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
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
Washington v. Xanodyne Pharm., Inc., et al.,	Civil Action No. 2: 11-187-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
Coney v. Xanodyne Pharm., Inc., et al.,	Civil Action No. 2: 11-197-DCR
Meeks v. Xanodyne Pharm., Inc., et al.,	Civil Action No. 2: 11-208-DCR
Simpson v. Qualitest Pharm. Inc., et al.,	Civil Action No. 2: 11-210-DCR
Lynch v. Xanodyne Pharm., Inc., et al.,	Civil Action No. 2: 11-213-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

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MEMORANDUM OPINION AND ORDER REGARDING ELI LILLY AND COMPANY'S MOTION TO DISMISS AND MOTION FOR JUDGMENT ON THE PLEADINGS

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This matter is pending for consideration of Defendant Eli Lilly and Company's ("Lilly") motion to dismiss the claims against it in twenty-one actions in this multidistrict litigation (MDL).[1] [Record No. 416] Lilly contends that the claims asserted against it by the plaintiffs in these cases should be dismissed under Rule 12(b)(6) of the Federal Rules of Civil Procedure. On December 19, 2011, Lilly moved the Court to convert its motion to dismiss into a motion for judgment on the pleadings. [Record No. 643][2] For the reasons explained below, the relief sought by Lilly will be granted.

BACKGROUND

This matter arises from injuries that the plaintiffs or their decedents allegedly suffered as a result of ingesting propoxyphene-containing products. In 1957, the federal Food and Drug Administration ("FDA") approved Lilly's New Drug Application ("NDA") for Darvon, a propoxyphene-containing drug used to treat mild to moderate pain. In 1973, the FDA approved Lilly's NDA for Darvocet, which contained propoxyphene and acetaminophen. According to the plaintiffs', during this time Lilly also manufactured generic propoxyphene products for "at least one set of generic drug companies." [Record No. 635, p. 10] Lilly retained all the rights to propoxyphene-containing drugs until February 2002, when it sold its NDA to NeoSan. The purported arrangement between Lilly and NeoSan involved NeoSan agreeing to pay royalties to Lilly in exchange for Lilly selling its marketing rights, transferring its existing inventory to

1 Lilly has also filed individual motions to dismiss in each of these cases.

2 A more complete discussion of the facts underlying this action is contained in the Court's Memorandum Opinion and Order Regarding Xanodyne Pharmaceuticals, Inc.'s Motions to Dismiss. [Record No. 1274]

NeoSan, and manufacturing the drugs for NeoSan until the end of 2004. Additionally, the plaintiffs allege that Lilly "retained the right to continue manufacturing propoxyphene products for at least one set of drug companies . . . [and] did continue manufacturing the generic product(s)." [*Id.*]

The claims against Lilly – as a brand-name manufacturer of propoxyphene products – include negligence, fraudulent nondisclosure, negligent misrepresentation, and fraudulent misrepresentation. Certain plaintiffs have also characterized Lilly as a generic defendant "to the extent that it was involved in the testing, *manufacture*, sale, distribution and/or marketing of generic propoxyphene products." [*Id.*, p. 21 (citing Record No. 287 ¶ 51 (*Alix* Complaint[3]) (emphasis added))] The claims asserted against Lilly based on this characterization include: strict liability – design defect; negligent design; negligence; negligent failure to warn; statutory negligence; breach of express warranty; and breach of implied warranty. [*Id.*, p. 27 n.12]

ANALYSIS

Lilly seeks dismissal of the claims asserted against it in all cases in which the plaintiffs "used propoxyphene products after Lilly sold its propoxyphene NDAs in February 2002." [Record No. 416-7, p. 4] It asserts that the plaintiffs' amended complaints lack facial plausibility because they have "failed to allege facts from which this Court can infer the essential elements of a product liability claim have been met." [*Id.*, p. 19] In other words, Lilly maintains that the plaintiffs have not alleged sufficient facts to support a reasonable inference that plaintiffs

3 The parties generally 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. 635, p. 9 n.1] Accordingly, in this opinion, references to the plaintiffs' claims are based on the *Alix* Amended Complaint unless otherwise indicated.

ingested a product that it sold or manufactured. Additionally, it argues the plaintiffs' fraud claims are not pleaded with particularity as required by Rule 9(b) of the Federal Rules of Civil Procedure. Thus, Lilly contends that all of the claims against it fail as a matter of law.

I. The Standard for a Motion for Judgment on the Pleadings

Lilly moved the Court to convert its master motion to dismiss, as well as the motions to dismiss filed in individual cases, into motions for judgment on the pleadings.[4] [Record No. 643] After a defendant has filed an answer, and therefore the "pleadings are closed," it may move to dismiss the complaint pursuant to Rule 12(c) of the Federal Rules of Civil Procedure. The "standard of review for a judgment on the pleadings is the same as that for a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6)." *Equal Emp't Opportunity Comm'n v. J.H. Routh Packing Co.*, 246 F.3d 850, 851 (6th Cir. 2001).

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 *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.* 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

4 The plaintiffs have not opposed Lilly's motion to convert its motions to dismiss into motions for judgment on the pleadings. [Record No. 875]

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

Lilly argues that the complaints fail to state a claim because they lack sufficient product identification information, and that the [l]ack of identification of a Lilly product . . . is a fatal defect." [*Id.*, p. 12] Indeed, in every state implicated by Lilly's motion, 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).[5] Therefore, in the context of product liability claims, a plaintiff must allege sufficient facts to allow at least the reasonable inference that the injury-causing product was sold, manufactured, or distributed by the defendant in question.

The plaintiffs do not contest this statement of the law. Instead, they attempt to use their product identification discovery responses to fulfill the requirement. 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

5 *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); *Bobryk v. Lincoln Amusements, Inc.*, No. CV950547084S, 1996 WL 24566, at *3 (Conn. Super. Ct. Jan. 5, 1996); *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); *Gorman-Rupp Co. v. Hall*, 908 So. 2d 749, 757 (Miss. 2005); *Namm v. Charles E. Frosst and 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); *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).

Court. If the necessary product identification information was not in the complaint itself, the product liability claims against Lilly cannot survive the motion to dismiss.

III. The Sufficiency of the Plaintiffs' Allegations

The Court must weigh the sufficiency of the complaints' factual allegations before considering whether the plaintiffs have stated a claim upon which relief can be granted. Rule 8 of the Federal Rules of Civil Procedure provides that 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). Lilly argues that if an individual plaintiff "cannot allege facts that show that Lilly marketed, sold and labeled the product ingested . . . [he] has failed to establish an essential element of his claim under any Count." [Record No. 416-7, p. 20] Additionally, it argues that the plaintiffs' amended complaints fail to meet the requirements of Rule 8(b) because they do not "plead *specific* facts implicating each named defendant." [*Id.*, p. 26 (citing *Iqbal*, 129 S. Ct. at 1949)] The plaintiffs counter that they have alleged sufficient facts to support a conclusion that they ingested propoxyphene products that were manufactured by Lilly.

A. Lilly's 2002 Divestiture

The chief argument in Lilly's master motion relates to the divestiture of its NDA for propoxyphene. Lilly sold its NDA for propoxyphene products to NeoSan in February 2002. This fact is undisputed, as it is conceded in most of the plaintiffs' amended complaints and established conclusively by judicially-noticeable documents. [Record Nos. 416-1, 416-2; *see, e.g.*, Record No. 287 ¶ 133 (*Alix* Complaint)] Lilly contends that the 2002 divestiture entitles it to dismissal of the majority of the claims against it. It argues that it "cannot be liable to

Plaintiffs who used propoxyphene products after Lilly sold its propoxyphene NDAs in February 2002." [Record No. 416-7, p. 4] Specifically, Lilly asserts that, "to the extent Plaintiffs allege they ingested a generic propoxyphene pain product at any time, or a branded product . . . after early 2002, it was not a product for which Lilly had relevant regulatory responsibility, and Lilly cannot be liable for any injuries or damages Plaintiffs claim relate to that ingestion." [*Id.*, p. 8]

Lilly also asserts that any complaint that alleges the ingestion of a Lilly product *before* the divestiture in 2002 fails.[6] It argues that "the FDA has stated that the potential injury associated with ingestion of propoxyphene pain products is not cumulative." [*Id.*, p. 4] Therefore, Lilly contends, it cannot be held liable to plaintiffs who allege the ingestion of brand-name propoxyphene prior to February 2002.

In support of this assertion, Lilly points to the FDA's November 19, 2010 News Release announcing the withdrawal of propoxyphene from the U.S. market. [*Id.*, p. 31] The news release stated that propoxyphene's effects on the "'heart's electrical activity are not cumulative. Once patients stop taking propoxyphene, the risk will go away.'" [Record No. 416-5, p. 3 (quoting Gerald Dal Pan, director of the Office of Surveillance and Epidemiology)] The parties differ regarding the import of this news release and whether it can be judicially noticed. Lilly contends that the Court can take judicial notice of the release "because it is a public record under Rule 201 of the Federal Rules of Evidence, and because Plaintiffs relied on it in framing their Amended Complaints." [Record No. 416-7, p. 31] The plaintiffs counter that the statement that

6 There is one case subject to Lilly's master motion that involves the use of brand-name propoxyphene before Lilly's divestiture in February 2002: *Dickerson v. Eli Lilly and Company, et al.*, Case Number 2: 11-cv-295-DCR.

the risks are not cumulative "is far from an adjudicative fact of which judicial notice can be taken," because it is not an "undisputed fact that is 'capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned.'" [Record No. 635, p. 24 (quoting *Chau v. First Fed. Bank*, No. 5:10-cv-396, 2011 WL 1769355, at *1 (E.D. Ky. May 9, 2011))]

When addressing a motion to dismiss, the Court can consider "any matters of which a court may take judicial notice." *Ashland, Inc. v. Oppenheimer & Co.*, 689 F. Supp. 2d 874, 881 (E.D. Ky. 2010). Under the Federal Rules of Evidence, a court may "judicially notice a fact that is not subject to reasonable dispute because it: (1) is generally known within the trial court's territorial jurisdiction; or (2) can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b). Therefore, the Court may take judicial notice of the news release "only to the extent that [its] existence or contents 'prove facts whose accuracy cannot be reasonably questioned.'" *Ashland*, 689 F. Supp. 2d at 881 (quoting *In re Cardinal Health, Inc.*, 426 F. Supp. 2d 688, 712 (S.D. Ohio 2006)).

Whether the effects of propoxyphene are cumulative is not a fact that can be judicially noticed. The statement that "[o]nce patients stop taking propoxyphene, the risk will go away," is subject to reasonable dispute at this stage of the litigation. [Record No. 416-5, p. 3] It is, as the plaintiffs point out, "the opinion of one person associated with the FDA — unsupported by any cited evidence — that changes in the heart's electrical activity are not cumulative." [Record No. 635, p. 24] Moreover, its verity cannot be readily determined by any undisputed external source. *See* Fed. R. Evid. 201(b)(2). The plaintiffs are correct that this issue should be more

properly presented through expert testimony and *Daubert* hearings at a later stage in this litigation. Therefore, with regard to plaintiffs that allege the ingestion of a brand-name product before 2002, Lilly is not entitled to dismissal on the ground that "ingestion of propoxyphene pain products is not cumulative." [Record No. 416-7, p. 4]

B. Lilly as NDA-Holder for Propoxyphene

Nonetheless, the plaintiffs's complaints do not set forth facts sufficient to allege that the plaintiffs ingested a product sold by Lilly before its divestiture in 2002. Not one of the plaintiffs in these cases has properly identified Lilly as the entity that marketed or sold the product he or she ingested. Most actually allege that the plaintiff ingested a "generic form of Darvocet." [*E.g.*, Record No. 291 ¶ 8 (*Balben* Complaint)] Several plaintiffs indicate that the product *might* have been sold by Lilly, but they plead themselves out of a claim by asserting that they ingested "Darvon, Darvocet and/or Propoxyphene." [*E.g.*, Record No. 302 ¶ 8 (*Hunsucker* Complaint)] Such allegations are insufficient to show that a 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). One plaintiff alleges only the ingestion of "Xanodyne's product." [Record No. 276 ¶ 9 (*Washington* Complaint)] Others allege that they ingested Darvon or Darvocet (*i.e.*, a brand-name propoxyphene product), 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 their injuries. [*E.g.*, Record No. 303 ¶¶ 10, 12 (*Kellehar* Complaint)] The

Dickerson Complaint phrases this somewhat differently, alleging that "Plaintiff cannot determine *every* Defendant" that marketed or distributed the particular product that caused the harm; however, the lack of specificity in his earlier allegations defeats a finding that Lilly sold the product Dickerson ingested.[7] [Record No. 310 ¶ 15 (emphasis added); *see 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 specific company or provide any specific dates of ingestion)] Finally, the plaintiff in *Meeks* alleges the use of a brand name drug, but her lack of factual allegations regarding the time frame in which the product was ingested make it impossible to determine which company sold the product. [Record No. 298 ¶¶ 8-9] Therefore, the Court finds that the plaintiffs failed to set forth allegations that establish — or even allow the Court to properly infer — that they ingested products sold by Lilly.

C. Lilly as a Manufacturer of Propoxyphene

The plaintiffs respond, however, that the facts alleged in their complaints should allow the Court to infer that at least some of them may have ingested brand-name or generic propoxyphene products that Lilly *manufactured*. [Record No. 635, p. 25] They point to facts alleged in the complaints that, they argue, create a reasonable inference that certain plaintiffs ingested products manufactured by Lilly. Thus, the plaintiffs contend that they have provided sufficient allegations to proceed against Lilly under product liability theories. [*See id.*]

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7 The plaintiff in *Dickerson* does not dispute that the complaint fails to sufficiently allege that Lilly sold the propoxyphene products that Dickerson ingested. The response to Lilly's individual motion in *Dickerson* instead focuses on the plausibility of the argument that "Lilly *manufactured* the drug taken by Mr. Dickerson." [Record No. 911, p. 5 (emphasis added)]

Lilly counters that this string of inferences is "nothing more than wild, unsupported speculation." [Record No. 1051, p. 16] Additionally, it attempts to dismiss as irrelevant the allegations that it manufactured the propoxyphene products, brand-name or generic, ingested by the plaintiffs. It argues that the plaintiffs' response is "devoid of any case law support . . . that these inferences — even if assumed to be true — could form the basis for a plausible claim." [*Id.*, p. 17] In other words, Lilly asserts that it cannot be held liable for any propoxyphene products that it manufactured for other companies, either before or after its divestiture in February 2002. However, Lilly's briefs contain no more case law support for this assertion than the plaintiffs' briefs do for their contention that "Lilly has not, and reasonably could not, dispute that it can be held liable under products liability causes of action to persons who ingested and were injured by the drugs it manufactured." [Record No. 635, p. 27] In most jurisdictions, there are several theories of product liability under which a plaintiff can recover from a manufacturer that did not directly sell the product. *See* 63 Am. Jur. 2d §§ 407, 533 (discussing negligence theories of product liability and strict liability theories of product liability). Assuming that the plaintiffs can, theoretically, bring a product liability claim against Lilly as the manufacturer of propoxyphene, the question becomes whether the allegations in the complaints are enough to create a reasonable inference that Lilly manufactured generic and brand-name propoxyphene products.

1. Generic Products

For plaintiffs who ingested generic propoxyphene products, the plaintiffs assert, the allegations that Lilly "manufactured generic propoxyphene products for at least one set of

generic drug companies from 1994 until it sold its NDAs . . . and likely continued to do so after" establish that the plaintiffs could have ingested generic propoxyphene that was manufactured by Lilly. [Record No. 635, p. 26] The plaintiffs' complaints allege that Lilly entered into a propoxyphene supply agreement with "Mylan and/or Mylan Pharmaceuticals" in 1994.[8] [Record No. 287 ¶ 142] Additionally, they state that the 2002 NDA-transfer agreement with NeoSan "specifically indicates that nothing therein would forbid Eli Lilly from fulfilling the requirements" of that supply agreement. [*Id.*] According to the plaintiffs, these allegations create a reasonable inference that "at least some of the generic propoxyphene products that Plaintiffs ingested both before and after the February 2002 divestiture had been manufactured by Lilly." [Record No. 635, p. 26]

Accepting all allegations as true, the complaints do sufficiently establish that Lilly manufactured generic propoxyphene for at least one of the Mylan defendants. This is not enough to state a claim that survives Lilly's motion to dismiss, however. At most, the complaints suggest that a plaintiff who has alleged the ingestion of a Mylan product after 1994 may have taken propoxyphene manufactured by Lilly. This establishes nothing more than a "sheer possibility" that Lilly is liable for those plaintiffs' injuries. *Iqbal*, 129 S. Ct. at 1949. Moreover, none of the plaintiffs have actually alleged the ingestion of a Mylan product. Therefore, the

8 This allegation is present in all of the complaints subject to Lilly's master motion, with the exception of the *Simpson* Complaint. [Record No. 319]

complaints do not plead sufficient facts to support a plausible claim that Lilly manufactured the generic propoxyphene ingested by the plaintiffs.[9]

2. Brand-Name Products

The plaintiffs allege that Lilly also manufactured some portion of the brand-name propoxyphene products ingested after its divestiture in 2002. Their reasoning is based on the following allegations:

> 143. In connection with the Assignment, Transfer, and Assumption Agreement, NeoSan and Eli Lilly also entered into a Manufacturing Agreement on February 18, 2002, which was set to expire on December 31, 2004, subject to a six month extension at NeoSan's election.
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> 144. Under the Manufacturing Agreement, NeoSan agreed to purchase a set percentage of its Darvocet and Darvon from Eli Lilly, who would manufacture the products, which equaled 60% in the first year of the contract, 50% in the second contract year, and 40% in the third contract year.
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> 145. The Manufacturing Agreement also obligated Eli Lilly to transfer its existing inventory of Darvocet and Darvon products to NeoSan, and provided that the aaiPharma Entities would "not re-label or over-label any such Product inventory without the prior written consent of Lilly. . . ."
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> . . . .
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> 172. This indicates that the aaiPharma Entities likely sold Eli Lilly-labeled product even after buying the NDA, and that Xanodyne may have sold the same, although Plaintiff will require discovery to determine the extent and amount of such sales.

[Record No. 287 ¶¶ 143-45, 172] From this, the plaintiffs assert, the Court can infer the following: (1) Lilly "transferred all of its existing brand-name inventory to NeoSan when it sold

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9 Even if they had, none of the complaints actually lists Lilly as a "Generic Defendant." [*See, e.g.*, Record No. 287 ¶¶ 27-51] Therefore, the counts asserted against the "Generic Defendants" do not apply to Lilly, in its capacity as a contract manufacturer for generic companies or otherwise.

its marketing rights to NeoSan"; (2) Lilly "also manufactured a significant portion of NeoSan's brand-name product throughout most, if not all, of the time that NeoSan owned the marketing rights"; and (3) when Xanodyne purchased the propoxyphene NDA, Neosan transferred all of its existing brand-name inventory to Xanodyne. [Record No. 635, p. 26; *see* Record No. 287 ¶¶ 23-24, 143-46, 148, 169, 171-74] Based on these three propositions, the plaintiffs reason that the Court can infer that at least a portion of the brand-name product that NeoSan transferred to Xanodyne was manufactured by Lilly. [Record No. 635, p. 26] As a result, the plaintiffs aver that "one can reasonably infer that much of the brand-name product that NeoSan and Xanodyne sold after February 2002 was product that was manufactured by Lilly." [*Id.*]

The plaintiffs have failed to state a plausible claim against Lilly as a manufacturer of brand-name drugs after 2002. Accepting the allegations as true, at most they establish a "mere possibility that the medicine used could have been made by [Lilly], rather than by any number of other manufacturers." [Record No. 416-7, p. 28 (quoting *Dittman v. DJO, LLC*, No. 08-cv-02791-WDM-KLM, 2009 WL 3246128, at *1 (D. Colo. Oct. 5, 2009))] This is simply insufficient under *Iqbal* or *Twombly* because the allegations are too speculative to state a plausible claim.

This is especially so because the complaints do not allege the products ingested with any specificity. Of the five plaintiffs who insist that they "ingested brand-name products after Lilly sold its propoxyphene NDAs in February 2002," only one contains specific allegations regarding the products ingested.[10] The *Washington* Complaint alleges that the plaintiff "was prescribed

10 The other plaintiffs are Corso, who only alleged the ingestion of generic propoxyphene [Record No. 317 ¶¶ 8, 37]; Dickerson, whose factual allegations are discussed in Part II.A, *supra*; Eldredge, whose

Darvocet from September 10-October 11, 2010" and that he "received Xanodyne's product." [Record No. 276 ¶ 9] However, the series of inferential leaps outlined above is far too attenuated with regard to the ingestion dates alleged by the plaintiff in *Washington*. The statement that "Xanodyne may have sold" products manufactured by Lilly is too vague to establish that *this* plaintiff ingested a Lilly drug on those specific dates. [*Id.* ¶ 136] Therefore, the plaintiffs' complaints fail to state a claim against Lilly in its capacity as a manufacturer of brand-name propoxyphene after February 2002. As a result, the product liability claims against Lilly in each of these cases will be dismissed as a matter of law.

Even if the complaints sufficiently alleged that the plaintiffs ingested a drug manufactured by Lilly, the claims against Lilly in its capacity as a manufacturer would likely fail. The plaintiffs have not brought a manufacturing defect claim against Lilly because their "allegations do not assert that Lilly, at any time, manufactured products that were adulterated, outside of specifications, or used defective ingredients." [Record No. 1041, p. 9] Additionally, any state failure-to-warn claims would be preempted by federal law because, as the plaintiffs concede, "Lilly had no power to change the labels for generic drugs, or for brand-name drugs that were made and sold by others." [Record No. 635, p. 28] *See generally Pliva v. Mensing*, 131 S. Ct. 2567 (2011) (holding that federal law, which requires warning labels on generic drugs to match those of the corresponding brand-name drugs, preempted the plaintiffs' failure-to-warn claims against generic drug manufacturers). Thus, it is not immediately apparent what purpose

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complaint alleges only the ingestion of "Propoxyphene containing medications" [Record No. 300 ¶ 9]; and Meeks, whose factual allegations are discussed in Part II.A, *supra*.

would be served by establishing that Lilly manufactured propoxyphene products for other companies, generic or brand-name.

IV. Misrepresentation Theories

Plaintiffs contend that, regardless of the viability of their product liability claims, they have asserted valid and separate claims for misrepresentation. [Record No. 635, pp. 27-33] They argue that their misrepresentation claims are distinct from product liability claims, and as such are not subject to the requirement that the complaints allege the ingestion of a Lilly product. As a result, the plaintiffs maintain that their misrepresentation claims against Lilly must survive dismissal despite the lack of product identification in the complaints. Lilly asserts that the claims brought under this theory should be dismissed as failing to state a claim with particularity, as required by Rule 9(b) of the Federal Rules of Civil Procedure. Additionally, Lilly argues that the claims fail as a matter of law because a "name-brand manufacturer simply 'has no duty to users of other manufacturers' products.'" [Record No. 1051, p. 22 (quoting *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 170 (4th Cir. 1994))]

A. Rule 9(b)

Lilly argues that the plaintiffs' "fraud claims are not pled with particularity and do not meet the requirements of Rule 9(b)." [Record No. 416-7, p. 5] Federal Rule of Civil Procedure 9(b) provides: "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). A complaint is sufficient for purposes of Rule 9(b) if it alleges "(1) the time, place, and content of the alleged

misrepresentation, (2) the fraudulent scheme, (3) the defendants' fraudulent intent, and (4) the resulting injury." *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 467 (6th Cir. 2011) (internal quotation marks omitted).

Here, Lilly contends, the plaintiffs: (1) failed to identify "the persons making the alleged misstatements or when or where the statements occurred," (2) failed to plead fraud specifically against each individual defendant,[11] and (3) made conclusory statements unsupported by fact. [*Id.*, p. 32] Plaintiffs, on the other hand, maintain that they have provided "sufficient notice to Lilly of the substance of Plaintiffs' fraud claims." [Record No. 635, p. 39] They assert that they have provided the who, what, when, and how required by Rule 9(b).

The plaintiffs have satisfied the requirements of Rule 9(b). They have sufficiently addressed the "who" and "what" requirements by alleging that Lilly made false statements to the FDA, physicians, and the health care community, and that the statements were made in "reports, press releases, advertising campaigns, television commercials, print advertisements, billboards, other commercial media, promotional materials, instructional material and labeling." [Record No. 287, p. 88] And they have met the "when" requirement by alleging that the statements were made in 1978. [*Id.*, p. 109] As a result, the plaintiffs' complaints are sufficient for the purposes of Rule 9(b). Despite this, however, Lilly cannot be held liable to plaintiffs who consumed other companies' products.

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11 For instance, Lilly points to blanket allegations such as statements that "the Brand Defendants at all relevant times . . . [had the duty to] assess, manage and communicate the risks, dangers and adverse effects associated with Propoxyphene Products to the health care community." [Record No. 302 ¶ 271] Because Lilly divested its NDA in 2002, it did not have that duty "at all relevant times."

B. Misrepresentation Claims

The plaintiffs maintain that even if their product liability claims fail, Lilly can still be held liable under misrepresentation theories "sounding in negligence and fraud." [Record No. 635, p. 28] According to this argument, the plaintiffs "do not seek to hold Lilly liable because its products caused them harm; rather, they seek to hold Lilly liable because its misrepresentations did." [*Id.*] Lilly counters that "the overwhelming majority of courts" have rejected the exact arguments advanced by the plaintiffs. [Record No. 1051, p. 18] It urges the Court to follow that line of precedent and refuse to hold Lilly liable to plaintiffs who ingested a drug that it did not sell or manufacture.

The Court rejects the plaintiffs' contention, for the reasons explained in the Memorandum Opinion and Order Regarding Xanodyne Pharmaceuticals, Inc.'s Motions to Dismiss, entered March 5, 2012. [Record No. 1274] In the absence of any binding authority that would dictate the application of the rule advocated by the plaintiffs, this Court must conclude that Lilly cannot be held liable to plaintiffs who consumed other manufacturers' drugs. Because the plaintiffs in this case have not sufficiently alleged the ingestion of a Lilly product, their misrepresentation claims fail.

V. Leave to Amend

The plaintiffs seek leave to amend their complaints to add product identification information "if this Court believes that the complaints are otherwise deficient without it." [Record No. 635, p. 22] However, "[p]laintiffs [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) (alteration in original) (internal quotation marks omitted). Furthermore, 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 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. This is especially true here, where many of the plaintiffs were already given leave to amend their complaints once. Therefore, the plaintiffs' request for leave to amend is denied.

CONCLUSION

In summary, the plaintiffs subject to this motion have failed to set forth allegations that establish — or even allow the Court to properly infer — that they ingested a product sold, marketed, or manufactured by Lilly. Moreover, they have not identified any rule of law that would allow them to recover from a defendant that did not sell, market, or manufacture the product that caused their injuries. Therefore, the plaintiffs' claims against Lilly fail to state a plausible claim upon which relief can be granted. Accordingly, it is hereby

ORDERED as follows:

1. Defendant Eli Lilly and Company's motion to convert [Record No. 643] is **GRANTED**. Lilly's Master Motion to Dismiss and individual Motions to Dismiss will be treated as filed pursuant to Rule 12(c) of the Federal Rules of Civil Procedure. To the extent the instant motion is captioned as a motion for judgment on the pleadings, it is duplicative of the now-converted motions and, therefore, **DENIED** as moot.

2. Eli Lilly's Master Motion to Dismiss [Record No. 416] is **GRANTED**.

3. Eli Lilly's individual motions to dismiss [Record Nos. 414, 418, 421, 423, 436, 437, 438, 439, 443, 446, 452, 455, 456, 460, 465, 467, 471, 472, 473, 476, 570] are **DENIED** as moot.

4. In accordance with this Memorandum Opinion and Order, the claims asserted against Defendant Eli Lilly and Company in the following cases are **DISMISSED**, with prejudice:

- Case No. 2: 11-175;
- Case No. 2: 11-179;
- Case No. 2: 11-182;
- Case No. 2: 11-185;
- Case No. 2: 11-186;
- Case No. 2: 11-187;
- Case No. 2: 11-189;
- Case No. 2: 11-190;
- Case No. 2: 11-191;
- Case No. 2: 11-195;
- Case No. 2: 11-197;
- 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; and
- Case No. 2: 11-301.

This 7th of March, 2012.

Signed By:
Danny C. Reeves DCR
United States District Judge