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
Trimboli v. Eli Lilly and Company, et al.,	)	Civil Action No. 2: 11-189-DCR
Eldredge v. Eli Lilly and Company, et al.,	)	Civil Action No. 2: 11-190-DCR
Meeks v. Eli Lilly and Company, et al.,	)	Civil Action No. 2: 11-208-DCR
Labit v. Eli Lilly and Company, et al.,	)	Civil Action No. 2: 11-296-DCR
Balben v. Eli Lilly and Company, et al.,	)	Civil Action No. 2: 11-297-DCR
Forrest v. Eli Lilly and Company, et al.,	)	Civil Action No. 2: 11-298-DCR
Noel v. Eli Lilly and Company, et al.,	)	Civil Action No. 2: 11-299-DCR
Green v. Eli Lilly and Company, et al.,	)	Civil Action No. 2: 11-300-DCR
Wheeler v. Eli Lilly and Company, et al.,	)	Civil Action No. 2: 11-301-DCR
Shumaker v. Eli Lilly and Company, et al.,	)	Civil Action No. 2: 11-328-DCR
Felts v. Eli Lilly and Company, et al.,	)	Civil Action No. 2: 11-329-DCR
Smith v. Eli Lilly and Company, et al.,	)	Civil Action No. 2: 11-330-DCR
Turner v. Eli Lilly and Company, et al.,	)	Civil Action No. 2: 11-331-DCR
Zickefoose v. Eli Lilly and Company, et al.,	)	Civil Action No. 2: 11-347-DCR
Shackelford v. Eli Lilly and Company, et al.,	)	Civil Action No. 2: 11-357-DCR
Nicholson v. Eli Lilly and Company, et al.,	)	Civil Action No. 2: 11-358-DCR
Brown v. Eli Lilly and Company, et al.,	)	Civil Action No. 2: 11-380-DCR

*** *** *** ***

MEMORANDUM OPINION AND ORDER REGARDING AAIPHARMA, LLC'S, AAIPHARMA, INC.'S, AAIPHARMA DEVELOPMENT SERVICES, INC.'S, AND NEOSAN PHARMACEUTICAL, INC.'S MOTION TO DISMISS

*** *** *** ***

This matter is pending for consideration of the motion by Defendants AAIPharma, LLC, AAIPharma, Inc., AAIPharma Development Services, Inc., and NeoSan Pharmaceuticals, Inc. (collectively, "AAI Defendants") to dismiss the claims asserted against them in seventeen

actions in this multidistrict litigation (MDL).[1] [MDL Record No. 1863] For the reasons explained below, the motion will be granted.

BACKGROUND

As this Court has explained in connection with motions involving other defendants, this matter arises from injuries that the plaintiffs or their decedents allegedly suffered as a result of ingesting propoxyphene-containing products.[2] In 1957, the federal Food and Drug Administration ("FDA") approved Eli Lilly and Company's ("Lilly") 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. Lilly retained all the rights to propoxyphene-containing drugs until February 2002, when it sold its NDA to NeoSan Pharmaceuticals, Inc.[3]

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 NeoSan, and manufacturing the drugs for NeoSan until the end of 2004. The AAI Defendants filed for Chapter 11 bankruptcy on May 9, 2005. [*Id.* ¶ 167] Xanodyne

---

[1]The AAI Defendants originally filed motions to dismiss in Civil Action Nos. 2: 11-364-DCR and 2: 11-378-DCR; however, they withdrew their motions as to those cases on June 7, 2012. [MDL Record No. 1918]

[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. [MDL Record No. 1274]

[3]NeoSan is a business unit of AAI Pharmaceuticals, Inc. [*E.g.*, MDL Record No. 291 ¶ 15 (*Balben* Amended Complaint)]

Pharmaceuticals, Inc. ("Xanodyne") in turn, purchased the NDAs for Darvon and Darvocet from NeoSan on July 25, 2005. [*Id.* ¶ 169]

The AAI Defendants filed the present motion on May 22, 2012, moving to dismiss all claims asserted against them by plaintiffs Heidi Balben, Donald Brown, Theresa Eldredge, Shannon Felts, Spencer Forrest, Carla Jo Green, Joseph F. Labit, Jenet Meeks, Steven Nicholson, Bobbie Noel, Betty Shackelford, Clarence Shumaker, Agnes Smith, Gregory P. Trimboli, Martha Turner, Darren Wheeler, and Gary Zickefoose (collectively "plaintiffs"). The claims against the AAI Defendants — as brand-name manufacturers of propoxyphene products — include strict product liability, negligence, fraud and misrepresentation, violation of state consumer protection statutes and breach of warranty.[4] [MDL Record No. 1863-1, p. 14]

ANALYSIS

The AAI Defendants seek dismissal of the claims asserted against them in all cases in which the plaintiffs "fail to properly identify [AAI Defendants] as the manufacturer, seller, or distributor of the product he or she ingested." [*Id.*, p. 12] Additionally, the AAI Defendants argue that "even if Plaintiffs had properly alleged that they ingested a product manufactured by [AAI Defendants] (which they do not), Plaintiffs' state law claims based on their ingestion of any drugs allegedly manufactured by [AAI] still fail," because the AAI Defendants sold the NDAs to Xandodyne on July 25, 2005.[5] [*Id.*, p. 13] The AAI Defendants largely rely on the

[4]The plaintiffs have not asserted manufacturing-defect claims against the AAI Defendants — as generic manufacturers — for any drugs they might have made for other companies on a contract basis after 2005. [*Id.*, p. 13]

[5]The AAI Defendants ask the Court to take judicial notice of the fact that the AAI Defendants "sold the propoxyphene-related NDAs to Xanodyne pursuant to an Asset Purchase

Court's previous Orders dismissing claims asserted by many of these same plaintiffs because "they did not allege that they ingested a product manufactured, sold, or distributed by those Defendants."[6] [*Id.*; *see also* MDL Record Nos. 1402, 1791.]

The plaintiffs first assert that the motion should be held in abeyance for plaintiffs from Arkansas, Connecticut, Georgia, Kentucky, Louisiana, Massachusetts, Oklahoma, and West Virginia, until the highest courts of those states resolve certified questions that the plaintiffs have represented they will file. [MDL Record No. 1950, p. 2] Alternatively, they argue that state product liability law does not bar their claims and that the motion should be denied in all cases.

I. The Standard for a 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*, 556 U.S. 662, 678 (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

---

Agreement dated May 6, 2005." [MDL Record No. 1863, p. 30] In support, they have attached a Bankruptcy Order and Asset Purchase Agreement, as well as other accurate sources. [MDL Record Nos. 1863-3 to 1863-9] Pursuant to Rule 201 of the Federal Rules of Evidence, the Court hereby takes judicial notice of the fact that the AAI Defendants sold the propoxyphene-related NDAs to Xanodyne by a purchase agreement dated May 6, 2005.

[6]The Court has previously dismissed claims against defendants Lilly and/or Xanodyne by plaintiffs Trimboli, Eldredge, Meeks, Labit, Balben, Forrest, Noel, Green, Wheeler, Shumaker, Felts, Smith, Zickefoose, Shackelford, Nicholson and Brown. [*See* MDL Record Nos. 1402, 1791.]

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

The AAI Defendants argue that the plaintiffs' claims are not plausible because the complaints fail to identify any AAI Defendants as the manufacturer, seller, or distributor of the products the plaintiffs ingested. In every state implicated by the AAI Defendants' 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).[7] There is no theory of product liability under which a defendant can be held liable for an injury caused by a product it did not sell, manufacture, or otherwise supply to the plaintiff. Therefore, in the context of product liability claims, a plaintiff must state sufficient

[7] *See Couick v. Wyeth, Inc.*, 691 F. Supp. 2d 643, 646 (W.D.N.C. 2010); *Fields v. Wyeth*, 613 F. Supp. 2d 1056, 1060 (W.D. Ark. 2009); *Meade v. Parsley*, No. 2:09-cv-0038, 2009 WL 3806716, at *3 (S.D.W. Va. Nov. 13, 2009); *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); *Holbrook v. Rose*, 458 S.W.2d 155, 157 (Ky. 1970); *Stanley v. Wyeth, Inc.*, 991 So. 2d 31, 34-35 (La. Ct. App. 2008); *Gorman-Rupp Co. v. Hall*, 908 So. 2d 749, 757 (Miss. 2005); *City of St. Louis v. Benjamin Moore & Co.*, 226 S.W.3d 110, 112-15 (Mo. 2007); *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).

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*, 556 U.S. at 678. In accordance with the Court's previous holding, the AAI Defendants are "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." [MDL Record No. 1274, p. 6]

With respect to the plaintiffs' request that the Court hold the motion to dismiss in abeyance pending the certification of the product identification issue to the highest courts in Arkansas, Connecticut, Georgia, Kentucky, Louisiana, Massachusetts, Oklahoma, and West Virginia, the Court has previously denied the plaintiffs' motions for certification of this and similar questions. [Record Nos. 1723, 1929, 1953, 2148] Thus, the Court will not hold this motion in abeyance.[8]

Regarding the issue of product identification, the complaints in these cases suffer from the same fatal defect as the claims dismissed against defendants Xanodyne and Eli Lilly. The Court has previously held that pleading requirements against a brand-name manufacturer are not satisfied in the following instances: when a plaintiff alleges injuries as a result of ingesting a generic form of Darvocet; when a plaintiff alleges that he or she ingested "Darvon, Darvocet

[8]Plaintiffs also assert that "AAI's motion should be denied, or held in abeyance, or granted without prejudice, in cases where plaintiffs may have ingested an AAI product." [MDL Record No. 1950, p. 7] The consolidated response points to the plaintiffs in *Nicholson v. Eli Lilly and Company, et al.*, (Civil Action No. 2: 11-358-DCR), stating that they do not yet have records to confirm whether the ingested propoxyphene products "might have been AAI products." [Record No. 1950, p. 7] Pursuant to the Agreed Order entered on May 4, 2012 [MDL Record No. 1792], the *Nicholson* plaintiffs were given an opportunity to amend their complaints, but chose not to do so. Because the time to amend has now passed, dismissal with prejudice is proper in these actions.

and/or Propoxyphene" without identifying a particular manufacturer of the brand-name drug; and when a plaintiff admits that he or she cannot determine the defendant or entity that manufactured, marketed, distributed or tested the propoxyphene in question. [MDL Record No. 1274, pp. 6, 16]

None of the plaintiffs in these cases has properly identified any of the AAI Defendants as the entity that marketed, sold, or manufactured the product he or she ingested. Instead, many simply allege that they ingested a "generic form of Darovet." [*E.g.*, MDL Record No. 291 ¶ 8 (*Balben* Complaint)] Other plaintiffs allege the ingestion of brand-name Darvon or Darvocet, specifically "Eli Lilly & Company products" and then generally assert that they "ingested various other unknown brand and/or generic name products . . . for which [they do] not have records available at this time." [MDL Record No. 1765 ¶¶ 9-12 (*Brown* Complaint)] As the Court has previously held, "[s]uch 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." [MDL Record No. 1274, p. 6 (citing *Patterson v. Novartis Pharm. Corp.*, No. 10-5886, 2011 WL 3701884, at *2 (6th Cir. Aug. 23, 2011))] Some plaintiffs allege they were "prescribed Darvocet and ingested its generic equivalent, Propoxy N/APAP100/650." [Record No. 278 ¶ 10 (*Trimboli* Complaint)] Still others state that they "cannot determine the Defendant and/or other entity that manufactured, marketed, distributed and/or tested the particular Propoxyphene Product" that they ingested. [MDL Record No. 293 ¶ 10 (*Labit* Complaint)]

Regardless of the wording, all of the plaintiffs fail to specifically allege in their complaints that the products they ingested were manufactured or sold by any of the AAI Defendants. The Court finds that the plaintiffs failed to set forth allegations that establish — or even allow the Court to plausibly infer — that they ingested products sold, manufactured or distributed by the AAI Defendants. Therefore, the product liability claims against the AAI Defendants in the above-captioned cases fail as a matter of law.

III. Misrepresentation

The plaintiffs also seek to avoid dismissal by arguing that some claims are not product liability claims, but misrepresentation claims. [MDL Record No. 1950, p. 5] Specifically, Plaintiff Gregory Trimboli contends that Connecticut law does not bar his claims because he is asserting a misrepresentation claim, not a product liability claim. [*Id.*] This 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). The Connecticut courts have issued no definitive rulings on whether a brand manufacturer may be held liable for misrepresentations that cause a plaintiff to ingest and suffer harm from a generic version of its drug.[9] It is not the position of this Court to announce a new

[9]The plaintiffs cite two cases — *Reed v. Comen,* No. CV94 31 12 92 S, 1994 WL 669633 (Conn. Super. Ct. Nov. 9, 1994), and *Doyle v. Ronald,* No. CVNO 8604 683, 1987 WL 349014 (Conn. Super. Ct. Feb. 3, 1987) — for the proposition that Connecticut courts recognize "the value of allowing a third party who is injured by direct or indirect reliance on misrepresentations to pursue claims against the misrepresenting party." [MDL Record No. 1950, p. 6] They maintain that these cases are predictive of the approach in Connecticut because they involve analysis under Sections 310 and 311 of the Restatement (Second) of Torts, which the California Court of Appeals relied on in *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299 (Cal. Ct. App. 2008). [MDL Record No. 1950, pp. 6-7] The cases are inapposite because neither involved a claim for product liability. In *Reed*, the court considered the Restatement in the context of a personal injury claim for a dog bite, 1994 WL 669633, at *1 and the *Doyle* court used the sections to analyze a claim for improper eviction. 1987 WL 349014, at *1. The Court is not persuaded that these cases indicate that the Connecticut courts

rule of law. Trimboli does not seek to hold the AAI Defendants liable under the Connecticut Products Liability Act ("CPLA") "for the simple reason that none of AAI's *products* caused harm;" instead he "seeks to hold AAI liable outside of the CPLA because AAI's *misrepresentations* caused harm." [*Id.*] This Court has previously rejected this argument. [*See* MDL Record No. 1402, pp. 16-18; *see also* MDL Record No. 1274, pp. 8-10.]

In the absence of any binding authority expanding the liability of brand-name manufacturers, the AAI Defendants cannot be held liable to plaintiffs who consumed other manufacturers' drugs Trimboli has not asserted any such law. Thus, the Court rejects Trimboli's contention for the reasons explained in the Memorandum Opinion and Order Regarding Xanodyne Pharmaceuticals, Inc.'s Motions to Dismiss, entered March 5, 2012. [*Id.*, pp. 8-10]

IV. Dismissal With Prejudice

Finally, the plaintiffs assert that if the Court grants the motions to dismiss in this case, it should do so without prejudice, "particularly in cases with complaints that have not yet been amended." [MDL Record No. 1950, p. 7] They assert that "when this Court granted Xanodyne's March 9, 2012 motion to dismiss, it did so without prejudice in every case where the complaint had not been amended." [*Id.*] However, in the Agreed Order entered on May 4, 2012, all plaintiffs with pending cases were given twenty-one days within which to file an amended complaint. [MDL Record No. 1792] The deadline has passed. [*Id.*] Generally, plaintiffs are

---

have abrogated the majority rule rejecting "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).

"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). Because each plaintiff was given an opportunity by the Court to amend their pleadings to specifically identify the defendant that sold the product they ingested, the Court finds it proper to dismiss the plaintiffs' claims with prejudice.

CONCLUSION

The plaintiffs subject to this motion have failed to set forth allegations that establish — or allow the Court to plausibly infer — that they ingested a product sold, marketed, or manufactured by AAIPharma, LLC, AAIPharma, Inc., AAIPharma Development Services, Inc., or NeoSan Pharmaceuticals, Inc. Moreover, the plaintiffs 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' complaints against the AAI Defendants fail to state a plausible claim upon which relief can be granted. Accordingly, it is hereby

ORDERED as follows:

1. To the extent that the plaintiffs' consolidated response to the motion to dismiss is construed as a motion to continue or a motion to hold the Court's ruling in abeyance, that request and/or motion is **DENIED**.

2. The Motion to Dismiss by defendants AAIPharma, LLC, AAIPharma, Inc., AAIPharma Development Services, Inc., and NeoSan Pharmaceuticals, Inc. [MDL Record No. 1863] is **GRANTED**.

3. The claims asserted against Defendants AAIPharma, Inc., AAIPharma, Inc., AAIPharma Development Services and NeoSan Pharmaceuticals, Inc. in the above-captioned actions are **DISMISSED**, with prejudice.

This 21st day of August, 2012.

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