

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

IN RE: DARVOCET, DARVON AND	)	
PROPOXYPHENE PRODUCTS	)	Master File No. 2: 11-md-2226-DCR
LIABILITY LITIGATION	)	MDL Docket No. 2226
	)	
<i>Esposito v. Eli Lilly and Company, et al.,</i>	)	Civil Action No. 2: 11-175-DCR
<i>Alix v. Eli Lilly and Company, et al.,</i>	)	Civil Action No. 2: 11-182-DCR
<i>Gilbert v. Eli Lilly and Company, et al.,</i>	)	Civil Action No. 2: 11-184-DCR
<i>Hunsucker v. Eli Lilly and Company, et al.,</i>	)	Civil Action No. 2: 11-185-DCR
<i>West v. Eli Lilly and Company, et al.,</i>	)	Civil Action No. 2: 11-186-DCR
<i>Eldredge v. Eli Lilly and Company, et al.,</i>	)	Civil Action No. 2: 11-190-DCR
<i>Kellehar v. Eli Lilly and Company, et al.,</i>	)	Civil Action No. 2: 11-191-DCR
<i>Hallaway v. Eli Lilly and Company, et al.,</i>	)	Civil Action No. 2: 11-195-DCR
<i>Lowe v. Eli Lilly and Company, et al.,</i>	)	Civil Action No. 2: 11-196-DCR
<i>Coney v. Eli Lilly and Company, et al.,</i>	)	Civil Action No. 2: 11-197-DCR
<i>Rogers v. Xanodyne Pharm. Inc., et al.,</i>	)	Civil Action No. 2: 11-200-DCR
<i>Daugherty v. Eli Lilly and Company, et al.,</i>	)	Civil Action No. 2: 11-204-DCR
<i>Meeks v. Eli Lilly and Company, et al.,</i>	)	Civil Action No. 2: 11-208-DCR
<i>Simpson v. Qualitest Pharm., Inc., et al.,</i>	)	Civil Action No. 2: 11-210-DCR
<i>Lynch v. Eli Lilly and Company, et al.,</i>	)	Civil Action No. 2: 11-213-DCR
<i>Dickerson v. Eli Lilly and Company, et al.,</i>	)	Civil Action No. 2: 11-295-DCR
<i>Labit v. Eli Lilly and Company, et al.,</i>	)	Civil Action No. 2: 11-296-DCR
<i>Balben v. Eli Lilly and Company, et al.,</i>	)	Civil Action No. 2: 11-297-DCR
<i>Forrest v. Eli Lilly and Company, et al.,</i>	)	Civil Action No. 2: 11-298-DCR
<i>Noel v. Eli Lilly and Company, et al.,</i>	)	Civil Action No. 2: 11-299-DCR
<i>Green v. Eli Lilly and Company, et al.,</i>	)	Civil Action No. 2: 11-300-DCR
<i>Wheeler v. Eli Lilly and Company, et al.,</i>	)	Civil Action No. 2: 11-301-DCR
<i>Knight v. Xanodyne Pharm., Inc., et al.,</i>	)	Civil Action No. 2: 11-307-DCR
<i>Del Favero v. Xanodyne Pharm., Inc., et al.,</i>	)	Civil Action No. 2: 11-311-DCR
<i>Blackwell v. Xanodyne Pharm., Inc., et al.,</i>	)	Civil Action No. 2: 11-312-DCR
<i>Sandel v. Eli Lilly and Company, et al.,</i>	)	Civil Action No. 2: 11-325-DCR
<i>Shumaker v. Eli Lilly and Company, et al.,</i>	)	Civil Action No. 2: 11-328-DCR
<i>Felts v. Eli Lilly and Company, et al.,</i>	)	Civil Action No. 2: 11-329-DCR
<i>Smith v. Eli Lilly and Company, et al.,</i>	)	Civil Action No. 2: 11-330-DCR
<i>Lewis-Crossno v. Eli Lilly and Co., et al.,</i>	)	Civil Action No. 2: 11-335-DCR
<i>Hect v. Eli Lilly and Company, et al.,</i>	)	Civil Action No. 2: 11-339-DCR
<i>Adams v. Eli Lilly and Company, et al.,</i>	)	Civil Action No. 2: 11-350-DCR

*Miller v. Eli Lilly and Company, et al.,* ) Civil Action No. 2: 11-352-DCR  
*Wagers v. Eli Lilly and Company, et al.,* ) Civil Action No. 2: 11-355-DCR  
*Brown v. Eli Lilly and Company, et al.,* ) Civil Action No. 2: 11-380-DCR

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**MEMORANDUM OPINION AND ORDER REGARDING  
XANODYNE PHARMACEUTICALS, INC.’S MOTIONS TO DISMISS**

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Xanodyne Pharmaceuticals, Inc. (“Xanodyne”) has filed three consolidated motions to dismiss in this multidistrict litigation. [MDL Record Nos. 444, 639, 666] It has also filed a motion to dismiss in an individual case, *Wagers v. Eli Lilly and Company, et al.*, on the same grounds. [Civil Action No. 2: 11-355, Record No. 6] Xanodyne contends that the claims asserted against it by the plaintiffs in these cases should be dismissed pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. The basic thrust of the argument in support of these motions is that Xanodyne cannot be held liable to plaintiffs who have failed to establish that they ingested a product that it sold, manufactured, or distributed. Plaintiffs attempt to prevent dismissal by characterizing their misrepresentation claims as separate theories of recovery for which identification of the defendant’s specific product is not required. For the reasons explained below, Xanodyne’s motions will be granted.

**BACKGROUND<sup>1</sup>**

In 1957, the federal Food and Drug Administration (“FDA”) approved a New Drug Application (“NDA”) for Darvon, a propoxyphene-containing drug used to treat mild to

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<sup>1</sup> This opinion provides a basic history of the MDL proceeding. Future opinions in this action will contain only a brief summary of information as necessary for the resolution of the particular motion at issue.

moderate pain. Darvon was developed by Eli Lilly and Company (“Lilly”). The FDA approved Lilly’s NDA for Darvocet, a drug which contained propoxyphene and acetaminophen, in 1973. Lilly retained all the rights to these propoxyphene-containing drugs until February 2002, when it sold its NDA to NeoSan. Xanodyne, in turn, purchased the rights from NeoSan on July 25, 2005.

In 2009, the FDA Advisory Committee voted to suspend the marketing of propoxyphene-containing drugs. The FDA ordered Xanodyne to conduct clinical trials to assess the dangers of cardiotoxicity from propoxyphene. The study confirmed that propoxyphene can cause “significant changes to the electrical activity of the heart.” News Release, U.S. Food & Drug Admin., Xanodyne Agrees to Withdraw Propoxyphene from the U.S. Market (Nov. 19, 2010). As a result, Xanodyne agreed to stop marketing propoxyphene products in the United States, and generic manufacturers of the drug were asked to do the same.

This multidistrict litigation (“MDL”) arises from injuries allegedly suffered as a result of ingesting propoxyphene products. Plaintiffs have brought various claims against Xanodyne, including: (1) strict liability theories of product liability; (2) negligence theories of product liability; (3) breach of express and implied warranty; (4) fraudulent nondisclosure; (5) negligent misrepresentation; and (6) fraudulent misrepresentation. Xanodyne filed its consolidated motions to dismiss on November 30, 2011, December 16, 2011, and December 20, 2011, respectively. [MDL Record Nos. 444, 639, 666] On February 27, 2012, the parties presented oral arguments on the issues raised in these motions.

## ANALYSIS

Xanodyne seeks dismissal of the claims against it in all cases in which the plaintiffs “ingested formulations of [propoxyphene] manufactured, sold, and distributed by entities other than Xanodyne.” [MDL Record No. 445, p. 11] It argues that it is “black-letter law that a plaintiff cannot state a claim for injuries allegedly due to a purportedly defective product against a defendant that did not manufacture or distribute the product the plaintiff actually ingested.” [Id.] Thus, Xanodyne asserts, the complaints do not satisfy the pleading requirements of Federal Rule of Civil Procedure 8(a), because they fail to sufficiently allege that Xanodyne sold or manufactured the product ingested and thus “contain merely ‘formulaic recitation[s] of the elements’ of their causes of action.” [Id., p. 22 (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007))] Moreover, Xanodyne maintains that the complaints fail to state claims upon which relief may be granted because, regardless of the theory on which the claim is asserted, the claims asserted by plaintiffs are product liability claims. As such, identification of a specific defendant’s product is required for a plaintiff to proceed against that defendant. [Id., pp. 22-23] Finally, Xanodyne contends that it is entitled to dismissal of any derivative claims asserted against it, “because the derivative claims cannot survive without the substantive claims.” [Id., p. 49]

### **I. Standard for Motion to Dismiss**

Rule 8 of the Federal Rules of Civil Procedure provides that, to state a claim for relief, a pleading must contain “a short and plain statement of the claim showing that the pleader is entitled to relief.” Fed. R. Civ. P. 8(a)(1). When evaluating a motion to dismiss under Rule

12(b)(6), the Court must determine whether the complaint alleges “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 *Twombly*, 550 U.S. at 555). 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.* Thus, although the complaint need not contain “detailed factual allegations” to survive a motion to dismiss, “a plaintiff’s obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” *Twombly*, 550 U.S. at 555 (internal quotation marks and alteration omitted).

## II. Product Identification

In every state implicated by Xanodyne’s motions, it is well-settled law that a “threshold requirement of any products-liability claim is that the plaintiff assert that the defendant’s product caused the plaintiff’s injury.” *Smith v. Wyeth*, 657 F.3d 420, 423 (6th Cir. 2011).<sup>2</sup> There is no theory of product liability under which a defendant can be held liable for an injury caused by a product that it did not sell, manufacture, or otherwise supply to the plaintiff. Therefore, in the

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<sup>2</sup> See also, e.g., *Barnes v. Kerr Corp.*, 418 F.3d 583, 588-89 (6th Cir. 2005) (applying Tennessee law); *Baughman v. Gen. Motors Corp.*, 627 F. Supp. 871, 874 (D.S.C. 1985); *Hoffman v. AC&S, Inc.*, 548 S.E.2d 379, 382 (Ga. Ct. App. 2001); *Bryant-Poff, Inc. v. Hahn*, 453 N.E.2d 1171, 1172-73 (Ind. 1983); *Stanley v. Wyeth, Inc.*, 991 So. 2d 31, 34-35 (La. Ct. App. 2008); *Flynn v. Am. Home Prods. Corp.*, 627 N.W.2d 342, 350 (Minn. Ct. App. 2001); *Gorman-Rupp Co. v. Hall*, 908 So. 2d 749, 757 (Miss. 2005); *Namm v. Charles E. Frosst & Co.*, 427 A.2d 1121, 1125 (N.J. Super. Ct. App. Div. 1981); *Diel v. Flintkote Co.*, 204 A.D.2d 53, 53 (N.Y. App. Div. 1994); *Sutowski v. Eli Lilly & Co.*, 696 N.E.2d 187, 190-93 (Ohio 1998); *Kirkland v. Gen. Motors Corp.*, 521 P.2d 1353, 1365 (Okla. 1974); *DeWeese v. Anchor Hocking Consumer & Indus. Prods. Grp.*, 628 A.2d 421, 423 (Pa. Super. Ct. 1993); *Gaulding v. Celotex Corp.*, 772 S.W.2d 66, 68 (Tex. 1989).

context of product liability claims, a plaintiff must state sufficient allegations to allow at least the reasonable inference that the product that caused the injury was made, sold, or distributed by the defendant in question. *See Iqbal*, 129 S. Ct. at 1949. In this case, then, Xanodyne is entitled to dismissal of product liability claims asserted by plaintiffs who have either alleged the ingestion of another company's product or who have simply alleged that they do not know which defendant sold or manufactured the product ingested.

Not one of the plaintiffs in these cases has properly identified Xanodyne as the entity that marketed, sold, or manufactured the product he or she ingested. Instead, most actually allege that the plaintiff ingested a "generic form of Darvocet." [*E.g.*, MDL Record No. 291 ¶ 8 (*Balben Complaint*)] Several plaintiffs indicate that the product *might* have been sold by Xanodyne, but they plead themselves out of a claim by asserting that they ingested "Darvon, Darvocet and/or Propoxyphene." [*E.g.*, MDL Record No. 302 ¶ 8 (*Hunsucker Complaint*)] Such allegations are insufficient to show that the plaintiff is entitled to relief because the "and/or" language permits the Court to infer the possibility that the plaintiff ingested only generic propoxyphene, and "it is this possibility that is fatal" to these complaints. *Patterson v. Novartis Pharm. Corp.*, No. 10-5886, 2011 WL 3701884, at \*2 (6th Cir. Aug. 23, 2011). Other plaintiffs allege the ingestion of Darvon or Darvocet, the brand name for propoxyphene, but then admit that they "cannot determine the Defendant and/or other entity that manufactured, marketed, distributed and/or tested the particular Propoxyphene Product that caused Decedent's harm."<sup>3</sup> [*E.g.*, MDL Record

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3 The *Dickerson* Complaint phrases this somewhat differently, instead alleging, "Plaintiff cannot determine *every* Defendant" that manufactured the particular product that caused the harm. [MDL Record No. 310 ¶ 15 (emphasis added)] While this could be interpreted to mean that the plaintiff in *Dickerson* is able to identify some but not all of the manufacturers, the lack of specificity in his earlier allegations defeats a

No. 303 ¶¶ 10, 12 (*Kellehar* Complaint)] Finally, two of the plaintiffs allege the use of a brand name drug, but the allegations fail to sufficiently identify that product as one marketed, sold, or manufactured by Xanodyne.<sup>4</sup> In light of the requirement that, in order to hold a defendant liable, a plaintiff must prove that defendant was responsible for the allegedly defective product, these allegations do not “allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Iqbal*, 129 S. Ct. at 1499. Therefore, the product liability claims against Xanodyne in each of these cases fail as a matter of law.<sup>5</sup>

The plaintiffs’ responses identify several individual cases in which, although the complaints did not identify Xanodyne as the supplier of the product that caused the injury, the

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finding that Xanodyne manufactured the product Dickerson ingested. [*Id.* ¶ 13 (alleging only the ingestion of “Darvocet (brand name), Darvon 65 mg (brand name), Propo-N/Apap 100-65 (generic) for pain management for nearly 38 years, dating back to September of 1970” and failing to name any defendant manufacturer or provide any specific dates of ingestion)] Plaintiffs do not dispute that the *Dickerson* Complaint does not specifically identify Xanodyne as the “seller of the drugs that [Dickerson] ingested.” [MDL Record No. 914, p. 21]

4 The *Meeks* Complaint alleges that the plaintiff ingested Darvocet, which is the brand-name product. However, the complaint lacks any factual allegations regarding the time frame in which the product was ingested, making it impossible to determine which company manufactured or sold the product. [Record No. 298 ¶¶ 8-9] The *Daugherty* Complaint, on the other hand, alleges the ingestion of Darvocet-N 100 (a brand-name product) and provides dates, but those dates do not support a plausible conclusion that Xanodyne manufactured the products ingested. [Record No. 312 ¶ 64 (alleging ingestion of products manufactured by Eli Lilly, Qualitest, Mylan, and TEVA, but not Xanodyne)]

5 The Court must also dismiss claims that require identification of a specific defendant’s product to proceed, even if they are not characterized as product liability claims. For instance, in Mississippi, warranty claims are separate from the Mississippi Product Liability Act. *Bennett v. Madakasira*, 821 So. 2d 794, 808 (Miss. 2002). However, under Mississippi law, a warranty can only be made by a distributor of goods. *Harmon v. Nat’l Auto. Parts Ass’n*, 720 F. Supp. 79, 82 (N.D. Miss. 1989). Thus, the failure to identify Xanodyne as the supplier of the product that caused the injury also defeats claims for breach of express or implied warranty, because a defendant that was not in the position to make a warranty cannot breach any warranty. The breach of express and implied warranty claims in *Dickerson* and *Hunsucker* will therefore also be dismissed. The claims for violations of New York General Business Law §§ 349 and 350 asserted in *Alix* and *Esposito* similarly fail. See *Goldych v. Eli Lilly & Co.*, No. 5:04-CV-1477, 2006 WL 2038436, at \*7-8 (N.D.N.Y. July 19, 2006) (dismissing claims under New York General Business Law because the brand-name company “did not manufacture the ingested drug”).

plaintiffs have subsequently confirmed the ingestion of a Xanodyne product through product identification interrogatories. [See, e.g., MDL Record No. 914, pp. 21-22] However, information that was not alleged in the complaints will not be considered for purposes of the motions to dismiss. See *Maiden v. N. Am. Stainless*, 183 F. App'x 485, 487 (6th Cir. 2005) (noting that courts are not required to consider matters outside the pleadings in a motion to dismiss). The plaintiffs cannot use their discovery responses to effectively amend their complaints without leave of Court. If the product identification information was not in the complaint itself, the product liability claims against Xanodyne cannot survive the motion to dismiss.

### **III. Misrepresentation Theories**

The plaintiffs contend that, regardless of the viability of their product liability claims, they have asserted a valid, separate claim for misrepresentation. [MDL Record No. 914, pp. 23-31] They maintain that even if their product liability claims fail, Xanodyne can still be held liable under misrepresentation theories “sounding in negligence and fraud.” [*Id.*, p. 23] According to this argument, the plaintiffs “do not seek to hold Xanodyne liable because its products caused them harm; rather, they seek to hold Xanodyne liable because its misrepresentations did.”<sup>6</sup> [*Id.*, p. 24] They argue that their misrepresentation claims are distinct

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<sup>6</sup> Xanodyne points out that this assertion is in contrast to the language of the complaints themselves. [MDL Record No. 1034, p. 8] Indeed, the introductory allegations of the complaints seemingly characterize the actions as product liability cases. Almost all begin with the following language: “This lawsuit concerns personal injury related to Plaintiff’s ingestion of prescription medication containing the active ingredient propoxyphene.” [E.g., MDL Record No. 287 ¶ 1] Even the complaint in *Eldredge*, in which the only claims against Xanodyne are brought under theories of misrepresentation, contains this language. [MDL Record No. 300 ¶ 1]



from product liability claims, and as such are not subject to the requirement that the complaints allege the ingestion of a Xanodyne product.

Xanodyne counters that “the overwhelming national consensus is that brand-name drug manufacturers, sellers, and distributors cannot be held liable for injuries caused by drugs manufactured, sold, or distributed by other companies.” [MDL Record No. 445, p. 48] It asserts that the misrepresentation claims “stem[] from the use of a product” and are therefore properly characterized as product liability claims. [MDL Record No. 1034, p. 7] Moreover, Xanodyne argues, even if the plaintiffs can successfully show that their claims are not based on product liability law, “they cannot escape another fundamental principle of tort law — legal duty.” [*Id.*, p. 9]

**A. Misrepresentation Claims Are Product Liability Claims.**

Xanodyne cites several cases in which the court found that misrepresentations such as those asserted by the plaintiffs here “are[] in fact ‘product liability’ claims that do not survive unless the plaintiff actually took the defendant’s product.” [*Id.*, p. 8 (citation omitted)] Indeed, the courts in many states have expressly rejected the argument that misrepresentation claims are distinct from product liability or failure-to-warn claims. *E.g.*, *Burke v. Wyeth, Inc.*, No. G-09-82, 2009 WL 3698480, at \*3 (S.D. Tex. Oct. 29, 2009) (“[U]nder Texas law[,] all claims for personal injury allegedly caused by a defective product are, regardless of the theory alleged, ‘products liability actions.’”); *Swicegood v. Pliva, Inc.*, 543 F. Supp. 2d 1351, 1357 (N.D. Ga. 2008) (finding that “misrepresentation claims against a manufacturer properly collapse into the failure to warn claims”); *Tarver v. Wyeth, Inc.*, No. 3-04-2036, 2006 WL 1517546, at \*2-3 (W.D.

La. Jan. 26, 2006) (rejecting argument that a negligent misrepresentation claim should be recognized as separate from a product liability claim, noting that “[t]he law is clear that Louisiana imposes on a manufacturer no duty to warn of the dangers of another company’s product”); *Kovach v. Alpharma, Inc.*, 890 N.E.2d 55, 65 (Ind. Ct. App. 2008) (“Indiana’s Product Liability Act governs all actions that are brought by a user or consumer against a manufacturer or seller for physical harm caused by a product regardless of the substantive legal theory or theories upon which the action is brought.”); *Monsanto Co. v. Reed*, 950 S.W.2d 811, 814 (Ky. 1997) (“The [Kentucky Product Liability Act] applies to all damage claims arising from the use of products, regardless of the legal theory advanced.”); *DeBenedetto v. Denny’s, Inc.*, 23 A.3d 496, 499, 328 (N.J. Super. Ct. Law. Div. 2010) (holding that plaintiff’s fraud claims were subsumed by the New Jersey Products Liability Act because it “is the exclusive remedy for harms caused by a product”). The rule in these states is that all claims arising from the use of a product are properly characterized as “product liability claims.” Therefore, plaintiffs must properly identify the entity responsible for the product at issue in order to proceed with such claims.

**B. Xanodyne Has No Legal Duty Toward Consumers of Generic Products.**

Even assuming that misrepresentation claims against Xanodyne can be seen as distinct and separate from product liability claims, these claims must be dismissed in cases where plaintiffs ingested propoxyphene products that Xanodyne did not sell, manufacture, or distribute. As acknowledged by the plaintiffs in their complaints, the existence of a duty of care on the part of a manufacturer is one of the elements that must be established to prevail on a claim for fraud

or misrepresentation. [See, e.g., MDL Record No. 287 ¶¶ 336, 358, 377 (*Alix* Complaint)] Thus, to hold Xanodyne liable for misrepresentation in cases that do not allege the ingestion of a Xanodyne product, plaintiffs must establish that Xanodyne owed them (or their prescribing physician) a legal duty.

Plaintiffs assert that the Court should “hold brand manufacturers liable for the damages their representations foreseeably caused to users of generic drugs.” [MDL Record No. 914, p. 31] In support, plaintiffs rely on two cases, *Conte v. Wyeth, Inc.* and *Kellogg v. Wyeth*, from the California Court of Appeal and the District of Vermont, respectively.<sup>7</sup> Both cases held that a brand-name drug manufacturer owes a duty to all consumers — both those who ingest brand-name drugs and those who ingest generic forms — when marketing its product. *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299, 315 (Cal. Ct. App. 2008); see *Kellogg v. Wyeth*, 762 F. Supp. 2d 694, 704 (D. Vt. 2010). In *Conte*, the court reasoned that the brand-name manufacturer “knows or should know that a significant number of patients whose doctors rely on its product information . . . are likely to have generic [medication] prescribed or dispensed to them.” 85 Cal Rptr. 3d at 315. The court looked “primarily to the foreseeability of physical harm” to determine the duty owed by a brand manufacturer, relying in part on Sections 310 and 311 of the Restatement (Second) of Torts. *Id.* at 312-13. It found that a brand manufacturer “should reasonably perceive that there could be injurious reliance on its product information” by patients who ingest a generic form of the drug. *Id.* As a result, the *Conte* court concluded that the “duty of care in disseminating product information” should extend to those patients who are injured by generic

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<sup>7</sup> None of the cases subject to these motions implicate the law of either California or Vermont.

drugs. *Id.* at 318. In *Kellogg*, the district court also considered this question and similarly concluded:

[I]t is reasonably foreseeable that a physician will rely upon a brand name manufacturer's representations — or the absence of representations — about the risk of side effects of its drug, when deciding to prescribe the drug for a patient, regardless of whether the pharmacist fills the prescription with a generic form of the drug.

*Kellogg*, 762 F. Supp. 2d at 709. Therefore, the *Kellogg* court held that “a brand name drug manufacturer owes a duty to use reasonable care to avoid causing injury to consumers of the generic bioequivalents of its drugs.” *Id.* at 706.

As the plaintiffs conceded at oral argument, *Conte* and *Kellogg* represent a minority position, with the overwhelming majority of courts instead adopting a rule that rejects “the contention that a name brand manufacturer’s statements regarding its drug can serve as the basis for liability for injuries caused by another manufacturer’s drug.” *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 170 (4th Cir. 1994); *see Smith*, 657 F.3d at 424 (“As have the majority of the courts to address this question, we reject the argument that a name-brand drug manufacturer owes a duty of care to individuals who have never taken the drug actually manufactured by that company.”). Fifty-five decisions from twenty-two states have rejected arguments similar to those put forward by the plaintiffs. [See MDL Record No. 669-2]<sup>8</sup> These courts have all concluded that a brand name defendant owes no duty of care to consumers of the generic bioequivalents of its product. *See, e.g., Fisher v. Pelstring*, No. 4:09-cv-252, 2010 WL 2998474, at \*6-8 (D.S.C. July 28, 2010) (rejecting *Conte* and dismissing claims for negligence and

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8 *See also Metz v. Wyeth LLC*, 2011 WL 5826005, at \*2 (M.D. Fla. Nov. 18, 2011).

negligent misrepresentation because “the plaintiff cannot establish that Schwarz or Wyeth manufactured or sold the products allegedly responsible for the plaintiff’s injuries, [so] the plaintiffs cannot establish that either defendant owed the plaintiffs a duty of care”); *Schrock v. Wyeth, Inc.*, 601 F. Supp. 2d 1262, 1266 (W.D. Okla. 2009) (finding that “the imposition of liability on brand name manufacturers for injuries caused by competitor generic manufacturers is inconsistent with Oklahoma law”); *Stanley v. Wyeth, Inc.*, 991 So. 2d 31, 34-35 (La. Ct. App. 2008) (holding that “a name brand drug manufacturer owes no legal duty to the consumer of a generic equivalent of its drug”).

Nevertheless, the plaintiffs maintain that these decisions do not bar their claims. [MDL Record No. 914, pp. 33-71] They contend that there are no “definitive rulings” in the states at issue because none of the decisions cited by Xanodyne were issued by the relevant state’s highest court. [*Id.*, pp. 30, 33 (arguing that “not one of the opinions on Xanodyne’s list is from the highest court of any state”)] Additionally, the plaintiffs assert that the cases contrary to *Conte* and *Kellogg* were wrongly decided, and they urge this Court to reach a different outcome. The Court finds this argument to be without merit.

A federal court sitting in diversity is bound to follow the law of the forum state. *See Erie R.R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938). It is not the place of this Court, sitting in diversity in an MDL proceeding, to announce a new rule of law. While it is true that the cases cited by Xanodyne do not “affirmatively establish the law of any jurisdiction,” they indicate a strong trend. [MDL Record No. 914, p. 30] Moreover, *Conte* and *Kellogg* represent an expansion of the duty of care owed by pharmaceutical companies. *See Conte*, 85 Cal. Rptr. 3d at 304-05. A

federal court should hesitate to expand the scope of state law without guidance from that state's highest court. *See Combs v. Int'l Ins. Co.*, 354 F.3d 568, 577 (6th Cir. 2004) (noting that federal courts should be reluctant to speculate on state law trends). Instead, “‘given a choice between an interpretation of [state] law which reasonably restricts liability, and one which greatly expands liability, we should choose the narrower and more reasonable path.’” *Id.* (quoting *Todd v. Societe Bic, S.A.*, 21 F.3d 1402, 1412 (7th Cir. 1994)). Therefore, in the absence of any binding authority that would dictate the application of the rule proffered by the plaintiffs, this Court concludes that Xanodyne cannot be held liable to plaintiffs who consumed other manufacturers' drugs. And because the plaintiffs in this case have not sufficiently alleged the ingestion of a Xanodyne product, their misrepresentation claims fail.

#### **IV. Wagers v. Eli Lilly and Company**

In addition to the consolidated motions in the MDL proceeding, Xanodyne has filed a motion to dismiss in the individual case of *Wagers v. Eli Lilly and Company, et al.* (Civil Action No. 2: 11-355). This case was removed by Eli Lilly on December 7, 2011, after which it was consolidated with the MDL proceeding. [MDL Record No. 662] The case was removed to this Court the basis of diversity of citizenship. Although both the plaintiff and Xanodyne are citizens of Kentucky, Lilly alleged in its notice of removal that Xanodyne had been fraudulently joined in order to defeat federal jurisdiction.<sup>9</sup> [Civil Action No. 2: 11-355, Record No. 1, p. 1]

There is fraudulent joinder when there is “sufficient evidence that a plaintiff could not have established a cause of action against non-diverse defendants under state law.” *Coyne ex*

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<sup>9</sup> Wagers has not opposed the removal or filed a motion to remand.

*rel. Ohio v. Am. Tobacco Co.*, 183 F.3d 488, 493 (6th Cir. 1999). As explained above, Kentucky product liability law requires the plaintiff to allege that the “*defendant’s* product . . . injured the plaintiff.” *Smith*, 657 F.3d at 423. Because the plaintiff in *Wagers* alleges only the ingestion of products manufactured by generic drug companies, there is no colorable cause of action against Xanodyne. [See Civil Action No. 2: 11-355, Record No. 1-4, p. 10 ¶ 8 (alleging that the decedent ingested propoxyphene manufactured by Qualitest Pharmaceuticals and Mallinckrodt, Inc.)] The Court therefore finds that Xanodyne was fraudulently joined; accordingly, its non-diverse citizenship will be disregarded. See *Estate of Shearer v. T&W Tool & Die Corp.*, No. 08-175-KSF, 2008 WL 2891168, at \*5 (E.D. Ky. July 24, 2008). Without Xanodyne, there is complete diversity in the *Wagers* action, and federal jurisdiction is proper pursuant to 28 U.S.C. § 1332.

Because the Court has subject matter jurisdiction, it has the authority to rule on Xanodyne’s motion to dismiss. Cf. *Baker v. Home Depot*, No. 6:06-cv-526, 2007 U.S. Dist. LEXIS 17086, at \*4-5 (E.D. Ky. Mar. 9, 2007) (granting fraudulently-joined defendant’s motion to dismiss for failure to state a claim). And, for the same reasons that Xanodyne was found to be fraudulently joined, the motion will be granted.

#### **V. Leave to Amend**

The plaintiffs seek leave to amend their complaints, in the event that the Court concludes that the product identifications provided in these cases are insufficient. [Record No. 914, p. 22] However, the Court notes that plaintiffs generally are “not entitled to an advisory opinion from the district 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). Under *Iqbal*, plaintiffs should not be 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. In this case, most of the plaintiffs have already been given leave to amend their complaints once. Therefore, this request is denied.

### **CONCLUSION**

The plaintiffs who have been identified in the motions to dismiss have failed to set forth allegations that establish — or even allow the Court to properly infer — that they ingested a Xanodyne product. Moreover, the plaintiffs have not identified any rule of law that would allow them to recover from a defendant that did not sell, manufacture, or distribute the product that caused their injuries. Therefore, the plaintiffs’ claims against Xanodyne will be dismissed as failing to state a plausible claim on which relief can be granted. Because claims for wrongful death and loss of consortium are derivative of the other claims asserted against Xanodyne, any derivative claims in the plaintiffs’ complaints will also be dismissed. Accordingly, it is hereby

**ORDERED** as follows:

1. Xanodyne’s Consolidated Motions to Dismiss [MDL Record Nos. 444, 639, 666] are **GRANTED**.

2. Xanodyne’s Motion to Dismiss in *Wagers v. Eli Lilly and Company, et al.*, [Civil Action No. 2: 11-355, Record No. 6] is **GRANTED**.



3. In accordance with this Memorandum Opinion and Order, the claims asserted against Defendant Xanodyne Pharmaceuticals, Inc. in the following cases are **DISMISSED**, with prejudice:

- Case No. 2: 11-175;
- Case No. 2: 11-182;
- Case No. 2: 11-184;
- Case No. 2: 11-185;
- Case No. 2: 11-186;
- Case No. 2: 11-190;
- Case No. 2: 11-191;
- Case No. 2: 11-195;
- Case No. 2: 11-196;
- Case No. 2: 11-197;
- Case No. 2: 11-200;
- Case No. 2: 11-204;
- Case No. 2: 11-208;
- Case No. 2: 11-210;
- Case No. 2: 11-213;
- Case No. 2: 11-295;
- Case No. 2: 11-296;
- Case No. 2: 11-297;

- Case No. 2: 11-298;
- Case No. 2: 11-299;
- Case No. 2: 11-300;
- Case No. 2: 11-301;
- Case No. 2: 11-307;
- Case No. 2: 11-311;
- Case No. 2: 11-312;
- Case No. 2: 11-325;
- Case No. 2: 11-328;
- Case No. 2: 11-329;
- Case No. 2: 11-330;
- Case No. 2: 11-335;
- Case No. 2: 11-339;
- Case No. 2: 11-350;
- Case No. 2: 11-352;
- Case No. 2: 11-355; and
- Case No. 2: 11-380.

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



**Signed By:**

**Danny C. Reeves** DCR

**United States District Judge**