

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF KENTUCKY  
NORTHERN DIVISION  
(at Covington)

IN RE: DARVOCET, DARVON AND  
PROPOXYPHENE PRODUCTS  
LIABILITY LITIGATION

Master File No. 2: 11-md-2226-DCR  
MDL Docket No. 2226

- Esposito v. Xanodyne Pharm., Inc., et al.,* ) Civil Action No. 2:11-175-DCR
- Corso v. Teva Pharm. USA, Inc., et al.,* ) Civil Action No. 2:11-179-DCR
- Alix v. Eli Lilly and Company, et al.,* ) Civil Action No. 2:11-182-DCR
- Smith v. Mylan Pharmaceuticals, Inc., et al.,* ) Civil Action No. 2:11-183-DCR
- Gilbert v. Eli Lilly and Company, et al.,* ) Civil Action No. 2:11-184-DCR
- Hunsucker v. Xanodyne Pharm., Inc., et al.,* ) Civil Action No. 2:11-185-DCR
- West v. Qualitest Pharm., Inc., et al.,* ) Civil Action No. 2:11-186-DCR
- Trimboli v. Xanodyne Pharm., Inc., et al.,* ) Civil Action No. 2:11-189-DCR
- Eldredge v. Xanodyne Pharm., Inc., et al.,* ) Civil Action No. 2:11-190-DCR
- Kellehar v. Xanodyne Pharm., Inc., et al.,* ) Civil Action No. 2:11-191-DCR
- Hallaway v. Eli Lilly and Company, et al.,* ) Civil Action No. 2:11-195-DCR
- Lowe v. Xanodyne Pharm., Inc., et al.,* ) Civil Action No. 2:11-196-DCR
- Coney v. Xanodyne Pharm., Inc., et al.,* ) Civil Action No. 2:11-197-DCR
- Kinter v. MI Holdings, Inc., et al.,* ) Civil Action No. 2:11-199-DCR
- Rogers v. Xanodyne Pharm., Inc., et al.,* ) Civil Action No. 2:11-200-DCR
- R. Knight v. Teva Pharm. USA, Inc., et al.,* ) Civil Action No. 2:11-201-DCR
- Oniate v. Eli Lilly and Company, et al.,* ) Civil Action No. 2:11-206-DCR
- Germain v. Teva Pharm. USA, Inc., et al.,* ) Civil Action No. 2:11-209-DCR
- Simpson v. Qualitest Pharm., Inc., et al.,* ) Civil Action No. 2:11-210-DCR
- Cook v. Teva Pharm. USA, Inc., et al.,* ) Civil Action No. 2:11-212-DCR
- Lynch v. Xanodyne Pharm., Inc., et al.,* ) Civil Action No. 2:11-213-DCR
- Turner v. Watson Pharm. (NJ), Inc., et al.,* ) Civil Action No. 2:11-221-DCR
- Dickerson v. Eli Lilly and Company, et al.,* ) Civil Action No. 2:11-295-DCR
- Labit v. Xanodyne Pharm., Inc., et al.,* ) Civil Action No. 2:11-296-DCR
- Balben v. Xanodyne Pharm., Inc., et al.,* ) Civil Action No. 2:11-297-DCR
- Forrest v. Xanodyne Pharm., Inc., et al.,* ) Civil Action No. 2:11-298-DCR
- Noel v. Xanodyne Pharm., Inc., et al.,* ) Civil Action No. 2:11-299-DCR
- Green v. Xanodyne Pharm., Inc., et al.,* ) Civil Action No. 2:11-300-DCR
- Wheeler v. Xanodyne Pharm., Inc., et al.,* ) Civil Action No. 2:11-301-DCR
- P. Knight v. Xanodyne Pharm., Inc., et al.,* ) Civil Action No. 2:11-307-DCR
- Del Favero v. Xanodyne Pharm., Inc., et al.,* ) Civil Action No. 2:11-311-DCR

*Blackwell v. Xanodyne Pharm., Inc., et al.,* ) Civil Action No. 2:11-312-DCR  
*Sandel v. Eli Lilly and Company, et al.,* ) Civil Action No. 2:11-325-DCR  
*Miller v. Eli Lilly and Company, et al.,* ) Civil Action No. 2: 11-352-DCR

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**MEMORANDUM OPINION AND ORDER REGARDING  
GENERIC DEFENDANTS’ MOTIONS TO DISMISS**

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This matter is pending for consideration of the joint Motion to Dismiss filed by Defendants Brenn Distribution, Inc.; Brenn Manufacturing, Inc.; Covidien, Inc.; Generics Bidco I, LLC; Generics Bidco II, LLC; Generics International (US Parent), Inc.; Generics International (US), Inc.; Mallinckrodt Holdings, LLC; Mallinckrodt, Inc.; Mylan Pharmaceuticals, Inc.; Mylan, Inc.; Propst Distribution, Inc.; Qualitest Pharmaceuticals, Inc.; Teva Biopharmaceuticals USA, Inc.; Teva Pharmaceuticals USA, Inc.; Vintage Pharmaceuticals, Inc.; Vintage Pharmaceuticals, LLC; Watson Pharmaceuticals (New Jersey), Inc.; and Watson Pharmaceuticals, Inc. (collectively, “the Generic Defendants”).<sup>1</sup> [Record No. 383] Also pending is the Generic Defendants’ First Supplemental Motion to Dismiss. [Record No. 458] The Generic Defendants argue that the claims asserted against them are preempted by federal law pursuant to the Supreme Court’s recent decision in *Pliva v. Mensing*, 131 S. Ct. 2567 (2011). For the reasons explained below, their motions to dismiss will be granted.

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<sup>1</sup> Not all of the Generic Defendants have moved for dismissal in all cases covered by the current motions. Instead, the motions — and, therefore, this Memorandum Opinion and Order — relate to those cases and defendants identified in Appendix A [Record No. 383-1] and First Supplemental Appendix A [458-1] to the motions. [See Record No. 383, p. 2 n.1; Record No. 458, p. 1 n.1; see also Record No. 1038, p. 15 (seeking dismissal as set forth in Appendix A and First Supplemental Appendix A).]

## I. BACKGROUND<sup>2</sup>

This multidistrict litigation (“MDL”) arises from injuries the plaintiffs or their decedents allegedly suffered as a result of ingesting propoxyphene, a prescription pain medication sold under the brand names Darvon and Darvocet as well as in generic form. Shortly before the MDL proceedings were transferred to this Court, the United States Supreme Court issued its decision in *Mensing*, holding that federal law, which requires warning labels on generic drugs to match those of the corresponding brand-name drugs, preempted the plaintiffs’ state-law failure-to-warn claims against generic drug manufacturers. *See* 131 S Ct. at 2572. Because state law placed a duty “on all drug manufacturers to adequately and safely label their products,” while federal law “prevented [generic] [m]anufacturers from independently changing their drugs’ safety labels,” *id.* at 2577, it was impossible for generic manufacturers to comply with both state and federal law. *Id.* at 2578. In other words, generic manufacturers’ state-law duty to strengthen the drug labels directly conflicted with their “ongoing federal duty of sameness.” *Id.* at 2575; *see id.* at 2578. Thus, under the doctrine of impossibility preemption, the Supremacy Clause mandated that state law must “give way.” *Id.* at 2577.

The plaintiffs in this MDL were permitted to amend their complaints following publication of the *Mensing* decision. [See Record No. 198] In their amended complaints, the plaintiffs generally allege the following claims against the Generic Defendants: design defect (strict liability), defect due to inadequate warning (strict liability), negligent design, negligence,

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<sup>2</sup> A more complete discussion of the facts underlying this action is contained in the Court’s Memorandum Opinion and Order, also entered this date, addressing Defendant Xanodyne Pharmaceuticals, Inc.’s consolidated motions to dismiss.

negligent failure to warn, fraudulent nondisclosure, negligent misrepresentation, fraudulent misrepresentation, statutory negligence, breach of express warranty, and breach of implied warranty.<sup>3</sup>

## II. ANALYSIS

The plaintiffs maintain that *Mensing* is inapplicable to their amended claims, primarily because they “are not contending that the Generic Defendants should have added new, unapproved warnings about propoxyphene’s risks,” but rather “that the Generic Defendants knew their product was unreasonably dangerous and should have voluntarily withdrawn it from the market.”<sup>4</sup> [Record No. 568, p. 13] Thus, the “central claim,” according to the plaintiffs, “is that Defendants wrongfully marketed an unreasonably dangerous product.” [*Id.*] But no matter how they frame their allegations, the plaintiffs cannot avoid *Mensing*’s effect.

### A. Wrongful Marketing

According to the plaintiffs, their “wrongful marketing” claims include design defect, negligent design, negligence, and breach of implied warranty. [*Id.* at 15] They point to two Sixth Circuit decisions, *Wimbush v. Wyeth*, 619 F.3d 632 (6th Cir. 2010), and *Tobin v. Astra*

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<sup>3</sup> The parties cite the Amended Complaint filed in *Alix v. Eli Lilly and Company*, Civil Action No. 2:11-182 [Record No. 287], as representative of the plaintiffs’ amended complaints. [*See* Record No. 383-2, p. 21 n.11; Record No. 568, p. 9 n.1.] Accordingly, in this opinion, references to the plaintiffs’ claims are based on the *Alix* Amended Complaint.

<sup>4</sup> Plaintiffs Yanise and Jackson Germain individually oppose the Generic Defendants’ motion to dismiss on the ground that it is not timely. [*See* Record No. 571.] Specifically, they argue that Defendant Teva Pharmaceuticals USA, Inc. may not properly move to dismiss under Rule 12(b)(6) because it has already filed an answer. [*Id.*, p. 4] They acknowledge, however, that the Court may construe the motion as one for judgment on the pleadings pursuant to Rule 12(c). [*Id.*] The Court finds that to be the appropriate course.

*Pharmaceutical Products, Inc.*, 993 F.2d 528 (6th Cir. 1993), that supposedly constitute “controlling precedent” requiring the Court to find against preemption. [Record No. 568, p. 16] In *Wimbush* and *Tobin*, the Sixth Circuit concluded that state-law tort claims were not preempted by the Food, Drug and Cosmetic Act (“FDCA”). See 619 F.3d at 646; 993 F.2d at 537. Both cases were decided prior to *Mensing*, however. More importantly, neither involved a generic manufacturer.<sup>5</sup>

The question in *Wimbush* and *Tobin* was whether initial approval of a drug by the federal Food and Drug Administration (“FDA”) resulted in preemption of state-law tort claims based on the brand-name manufacturer’s alleged wrongdoing “in the process leading up to . . . approval.” *Wimbush*, 619 F.3d at 643; see *id.* at 642 (“As the district court framed it, the issue is whether a state-court finding that a manufacturer was negligent in bringing the drug to market conflicts or is inconsistent with the FDA’s subsequent approval of that drug for the market.”); *Tobin*, 993 F.2d at 537 (rejecting defendants’ contention that allowing state products liability claims amounted to “a mockery of the scientific analysis employed by the FDA and the Advisory Committee which conclusively found that [the drug] was efficacious” (internal quotation marks omitted)). Here, by contrast, the conflict between state and federal law arises out of the sameness requirement imposed on generic manufacturers by the FDCA after the drug is approved. As the *Mensing* Court recognized, this distinction is significant.

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<sup>5</sup> Likewise, all but one of the other cases cited by the plaintiffs on this point involved brand-name manufacturers, and all were decided before *Mensing*. [See Record No. 568, p. 19 (citing cases from the Second, Fourth, Fifth, and Tenth Circuits, as well as the Southern District of Indiana, District of New Hampshire, and Eastern District of Virginia).]

It is beyond dispute that the federal statutes and regulations that apply to brand-name drug manufacturers are meaningfully different than those that apply to generic drug manufacturers. Indeed, it is the special, and different, regulation of generic drugs that allowed the generic drug market to expand, bringing more drugs more quickly and cheaply to the public. But different federal statutes and regulations may, as here, lead to different pre-emption results.<sup>6</sup>

131 S. Ct. at 2582; *see id.* at 2581 & n.8 (distinguishing *Wyeth*, 555 U.S. 555). In short, the Court agrees with the Generic Defendants that *Wimbush* and *Tobin*, “which involve different legal theories, implicate a different regulatory scheme, and were decided prior to *Mensing*, are inapposite.” [Record No. 1038, p. 10]

This leaves the plaintiffs’ contention that there is no conflict between state and federal law (and thus, no preemption) because the Generic Defendants were always free to simply remove propoxyphene products from the market. [See Record No. 568, pp. 15-24.] The *Mensing* plaintiffs made the same argument, without success, in their petition for rehearing. *See* Respondents’ Petition for Rehearing, *Pliva, Inc. v. Mensing*, 131 S. Ct. 2567 (July 18, 2011) (No. 09-993), 2011 U.S. S. Ct. Briefs LEXIS 878, at \*3-6. And on remand, the Eighth Circuit interpreted *Mensing* to encompass such claims, vacating the portion of its earlier opinion that embraced the failure-to-withdraw theory and denying the plaintiff’s motion to file a supplemental brief on that issue, among others. *See Mensing v. Wyeth, Inc.*, 658 F.3d 867 (8th Cir. 2011), *and* 588 F.3d 603, 611 (8th Cir. 2009) (“The generic defendants were not compelled to market metoclopramide. If they realized their label was insufficient but did not believe they could even propose a label change, they could have simply stopped selling the product.”);

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<sup>6</sup> For this reason, Plaintiff Cook’s contention that the Court should follow *Wyeth v. Levine*, 555 U.S. 555 (2009), which held that failure-to-warn claims against a brand-name drug manufacturer were not preempted, is without merit. [See Record No. 577.]

Appellant Gladys Mensing’s Motion for Leave to File a Supplemental Brief at 4-5, *Mensing*, 658 F.3d 867 (Sept. 8, 2011) (No. 08-3850). The Sixth Circuit was likewise unpersuaded by the post-*Mensing* failure-to-withdraw argument. *See Smith v. Wyeth, Inc.*, 657 F.3d 420, 423 (6th Cir. 2011); Appellants’ Supplemental Letter Brief Regarding *Pliva, Inc. v. Mensing* at 5-6, *Smith*, 657 F.3d 420 (Aug. 15, 2011) (Nos. 09-5460, 09-5466, 09-5509); *see also Gross v. Pfizer, Inc.*, No. 10-cv-00110-AW, 2011 U.S. Dist. LEXIS 134895, at \*8-9 (D. Md. Nov. 22, 2011) (noting rejection of failure-to-withdraw argument in *Mensing* and *Smith*).

While the plaintiffs attempt to get around *Mensing* by asserting “failure to withdraw” rather than failure to warn, they have not demonstrated that their so-called wrongful marketing claims escape preemption.<sup>7</sup> The claims — strict liability design defect, negligent design, negligent marketing, and breach of implied warranty — are all based on the allegedly defective design of the drug, which the Generic Defendants, bound by their “ongoing federal duty of sameness,” were powerless to change. *Mensing*, 131 S. Ct. at 2575. And as the Generic Defendants observe, the idea that they should have simply stopped selling propoxyphene is an oversimplified solution that could apply anytime the issue of impossibility preemption arises: avoid a conflict between state and federal law by withdrawing from the regulated conduct altogether. *Cf. id.* at 2579 (“Accepting [the plaintiffs’] argument would render conflict preemption largely meaningless because it would make most conflicts between state and federal law

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<sup>7</sup> That the plaintiffs have merely repackaged their failure-to-warn claims is evident from the second paragraph of the *Alix* Amended Complaint, which summarizes the new allegations as follows: “Plaintiff alleges that Defendants knowingly or negligently marketed and sold defectively designed Propoxyphene Products *without adequate warnings*.” [Record No. 287, p. 2 ¶ 2 (emphasis added)]

illusory.”). [See Record No. 383-2, p. 32; Record No. 1038, p. 9.] Moreover, as noted previously, the failure-to-withdraw argument was rejected by the *Mensing* Court, the Eighth Circuit following *Mensing*’s remand, and the Sixth Circuit in *Smith*. This Court likewise rejects the plaintiffs’ arguments. Accordingly, these claims will be dismissed.

### **B. Failure to Warn**

The plaintiffs assert that *Mensing* does not preclude warning claims premised on the Generic Defendants’ alleged failure to timely change the labeling on their propoxyphene products after July 2009, when the FDA ordered Xanodyne to strengthen the label. [See Record No. 568, pp. 31-33.] At least two courts have found, since *Mensing*, that generic manufacturers may be liable for failure to warn if the FDA had already approved a label change — *i.e.*, if it would not have been impossible for the generic manufacturer to comply with both state and federal law. See *Lyman v. Pfizer, Inc.*, No. 2:09-cv-262, 2012 U.S. Dist. LEXIS 13185, at \*16-19 (D. Vt. Feb. 3, 2012); *Fisher v. Pelstring*, No. 4:09-cv-00252-TLW, 2011 U.S. Dist. LEXIS 116162, at \*12 (D.S.C. Sept. 30, 2011). Both cases, however, involved metoclopramide (the drug at issue in *Mensing*), which the generic manufacturer acknowledged did not bear a strengthened warning approved by the FDA in 2004. See *Fisher*, 2011 U.S. Dist. LEXIS 116162, at \*12 (“[The] possible deviation in PLIVA’s label for generic metoclopramide, *which both parties indicate exists*, is sufficient to conclude the plaintiffs’ claims are not entirely preempted.” (emphasis added)).

There is no such consensus in this case. Instead, the sole indication that a failure to update occurred is the following vague allegation:



The FDA mandate [to Xanodyne] likewise effectively required the Generic Defendants to issue the Black Box warning and label changes, but upon information and belief, the Generic Defendants did not timely implement the Black Box warning or revise the labels for their [p]ropoxyphene [p]roducts, or publish the information in the [Physicians' Desk Reference], or communicate the information to prescribing physicians in Dear Health Care Professional letters or by other means.

[See Record No. 287, p. 43 ¶ 205; see also *id.*, p. 19 ¶ 96, p. 51 ¶ 241, p. 57 ¶ 258 (same).]

Regardless of any preemption issues, the plaintiffs are still subject to basic pleading requirements. Thus, their complaints “must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). The plausibility standard is met “when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* (citing *Twombly*, 550 U.S. at 556). It requires “more than a sheer possibility that a defendant has acted unlawfully.” *Id.*

Under this standard, the plaintiffs’ conclusory allegations, which consist of “pure conjecture” that generic propoxyphene labels were not timely updated, fail. *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig. (No. II)*, No. 08-008 (GEB-LHG), 2011 U.S. Dist. LEXIS 135006, at \*38 (D.N.J. Nov. 21, 2011) (“That a failure to timely update [drug] labeling ‘could have occurred’ is nothing ‘more than a sheer possibility’ and is not ‘sufficient to state a claim for relief.’” (quoting *Iqbal*, 129 S. Ct. at 1949)). Here, the complaints do not: (1) identify which of the Generic Defendant(s) allegedly failed to make the label changes; (2) elaborate on the allegation of untimeliness (*e.g.*, length of delay or why it was unreasonable); or (3) explain

how any alleged failure to update injured the plaintiffs. The plaintiffs thus have offered “nothing ‘more than a sheer possibility’” that one or more of the Generic Defendants may have failed to timely update the labeling on propoxyphene products after July 2009 and that the plaintiffs were injured as a result. *Id.* (quoting *Iqbal*, 129 S. Ct. at 1949). Preemption issues aside, these claims cannot withstand the Generic Defendants’ motion to dismiss.<sup>8</sup> To the extent the plaintiffs seek to hold the Generic Defendants liable for failing to communicate the 2009 label change to health care professionals, their allegations are similarly deficient.<sup>9</sup>

Finally, the plaintiffs assert that Defendants Mylan Pharmaceuticals, Inc.; Mylan, Inc. (collectively “Mylan”); and Watson Pharmaceuticals, Inc. are not protected by *Mensing* because they were the reference listed drug (“RLD”) holders for certain propoxyphene products. [See Record No. 568, pp. 35-37.] The Generic Defendants do not dispute that Mylan and Watson were RLD holders. However, they point to FDA publications indicating that the FDA, not the RLD holder, controls label changes if the new drug application (“NDA”) holder has removed its product from the market for reasons other than safety or effectiveness. *See, e.g.,*

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<sup>8</sup> It appears that *Mensing* would apply to the failure-to-update claims in any event, as the *Mensing* Court, the Eighth Circuit on remand in *Mensing*, and the Sixth Circuit in *Smith* were presented with similar arguments and nevertheless found the plaintiffs’ failure-to-warn claims to be preempted.

<sup>9</sup> In any event, the *Mensing* Court, adopting the FDA’s interpretation of its regulations, recognized that generic manufacturers are not free to send “Dear Doctor” letters containing new drug warning information, as such letters “would inaccurately imply a therapeutic difference between the brand and generic drugs and thus could be impermissibly ‘misleading.’” 131 S. Ct. at 2576 (citing 21 C.F.R. § 314.150(b)(3)). Several courts have held failure-to-communicate claims to be preempted in light of this statement from *Mensing*. *See, e.g., Gross*, 2011 U.S. Dist. LEXIS 134895, at \*10-11; *In re Fosamax*, 2011 U.S. Dist. LEXIS 135006, at \*29-30. Furthermore, as the Generic Defendants note, similar claims failed to sway either the Eighth Circuit on remand in *Mensing* or the Sixth Circuit in *Smith*. [See Record No. 383-2, p. 26.]

Determination That Brethine (Terbutaline Sulfate) Injection Was Not Withdrawn from Sale for Reasons of Safety or Effectiveness, 72 Fed. Reg. 39,629 (July 12, 2007) (“If the FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise [Abbreviated New Drug Application] applicants to submit such labeling.”). Further, they cite a recent federal case in which the same argument was rejected. *See Moore v. Mylan, Inc.*, No. 1:11-CV-03037-MHS, 2012 U.S. Dist. LEXIS 6897, at \*20-25 (N.D. Ga. Jan. 5, 2012). The plaintiffs, meanwhile, provide no authority to support their contention that when a generic drug manufacturer becomes an RLD holder, it is thereby empowered to independently change the drug’s warning label. Thus, the Court is unpersuaded that Mylan and Watson are subject to liability based on their status as RLD holders.

**C. Misrepresentation, Fraud, Consumer Protection, Express Warranty, and Statutory Negligence**

All remaining claims relate to the sufficiency of the warnings on propoxyphene products and, therefore, are preempted in accordance with *Mensing*. As the plaintiffs admit, their fraud, misrepresentation, and consumer-protection claims challenge label content. [See Record No. 568, p. 39 n.20 (“Plaintiffs have alleged that these claims relate to misrepresentations on the products['] labeling . . . .”); see Record No. 287, p. 62 ¶ 272 (describing representations allegedly made by the Generic Defendants “in their instructional materials and labeling”); see *also id.*, p. 67 ¶ 287 (same).] Because the Generic Defendants were required to conform their labeling to that of the brand-name drugs, they could not have corrected any alleged misrepresentation without running afoul of federal law. *Cf. Mensing*, 131 S. Ct. at 2577-78.

Likewise, any express warranty contained in the labeling was beyond the Generic Defendants' control.<sup>10</sup> These claims are therefore preempted per *Mensing*.

The plaintiffs' claim of statutory negligence is also preempted. Although they state in their response that this claim "assert[s] only traditional state common law causes of action" [Record No. 568, p. 41], as described in the complaint, it is premised on the Generic Defendants' alleged "violat[ion of] federal standards for the sale of prescription drugs set forth in the [FDCA]." [Record No. 287, p. 69 ¶ 300; *see id.*, p. 70 ¶ 301 (same)] The count includes a laundry list of federal regulations, mostly relating to labeling or "misbranding," allegedly violated by the Generic Defendants. [*See id.*, pp. 70-71 ¶¶ 301(a)-(i).] Such claims are precluded by *Mensing* insofar as they challenge the content of generic drug labels.

To the extent the plaintiffs allege that the Generic Defendants failed to comply with the FDCA or FDA regulations, their claim is preempted pursuant to *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). In *Buckman*, the Supreme Court held that because the exclusive power to enforce the FDCA rests with the FDA, state-law claims "based on failure to properly communicate with the FDA" were preempted. *Mensing*, 131 S. Ct. at 2578 (citing *Buckman*, 531 U.S. 341). Because there is no private right to enforce the FDCA, *see Buckman*, 531 U.S. at 349 n.4, the plaintiffs' statutory negligence claim, which is based solely on alleged FDCA violations, must fail. Finally, the plaintiffs acknowledge that if their underlying tort claims are preempted, their derivative claims — *e.g.*, wrongful death, survivorship, unjust

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<sup>10</sup> Again, the plaintiffs insist that precedent is on their side but cite cases that are not on point: *Altria Group, Inc. v. Good*, 555 U.S. 70 (2008), *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005), and *Cipollone v. Liggett Group*, 505 U.S. 504 (1992), dealt with express preemption, not impossibility preemption.

enrichment, and loss of consortium — likewise cannot survive the Generic Defendants’ motions to dismiss. [See Record No. 568, p. 42.]

#### **D. Discovery/Amendment of Complaints**

The Court rejects the plaintiffs’ contention that they should be allowed discovery and another chance to amend their complaints. “Plaintiffs [are] not entitled to an advisory opinion from the Court informing them of the deficiencies of the complaint and then an opportunity to cure those deficiencies.” *Winget v. JP Morgan Chase Bank, N.A.*, 537 F.3d 565, 573 (6th Cir. 2008) (alteration in original) (internal quotation marks omitted). Under *Iqbal*, plaintiffs are not permitted to conduct discovery in order to fix factually deficient complaints, even where the necessary information is within the defendant’s exclusive possession. *New Albany Tractor, Inc. v. Louisville Tractor, Inc.*, 650 F.3d 1046, 1051 (6th Cir. 2011) (citing *Iqbal*, 129 S. Ct. at 1954). Rather, in such cases, dismissal with prejudice is proper. *See id.* at 1053.

Furthermore, the Court should deny leave to amend a pleading if amendment would be futile. *Winget*, 537 F.3d at 573. Counsel for the plaintiffs acknowledged at oral argument that if the Court found their claims to be preempted, there would be no reason to amend the complaints. Likewise, insofar as certain plaintiffs individually opposed the Generic Defendants’ motions to dismiss on the ground that they had not had an opportunity to amend their complaints to conform to the “master complaint” (*i.e.*, the *Alix* Amended Complaint), the futility of such an amendment renders their request moot. [See Record No. 574.]

### **III. CONCLUSION**

In accordance with this memorandum opinion, it is hereby

**ORDERED** that the Generic Defendants' Motion to Dismiss [MDL Record No. 383] and First Supplemental Motion to Dismiss [MDL Record No. 458] are **GRANTED**. Subject to previous orders,<sup>11</sup> the claims asserted against the following defendants in the following actions are **DISMISSED**, with prejudice:

- [Civil Action No. 2: 11-175; Record No. 85]: Defendant Teva Pharmaceuticals USA, Inc.;
- [Civil Action No. 2: 11-179; Record No. 49]: Defendant Teva Pharmaceuticals USA, Inc.;
- [Civil Action No. 2: 11-182; Record No. 76]: Defendant Qualitest Pharmaceuticals, Inc. and Defendant Vintage Pharmaceuticals, Inc.;
- [Civil Action No. 2: 11-183; Record No. 45]: Defendant Propst Distribution, Inc., formerly known as Qualitest Pharmaceuticals, Inc.; Defendant Mylan Pharmaceuticals Inc.; Defendant Teva Biopharmaceuticals USA, Inc.; and Defendant Vintage Pharmaceuticals, LLC;
- [Civil Action No. 2: 11-184; Record No. 32]: Defendant Brenn Distribution, Inc., formerly known as Qualitest Pharmaceuticals, Inc.; Defendant Brenn Manufacturing, Inc., formerly known as Vintage Pharmaceuticals, Inc.; Defendant Vintage Pharmaceuticals, LLC; Defendant Generics International (US), Inc.; Defendant Generics Bidco I, LLC; Defendant Generics Bidco II, LLC; and Defendant Generics International (US Parent), Inc.;

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<sup>11</sup> The Court recognizes that some of the defendants listed have already been dismissed voluntarily.

- [Civil Action No. 2: 11-185; Record Nos. 68 and 105]: Defendants Mylan Inc.; Defendant Watson Pharmaceuticals, Inc.; Defendant Teva Pharmaceuticals USA, Inc.; Defendant Vintage Pharmaceuticals, LLC; Defendant Generics International (US), Inc.; Defendant Generics Bidco I, LLC; Defendant Generics Bidco II, LLC; Defendant Generics International (US Parent), Inc.; Defendant Brenn Distribution, Inc., formerly known as Qualitest Pharmaceuticals, Inc.; Defendant Propst Distribution, Inc., formerly known as Qualitest Pharmaceuticals, Inc.; Defendant Brenn Manufacturing, Inc., formerly known as Vintage Pharmaceuticals, Inc.; Defendant Covidien Inc.; and Defendant Mallinckrodt Inc.;
- [Civil Action No. 2: 11-186; Record Nos. 51 and 89]: Defendant Teva Biopharmaceuticals USA, Inc., misnamed as Teva Biopharmaceuticals, Inc.; Defendant Covidien Inc.; Defendant Mallinckrodt Inc.; Defendant Qualitest Pharmaceuticals, Inc.; Brenn Distribution, Inc., formerly known as Qualitest Pharmaceuticals, Inc.; Propst Distribution, Inc., formerly known as Qualitest Pharmaceuticals, Inc.; Brenn Manufacturing, Inc., formerly known as Vintage Pharmaceuticals, Inc.; Mylan, Inc.; Vintage Pharmaceuticals, LLC; Generics International (US), Inc.; Generics Bidco I, LLC; Generics Bidco II, LLC; Generics International (US Parent), Inc.; Watson Pharmaceuticals, Inc.; and Teva Pharmaceuticals USA, Inc.;
- [Civil Action No. 2: 11-189; Record Nos. 68 and 98]: Defendant Qualitest Pharmaceuticals, Inc.; Defendant Propst Distribution, Inc., formerly known as

Qualitest Pharmaceuticals, Inc.; Defendant Generics International (US), Inc.; Defendant Generics International (US Parent), Inc.; Defendant Generics Bidco I, LLC; Defendant Vintage Pharmaceuticals, LLC; Defendant Generics Bidco II, LLC; Defendant Vintage Pharmaceuticals, Inc.; Defendant Brenn Manufacturing, Inc., formerly known as Vintage Pharmaceuticals, Inc.; and Defendant Brenn Distribution, Inc., formerly known as Qualitest Pharmaceuticals, Inc.;

- [Civil Action No. 2: 11-190; Record Nos. 78, 99 and 100]: Defendant Generics Bidco I, LLC; Defendant Vintage Pharmaceuticals, LLC; Defendant Propst Distribution, Inc., formerly known as Qualitest Pharmaceuticals, Inc.; Defendant Covidien, Inc.; Defendant Mallinckrodt, Inc.; Defendant Generics International (US), Inc.; Defendant Generics International (US Parent), Inc.; Defendant Generics Bidco II, LLC; Defendant Brenn Manufacturing, Inc., formerly known as Vintage Pharmaceuticals, Inc.; Defendant Brenn Distribution, Inc., formerly known as Qualitest Pharmaceuticals, Inc.; and Defendant Vintage Pharmaceuticals, Inc.;
- [Civil Action No. 2: 11-191; Record Nos. 56 and 98]: Defendant Mylan Inc.; Defendant Brenn Distribution, Inc., formerly known as Qualitest Pharmaceuticals, Inc.; Defendant Propst Distribution, Inc., formerly known as Qualitest Pharmaceuticals, Inc.; Defendant Brenn Manufacturing, Inc., formerly known as Vintage Pharmaceuticals, Inc.; Defendant Vintage Pharmaceuticals, LLC; Defendant Generics International (US), Inc.; Defendant Generics Bidco I, LLC;



Defendant Generics Bidco II, LLC; Defendant Generics International (US Parent), Inc.; Defendant Teva Pharmaceuticals USA, Inc.; Defendant Watson Pharmaceuticals, Inc.; Defendant Teva Biopharmaceuticals USA, Inc., misnamed Teva Biopharmaceuticals, Inc.; Defendant Covidien Inc.; and Defendant Mallinckrodt Inc.;

- [Civil Action No. 2: 11-195; Record Nos. 71 and 87]: Defendant Qualitest Pharmaceuticals; Defendant Vintage Pharmaceuticals, Inc.; Defendant Vintage Pharmaceuticals, LLC; Defendant Generics International (US), Inc.; Defendant Generics Bidco I, LLC; Defendant Generics Bidco II, LLC; Defendant Generics International (US Parent), Inc.; Defendant Mylan Inc.; Defendant Watson Pharmaceuticals, Inc.; Defendant Teva Pharmaceuticals USA, Inc.; Defendant Teva Biopharmaceuticals USA, Inc., misnamed as Teva Biopharmaceuticals, Inc.; Defendant Brenn Distribution, Inc., formerly known as Qualitest Pharmaceuticals, Inc.; Defendant Propst Distribution, Inc., formerly known as Qualitest Pharmaceuticals, Inc.; Defendant Covidien Inc.; and Defendant Mallinckrodt Inc.;
- [Civil Action No. 2: 11-196; Record Nos. 41 and 51]: Defendant Covidien, Inc. and Defendant Mallinckrodt Holdings, LLC;
- [Civil Action No. 2: 11-197; Record Nos. 66 and 104]: Defendant Teva Pharmaceuticals USA, Inc.; Defendant Mylan Inc.; Defendant Brenn Distribution, Inc., formerly known as Qualitest Pharmaceuticals, Inc.; Defendant Propst Distribution, Inc., formerly known as Qualitest Pharmaceuticals, Inc.; Defendant

Brenn Manufacturing, Inc., formerly known as Vintage Pharmaceuticals, Inc.; Defendant Vintage Pharmaceuticals, LLC; Defendant Generics International (US), Inc.; Defendant Generics Bidco I, LLC; Defendant Generics Bidco II, LLC; Defendant Generics International (US Parent), Inc.; Defendant Watson Pharmaceuticals, Inc.; Defendant Covidien Inc.; Defendant Mallinckrodt Inc.; and Defendant Teva Biopharmaceuticals USA, misnamed as Teva Biopharmaceuticals, Inc.;

- [Civil Action No. 2: 11-199; Record Nos. 36 and 40]: Defendant Covidien, Inc. and Defendant Mallinckrodt, Inc.;
- [Civil Action No. 2: 11-200; Record No. 41]: Defendant Teva Pharmaceuticals USA, Inc.; Defendant Vintage Pharmaceuticals, LLC; Defendant Generics International (US), Inc.; Defendant Generics Bidco I, LLC; and Defendant Generics International (US Parent), Inc.;
- [Civil Action No. 2: 11-201; Record No. 41]: Defendant Teva Pharmaceuticals USA, Inc.;
- [Civil Action No. 2: 11-206; Record No. 67]: Defendant Vintage Pharmaceuticals, Inc. and Defendant Qualitest Pharmaceuticals, Inc.;
- [Civil Action No. 2: 11-209; Record No. 37]: Defendant Teva Pharmaceuticals USA, Inc.;
- [Civil Action No. 2: 11-210; Record No. 48]: Defendant Vintage Pharmaceuticals, LLC and Defendant Generics Bidco I, LLC;

- [Civil Action No. 2: 11-212; Record No. 32]: Defendant Vintage Pharmaceuticals, LLC and Defendant Teva Pharmaceuticals USA, Inc.;
- [Civil Action No. 2: 11-213; Record No. 58 and 79]: Defendant Qualitest Pharmaceuticals, Inc.; Defendant Generics Bidco II, LLC; Defendant Vintage Pharmaceuticals LLC; Defendant Generics International (US), Inc.; Defendant Generics Bidco I, LLC; Generics International (US Parent), Inc.; Defendant Brenn Manufacturing, Inc., formerly known as Vintage Pharmaceuticals, Inc.; and Defendant Brenn Distribution, Inc., formerly known as Qualitest Pharmaceuticals, Inc.;
- [Civil Action No. 2: 11-221; Record No. 30]: Defendant Watson Pharmaceuticals (New Jersey), Inc.;
- [Civil Action No. 2: 11-295; Record Nos. 17, 49, and 56]: Defendant Generics Bidco II, LLC; Defendant Vintage Pharmaceuticals, LLC; Defendant Generics International (US), Inc.; Defendant Generics Bidco I, LLC; Defendant Generics International (US Parent), Inc.; Defendant Mylan Inc.; Defendant Qualitest Pharmaceuticals, Inc.; Defendant Brenn Manufacturing, Inc., formerly known as Vintage Pharmaceuticals, Inc.; and Defendant Brenn Distribution, Inc., formerly known as Qualitest Pharmaceuticals, Inc.;
- [Civil Action No. 2: 11-296; Record Nos. 35, 57, 67, and 73]: Defendant Mylan Inc.; Defendant Generics Bidco II, LLC; Defendant Teva Pharmaceuticals USA,

Inc.; Defendant Watson Pharmaceuticals, Inc.; Defendant Mylan Pharmaceuticals Inc.; Defendant Covidien Inc.; and Defendant Mallinckrodt Inc.;

- [Civil Action No. 2: 11-297; Record Nos. 37, 60, and 75]: Defendant Mylan Inc.; Defendant Generics Bidco II, LLC; Defendant Teva Pharmaceuticals USA, Inc.; Defendant Watson Pharmaceuticals, Inc.; Defendant Mylan Pharmaceuticals Inc.; Defendant Covidien Inc.; and Defendant Mallinckrodt Inc.;
- [Civil Action No. 2: 11-298; Record Nos. 31, 52, and 69]: Defendant Mylan Inc.; Defendant Generics Bidco II, LLC; Defendant Teva Pharmaceuticals USA, Inc.; Defendant Watson Pharmaceuticals, Inc.; Defendant Mylan Pharmaceuticals Inc.; Defendant Covidien Inc.; and Defendant Mallinckrodt Inc.;
- [Civil Action No. 2: 11-299; Record Nos. 31, 52, and 69]: Defendant Mylan Inc.; Defendant Generics Bidco II, LLC; Defendant Teva Pharmaceuticals USA, Inc.; Defendant Watson Pharmaceuticals, Inc.; Defendant Mylan Pharmaceuticals Inc.; Defendant Covidien Inc.; and Defendant Mallinckrodt Inc.;
- [Civil Action No. 2: 11-300; Record Nos. 33, 55, 65, and 70]: Defendant Mylan Inc.; Defendant Generics Bidco II, LLC; Defendant Teva Pharmaceuticals USA, Inc.; Defendant Watson Pharmaceuticals, Inc.; Defendant Mylan Pharmaceuticals Inc.; Defendant Covidien Inc.; and Defendant Mallinckrodt Inc.;
- [Civil Action No. 2: 11-301; Record Nos. 31, 52, and 69]: Defendant Mylan Inc.; Defendant Generics Bidco II, LLC; Defendant Teva Pharmaceuticals USA, Inc.;

Defendant Watson Pharmaceuticals, Inc.; Defendant Mylan Pharmaceuticals Inc.;  
Defendant Covidien Inc.; and Defendant Mallinckrodt Inc.;

- [Civil Action No. 2: 11-307; Record No. 15]: Defendant Brenn Distribution, Inc., formerly known as Qualitest Pharmaceuticals, Inc.;
- [Civil Action No. 2: 11-311; Record No. 16] Defendant Brenn Distribution, Inc., formerly known as Qualitest Pharmaceuticals, Inc.;
- [Civil Action No. 2: 11-312; Record No. 15]: Defendant Brenn Distribution, Inc., formerly known as Qualitest Pharmaceuticals, Inc.; and
- [Civil Action No. 2: 11-325; Record No. 8]: Defendant Qualitest Pharmaceuticals, Inc.

Additionally, the motions to dismiss filed by Defendants Covidien, Inc. and Mallinckrodt, Inc. [MDL Record No. 674] and Defendants Mylan, Inc. and Mylan Pharmaceuticals, Inc. [MDL Record No. 684] in Civil Action No. 2: 11-352, which are based on the same arguments addressed herein, are likewise **GRANTED**. The claims asserted against Defendants Covidien, Inc.; Mallinckrodt, Inc.; Mylan, Inc.; and Mylan Pharmaceuticals, Inc. by Plaintiff Marcia Miller are **DISMISSED**, with prejudice.

In light of the Court's resolution of the Generic Defendants' joint motions to dismiss, the supplemental Motions to Dismiss filed by Defendants Covidien, Inc.; Mallinckrodt, Inc.; and/or Mallinckrodt Holdings, LLC [MDL Record Nos. 459, 469, 474, 542, 544, 546, 555, 557, and 559]; Teva Pharmaceuticals USA, Inc. [MDL Record Nos. 462, 561, 562, 563, 564, 565, and

566]; Teva Biopharmaceuticals USA, Inc. [MDL Record No. 567]; and Mylan, Inc. and/or Mylan Pharmaceuticals, Inc. [MDL Record Nos. 503, 517, and 520] are **DENIED** as moot.

Finally, because the plaintiffs' proposed First Supplemental and Amended Complaints in Civil Action Nos. 2: 11-307, 2: 11-311, and 2: 11-312 seek to assert claims against defendants dismissed from this action under the rationale set forth above and in other opinions issued this date, their motions to file First Supplemental Amended Complaints [MDL Record Nos. 1111, 1113, and 1114] are **DENIED**.

This 5<sup>th</sup> day of March, 2012.



**Signed By:**

**Danny C. Reeves** DCR

**United States District Judge**