Wellbutrin XL employed a membrane-release technology, meaning that "the drug was not released through a dissolving pill, but seeped at a controlled rate through a membrane that actually passed through the entire GI tract intact." (*Id*. ¶ 31.) This release

mechanism solved the dose dumping problem and Glaxo updated its label accordingly. (*Id*. ¶ 32.) Concentrations of Buproprion in the blood peaked five hours after taking Wellbutrin XL. (*Id*.) The membrane-release technology was patented and thus generic drug manufacturers had to devise an extended-release formulation that did not infringe upon the patent. (*Id*. ¶ 34.) Generic drug companies such as Watson Pharmaceuticals and Anchen Pharmaceuticals developed a similar membrane technology but Defendants did not. (*Id*. ¶¶ 35-36.)

Defendant Impax Laboratories, Inc. currently makes a 150 mg generic product called "bupropion hydrochloride XL," which is distributed by Global Pharmaceuticals, an Impax subsidiary. (*Id*. ¶ 50.) Impax also makes a 300 mg generic drug, Budeprion XL, which is distributed by Defendant Teva Pharmaceuticals. (*Id*. ¶ 49.) The generic versions of Wellbutrin XL involved in this litigation entered the market in late 2006/early 2007. (*Id*. ¶ 41.) These generics use a matrix technology rather than a membrane-release technology and rely on the size of the pill to control the release of the medication. (*Id*.) The generics subject to this litigation achieve peak concentrations in two hours, versus five hours for Wellbutrin XL and generic versions produced by Anchen and Watson. (*Id*. ¶ 43.) The matrix technology caused Defendants' pills to break apart quicker than the name brand drugs and metabolize in the upper GI tract. (*Id*. ¶ 44.) Thus, the amount and rate of the active chemical released into the body from Defendants' drugs depended upon factors like food and alcohol consumption, other medications, and other GI issues. (*Id*. ¶ 44.) Wellbutrin XL users, on the other hand, attain the benefits of their medication without focusing on these issues. (*Id*.)

Plaintiffs do not dispute the FDA's finding of bioequivalence, which was necessary to approve the generic drugs before they could be marketed. Instead, Plaintiffs claim that post-approval, Defendants became aware that the differences between Wellbutrin and their products were

material, and thus they had a duty to disclose this information. (*Id*. ¶ 48.) Specifically, Plaintiffs say the more rapid release of Defendants' drugs renders them less effective in treating depression and more dangerous than those products using a membrane-release technology. (*Id*. ¶ 52.) After Defendants' products arrived on the market, complaints poured in from patients who claimed that the generic drugs they were taking was not as effective as Wellbutrin XL and they were experiencing adverse side effects. (*Id*. ¶ 54-56.) Those patients who switched back to Wellbutrin XL or a non-Impax generic drug immediately improved. (*Id*. ¶ 57.) Although Defendants were made aware of the problems with their drugs, they failed to disclose this information or warn patients and doctors about the differences between the medications. (*Id*. ¶ 59.) In fact, to protect their market share, Defendants continued to misrepresent that the release profile of their products was identical to those of the name brand product. (*Id*. ¶¶ 60-62.) Furthermore, during patent litigation involving the delivery method of Defendants' drugs, Defendants touted the differences between their method of delivery and that used in Wellbutrin XL. (*Id*. ¶ 63.) This litigation was sealed from the public. (*Id*.) Additionally, studies showed that Budeprion XL released 34% of its Bupropion within the first hour, compared to only 8% for Wellbutrin XL (300 mg). (*Id*. ¶ 64.) And within two hours of ingestion, Budeprion XL released between 25% and 50% of its Bupropion, compared with less than 20% for Wellbutrin XL. (*Id*. ¶ 66.) In April of 2008, under pressure from consumers, non-profit watchdogs, and the medical community, the FDA issued a report explaining some of the differences between Wellbutrin XL and Defendants' generic product; however, the FDA made no determination as to whether Defendants' warnings were adequate. (*Id*. ¶ 69.)

According to the Complaint, Defendants have made the following omissions and misrepresentations, among others: (1) failure to disclose that the Bupropion contained in Budeprion

XL reaches its peak concentration in the bloodstream in just two hours and instead insisting that maximum levels are only reached after five hours; (2) failure to disclose that taking Defendants' products with food increases the amount of the drug eventually released into the body thereby causing adverse events; (3) failure to disclose that the 300 mg generic drug was never tested for bioequivalence with Wellbutrin XL; (4) failure to disclose the existence of tests indicating that the dissolution of Defendants' products varied significantly from Wellbutrin XL; (5) failure to disclose numerous complaints of adverse side effects and decreased efficacy suffered by persons who switched from Wellbutrin XL to Defendants' products; (6) failure to disclose that their products had a different physiological and therapeutic effect than Wellbutrin XL; (7) failure to disclose that Defendants' products employed an inferior release technology; and (8) misrepresenting that their product worked the same as Wellbutrin XL. (*Id.* ¶ 71.) Defendants also failed to inform those taking their drugs that they needed to be closely monitored. (*Id.* ¶¶ 72-75.) Defendants kept all of this information secret in an effort to protect their market share. (*Id.* ¶ 76.) Indeed, after word of the patient complaints became public, Budeprion XL lost significant market share. (*Id.* ¶ 79.) According to the Complaint, if Plaintiffs knew the truth about Defendants' generic products, they would not have purchased those products. (*Id.* ¶ 142.) As a result, they suffered injury and lost money because they paid for an unsatisfactory product. (*Id.* ¶ 153.)

According to Plaintiffs, Defendants' actions have disrupted the generic market for antidepressants. The problems relate only to Defendants' generic antidepressants; doctors, however, cannot direct pharmacists to fill a prescription with a particular version of a generic drug. (*Id.* ¶ 84.) Instead, doctors have been insisting that pharmacists use the brand name drug rather than a generic. (*Id.* ¶ 85.) Thus, Wellbutrin XL has managed to recapture a chunk of the Bupropion market despite

the existence of comparable generic drugs and has actually increased in price. (*Id*. ¶¶ 86, 89.)

The named Plaintiffs in this putative class action are Andrew Richards and Micki Sackler. Richards is an adult citizen of California who suffers from depression and used Defendants' product to treat his depression from January to March 2008. (*Id*. ¶ 114.) Prior to using Defendants' product, he used Wellbutrin XL (300 mg), which treated his depression with little or no side effects. (*Id*.) He believed that Defendants' generic was identical to Wellbutrin XL but while on the generic, his depressive symptoms returned and/or increased and he also suffered a seizure. (*Id*.) Sackler is also an adult citizen of California who, in or around 2008, used Defendants' product to treat her depression. (*Id*. ¶ 115.) She had been taking Wellbutrin XL (150 mg) and when she switched to Defendants' generic drug, she noticed an immediate return of her depression and also had trouble sleeping. (*Id*.) As stated in the Administrative Class Action Complaint, "[t]his lawsuit seeks to apply California's statutory business standards to a California drug manufacturer (Impax) and its distribution partner (Teva) for uniform national conduct emanating from California. Defendants engage in nationwide market activity, providing the same label with every Impax Product that omits material information. A national solution makes sense." (*Id*. ¶¶ 99-100.) Plaintiffs have sued under California law, specifically, the California Business and Professions Code and the California Consumer Legal Remedies Act. (*Id*. ¶¶ 104-10.) Plaintiffs are not seeking recovery for any personal injuries that any Class member may have suffered but rather want an injunction and restitution for money they have spent to purchase the deceptive products. (*Id*. ¶ 121.)

The Class asserts jurisdiction under the Class Action Fairness Act, 28 U.S.C. § 1332(d)(2), and claims that this litigation may be maintained as a class action under either Rule 23(b)(2) or 23(b)(3) of the Federal Rules of Civil Procedure. (*Id*. ¶¶ 111-12, 122-28.) The Class consists of:

> All persons or entities in the United State who purchased, paid-for (in whole or in part), Bupropion Hydrochloride XL (150 mg) and/or Budeprion XL (300 mg) manufactured by Impax.
>
> Excluded from the Classes are Defendants, any parents, subsidiary or affiliate of Defendants, and their officers, directors, and employees, who are or have been employed by Defendants, and any judicial officer who may preside over this action.

(*Id*. ¶ 119.)

Count I is a claim under California's Unfair Competition Law based on the omissions and misrepresentations surrounding Defendants' products. (*Id*. ¶¶ 129-45.) Plaintiffs allege that Defendants engaged in a pattern of unfair business practices that has harmed consumers, physicians, pharmacies, and insurance companies. (*Id*. ¶ 132.) Furthermore, Defendants' actions have also harmed competitors in that they have unfairly seized market share. (*Id*. ¶¶ 134, 136, 138.) Count II is a claim under the California Consumer Legal Remedies Act and is brought on behalf of Richards and Sackler as well as a subclass of the putative class, comprised of those members who bought Defendants' products within three years of the commencement of the action. (*Id*. ¶ 147.)

This litigation developed from the numerous complaints filed in both federal and state courts throughout this country. In all of the cases, the plaintiffs sought to represent themselves and a class of individuals who had taken Defendants' generic version of Wellbutrin and whose conditions had worsened after switching to the drug. Both Plaintiffs and Defendants agreed that the cases should go to the United States Judicial Panel on Multidistrict Litigation and be consolidated for pretrial purposes, although the parties disputed to which district the cases should be transferred. On December 2, 2009, the MDL panel issued its decision and, pursuant to 28 U.S.C. § 1407, transferred the cases to this District. Following the decision of the MDL panel, this Court conducted a case management conference and issued a Scheduling Order. Pursuant to that Order, Defendants have

moved to dismiss Plaintiffs' case.

B. Prescription Drug Statutes and Regulations

The Federal Food, Drug, and Cosmetic Act (FDCA) allows any person to file an application with the FDA, known as a new drug application ("NDA"), with respect to any new drug. 21 U.S.C. § 355(b)(1). The application must include: (1) full reports of investigations which have been made to show whether or not the drug is safe and effective, and (2) specimens of the labeling proposed to be used for the drug. *Id*. Pursuant to the Hatch-Waxman Act, a generic drug maker, on the other hand, may file an abbreviated new drug application ("ANDA") for the approval of a generic drug. *Id*. § 355(j)(1). The ANDA must include information to show: (1) that the conditions of use prescribed, recommended, or suggested in the proposed labeling for the drug has been previously approved for a listed drug; (2) the active ingredient(s) of the new drug is the same as that of the listed drug; (3) that the route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug; (4) that the new drug is bioequivalent to the listed drug; and (5) that the labeling proposed for the new drug is the same as the labeling approved for the listed drug.[1] *Id*. § 355(j)(2)(A)(i)-(v). A failure to demonstrate bioequivalence or a failure to show that the proposed label for the generic drug is the same as the label approved for the listed drug is grounds to deny the ANDA. 21 U.S.C. § 355(j)(4)(F) - (G). Thus, absent certain exceptions, federal regulations require that the label for a proposed generic drug be the same as the labeling approved for the listed drug before an ANDA will be approved. 21 C.F.R. § 314.94(a)(8)(iv). A drug is considered to be

[1] A "listed drug" is a "drug which has been approved for safety and effectiveness under subsection (c) of this section." 21 U.S.C. § 355(j)(7)(A)(i)(I). This Court will use the terms "listed drug," "name drug," "name brand drug," interchangeably and in contrast to "generic drug."

bioequivalent to a listed drug if "the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug . . ." or if the rate of absorption does show a significant difference, such difference "is intentional, is reflected in its proposed labeling . . . and is considered medically insignificant for the drug." 21 U.S.C. § 355(j)(8)(B)(i) - (ii). This abbreviated process allows a generic drug maker to skip the pre-market trials conducted by the name brand drug manufacturer upon a showing that the generic drug is the pharmaceutical equivalent of its name brand counterpart. *See Fulgenzi v. Wyeth, Inc.*, Civ. A. No. 09-1767, 2010 WL 649349, at *3 (N.D. Ohio Feb. 19, 2010); *see also Stacel v. Teva Pharms. USA*, 620 F. Supp. 2d 899, 905 (N.D. Ill. 2009) ("The underlying presumption is that so long as the [generic] drug is shown to be pharmaceutically equivalent to an existing reference-listed drug . . . FDA approval can be assumed without requiring duplication of previously-performed studies.").

After a drug is approved, the manufacturer may submit additional information to the FDA to change the label to add or strengthen a contraindication, warning, precaution or adverse reaction. 21 C.F.R. § 314.70(c)(6)(iii)(A) & (C). This provision, known as the "changes being effected" or "CBE" provision, allows a drug maker to immediately implement any proposed change in the warning label while awaiting a ruling from the FDA on the proposed changes. *See Fulgenzi*, 2010 WL 649349, at *3.

A plain reading of the federal regulations demonstrates that generic drug makers may avail themselves of the CBE process. *See Dorsett v. Sandoz, Inc.*, Civ. A. No. 06-7821, 2010 WL 1174204, at **17-18 (C.D. Cal. Mar. 26, 2010); *Stacel*, 620 F. Supp. 2d at 905 ("In other words, the regulations affecting generic drug applications state explicitly that the CBE provisions apply to generic drug manufacturers just as they do to name-brand manufacturers."); *Bartlett v. Mutual*

Pharm. Co., 659 F. Supp. 2d 279, 296 (D.N.H. 2009) ("Just as nothing in the text of the Hatch-Waxman Amendments forbids a generic manufacturer from changing its label from the listed version's post-approval, nothing in the text of the CBE regulation forbids a generic manufacturer from using the CBE process to do so.") Furthermore, federal regulations require both brand name and generic drug makers to revise their labeling to "include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug; a causal relationship need not have been definitely established." 21 C.F.R. § 201.57(c)(6).

II. STANDARD OF REVIEW

In reviewing a motion to dismiss for failure to state a claim, a district court must accept as true all well-pleaded allegations and draw all reasonable inferences in favor of the non-moving party. *See Bd. of Trs. of Bricklayers and Allied Craftsman Local 6 of N.J. Welfare Fund v. Wettlin Assocs.*, 237 F.3d 270, 272 (3d Cir. 2001). A court need not, however, credit "bald assertions" or "legal conclusions" when deciding a motion to dismiss. *Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 906 (3d Cir. 1997); *see also Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009).

"Factual allegations [in a complaint] must be enough to raise a right to relief above the speculative level." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). To survive a motion to dismiss, a complaint must include "enough facts to state a claim to relief that is plausible on its face." *Iqbal*, 129 S. Ct. at 1974. Although the federal rules impose no probability requirement at the pleading stage, a plaintiff must present "enough facts to raise a reasonable expectation that discovery will reveal evidence of the necessary element[s]" of a cause of action. *Phillips v. County of Allegheny*, 515 F.3d 224, 234 (3d Cir. 2008). "A claim has facial plausibility when the plaintiff

pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 129 S. Ct. at 1949. Simply reciting the elements will not suffice. *Id*. (concluding that pleading that offers labels and conclusions without further factual enhancement will not survive motion to dismiss); *see also Phillips*, 515 F.3d at 231.

The Third Circuit Court of Appeals has recently directed district courts to conduct a two-part analysis when faced with a 12(b)(6) motion. First, the legal elements and factual allegations of the claim should be separated, with the well-pleaded facts accepted as true but the legal conclusions disregarded. *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210-11 (3d Cir. 2009). Second, the court must make a common sense determination of whether the facts alleged in the complaint are sufficient to show a plausible claim for relief. *Id*. at 211. If the court can only infer the mere possibility of misconduct, the complaint must be dismissed because it has alleged – but has failed to show – that the pleader is entitled to relief. *Id*.

III. DISCUSSION

A. Preemption

1. Basic Principles

Defendants argue that Plaintiffs' claims are preempted by federal law, specifically, the FDCA and the FDA's bioequivalence determination. They argue that Plaintiffs' claims cannot proceed because a finding in their favor would contradict the FDA's finding of bioequivalence and interfere with the authority the FDA has to determine whether a generic drug is safe and effective. (Br. in Supp. of Defs.' Mot. to Dismiss [Defs.' Br.] at 11-12.) According to Defendants, Plaintiffs' claims both "actually conflict" with federal law and pose an obstacle to the purposes and objectives of

Congress. (*Id*. at 12.)

Preemption doctrine is rooted in the Supremacy Clause of the Constitution, which reads that the laws of the United States "shall be 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. There are three types of preemption: express, implied conflict, and field. *Bruesewitz v. Wyeth, Inc.*, 561 F.3d 233, 239 (3d Cir. 2009) (citations omitted). In this case, the focus is on conflict preemption. Implied conflict preemption may occur if it is "impossible for a private party to comply with both state and federal requirements." *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990). It may also occur if state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

As directed by the Supreme Court, this Court's preemption analysis begins with two fundamental precepts: (1) Congress' intent is paramount, and (2) there is a presumption against preemption in those cases that touch upon areas traditionally left to the police powers of the states; federal law should not upend those powers except upon a showing of clear and manifest intent on the part of Congress. *See Wyeth v. Levine*, 129 S. Ct. 1187, 1194-95 (2009). Plaintiffs' claims fall within such a realm of historic police powers. *See id*. at 1195 n.3; *see also Fellner v. Tri-Union Seafoods, L.L.C.*, 539 F.3d 237, 248 (3d Cir. 2008) ("[I]t is hard to imagine a field more squarely within the realm of traditional state regulations than a state tort-like action seeking damages for an alleged failure to warn consumers of dangers arising from the use of a product.").

2. The Supreme Court's Levine *Decision*

In *Levine*, the Court had to decide whether the FDA's drug labeling decisions preempted state law product liability claims premised on the theory that different labeling judgments were necessary

to make drugs reasonably safe for use. *Levine*, 129 S. Ct. at 1193. The drug in that case, Phenergan, could be given through the "IV-push" method, whereby it was directly injected into a patient's vein, or the "IV-drip" method, whereby it was introduced into a saline solution in a hanging intravenous bag and slowly descended through a catheter inserted in a patient's vein. *Id*. at 1191. Diana Levine received an IV-push, but the drug entered her artery, where it came into contact with arterial blood. She thereafter developed gangrene requiring the amputation of her right hand and entire forearm. *Id*. Levine sought damages for negligence and strict liability, and she argued that Wyeth's Phenergan label was defective because it failed to warn clinicians about the risks of the IV-push method. *Id*. at 1191-92. She also claimed that the drug was unsafe for intravenous administration given the risks attendant to its use. *Id*. at 1192.

A Vermont jury concluded that Wyeth, the manufacturer of Phenergan, failed to adequately warn users, including Levine, of the risks associated with directly injecting the drug into the vein. Because the FDA approved both the drug's label as well as a subsequent change to the label, Wyeth argued on appeal that the FDA's approvals provided the company with a complete defense to Levine's state-law tort claims. Wyeth argued both that it would be impossible for it to comply with the state-law duty to modify its label without violating federal law and that a state law cause of action was an unacceptable obstacle to Congress' purposes and objectives "because it substitutes a lay jury's decision about drug labeling for the expert judgment of the FDA." *Id*. at 1194.

The Court rejected Wyeth's preemption arguments. The Court started with the presumption against preemption. Despite increased federal regulations in the field of prescription medication and drug labeling, Congress maintained an important place for state law. Indeed, although Congress enacted an express preemption provision for medical devices in 1976, it declined to enact a similar

provision for prescription drugs. *Id*. at 1196.

It was not impossible for Wyeth to comply with state-law duties and federal labeling regulations because the "changes being effected" process permitted a drug maker to alter its label before receiving FDA approval. *Id*. at 1196. Nothing in the federal regulations or the law prevented Wyeth from adding a stronger warning about the administration of Phenergan. *Id*. at 1197. The Court also rejected Wyeth's contention that forcing it to comply with state law would frustrate the purposes and objectives of federal drug labeling regulations, including entrusting the FDA as the expert on drug labeling decisions. *Id*. at 1199.

Wyeth made an argument similar to the one posited by Defendants here: that the FDA has spoken on the adequacy of the label and the FDA's voice silences state law. But, according to the Supreme Court, this argument ignored the fact that the FDA "traditionally regarded state law as a complementary form of drug regulation." *Id*. at 1202. Given the limited resources of the FDA and the drug manufacturers' greater access to information about their drug, especially post-approval, Congress intended to leave in place an "additional, and important layer of consumer protection that complements FDA regulation." *Id*. If Congress believed state law remedies would have hindered its goal of ensuring that only safe and effective drugs are consumed by the public, surely it would have enacted an express preemption provision in the law. *Id*. at 1200.

3. The Aftermath of Levine

Numerous courts have considered the import of the decision in *Levine* as it relates to generic drug manufacturers. However, because neither the Third Circuit Court of Appeals nor the Eastern District of Pennsylvania has written extensively on the subject following *Levine*, this Court will take the opportunity to survey the legal landscape.

The Eighth Circuit Court of Appeals considered the import of *Levine* in *Mensing v. Wyeth, Inc.*, 588 F.3d 603 (8th Cir. 2009). Gladys Mensing sued a number of manufacturers of the drug Reglan and its generic form for failure to warn and misrepresentation, claiming that the drugs she took caused her to develop a severe neurological movement disorder. The district court dismissed the claims against the generic drug makers, holding they were preempted because the failure to warn claims would require them to alter their label and deviate from the name brand drug label approved by the FDA. The Eighth Circuit Court of Appeals reversed. The generic drug makers in *Mensing* attempted to distinguish *Levine* on the grounds that *Levine* concerned only brand name manufacturers, but the court of appeals concluded that the case "carries important implications for [generic drug makers'] situation as well." *Id*. at 607. Although the generic manufacturers argued that their hands were tied because federal regulations prohibited them from unilaterally altering the label of their drugs without prior FDA-approval, the court concluded that the generic manufacturers could have proposed a label change to the FDA. *Id*. at 608. Furthermore, "[t]he regulatory framework makes clear that a generic manufacturer must take steps to warn its customers when it learns it may be marketing an unsafe drug." *Id*. at 608. The generic drug manufacturers could not passively accept inadequate warnings on their labels simply by arguing that their label matched that of the name brand label. *Id*. at 609. The generic drug manufacturers could also have suggested that the FDA send out a warning letter to health care professionals. *Id*. at 610. They also could have stopped selling their product if they learned that their label was insufficient but did not believe they could propose a change to it. *Id*. at 611. Because it was not impossible for generic drug makers to comply with both federal law and state law, nor did compliance with state law obstruct the purposes

and objectives of state law, Mensing's state law claims were not preempted.[2]

The Fifth Circuit Court of Appeals recently considered "whether the federal regulatory regime governing pharmaceuticals preempts state-law failure-to-warn claims against manufacturers of generic drugs." *Demahy v. Actavis, Inc.*, 593 F.3d 428, 430 (5th Cir. 2010). The court held that while *Levine* did not dictate the result, it "shadow[ed] our conclusion that the federal regulatory regime governing generics is also without preemptive effect." *Id*. The generic drug maker in *Demahy*, Actavis, argued that *Levine* was distinguishable because a generic drug maker was required to make the same drug and use the same label as the name brand drug maker. *Id*. at 433. The court rejected this argument. While Congress required a generic drug maker to submit a label identical to the brand name drug when seeking ANDA approval, the law did not address the generic drug maker's obligations after approval. *Id*. at 436. And federal regulations did not bar generic drug makers from making labeling modifications following initial approval of the ANDA. *Id*. at 436-37. As pointed out in *Levine*, the ultimate responsibility for ensuring the continued safety of those ingesting medication rested with the maker of the drug, regardless of whether the drug was a brand name drug or a generic. Generic drug manufacturers could not sell a drug and then ignore its later-presented dangers. Rather, they too were seen as a key component for ensuring the safety of medication. *Id*. at 438 ("At the very least, then, the FDA contemplates that generic manufacturers will initiate label changes in addition to echoing changes to the name brand label."). Although generic drug makers were not free to alter labels at any time in any manner they saw fit, federal regulations did not prevent such drug makers from improving or strengthening their labels; the court

[2] A petition for certiorari is currently pending in the *Mensing* case, and the Supreme Court recently invited the Solicitor General to file a brief in the matter.

also found it difficult to contemplate the FDA bringing an enforcement action against a generic drug manufacturer for strengthening the label of one of its drugs. *Id*. at 439. Generic manufacturers could alter their labels through the CBE process, through the prior approval process, or by communicating to doctors directly, through "dear doctor" letters.[3] *Id*. at 439-46. "In passing the FDCA, Congress 'determined that widely available state rights of action provided appropriate relief for injured [drug] consumers' and that 'state-law remedies further consumer protection by motivating manufacturers . . . to give adequate warnings.' We see no reason why the same cannot be said for the Hatch-Waxman Amendments to the FDCA." *Id*. at 449 (citing *Levine*, 129 S. Ct. at 1199-1200). Finally, the court noted that if the plaintiff's state law claims were preempted, she would be left with no remedy at all. *Id*. at 435. The court refused to hold that Congress implicitly barred her any recovery simply because she did not demand a name brand drug. *Id*. at 449.

Numerous district courts have also concluded that state law tort claims against generic manufacturers are not preempted by federal law. For example, Melanie Stacel took minocycline, a generic drug made by Teva. She developed drug-induced lupus and sued Teva for negligent failure to warn, common law fraud, misrepresentation, and violation of Illinois' Consumer Protection Act. Teva moved to dismiss based on federal preemption. It argued that it could not comply with both the FDCA's labeling requirements and state law; it also contended that state law would frustrate the purpose and intent of Congress. *Stacel*, 620 F. Supp. 2d at 903. Teva argued that federal law required its label to be identical to the name brand drug, even if it later learned the efficacy of the

[3] Defendants note that generic manufacturers cannot send "Dear Doctor" letters without FDA approval. (Defs.' Br. at 24.) This may be true but Defendants fail to note that generic drug makers can request the FDA send out such letters on their behalf. *See Demahy*, 593 F.3d at 444-45.

drug was questioned.

The *Stacel* court recognized that *Levine* was not directly controlling because it involved a new drug manufacturer. Nonetheless, "key parts of [*Levine's*] analysis are applicable." *Id*. at 904. For instance, *Levine* confirmed that drug makers were ultimately responsible for the contents of their labels. *Id*. (citing *Levine*, 129 S. Ct. at 1197).

The court noted that Teva pointed to no cases in which the FDA withdrew approval of an ANDA because a generic drug maker added or strengthened warnings. *Id*. at 905. The court also concluded that the CBE process was available to generic manufacturers. *Id*. at 905, 907. Finally, the court determined that Congressional silence on the preemption issue, coupled with its awareness of state tort remedies, was evidence that Congress intended that the burdens of drug safety and efficacy not be borne solely by the FDA. *Id*. at 907 (citing *Levine*, 129 S. Ct. at 1200). "There is not reason to conclude that Congress felt differently about generic drugs." *Id*.

Since *Levine*, district courts have repeatedly refused to hold that state law tort causes of action are preempted. These courts have noted that generic drug makers can avail themselves of the CBE process and they have rejected claims that a generic drug label must forever match that of the listed drug. *See Dorsett*, 2010 WL 1174204, at *16 (noting that although Congress intended generic drug maker to submit label identical to that of name drug when first seeking ANDA approval, Congress said nothing about generic label once approval was granted) (citing *Demahy*, 593 F.3d at 436; *Laisure-Radke v. Par Pharm., Inc.*, 426 F. Supp. 2d 1163, 1169 (W.D. Wash. 2006)); *Bartlett*, 659 F. Supp. 2d at 294-95; *Kellogg v. Wyeth*, 612 F. Supp. 2d 421, 431 (D. Vt. 2008); *but see Gaeta v. Perrigo Pharms. Co.*, Civ. A. No. 05-4115, 2009 WL 4250690 (N.D. Cal. Nov. 24, 2009) (holding state law failure to warn claims preempted and noting that *Levine* did not address issue whether

generic drug makers can unilaterally alter their labels). Additionally, courts frequently view preemption in this context with skepticism because it is unlikely that the FDA would object to a drug maker seeking to provide additional warnings and information to its customers. *Kellogg*, 612 F. Supp. 2d at 430; *Weilbrenner v. Teva Pharms. USA, Inc.*, Civ. A. No. 08-23, 2010 WL 924915, at *7 (M.D. Ga. Mar. 10, 2010); *Dorsett*, 2010 WL 1174204, at **14-16. Other courts have noted that if plaintiffs cannot bring their cause of action, they are left without a remedy despite being injured by defendants' conduct – a result inconsistent with the purpose behind the Hatch-Waxman Act. *See Demahy*, 593 F.3d at 435; *Fulgenzi*, 2010 WL 649349, at *6 (noting that Hatch-Waxman allowed generic drug makers to get their products to market cheaply and quickly, not engage in negligence); *Stacel*, 620 F. Supp. 2d at 907; *Kellogg*, 612 F. Supp. 2d at 431-32. Several courts have emphasized that generic drug makers, and not the FDA, bear the ultimate responsibility for the product they market. *See, e.g., Levine*, 129 S. Ct. at 1197-98; *Dorsett*, 2010 WL 1174204, at **17-18; *Fulgenzi*, 2010 WL 649349, at *6; *Schrock v. Wyeth, Inc.*, 601 F. Supp. 2d 1262, 1265 (W.D. Okl. 2009). Absent clear Congressional intent to preempt plaintiffs' claims, courts have allowed such claims to proceed. *See Bartlett*, 2009 WL 3126305, at *25; *Kellogg*, 612 F. Supp. 2d at 431-32 ("The regulation of drugs has never been a strictly federal operation. In fact, the FDA's regulatory scheme has consistently relied on a role for state tort law. . . . FDA drug labeling regulations have long been regarded as minium standards of conduct."); *Weilbrenner*, 2010 WL 924915, at *7 (holding that state law claims furthered, rather than inhibited, the goal of federal prescription drug laws – ensuring the public receives safe drugs).

4. Analysis

Defendants argue that *Levine* does not apply to this case because that case did not involve

a generic drug manufacturer or the warning applicable to a generic drug. (Defs.' Br. at 17.) Instead, Defendants point to *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000), to support their preemption argument. In *Geier*, the Secretary of Transportation promulgated a safety regulation whereby car manufacturers were required to include passive restraint systems in a percentage of their cars built in or after 1987. The regulations did not mandate a particular type of passive restraint systems, instead leaving it to the manufacturers to decide which product to install. Despite wearing her seatbelt, Geier was seriously injured when she drove her Honda Accord into a tree. She sued Honda under state tort law, arguing that her car was negligently and defectively designed because it lacked a driver's-side airbag. The Court held that Geier's lawsuit was preempted because states were not free to deem certain passive restraint systems unsafe despite the Secretary of Transportation's decision that those same systems were safe.

Contrary to Defendants' argument, *Levine* applies to this case. The Court in *Levine* rejected the *Geier* approach, notwithstanding the opinion of the dissenting Justices that *Geier* was indistinguishable from the facts presented in *Levine*. *Levine*, 129 S. Ct. at 1203. Furthermore, Defendants' preemption argument flies in the face of the Supreme Court's clear pronouncement that "it has remained 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 that its warnings remain adequate as long as the drug is on the market." *Id*. at 1197-98. Unquestionably, federal regulations of generic drugs differ from regulations of name brand drugs in numerous respects. Those differences, however, allow generic drug makers to quickly get their products to market but do not absolve them from their duty to warn customers of their products' dangers or leave injured patients uncompensated for deceptive conduct. And the

argument that Congress would permit state law to apply to the labeling of name brand drugs but would preempt state law actions against generic drug makers is a tough pill to swallow. The reasoning in *Levine* applies equally well to generic drugs. Upon becoming aware of their drugs' shortcomings, Defendants could have offered warnings and submitted a CBE application to the FDA. Alternatively, Defendants could have removed their product from the market. Thus, simultaneous compliance with federal and state law is not impossible. *See id*. at 1198 ("[A]bsent clear evidence that the FDA would not have approved a change to Phenergan's label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements."). *Levine* teaches that the ultimate responsibility rests with the drug maker, not the FDA, to either adequately inform the public or remove the drug from the market. Defendants have offered no compelling reason why Congress would have given generic drug makers favored status.

Defendants suggest that regardless of how Plaintiffs frame their argument, they cannot recover without contradicting the FDA's bioequivalence finding and proving that Defendants' products are not as safe or effective as the name brand product. Defendants argue that on numerous occasions, the FDA has determined that their product is bioequivalent to the name brand drug. Not only did the FDA approve the ANDA, but it denied a Citizen Petition attacking the safety and efficacy of its drug. (Defs.' Br. at 8-9.) Finally, the FDA reaffirmed the safety of Budeprion XL when it performed post-marketing reports on eighty-five people who reported adverse effects when switching from Wellbutrin XL to the 300 mg generic drug. (*Id*.) The FDA determined that the side effects certain people suffered was not attributable to differences between the generic and the name brand drugs. (*Id*. at 9-10.)

This Court does not read *Levine* so narrowly as to foreclose Plaintiffs' claims here. *Levine*

and the cases that applied it to generic drug manufacturers provide lessons applicable here. First, a generic drug manufacturer is not absolved of liability because the FDA has approved its generic product. The Hatch-Waxman Act allows generic drug makers to expeditiously get their products to market – it does not allow generic drug makers to wash their hands of any responsibility for monitoring the safety and efficacy of their drugs once sold. *See Stacel*, 620 F. Supp. 2d at 907. Second, preemption is not to be lightly applied, particularly in this case because the field of law is one in which states have historically played a role. Defendants have not pointed to any evidence of clear Congressional intent to preempt Plaintiffs' claims, instead retracing arguments other courts have rejected. Congress passed the FDCA – and delegated authority to regulate the manufacture and sale of prescription medication – to ensure that such medication is safe and effective. *Kellogg*, 612 F. Supp. 2d at 431. Congress passed the Hatch-Waxman Act so that lower-cost generic drugs would be readily accessible to the public. *See id*. at 431-32; *Stacel*, 620 F. Supp. 2d at 907. Nonetheless, "[t]he statutory scheme governing premarketing approval for drugs does not evidence Congressional intent to insulate generic drug manufacturers from liability for misrepresentations made regarding their products, or to otherwise alter state products liability law. Manufacturers of generic drugs, like all other manufacturers, are responsible for the representations they make regarding their products." *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 170 (4th Cir. 1994). Furthermore, Plaintiffs would be left without a remedy if their state-law claim were preempted. Defendants need to posit more than the FDA's bioequivalence determination to show that Congress meant to leave those injured by generic drug makers unable to seek redress for their injuries. Third, *Levine* leaves it beyond doubt that ultimate responsibility for the labeling of drugs remains with the maker of the drug, not the FDA. Fourth, although Defendants repeatedly assert that this is a case in which the FDA has already

spoken and therefore a jury may not reassess the position taken by the FDA, that fact, even if correct, would not render Plaintiffs' claims preempted. In *Levine* and the cases interpreting it, the drugs at issue had all been approved as safe and effective for use by the public. But in none of those cases did prior FDA approval equate to a finding of preemption. Drug makers must continue to monitor their products and address issues that arise. Federal laws and regulations do not leave generic drug makers impotent upon learning that their labels are inadequate or that their medication causes adverse side effects that must be reported. Generic drug makers may add or strengthen warning labels, even without prior FDA approval. *Foster*, 29 F.3d at 170.

Defendants stand behind their products and contend that both before and after approving their products for sale, the FDA has determined that the warnings Plaintiffs seek are not necessary. These arguments are not dispositive at this procedural stage. *See Kellogg*, 612 F. Supp. 2d at 435 (holding that pre-discovery, court was unable to determine if FDA considered and rejected stronger warnings). Plaintiffs have asserted viable claims that the drugs they took caused side effects and injuries and that Defendants failed to disclose certain information about their products that, had Plaintiffs been aware of, would have convinced them not to purchase the products. Defendants cannot argue that the FDA has already spoken on Plaintiffs' claims. The FDA has not rejected additional warnings here because no such strengthened warnings have been proposed to the FDA. While the FDA has to date not required additional warnings on Budeprion XL, that is very different from saying they have rejected such a proposed alteration. Similar to other courts, this Court finds it difficult to believe that the FDA would balk at a drug maker seeking to strengthen the warning label on its product. Finally, Defendants' argument that the FDA's pronouncement forecloses state law claims both proves too much and fails to address Plaintiffs' claims. Plaintiffs have explicitly stated that

Defendants' products meet the FDA definition of bioequivalence. (Admin. Compl. ¶ 48.) Additionally, in every case involving a prescription drug, whether a name brand drug or a generic is involved, the FDA will at some point have approved the drug as safe and effective and the label as adequate. Defendants would turn that approval into a lock that would forever shut the courthouse door and would remove any incentive for generic drug makers to monitor the safety of their medications and update their labels accordingly. Such a result runs counter to Congressional purpose and finds no support in the law.

B. Primary Jurisdiction

Defendants argue that this Court should decline to hear Plaintiffs' case pursuant to the doctrine of primary jurisdiction, which says that courts may, under appropriate circumstances, determine that the initial decision making responsibility should be performed by the relevant agency rather than the courts. *Syntek Semiconductor Co. v. Microchip Tech., Inc.*, 307 F.3d 775, 780 (9th Cir. 2002). The doctrine calls for courts to abstain if a particular agency should first render a decision. *Clark v. Actavis Group HF*, 567 F. Supp. 2d 711, 715 (D.N.J. 2008). Deference to the expertise of a particular agency in appropriate scenarios protects the integrity of the relevant regulatory scheme. *Id*. (citations omitted). The doctrine does not force courts to turn to agencies for expert advice nor abdicate their judicial function for all decisions touching on an agency's area of expertise. *Syntek*, 307 F.3d at 780.

The following factors are relevant in determining whether the doctrine applies: (1) whether the question at issue involves technical or policy considerations within the particular purview of an agency; (2) whether the question at issue is particularly within the agency's discretion; (3) whether there is a substantial danger of inconsistent rulings; and (4) whether a prior application to the agency

has been made. *Phone-Tel Commc'ns v. AT & T Corp.*, 100 F. Supp. 2d 313, 316 n.3 (E.D. Pa. 2000) (citations omitted). The party seeking to impose the primary jurisdiction doctrine bears the burden of demonstrating its application. *See id*. at 316. Courts should refrain from reflexively applying the doctrine simply because litigation touches on an area within the expertise of an agency. *Id*.

Defendants argue that the doctrine is applicable here because the issue of whether their products are as safe and effective as Wellbutrin is a matter requiring specialized knowledge and is thus better left to the FDA to decide. (Defs.' Br. at 18.) To support their argument, they rely on *Wyeth v. Sun Pharmaceutical Industries*, Civ. A. No. 09-11726, 2010 WL 746394 (E.D. Mich. Mar. 2, 2010). In *Sun*, the plaintiff made Protonix, a prescription drug for gastro-intestinal disorders. The defendants produced a generic version of Protonix. The plaintiff alleged that although the FDA had approved the defendants' generic product as containing sesquihydrate (the active ingredient in plaintiff's products), in reality, the defendants' generic product contained pantoprazole sodium monohydrate, a different active ingredient. *Id*. at *2. The plaintiff sued the defendants under the Lanham Act and Michigan's Consumer Protection Act for misrepresenting the active ingredient of their generic product. The court dismissed the plaintiff's complaint. It noted that the FDA had already commenced an investigation of the plaintiff's allegations. *Id*. at *3. The court believed that the plaintiff requested a finding either: (1) that the FDA erred or was misled in approving the defendants' ANDA, or (2) the defendants received FDA approval to market sesquihydrate yet instead sold a non-approved product with monohydrate as the active ingredient. *Id*. at *4. The court concluded that the FDA's approval of the defendants' ANDA was a matter for the FDA. *Id*. The allegations that the defendants were lying about the active ingredient in their product was "an

extremely serious allegation" and "it is solely the FDA's duty to investigate and prosecute allegations of misbranding or adulterating drugs." *Id*. Finally, the court refused to allow a challenge to the FDA's bioequivalence finding. *Id*. at *7. The case was dismissed without prejudice to allow the FDA to finish its investigation into the plaintiff's allegations. *Id*.

A number of differences between *Sun* and this case render it inapposite here. First, there was an ongoing investigation by the FDA in *Sun*. Second, Plaintiffs have stated that they "do not ask this Court to decide whether the Impax Product is 'bioequivalent to' Wellbutrin XL under federal regulatory standards." (Pls.' Mem. in Opp'n to Mot. to Dismiss at 24.) This case is about the content of the label on Defendants' products. Finally, in *Sun*, the name brand drug maker argued that its competitor lied about the active ingredient in the product sold by the generic drug maker. The Complaint here contains no such allegations that the generic manufacturers have perpetrated a fraud by mislabeling the active ingredient in their product. Plaintiffs' claim that they were injured when Defendants failed to disclose material information about their products. Plaintiffs' charges will not require this Court or a jury to decide what is in Defendants' medication. Instead, this case involves an inquiry that frequently falls upon judges and juries: whether a defendant gave an appropriate warning when it sold its product to the public.

The Court does not agree that, at this stage in the proceedings, the FDA's bioequivalence determination is at issue, nor would a judge or jury need to render scientific findings of facts to find for Plaintiffs on their fraud claim. Plaintiffs' fraud allegations do not implicate technical or specialized knowledge. Ultimately, an initial finding of bioequivalence by the FDA does not foreclose a jury's decision that Defendants failed to properly label their product. And awarding restitution would not require this Court or a jury to usurp the role of the drug maker or the FDA with

respect to labeling. *See Kellogg*, 612 F. Supp. 2d at 430, 435 ("[A] plaintiff's judgment in a damages action does not require a drug manufacturer defendant to do anything with respect to its label.") (citing *In re Zyprexa Prods. Liab. Litig.*, 489 F. Supp. 2d 230, 276-77 (S.D.N.Y. 2007)). The Court does not believe Plaintiffs' state-law claims are uniquely within the purview of the FDA nor do they risk contradicting an agency decision. If successful, however, Defendants' argument would stall lawsuits against drug makers because injured persons would first be required to take their claims against an FDA-approved drug to the FDA. The Court holds that the primary jurisdiction doctrine is not implicated at this time.

C. Pleading Fraud

Defendants also argue that Plaintiffs failed to plead their allegations of fraud with sufficient particularity as required by Rule 9(b) of the Federal Rules of Civil Procedure. (Defs.' Br. at 30-31.) Defendants contend that Plaintiffs failed to allege reliance on Defendants' purported fraud and omitted the "who," "where," "when," and "why" of the alleged fraud. (Defs.' Br. at 31.) These arguments cannot be squared with a fair reading of Plaintiffs' Complaint. Plaintiffs allege that Defendants' misrepresentations and material omissions failed to adequately inform them of problems with the generic medication that Defendants marketed. As a result, Plaintiffs allege that they spent money on medication they would not have purchased had they been properly informed by Defendants.

Rule 9(b) requires that a plaintiff plead the circumstances of the alleged fraud with enough particularity to put the defendants on notice of the precise misconduct with which they are charged. *Lum v. Bank of Am.*, 361 F.3d 217, 223-24 (3d Cir. 2004) (quoting *Seville Indus. Mach. Corp. v. Southmost Mach. Corp.*, 742 F.2d 786, 791 (3d Cir. 1984)). A plaintiff can do this by pleading the

date, time, and place surrounding the alleged fraud, but Rule 9(b) can also be satisfied through "alternate means of injecting precision and some measure of substantiation into their allegations of fraud." *Seville Indus.*, 742 F.2d at 791. Thus, this Court must be mindful that Rule 9(b) exists to prevent defendants from being forced to defend against shapeless allegations of nefarious behavior. It should not be read to include a checklist of necessities to avoid a motion to dismiss or read so narrowly as to make pleading fraud impossible. *See id*.

Plaintiffs have met their duty under Rule 9(b). They have adequately pleaded the factual circumstances of the alleged fraud. Defendants cannot persuasively argue that they lack notice of the specific conduct Plaintiffs alleged was fraudulent, to whom the conduct was directed, how the fraud was accomplished, and the reasons behind the fraud. Rule 9(b) requires no more. *See Stacel*, 620 F. Supp. 2d at 902.

Defendants' argument that Plaintiffs failed to allege specific misrepresentations is off-mark. Here, it is not simply what Defendants said but what they purportedly failed to say. They allegedly omitted material information that, had Plaintiffs been informed of, would have caused them to purchase different medication and would have spared them money and injury. Therefore, the argument that Plaintiffs could not have relied on information on the label because they viewed the label only after they purchased Defendants' products does not address the allegations in the Complaint. Furthermore, Plaintiffs continued to purchase Defendants' product, thus making information in the label a possible source of reliance.

Defendants also suggest that Plaintiffs cannot show materiality because the FDA's bioequivalence decision means that the generic drugs are the same as the listed drugs in all material ways. As stated previously, the FDA's prior determination does not foreclose a state law cause of

action here. Plaintiffs' Complaint amply pleads that Class members suffered injury when they bought Defendants' product, which left out important information. It further alleges that had Plaintiffs been presented with this information, they would not have purchased the offending product. The ultimate truth of these allegations is for a jury to decide. But because the Court must accept Plaintiffs' allegations as true at this stage, Defendants' contentions that Plaintiffs did not show reliance, causation, and materiality do not warrant dismissal of Plaintiffs' Complaint.

IV. CONCLUSION

The Supreme Court in *Levine* broadly and unequivocally held that state law complemented federal law to ensure that drug makers market and sell only safe and effective drugs. That holding applies here. State law causes of action do not frustrate Congressional intent with respect to the regulation of generic drugs. To the contrary, such litigation serves a vital role in furthering the goal of ensuring that only safe drugs reach the consumer. Congressional intent, recent case law, and public safety all overwhelmingly point to permitting Plaintiffs' claims to survive Defendants' preemption argument. Therefore, Defendants' motion is denied. An Order consistent with this Memorandum will be docketed separately.