UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE : ZOFRAN® (ONDANSETRON) PRODUCTS LIABILITY LITIGATION	MDL No. 1:15-md-2657-FDS This document relates to: All Actions

DEFENDANT GLAXOSMITHKLINE LLC'S
MEMORANDUM IN SUPPORT OF ITS MOTION FOR ENTRY OF AN ORDER CONCERNING PRODUCT IDENTIFICATION

Defendant GlaxoSmithKline LLC ("GSK"), pursuant to Rules 16 and 26 of the Federal Rules of Civil Procedure and Local Rules 16.1(f) and 26.3, hereby moves for entry of an Order concerning product identification, a fundamental and threshold question in this MDL. GSK specifically seeks documentation of product identification to establish whether a Plaintiff used GSK's brand-name Zofran® or another company's generic ondansetron product. As this Court has already noted, product identification is "surely a fair threshold question." *See* MDL Status Conference Transcript (Nov. 17, 2015) at 15:16-22, attached as Exhibit B. The importance of product identification is further magnified here given the substantial number of companies selling generic ondansetron. Requiring disclosure of product information now—information that Plaintiffs should already possess—is the most sensible and fair way to proceed with initial discovery in this litigation. It will allow for a meaningful and fair assessment of the viability (or lack thereof) of the cases before time and money are expended on cases and claims that can and should be dismissed at an early stage. *See In re Darvocet, Darvon, & Propoxyphene Products Liab. Litig*., 756 F.3d 917, 938 (6th Cir. 2014) (stating that an "overwhelming majority" of courts held that brand-name manufacturers cannot be liable to plaintiffs who ingested other

manufacturers' drugs). Beginning the outset of discovery with product identification therefore fulfills the directive of Rule 1 of the Federal Rules of Civil Procedure that the Rules "should be construed, administered, and employed by the court and the parties to secure the just, speedy, and inexpensive determination of every action and proceeding." It is also consistent with the purpose of an MDL—to ensure the "just and efficient" resolution of pretrial proceedings. *See* 28 U.S.C. § 1407(a). In addition, product identification information is a prerequisite to the master pleadings process, as the claims and underlying theories of those who used GSK's product will vary from those who seek to hold GSK liable for use of another company's product.

GSK therefore requests that the Court order Plaintiffs to provide product identification information as set forth in the [Proposed] Order Concerning Product Identification, attached as Exhibit A.

I. LEGAL STANDARD

Federal Rules of Civil Procedure 16 and 26(b), (c) and (d) "vest the trial judge with broad discretion to tailor discovery narrowly and to dictate the sequence of discovery." *Crawford-El v. Britton*, 523 U.S. 574, 598-99 (1998) (noting that "the court may postpone all inquiry" regarding certain matters "until discovery has been had on objective factual questions such as whether the plaintiff suffered any injury"). In order to facilitate the "efficient completion of discovery" and to best develop "information needed for a realistic assessment of the case," Local Rule 26.3 also specifically affords the trial judge "discretion to structure discovery activities by phasing and sequencing the topics which are subject to discovery." The court's control over the execution of discovery exists so that "[t]he trial judge can therefore manage the discovery process to facilitate prompt and efficient resolution of the lawsuit." *Crawford-El*, 523 U.S. at 598-99. Similarly, "[f]ederal district courts enjoy wide discretion in their crafting of the pretrial process." *Berkovitz*

v. Home Box Office, Inc., 89 F.3d 24, 28 (1st Cir. 1996). The Judicial Panel on Multidistrict Litigation has explained that, because "[e]ach multidistrict litigation is unique, . . . transferee judges have broad discretion to determine the course and scope of pretrial proceedings." *In re Light Cigarettes Mktg. & Sales Practices Litig.*, 856 F. Supp. 2d 1330, 1332 n.2 (J.P.M.L. 2012).

II. ARGUMENT

A. Product Identification Is a Threshold Issue Impacting All Cases.

Product identification is a fundamental and pressing issue in this MDL. Because product identification is "surely a fair threshold question," the Court recognized that "collection of product identification evidence" should be among the first discovery measures that the parties consider, since it is "relatively less complicated" than other types of discovery. *See* MDL Status Conference Transcript (Nov. 17, 2015) at 15:16-22, attached as Exhibit B. The Court's recognition has been endorsed in commentary on MDL practices and procedures. *See* Duke Law School Center for Judicial Studies, *MDL Standards and Practices*, at 7-8 (Sept. 11, 2014) ("*MDL Standards*") ("For example, in MDL proceedings in which product identification is an overarching issue, the transferee judge might consider 'establish[ing] an early focus on evidence of product exposure."); *see also* Manual for Complex Litigation, Fourth, § 11.422 (instructing that "initial discovery" should focus on matters that "appear pivotal" and should target "information that might facilitate settlement negotiations or *provide the foundation for a dispositive motion*") (emphasis added).[1]

[1] Beginning with product identification is also consistent with the newly amended "proportionality" standard—providing that parties may only obtain relevant and non-privileged discovery that is also "proportional to the needs of the case." Fed. R. Civ. P. 26(b) (2015). Before engaging in merits discovery, Plaintiffs should disclose what product they claim is at issue. While the 2015 Amendments only recently went into effect on December 1, 2015, "[b]y order of the United States Supreme Court, these amendments 'govern . . . insofar as just and practicable, [in] all proceedings then pending.'" *Gilbert v. Rare Moon Media, LLC*, No. 15-MC-217-CM, 2016 WL 141635, at *4 n.4 (D. Kan. Jan. 12, 2016) (quoting Fed. R. Civ. P., Orders of the Supreme Court of the United States Adopting and Amending Rules (Apr. 29, 2015)); *Carr v. State Farm Mut. Auto. Ins. Co.*, No. 3:15-cv-1026-M, 2015 WL 8010920, at *3-*10 (N.D. Tex. Dec. 7, 2015) (same).

Product identification is especially important here because a significant number of Plaintiffs likely used generic ondansetron products sold by companies other than GSK. In 2006, FDA approved the first generic version of ondansetron, and the market for generic versions quickly blossomed. In 2007, GSK's sales of Zofran® declined by 88% in the United States due to generic competition. *See* GlaxoSmithKline plc, 2007 Annual Report (Form 20-F), 2008 WL 10046482, at *66 (Feb. 29, 2008). Today, generic ondansetron in its various forms is among the most widely distributed generic drug products available. No fewer than 30 different companies currently manufacture different forms of generic ondansetron. *See* http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm. Of the more than 200 complaints pending in this litigation, Plaintiffs in at least 153—over half—allege or allude to use of generic ondansetron. Only 68 Plaintiffs assert exclusive use of brand-name Zofran®. Many complaints contain allegations that are vague, ambiguous, or that otherwise make it impossible to know for certain which product(s) those Plaintiffs actually used.

The lack of product identification information unfairly impacts GSK's ability to plan for future discovery and dispositive motion practice. GSK is entitled to know whether its product was even consumed to meaningfully proceed in this MDL.[2] For purposes of initial discovery, GSK requests only that Plaintiffs complete a straightforward, one-page "Product Identification Disclosure,"[3] identifying and documenting the ondansetron product(s) that each Plaintiff claims to have used. Plaintiffs should already possess such information, as they presumably needed it to bring these lawsuits in the first place, consistent with their obligations under the Federal Rules.

[2] The fact that some Plaintiffs may claim that GSK is liable for injuries allegedly caused by a generic manufacturer's product does not relieve them of their obligation to identify the product they allegedly ingested. GSK is still entitled to know the legal theory on which each Plaintiff intends to proceed.

[3] The Product Identification Disclosure is not intended to substitute for Plaintiffs' Fact Sheets ("PFS"), which GSK anticipates will be served as part of subsequent discovery. The threshold issue of product identification should not be delayed as part of the PFS process.

Providing product identification information will cause Plaintiffs little to no burden and will guide the Court and the parties in determining the most efficient and fair course of pretrial proceedings, including the structure of and procedures for master pleadings.

B. Addressing Product Identification Now Preserves Judicial and Party Resources.

Requiring Plaintiffs to disclose what product they used now will promote efficiency and preserve the resources of the parties and the Court. Some or all of Plaintiffs' claims may be subject to early dismissal because they never actually used GSK's product. Indeed, there is a "mountain of authority" establishing that name-brand manufacturers should not be liable for claims arising from generic drugs. *Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1253 (11th Cir. 2013); *see also In re Darvocet, Darvon, & Propoxyphene Products Liab. Litig*., 756 F.3d 917, 938 (6th Cir. 2014) (noting that an "overwhelming majority of courts" have held that brand-name manufacturers cannot be liable to plaintiffs who ingested other manufacturers' drugs); *In re Darvocet, Darvon & Propoxyphene Products Liability Litig.*, No. 2:11-MD-2226-DCR, 2012 WL 3610237, at *2 (E.D. Ky. Aug. 21, 2012) *aff'd sub nom.* 756 F.3d 917 (6th Cir. 2014) ("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."); *Madden v. Teva Pharma. USA, Inc.*, No. 0087, 2012 WL 4757253, at *1 (Pa. Com. Pl. Phila. Cty. Oct. 1, 2012) (recognizing that "courts across the country have overwhelmingly refused to allow claims against the manufacturer of a name-brand medication for damages allegedly caused by the use of another manufacturer's generic-equivalent medication on both legal and policy grounds").

Other pharmaceutical MDLs facing similar product identification issues have required that plaintiffs provide product identification information at the outset of the litigation. For example, in the *Darvocet, Darvon and Propoxyphene* litigation (MDL No. 2226), the Eastern

District of Kentucky addressed product identification in the first CMO it issued. In the Order, the court permitted limited initial discovery on product identification. *See* Darvocet CMO 1, attached as Exhibit C (discussing document requests and interrogatories on the issue of product identification). All other discovery was stayed. Over the course of the next year, the court dismissed brand manufacturers from over 100 actions because the plaintiffs either did not use the brand manufacturer's product or were unable to properly identify the company that marketed, sold, or manufactured the product that the plaintiffs claimed to have ingested. *See, e.g.*, Orders dismissing brand defendants, attached as Exhibit D. The use of early product identification discovery, therefore, resulted in the appropriate dismissal of brand manufacturers in cases where plaintiffs were unable to show adequate product identification, and prevented needless and costly merits discovery.

Similarly, here, identifying such cases early will ensure that the parties do not expend resources on legally nonviable cases and claims. And the Court will not be forced to oversee unnecessary discovery or to decide needless motions. Addressing product identification now is consistent with the mandate of Rule 1; that is, that the Federal Rules "should be construed, administered, and employed by the court and the parties to secure the just, speedy, and inexpensive determination of every action and proceeding." Fed. R. Civ. P. 1. It also furthers the purpose for which this MDL was created—to "conserve the resources of the parties, their counsel, and the judiciary." Transfer Order, MDL No. 2657 (Oct. 13, 2015) (JPML Dkt. #116).

C. Product Identification Is a Prerequisite to Master Pleadings.

Product identification should be addressed now—before the Court considers the use of master pleadings. Indeed, the master pleadings will be guided by the legal theories that are advanced by each Plaintiff. For example, Plaintiffs who used a generic product cannot rely on a

master complaint that alleges theories of liability based on ingestion of brand-name Zofran®. If a master complaint is intended to capture the allegations and legal theories at issue, it must reflect the fact that some Plaintiffs did not use GSK's product. Thus, which product is at issue—GSK's product or a generic product sold by another company—is information that must be known and disclosed before turning to master pleadings.

The uncertainty created by lack of product identification is illustrated by a number of individual complaints that provide vague allegations as to the specific product at issue. *See, e.g.*, Complaint and Jury Demand at ¶ 90, *Faciane v. GlaxoSmithKline LLC*, No. 1:16-cv-10055-FDS (D. Mass. Jan. 14, 2016) (alleging use of "Zofran **and/or** ondansetron") (emphasis added), attached as Exhibit E. This type of pleading does not provide GSK "fair notice of what the . . . claim is and the grounds upon which it rests," as required by Fed. R. Civ. P. 8(a)(2). *See Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007). Basic product identification information is critical to allowing the parties to fully and fairly evaluate the structure of and procedures for master pleadings. Identifying this information should, therefore, precede consideration of master pleadings.

III. CONCLUSION

For the foregoing reasons, GSK respectfully requests that this Court enter an Order requiring Plaintiffs to identify and document the ondansetron product(s) that each Plaintiff claims to have used, as set forth in the [Proposed] Order Concerning Product Identification, attached as Ex. A**.**

Dated: February 22, 2015

Respectfully submitted,

GLAXOSMITHKLINE LLC,
By its attorneys,

/s/ Madeleine M. McDonough
Madeleine M. McDonough
Jennifer Stonecipher Hill
SHOOK, HARDY & BACON L.L.P.
2555 Grand Blvd.
Kansas City, MO 64108
Telephone: (816) 474-6550
Facsimile: (816) 421-5547
mmcdonough@shb.com
jshill@shb.com
Admitted pro hac vice

Mark D. Seltzer (BBO # 556341)
Joshua S. Barlow (BBO # 667472)
NIXON PEABODY LLP
100 Summer Street
Boston, MA 02110
Telephone: 617-345-1000
Facsimile: 617-345-1300
mseltzer@nixonpeabody.com
jbarlow@nixonpeabody.com

George W. Vien (BBO # 547411)
DONNELLY, CONROY & GELHAAR LLP
260 Franklin Street, Suite 1600
Boston, MA 02110
Telephone: 617-720-2880
Facsimile: 617-720-3554
gwv@dcglaw.com

Attorneys for Defendant GlaxoSmithKline LLC

CERTIFICATE OF SERVICE

I hereby certify that the foregoing Memorandum in Support of GlaxoSmithKline LLC's Motion for Sequenced Discovery, which was filed with the Court through the CM/ECF system, will be sent electronically to all registered participants as identified on the Notice of Electronic Filing ("NEF") and paper copies will be sent via first class mail to those identified as non-registered participants.

/s/ Madeleine M. McDonough
Madeleine M. McDonough

Exhibit A

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: ZOFRAN (ONDANSETRON) PRODUCTS LIABILITY LITIGATION,	)	**MDL. No. 1:15-md-2657-FDS**
This Document Relates To :	)	
All Cases	)	

MDL Order No. __
February __, 2016

[PROPOSED] ORDER CONCERNING PRODUCT IDENTIFICATION

1. *Scope.* This Order shall govern the actions transferred to this Court by the Judicial Panel on Multidistrict Litigation ("JPML") pursuant to its Transfer Order, dated October 13, 2015, all related actions directly filed in this Court, and any "tag-along" actions transferred to this Court by the JPML.

2. *Required Disclosure.* All current and future Plaintiffs shall provide the following information by completing the Product Identification Disclosure form attached as Exhibit 1:

a. Name of the Plaintiff who allegedly ingested ondansetron;

b. Name of the manufacturer(s) of the ondansetron allegedly ingested by Plaintiff;

c. National Drug Codes ("NDC") identifying the manufacturer(s) of ondansetron allegedly ingested by Plaintiff;

d. Plaintiff's alleged dates of ingestion of ondansetron; and

e. Pharmacy, insurance, or other records that document dispensation of any and all ondansetron to Plaintiff.

3. *Timing.* For all cases currently coordinated in this MDL, each Plaintiff shall serve her completed Product Identification Disclosure on Defendant(s) no later than thirty (30) days from this Order or thirty (30) days from the entry of a protective order governing confidential and privileged information, whichever is longer. For any case subsequently directly filed in or transferred to this MDL, Plaintiffs shall serve a Product Identification Disclosure on Defendant(s) no later than thirty (30) days from direct filing or transfer or the entry of a protective order of confidentiality, whichever is longer.

4. *Full Compliance Required.* To satisfy their obligations under this Order, Plaintiffs must complete all fields in the Product Identification Disclosure. To the extent that Plaintiffs lack information for one or more of the fields, Plaintiffs must complete all fields for which they have required information. An answer such as "Zofran® and/or ondansetron" in any of the fields, or a similar non-responsive answer, shall be deemed deficient and a failure to comply with this Order.

5. *Failure to Comply.* In the event that Plaintiffs are unable to complete all required entries and/or substantiate product identification after engaging in a good faith effort to do so, Plaintiff's counsel shall notify the opposing counsel by letter of such fact within the period for serving the Product Identification Disclosure. If Defendant(s) receives a Product Identification Disclosure that is not substantially complete, counsel for Defendant(s) shall send a deficiency letter within fourteen (14) days of receipt of the Product Identification Disclosure. All parties shall meet and confer in a good faith effort to resolve outstanding product identification issues. A Plaintiff shall have fourteen (14) days to cure any deficiencies.

6. *Failure to Cure Deficiencies.* In the event an individual Plaintiff fails to timely provide the information and records requested in the Product Identification Disclosure, as set forth above and in the attached Exhibit 1, Defendant(s) may move the Court for dismissal of the individual matter.

7. *Other Evidence.* To the extent that an individual Plaintiff provides pharmacy or other records for all periods of alleged ingestion and those records do not provide NDC codes identifying the manufacturer of ondansetron purchased by Plaintiff, that Plaintiff shall then have sixty (60) days from the date of serving the Product Identification Disclosure to provide any records, affidavits, and/or other evidence on which the Plaintiff intends to rely as to the identity of the manufacturer of ondansetron that she ingested.

8. *Effect of Product Identification Disclosure.* A completed Product Identification Disclosure shall be considered interrogatory answers under Fed. R. Civ. P. 33 and responses to requests for production under Fed. R. Civ. P. 34 and will be governed by the standards applicable to written discovery under the Federal Rules of Civil Procedure. Plaintiffs are responsible for identifying all ondansetron products giving rise to their claims. The factual information provided in an individual Plaintiff's Product Identification Disclosure overrides any conflicting information previously set forth in a Complaint.

Dated: February __, 2016

_____

Hon. F. Dennis Saylor, IV

Exhibit 1

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE : ZOFRAN® (ONDANSETRON) PRODUCTS LIABILITY LITIGATION	MDL NO. 1:15-md-2657-FDS

PRODUCT IDENTIFICATION DISCLOSURE

In completing this disclosure, you are under oath and must provide information that is true and correct to the best of your knowledge. You must answer every question as specifically as possible. This disclosure shall be completed in accordance with the requirements and guidelines set forth in the applicable Case Management Order.

1. **Individual case caption: _____**

2. **Docket No.: _____**

3. **Plaintiffs' attorney and contact information:**

   _____

   _____

   _____

4. **Name of the plaintiff who allegedly ingested ondansetron:**

   _____

5. **Name of the manufacturer(s) of the ondansetron allegedly ingested by Plaintiff:**

   _____

6. **National Drug Codes ("NDC") identifying the manufacturer(s) of ondansetron allegedly ingested by Plaintiff:**

   _____

7. **Plaintiff alleges that she used ondansetron from _____ (date) to _____ (date).**

8. **Attach pharmacy, insurance, or other records that document dispensation of any and all ondansetron to Plaintiff.**

Verification

I declare under penalty of perjury that all of the information provided in this Product Identification Disclosure is true and correct to the best of my knowledge, information, and belief, and that I have supplied all the documents requested in this Product Identification Disclosure, to the extent that such documents are in my possession or in the possession of my lawyers.

_____	_____
Plaintiff's Signature	Plaintiff's Signature
_____	_____
Plaintiff's Printed Name	Plaintiff's Printed Name
_____	_____
Date	Date

Exhibit B

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: ZOFRAN (Ondansetron) PRODUCTS LIABILITY LITIGATION) MDL No. 15-02657-FDS

BEFORE: THE HONORABLE F. DENNIS SAYLOR, IV

STATUS CONFERENCE

John Joseph Moakley United States Courthouse
Courtroom No. 2
1 Courthouse Way
Boston, MA 02210

November 17, 2015
9:32 a.m.

Valerie A. O'Hara, FCRR, RPR
Official Court Reporter
John Joseph Moakley United States Courthouse
1 Courthouse Way, Room 3204
Boston, MA 02210
E-mail: vaohara@gmail.com

Court will enter in that stay is those counsel for those other defendants will get a chance to appear and confer with the plaintiffs and discuss whatever responsive pleading may be coming, and then we'll deal with that procedurally in due course.

THE COURT: Okay. Again, at least in the short term, my concern is that we be organized.

MS. McDONOUGH: Yes. I think as a practical matter, your Honor, step 1 is to figure out what product these people used, and presumably that should have been known before filing, so I think if the plaintiffs can come forward with the identification of the product just based on medical records or pharmacy records, we could sort out which, if any, cases GSK is involved in versus other defendant manufacturers. That to me seems like a threshold question.

09:50AM

09:50AM

THE COURT: Well, it may not answer everything, but it's surely a fair threshold question, and I think that one of the things that ought to be done, I guess, upfront is first off -- well, I guess we can talk about this, but preservation of evidence, initial disclosures, collection of product identification evidence, which I imagine is, at least in my experience, is relatively less complicated. You have a prescription that says X or Y, and it was filled with product A or B. Again, there may be legal theories that go beyond the prescription. I can't speak to that now.

Exhibit C

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

IN RE: DARVOCET, DARVON AND PROPOXYPHENE PRODUCTS LIABILITY LITIGATION	MDL No. 2226 ALL CASES
	CASE MANAGEMENT AND SCHEDULING ORDER NO. 1

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

The Court conducted a hearing on Monday, September 26, 2011, to establish a case management schedule and to discuss the various pending motions in the cases consolidated before it by the Judicial Panel on Multidistrict Litigation. After considering the parties' submissions and statements during the hearing, the Court adopts the following rules regarding the case management schedule.

1. Scope

This Order will govern the practice and procedure in those actions transferred to this Court by the Judicial Panel on Multidistrict Litigation ("JPML") pursuant to its Order of August 16, 2011. This Order will also govern the practice and procedure in any tag-along actions transferred to this Court by the JPML pursuant to Rules 7.1 and 7.2 of the Rules of Procedure of that Panel ("JPML Rules") and any related actions subsequently transferred or removed to this

Court or, if appropriate, filed in this Court. Cases may not be filed directly into this Court unless otherwise appropriate. Related cases, if any, must be filed in an appropriate jurisdiction and then transferred in accordance with 28 U.S.C. § 1407 or reassigned in accordance with JPML Rule 7.2.

Counsel should familiarize themselves with the Local Rules of this Court. The provisions of this Order, and any subsequent Scheduling Order, supersede any inconsistent provisions of the Court's Local Rules.

2. Status Conferences

The Court will hold status conferences at approximately 60-day intervals, at dates set by the Court. The first status conference will occur on **Monday, December 19, 2011, at 1:30 p.m. EST**. To minimize costs and facilitate manageable conferences, all parties need not attend any of these status conferences unless directed to do so by the Court. Instead, parties may be represented by a member of the Plaintiffs' Steering Committee ("PSC") or the Defendants' Steering Committee ("DSC"). A party will not, by designating an attorney to represent its interests at a status conference, be precluded from other representation during the litigation, and attendance at the conference will not waive objections to jurisdiction, venue, or service.

To aid the Court and the parties in preparing for future conferences, not less than seven (7) days prior to each conference, the PSC and DSC shall submit proposed agendas that identify any issue that any party wishes to raise with the Court, including a brief statement of the party's respective position on such issue. The agendas are intended to inform the Court of matters that the parties desire to raise at the status conference, and the Court may amend or augment the

proposed agendas as it deems appropriate. For the December 19, 2011, hearing, the parties should be prepared to address: (i) briefing, scheduling oral argument, and/or other resolution of any motions to dismiss or for summary judgment pending at that time; (ii) class certification issues; and (iii) a schedule for merits discovery.

Except for emergencies or unless otherwise agreed by the parties, motions shall not be brought for hearing at any time other than a regularly-scheduled status conference. To be heard at a regularly scheduled status conference, a motion must be filed and served by 5:00 p.m. EST, at least sixty (60) days before that conference. Any motion filed and served less than sixty (60) days before a status conference or not fully briefed seven (7) days before the status conference shall not be heard at the upcoming status conference, but at the status conference thereafter.

3. Service of Process

Service of all papers filed with the Court shall be accomplished by electronic filing, and no other type of service is permitted or required. The Court modifies Paragraph 6 of its August 30, 2011, Order Regarding Practice and Procedure Upon Transfer and Setting Initial Conference in the following respect: Filings that pertain only to an individual case pending in the MDL should be served only upon all counsel of record in the docket for that individual case, rather than on each attorney who has appeared in the MDL.

Service of all papers that pertain to the MDL docket that are not filed with the Court shall be accomplished by plaintiffs serving each individual defendant's national counsel, and by the defendants serving Plaintiffs' Co-Lead Counsel, by either: (i) overnight mail service; (ii) e-mail; or (iii) hand-delivery. Whenever feasible, the serving party shall send courtesy copies

simultaneously *via* e-mail in PDF format to such defendants' national counsel or to Plaintiffs' Co-Lead Counsel, as applicable, of any documents otherwise served by overnight mail service or hand-delivery. For service of all papers that pertain to an individual case only, service shall be accomplished in the same manner, but only upon the attorneys who have appeared in the docket number for that individual case.

4. Discovery and Motions

a. General Provisions

No motion (other than under Federal Rule of Civil Procedure 12) will be filed unless it includes a certification that the movant has conferred with opposing parties and made a good faith effort to resolve the matter without court action. No motions for class certification may be filed until further order of this Court. Discovery requests and responses will not be filed with the Court except when specifically ordered by the Court or to the extent needed in connection with a motion.

All disclosure obligations and discovery proceedings in these actions are **STAYED**, except as provided in this Order. However, cases may proceed with *limited* discovery prior to the December 19, 2011 hearing, as set forth below.

b. Defendants' Discovery: Product Identification

Defendants contend that they have been named in lawsuits by plaintiffs who did not actually ingest a product that the defendants manufactured, sold, or distributed. Defendants further contend that if they did not manufacture, sell, or distribute the particular product(s) the plaintiff ingested, the claims against them should be dismissed with prejudice.

Defendants may proceed with limited discovery regarding the issue of product identification, through the use of document requests and interrogatories. Product-identification evidence is any evidence that identifies the manufacturer, seller, or distributor of the product(s) that the plaintiff(s) ingested. With regard to any case currently docketed in this District as of the date of this Order, defendants must submit their requests within fifteen (15) days of this Order, and plaintiffs must submit their responses no less than thirty (30) days after receiving the request(s). With regard to any case transferred to and docketed in this District after the date of this Order, defendants must submit their requests within fifteen (15) days of the ECF docketing of the case in the District, and plaintiffs must submit their responses no less than thirty (30) days after receiving the request(s).

Product-identification evidence that defendants may seek through document requests and/or interrogatories may include one or more of the following: (i) pharmacy or medical records that contain the National Drug Code ("NDC") and/or the manufacturer, seller, or distributor's name for the product; (ii) an original or photocopy of the pill bottle that contains the NDC and/or the manufacturer, seller, or distributor's name for the product; (iii) an affidavit or declaration from an authorized representative of the pharmacy or pharmacies at which the plaintiff(s) filled his or her prescriptions, which sets forth the NDC and/or manufacturer, seller, or distributor's name for the product(s) dispensed to the plaintiff(s); and/or any other circumstantial evidence that a plaintiff may seek to rely on in support of it claim relating to a particular defendant.

c. Plaintiffs' Discovery: Ownership Interest Information

A related issue in this case is the sequence and timing of ownership interests in the products ingested by the plaintiffs. Plaintiffs may proceed with limited discovery regarding the issue of ownership interests in the products at issue, as well as retention and/or transfers of any ownership interests to other parties. Plaintiffs may proceed with limited discovery regarding ownership interests through the use of document requests and interrogatories

Discovery conducted by plaintiffs related to acquisition and transfer information will be conducted as coordinated discovery on behalf of all plaintiffs. All discovery initiated on behalf of the plaintiffs shall be conducted and coordinated through the Plaintiffs' Executive Committee ("PEC"). The PEC shall manage all plaintiffs' discovery to ensure that such discovery is conducted on a coordinated and, where practical, consolidated basis.

If a party exceed the scope of discovery permitted, the party subject to the request may file a motion for a protective order. If granted, the party seeking discovery will not be allowed to seek information concerning product information or ownership interests until the Court allows the parties to proceed with discovery on the merits.

5. Communications

Unless otherwise ordered by this Court, all substantive communications with this Court shall be in writing, with copies to opposing counsel.

The Court recognizes that cooperation by and among plaintiffs' counsel and by and among defendants' counsel is essential for the orderly and expeditious resolution of this litigation. The communication of information among and between plaintiffs' counsel and among and between defendants' counsel shall not be deemed a waiver of the attorney-client privilege

or the protection afforded attorneys' work product, and cooperative efforts contemplated above shall in no way be used against any plaintiff by any defendant, or against any defendant by any plaintiff. Nothing contained in this Order shall be construed to limit the rights of any party or counsel to assert the attorney-client privilege or attorney work product doctrine.

This 4th day of October, 2011.

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

Exhibit D

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. Eli Lilly and Company, et al.,	Civil Action No. 2: 11-175-DCR
Alix v. Eli Lilly and Company, et al.,	Civil Action No. 2: 11-182-DCR
Gilbert v. Eli Lilly and Company, et al.,	Civil Action No. 2: 11-184-DCR
Hunsucker v. Eli Lilly and Company, et al.,	Civil Action No. 2: 11-185-DCR
West v. Eli Lilly and Company, et al.,	Civil Action No. 2: 11-186-DCR
Eldredge v. Eli Lilly and Company, et al.,	Civil Action No. 2: 11-190-DCR
Kellehar v. Eli Lilly and Company, et al.,	Civil Action No. 2: 11-191-DCR
Hallaway v. Eli Lilly and Company, et al.,	Civil Action No. 2: 11-195-DCR
Lowe v. Eli Lilly and Company, et al.,	Civil Action No. 2: 11-196-DCR
Coney v. Eli Lilly and Company, et al.,	Civil Action No. 2: 11-197-DCR
Rogers v. Xanodyne Pharm. Inc., et al.,	Civil Action No. 2: 11-200-DCR
Daugherty v. Eli Lilly and Company, et al.,	Civil Action No. 2: 11-204-DCR
Meeks v. Eli Lilly and Company, 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. Eli Lilly and Company, 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. 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
Knight v. Xanodyne Pharm., Inc., et al.,	Civil Action No. 2: 11-307-DCR
Del Favero v. Xanodyne Pharm., Inc., et al.,	Civil Action No. 2: 11-311-DCR
Blackwell v. Xanodyne Pharm., Inc., et al.,	Civil Action No. 2: 11-312-DCR
Sandel v. Eli Lilly and Company, et al.,	Civil Action No. 2: 11-325-DCR
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
Lewis-Crossno v. Eli Lilly and Co., et al.,	Civil Action No. 2: 11-335-DCR
Hect v. Eli Lilly and Company, et al.,	Civil Action No. 2: 11-339-DCR
Adams v. Eli Lilly and Company, et al.,	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

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

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

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

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[1]

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

1 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).[2] 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

2 *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."[3] [*E.g.*, MDL Record

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.[4] 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 1949. Therefore, the product liability claims against Xanodyne in each of these cases fail as a matter of law.[5]

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

---

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."[6] [*Id.*, p. 24] They argue that their misrepresentation claims are distinct

6 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.[7] 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

7 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][8] 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

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.[9] [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*

9 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 5th day of March, 2012.

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

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

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

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

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

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.*]

---

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.
>
> 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.
>
> 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. . . ."
>
> . . . .
>
> 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

---

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

---

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.

---

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

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
Smith, et al., v. Mylan Pharm., Inc., et al.,	)	Civil Action No. 2: 11-183-DCR
Gianoli v. Xanodyne Pharm., Inc., et al.,	)	Civil Action No. 2: 11-220-DCR
Waters v. Eli Lilly and Company, et al.,	)	Civil Action No. 2: 11-248-DCR
Zickefoose, et al., v. Eli Lilly and Co., et al.,	)	Civil Action No. 2: 11-347-DCR
Shackelford, et al., v. Eli Lilly & Co., et al.,	)	Civil Action No. 2: 11-357-DCR
Nicholson, et al., v. Eli Lilly and Co., et al.,	)	Civil Action No. 2: 11-358-DCR
B. Black v. Eli Lilly and Company, et al.,	)	Civil Action No. 2: 11-392-DCR
Ooten v. Eli Lilly and Company, et al.,	)	Civil Action No. 2: 11-397-DCR
Breault v. Xanodyne Pharm., Inc., et al.,	)	Civil Action No. 2: 12-002-DCR
Adegbayi v. Xanodyne Pharm., Inc., et al.,	)	Civil Action No. 2: 12-013-DCR
Marsalis v. Eli Lilly and Company, et al.,	)	Civil Action No. 2: 12-032-DCR
Dunn v. Xanodyne Pharm., Inc., et al.,	)	Civil Action No. 2: 12-068-DCR
Morel v. Xanodyne Pharm., Inc., et al.,	)	Civil Action No. 2: 12-074-DCR
Angell v. Xanodyne Pharm., Inc., et al.	)	Civil Action No. 2: 12-080-DCR

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

ORDER GRANTING DEFENDANT XANODYNE PHARMACEUTICALS, INC.'S MOTION TO DISMISS AND MOTION FOR JUDGMENT ON THE PLEADINGS IN 14 CASES

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

On March 29, 2012, Defendant Xanodyne Pharmaceuticals, Inc. (hereafter, "Xanodyne") filed a motion to dismiss or, alternatively, for judgment on the pleadings in 65 cases. [Record No. 1546] Since that time, Xanodyne's motions have been granted and final judgments have been entered in 18 of those cases. Agreed orders of dismissal have been entered in an additional 33 cases. Thus, the motions remain pending in the 14 cases that are listed in the caption of this

Order. For the reasons that follow, the defendant's motion for judgment on the pleadings will be granted.

I.

Xanodyne filed a series of dispositive motions in 35 cases in November and December 2011 after a number of individual actions were transferred to this MDL proceeding. [MDL Record Nos. 444, 639, 666] In relevant part, Xanodyne argued that it cannot be held liable to plaintiffs who have failed to establish or properly assert that it sold, manufactured, or distributed a product containing propoxyphene. Following extensive briefing by the parties, the Court granted the motions pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. [MDL Record No. 1274] The Court's Memorandum Opinion and Order summarized the relevant background of the Food and Drug Administration's approval process for Darvon, a propoxyphene-containing drug used to treat mild to moderate pain, as well as the allegations asserted against Xanodyne in the MDL. After addressing the standard applicable to issues raised by the parties, the Court noted that, "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.'" [*Id*. at p. 5 (quoting *Smith v. Wyeth*, 657 F.3d 420, 423 (6th Cir. 2011))] And after reviewing the plaintiffs' complaints that were subject to Xanodyne's motions, the Court found that not one of the plaintiffs had properly identified Xanodyne as the entity that marketed, sold, or manufactured the product he or she claimed to have ingested. Further, under the pleading standards applicable to product liability claims, the Court concluded that it is insufficient to simply allege that a plaintiff *might* have been

sold a Xanodyne product, together with a claim that they ingested "Darvon, Darvocet and/or Propoxyphene." [*Id*. at 6] Similarly, the Court found the plaintiffs had not met their pleading burden to assert ingestion of the brand-name products in issue (*i.e.*, Darvon or Darvocet), coupled with an admission that he or she could not determine the defendant or other entity to at manufactured, marketed, distributed and/or tested the particular propoxyphene product that allegedly cause a plaintiff's or decedent's harm.

The plaintiffs' misrepresentation theories were also found to be deficient. As noted at page 10 of the Court's March 5, 2012, Memorandum Opinion and Order:

> 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.

[*Id*., pp. 10-11] After analyzing the authorities cited by the plaintiffs, the Court concluded that they represent a minority position with the overwhelming majority of courts 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." [*Id.*, p. 12 (internal quotation marks and citations omitted)] Thus, because the plaintiffs whose claims were the subject of the defendant's original motions had not sufficiently alleged that they ingested a Xanodyne product, their misrepresentation claims were also dismissed.

II.

As noted above, Xanodyne's current motion was filed on March 29, 2012. [Record No. 1546] Unlike its original motion, the current motion seeks relief under Rule 12(b)(6) or, alternatively, under Rule 12(c) of the Federal Rules of Civil Procedure. The latter rule is applicable in those cases in which Xanodyne has filed an answer in response to the plaintiff's complaint. However, as this Court has noted previously, the standard applicable to both rules is the same. [*See* MDL Record No. 1402, p. 4 (citing *Equal Emp't Opportunity Comm'n v. J.H. Routh Packing Co.*, 246 F.3d 850, 851 (6th Cir. 2001)).]

The plaintiffs filed a consolidated response to Xanodyne's present motions on April 23, 2012. [MDL Record No. 1707] In that response, they assert initially that the motion should be held in abeyance for cases in which certification to a number of state courts was being sought. However, the Court subsequently denied the motions for certification, effectively mooting this argument. Next, the plaintiffs reassert the arguments made in opposition to Xanodyne's initial motion. However, the Court has previously rejected this argument and has thoroughly explained its reasons for doing so. [MDL Record No. 1274]

The plaintiffs argue that the highest courts of several states (*i.e.*, Arizona, Maine, Nebraska, Washington, and West Virginia) have not issued definitive rulings regarding misrepresentation claims similar to those they attempt to assert. They contend that the courts in these states are likely to adopt a rule that would hold brand-name manufacturers liable to consumers of generic drugs. Therefore, they contend that Xanodyne's motion in eight of the

cases should be denied with respect to the fraud and misrepresentation claims.[1] Having reviewed the authorities contained at pages 6 through 19 of the plaintiffs' consolidated response, the Court is not convinced that any of the subject states' highest courts would reach a different conclusion than that of this Court. In the absence of a definitive statement from the courts of these states that they intend to depart from the majority position and hold brand-name manufacturers liable for damages caused by the use of generic drugs, this Court reiterates its position that "[i]t is not the place of the Court, sitting in diversity in an MDL proceeding, to announce a new rule of law." [*Id.*, p. 13]

The plaintiffs also ask that the Court hold its ruling in abeyance in four cases in which the plaintiffs "may" have ingested a Xanodyne product (i.e., *Nicholson, et al., v. Eli Lilly and Company, et al.*, Civil Action No. 2: 11-358-DCR; *Adegbayi v. Xanodyne Pharmaceuticals, Inc., et al.*, Civil Action No. 2: 12-013-DCR; *Morel v. Xanodyne Pharmaceuticals, Inc., et al.*, Civil Acton No. 2: 12-74-DCR; and *Angell v. Xanodyne Pharmaceuticals, Inc.*, Civil Action No. 2: 12-080-DCR). Alternatively, they seek dismissal without prejudice in any case in which the plaintiffs have not been given the opportunity to amend their complaints. [MDL Record No. 1707, pp. 16-18]

---

[1] The cases subject to this argument are: *Zickefoose, et al., v. Eli Lilly and Company, et al.*, Civil Action No. 2: 11-347-DCR; *Shackelford, et al., v. Eli Lilly and Company, et al.*, Civil Action No. 2: 11-357-DCR; *Nicholson, et al., v. Eli Lilly and Company, et al.*, Civil Action No. 2: 11-358-DCR; *B. Black v. Eli Lilly and Company, et al.*, Civil Action No. 2: 11-392-DCR; *Breault v. Xanodyne Pharmaceuticals, Inc., et al.*, Civil Action No. 2: 12-002-DCR; *Adegbayi v. Xanodyne Pharmaceuticals, Inc., et al.*, Civil Action No. 2: 12-013-DCR; *Marsalis v. Eli Lilly and Company, et al.*, Civil Acton No. 2: 12-32-DCR; *Dunn v. Xanodyne Pharmaceuticals, Inc.*, Civil Action No. 2: 12-068-DCR;

The plaintiffs have filed amended complaints in three of the cases subject to this motion: *Smith et al. v. Mylan Pharm., Inc., et al.*, Civil Action No. 2: 11-183-DCR; *Breault v. Xanodyne Pharm., Inc., et al.*, Civil Action No. 2: 12-02-DCR; and *Adegbayi v. Xanodyne Pharm., Inc., et al.*, Civil Action No. 2: 12-13-DCR. Regarding the remaining plaintiffs who are subject to Xanodyne's motion but who have not previously sought to amend their complaints, dismissal will be without prejudice.[2] The plaintiffs are advised, however, that if they seek to amend their complaints at a later date – and their proposed pleadings include claims or defendants that the Court has dismissed – amendment would not likely be permitted. The plaintiffs are also advised that if they seek to inject claims against manufacturers and/or distributors of generic products containing propoxyphene, their amended pleadings will be stricken from the record.

III.

For the reasons discussed above and in the Memorandum Opinions and Orders which the Court has cited, it is hereby

ORDERED as follows:

[2]The cases subject to this motion in which the plaintiffs have not filed an amended complaint are: *Gianoli v. Xanodyne Pharm., Inc., et al.*, Civil Action No. 2:11-220-DCR; *Waters v. Eli Lilly & Company, et al.*, Civil Action No. 2: 11-248-DCR; *Zickefoose et al. v. Eli Lilly & Company, et al.*, Civil Action No. 2: 11-347-DCR; *Shackelford et al. v. Eli Lilly & Company, et al.*, Civil Action No. 2: 11-357-DCR; *Nicholson et al. v. Eli Lilly & Company, et al.*, Civil Action No. 2: 11-358-DCR; *Black v. Eli Lilly & Company, et al.*, Civil Action No. 2: 11-392-DCR; *Ooten v. Eli Lilly & Company, et al.*, Civil Action No. 2: 11-397-DCR; *Marsalis v. Eli Lilly & Company, et al.*, Civil Action No. 2: 12-32-DCR; *Dunn v. Xanodyne Pharm., Inc., et al.*, Civil Action No. 2: 12-68-DCR; *Morel v. Xanodyne Pharm., Inc., et al.*, Civil Action No. 2: 12-74-DCR; and *Angell v. Xanodyne Pharm., Inc., et al.*, Civil Action No. 12-80-DCR.

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

2. The motion to dismiss filed by Defendant Xanodyne Pharmaceuticals on March 29, 2012 [Record No. 1546] is **GRANTED**. With the exception of the cases listed below, the claims asserted by the plaintiffs against Defendant Xanodyne Pharmaceuticals, Inc. in the above-captioned cases are **DISMISSED**, without prejudice.

3. With respect to the claims asserted by the plaintiffs in Civil Action No. 2: 11-183-DCR, Civil Action No. 2: 12-02-DCR, and Civil Action No. 2: 12-13-DCR against Defendant Xanodyne Pharmaceuticals, Inc., those claims are **DISMISSED**, with prejudice.

This 3rd day of May, 2012.

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

Exhibit E

Richard A. Gurfein, Esq.
GURFEIN DOUGLAS LLP
11 Park Place, Suite #1100
New York, New York 10007
Phone: (212) 406-1600
Fax: (212) 406-4779

Attorneys for Plaintiffs

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

ASHAE FACIANE, Individually and as Parent and Natural Guardian of Z.A.P., a Minor,	:	CIVIL ACTION NO.
Plaintiffs,	:	MDL Docket No.: 2657
-against-	:	**COMPLAINT AND DEMAND FOR JURY TRIAL**
GlaxoSmithKline LLC,	:	
Defendant.	:	

COMPLAINT AND JURY DEMAND

COMES NOW Plaintiff, ASHAE FACIANE, individually and on behalf of her son, Z.A.P., a minor, ("Plaintiff"), who by and through the undersigned counsel hereby submit this Complaint and Jury Demand against GlaxoSmithKline LLC d/b/a GlaxoSmithKline ("GSK" or "Defendant") for compensatory and punitive damages, equitable relief, and such other relief deemed just and proper arising from the injuries to Z.A.P. as a result of his prenatal exposures to the prescription drug Zofran®, also known as ondansetron. In support of this Complaint, Plaintiff alleges the following.

INTRODUCTION

1. Zofran is a powerful drug developed by GSK to treat only those patients who were afflicted with the most severe nausea - that suffered as a result of chemotherapy or radiation treatments in cancer patients.

2. The U.S. Food and Drug Administration ("FDA") approved Zofran in 1991 for use in cancer patients who required chemotherapy or radiation therapy.

3. Although the only FDA approval for this drug was for seriously ill patients, GSK marketed Zofran "off label" as a safe and effective treatment for the very common side effect of a normal pregnancy – pregnancy-related nausea and vomiting - otherwise known as "morning sickness." GSK further marketed Zofran during this time as a "wonder drug" for pregnant women, despite having knowledge that such representations were utterly false, as GSK had never once undertaken a single study on the effects of this powerful drug on a pregnant mother or her growing child in utero. Unlike another anti-nausea prescription drug available on the market – which is FDA-approved in the United States for treating morning sickness in pregnant women – GSK simply chose not to study Zofran in pregnant women or seek FDA approval to market the drug for treatment during pregnancy. GSK avoided conducting these studies because they would have hampered its marketing of Zofran and decreased profits by linking the drug to serious birth defects. GSK's conduct was tantamount to using expectant mothers and their unborn children as human guinea pigs.

4. As a result of GSK's fraudulent marketing campaign, Zofran was placed into the hands of unsuspecting pregnant women throughout the United States. These women ingested the drug because they innocently believed that Zofran was an appropriate drug for use in their circumstance. When they ingested the drug, these pregnant women had no way of knowing that Zofran had never been studied in pregnant women, much less shown to be a safe and effective treatment for pregnancy-related nausea.

5. By contrast, GSK knew that Zofran was unsafe for ingestion by expectant mothers. In the 1980's, GSK conducted animal studies which revealed evidence of toxicity, intrauterine deaths and malformations in offspring, and further showed that Zofran's active ingredient transferred through the placental barrier of pregnant mammals to fetuses. A later study conducted in humans confirmed that ingested Zofran readily crossed the human placenta barrier and exposed

fetuses to substantial concentrations. GSK did not disclose this information to pregnant women or their physicians.

6. In 1992, GSK began receiving mounting evidence of reports of birth defects associated with Zofran. GSK had received at least 32 such reports by 2000, and has received more than 200 such reports to date. GSK never disclosed these reports to pregnant women or their physicians. In addition, scientists have conducted large-scale epidemiological studies that have demonstrated an elevated risk of developing birth defects such as those suffered in this case. GSK has not disclosed this to pregnant women or their physicians. Instead, GSK sales representatives specifically marketed and promoted Zofran as a morning sickness drug throughout the relevant time periods discussed herein.

7. In 2012, GSK pled guilty to criminal charges lodged by the United States of America, through the Department of Justice, for its "off-label" promotion of its drugs for uses never approved by the FDA.

8. At or around the same time, GSK also entered civil settlements with the United States that included more than $1 billion in payments to the federal government for its illegal marketing of various drugs, including Zofran specifically.

9. GSK's written agreement with the United States reports GSK's settlement of claims that GSK:

(a) "promoted the sale and use of Zofran for a variety of conditions other than those for which its use was approved as safe and effective by the FDA (including hyperemesis and pregnancy-related nausea)"

(b) "made and/or disseminated unsubstantiated and false representations about the safety and efficacy of Zofran concerning the uses described in subsection (a) [hyperemesis and pregnancy-related nausea]"

(c) "offered and paid illegal remuneration to health care professionals to induce them to promote and prescribe Zofran"

(Settlement Agreement, p. 5, July 2, 2012.)

10. GSK's conduct has caused devastating, irreversible, and life-long consequences and suffering to innocent newborns and their families, like Plaintiff herein.

11. Plaintiff's minor child, Z.A.P. was born in 2015 with numerous congenital defects after his mother, Plaintiff ASHAE FACIANE, was prescribed and began taking Zofran/ondansetron beginning early in her first trimester of pregnancy to alleviate the symptoms of morning sickness. After birth, Z.A.P. suffered from an atrial septal defect.

12. Had plaintiff known the truth about Zofran's unreasonable risk of harm, long concealed by GSK, she would never have taken Zofran/ondansetron, and her child would never had been injured as described herein.

13. Plaintiff brings claims for compensatory and punitive damages, as well as equitable relief in an effort to ensure that similarly situated mothers-to-be are fully informed about the risks, benefits and alternatives attending drugs marketed for use in pregnant women, and such other relief deemed just and proper arising from injuries and birth defects as a result of exposure to Zofran.

JURISDICTION AND VENUE

14. This case is being directly filed in MDL No. 2657 in the District of Massachusetts solely for the purposes of consolidated discovery and related pretrial proceedings, as provided by 28 U.S.C. § 1407 and pursuant to Case Management Order No. 6 dated December 17, 2015 in MDL No. 2657, which allowed direct filing of Zofran (Ondansetron)-related actions in this District. Upon the completion of all pretrial proceedings applicable to this case, this Court, pursuant to the Rules of the Judicial Panel on Multidistrict Litigation and 28 U.S.C. § 1404(a), will transfer the case to a federal district court of proper venue as defined by 28 U.S.C. § 1391.

15. A substantial part of the events or omissions giving rise to the claims occurred in the Eastern District of Louisiana and pursuant to 28 U.S.C. § 1391, the Eastern District of Louisiana is a proper venue. Absent Case Management Order No. 6 in MDL NO. 2657, plaintiff would have file this case in the Eastern District of Louisiana.

16. This court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy exceeds $75,000.00, exclusive of interest and costs, and because GSK is a citizen of a state other than the state in which Plaintiff is a citizen.

17. The United States District Court, District of Massachusetts has supplemental jurisdiction over any remaining common law and state claims pursuant to 28 U.S.C. § 1367.

18. Venue in this judicial district is proper under 28 U.S.C. § 1391 inasmuch as a substantial part of the events or omissions giving rise to the claims occurred in this district.

19. At all times herein mentioned, GSK conducted a tort, in whole or in part, in this judicial district. GSK engaged in interstate commerce when they advertised, promoted, supplied, and sold pharmaceutical products, including Zofran, to distributors and retailers for resale to physicians, hospitals, medical practitioners, and the general public, deriving substantial revenue in this district.

PARTIES

20. Plaintiff, ASHAE FACIANE, is a citizen of the United States. She is the mother and natural guardian of Z.A.P., who lives with Ms. Faciane. Plaintiff resides in,Slidell, St. Tammany Parish , Louisiana.

21. GSK is a limited liability company organized under the laws of the State of Delaware. GSK's sole member is GlaxoSmithKline Holdings, Inc., which is a Delaware corporation, and which has identified its principal place of business in Wilmington, Delaware.

22. GSK is the successor in interest to Glaxo, Inc. and Glaxo Wellcome Inc. Glaxo, Inc. was the sponsor of the original New Drug Application ("NDA") for Zofran. Glaxo, Inc., through its division Cerenex Pharmaceuticals, authored the original package insert and labeling for Zofran, including warnings and precautions attendant to its use. Glaxo Wellcome Inc. sponsored additional NDAs for Zofran, monitored and evaluated post-market adverse event reports arising from Zofran, and authored product labeling for Zofran. The term GSK used herein refers to GSK, its predecessors Glaxo, Inc. and Glaxo Wellcme Inc., and other GSK predecessors and/or affiliates that discovery reveals were involved in the testing, development, manufacture, marketing, labeling, sale and/or distribution of Zofran.

23. At all relevant times, GSK conducted business in the State of Louisiana and have derived substantial revenue from products, including Zofran, sold in this State.

PERTINENT BACKGROUND OF ZOFRAN

24. Zofran is a prescription drug indicated for the prevention of chemotherapy-induced nausea and vomiting, radiation therapy-inducted nausea and vomiting and post-operative nausea and/or vomiting:

INDICATIONS AND USAGE

1. Prevention of nausea and vomiting associated with highly emetogenic **cancer chemotherapy**, including cisplatin 2≥ 50 mg/m2.
2. Prevention of nausea and vomiting associated with initial and repeat courses of moderately emetogenic **cancer chemotherapy**.
3. Prevention of nausea and vomiting associated with **radiotherapy** in patients receiving either total body irradiation, single high-dose fraction to the abdomen, or daily fractions to the abdomen.
4. Prevention of **postoperative nausea/and or vomiting.**

(GSK, Zofran Prescribing Information, Sept. 2014) (emphasis added.)

25. The medical term for nausea and vomiting is emesis, and drugs that prevent or treat nausea and vomiting are called anti-emetics.

26. Zofran is part of a class of anti-emetics called selective serotonin 5HT3 receptor antagonists. The active ingredient in Zofran is ondansetron hydrochloride, which is a potent and selective antagonist at the 5-hydroxytryptamine receptor type 3 (5-HT3).

27. Although 5-hydroxytryptamine (5HT) occurs in most tissues of the human body, Zofran is believed to block the effect of serotonin at the 5HT3 receptors located along vagal afferents in the gastrointestinal tract and at the receptors located in the area postrema of the central nervous system (the structure in the brain that controls vomiting). Put differently, Zofran antagonizes, or inhibits, the body's serotonin activity, which triggers nausea and vomiting.

28. Zofran was the first 5HT3 receptor antagonist approved for marketing in the United States. Other drugs in the class of 5HT3 receptor antagonist include Kytril® (granisetron) (FDA-approved 1994), Anzemet® (dolasetron) (FDA-approved 1997), and Aloxi® (palonosetron) (FDA – approved 2003).

29. Zofran is available as an injection (2mg/mL), a premixed injection (32 mg/50ml and 4 mg/50ml), oral tablets (4 mg, 8 mg and 24 mg); orally disintegrating tablets (4mg and 8mg) and an oral solution (4mg/5mL).

30. More specifically, GSK has obtained FDA approval for the following formulations of Zofran:

a. NDA 20-007- Zofran Injection (FDA approved January 4, 1991)

b. NDA 20-103 – Zofran Tablets (FDA approved December 31, 1992)

c. NDA 20-403 – Zofran Premixed Injection (FDA approved January 31, 1995)

d. NDA 20-605 – Zofran Oral Solution (FDA approved January 24, 1997)

e. NDA 20-781 – Zofran (alk/a Zofran-Zydis) Orally Disintegrating Tablets (FDA approved January 27, 1999)

31. The FDA has never approved Zofran for the treatment of morning sickness or any other condition in pregnant women.

32. For GSK to market Zofran lawfully for the treatment of morning sickness in pregnant women, it must first adequately test the drug (including performing appropriate clinical studies) and formally submit to the FDA evidence demonstrating that the drug is safe and effective for treatment of morning sickness.

33. A team of the FDA's physicians, statisticians, chemists, pharmacologists, microbiologists and other scientists would then have an opportunity to: (a) review the company's data and evidence supporting its request for approval to market the drug; and (b) determine whether to approve the company's request to market the drug in the manner requested. Without first obtaining approval to market a drug for the treatment of pregnant women, a pharmaceutical company may not legally market its drug for that purpose.

34. GSK has not performed any clinical studies of Zofran use in pregnant women. GSK, however, had the resources and know-how to perform such studies, and such studies were performed to support another prescription drug that, unlike Zofran, is FDA-approved for the treatment of morning sickness.

35. GSK also has not submitted to the FDA any data demonstrating the safety or efficacy of Zofran for treating morning sickness in pregnant women. Instead, GSK has illegally circumvented the FDA-approval process by marketing Zofran for the treatment of morning sickness in pregnant women without applying for the FDA's approval to market Zofran to treat that condition or any other condition in pregnant women. This practice is known as "off-label" promotion, and in this case it constitutes fraudulent marketing.

36. At all relevant times, GSK was in the business of and did design, research, manufacture, test, package, label, advertise, promote, market, sell and distribute Zofran, and GSK continues to market and sell Zofran today.

GSK's Knowledge That Zofran Presents an Unreasonable Risk of Harm to Babies Who Are Exposed to It During Pregnancy

Preclinical Studies

37. Since at least the 1980s, when GSK received the results of the preclinical studies that it submitted in support of Zofran's NDA 20-007, GSK has known of the risk that Zofran ingested during pregnancy in mammals crosses the placental barrier to expose the fetus to the drug. For example, at least as early as the mid-1980s, GSK performed placental-transfer studies of Zofran in rats and rabbits, and reported that the rat and rabbit fetuses were exposed prenatally to Zofran during pregnancy.

38. The placental transfer of Zofran during human pregnancy at concentrations high enough to cause congenital malformations has been independently confirmed and detected in every sample of fetal tissue taken in a published study involving 41 pregnant patients. The average fetal tissue concentration of Zofran's active ingredient was 41 % of the corresponding concentration in the mother's plasma.

39. GSK reported four animal studies in support of its application for approval of NDA 20-0007: (1) Study No. R10937 LV. Segment II teratological study of rats; (2) Study No. R10873 LV. Segment II teratological study of rabbits; (3) Study No. R10590 Oral Segment II teratological study of rats; (4) Study No. L10649 Oral Segment II teratological study of rabbits. These preclinical teratogenicity studies in rats and rabbits were stated by the sponsor, GSK, to show no harm to the fetus, but the data also revealed clinical signs of toxicity, premature births, intrauterine fetal deaths, and impairment of ossification (incomplete bone growth).

40. Study No. R10937 was a Segment II teratological study of pregnant rats exposed to Zofran injection solution. Four groups of 40 pregnant rats (160 total) were reportedly administered Zofran through intravenous (IV.) administration at doses of 0, 0.5, 1.5, and 4 mg/kg/day, respectively. Clinical signs of toxicity that were observed in the pregnant rats included "low posture, ataxia, subdued behavior and rearing, as well as nodding and bulging eyes." No observations were reported as teratogenic effects.

41. Study No. R10873 was a Segment II teratological study of pregnant rabbits exposed to Zofran injection solution. Four groups of 15 pregnant rabbits (60 total) were reportedly given

Zofran doses of 0, 0.5, 1.5, and 4 mg/kg/day, respectively. In this study, there was a reported increase in the number of intra-uterine deaths in the 4 mg/kg group versus lower- dose groups. The study also reported maternal weight loss in the exposed groups. Developmental retardation in off-spring and fetuses were noted- namely, areas of the parietal (body cavity) were not fully ossified, and the hyoid (neck) failed to ossify completely.

42. Study No. R10590 Oral Segment II teratological study of rats. Four groups of 30 pregnant rats (120 total) were given Zofran orally at doses of 0, 1, 4 and 15 mg/kg/day, respectively. Subdued behavior, labored breathing, which is a symptom of congenital heart defects, and dilated pupils were observed in the 15 mg/kg/day group. Body weight, gestational duration and fetal examinations were reported as normal, but "slight retardation in skeletal ossification" was noted in the offspring.

43. Study No. L10649 Oral Segment II teratological study of rabbits. Four groups of 14-18 pregnant rabbits (56-64 total) were given Zofran orally at doses of 0, 1, 5.5 and 30 mg/kg/day. The study reported lower maternal weight gain in all of the exposed groups, as well as premature delivery and "total litter loss," referring to fetal deaths during pregnancy in the 5.5 mg/kg/day group. Examination of the fetuses showed "slight developmental retardation as evident by incomplete ossification or asymmetry of skeleton."

44. Even if animal studies do not reveal evidence of harm to a prenatally exposed fetus, that result is not necessarily predictive of human response. For example, a drug formerly prescribed to alleviate morning sickness, thalidomide, is an infamous teratogen in humans, but animal studies involving the drug failed to demonstrate such an increased risk of birth defects in animals. GSK conducted studies of thalidomide and its toxicity before GSK developed Zofran and before it marketed Zofran for the treatment of morning sickness in pregnant women. Moreover, since at least 1993, GSK has stated in its prescribing information for Zofran that "animal reproduction studies are not always predictive of human response." Therefore, GSK has been aware since at least when it began marketing and selling Zofran that GSK could not responsibly rely on its animal studies as a basis for promoting Zofran use in pregnant women. But that is what GSK did.

Early Reports to GSK of Zofran-Related Birth Defects to GSK

45. At least as early as 1992, GSK began receiving reports of birth defects associated with the use of Zofran by pregnant women.

46. By 2000, GSK had received at least 32 reports of birth defects arising from Zofran treatment in pregnant women. These reports included congenital heart disease, dysmorphism, intrauterine death, stillbirth, kidney malformation, congenital diaphragmatic anomaly, congenital musculoskeletal anomalies, and orofacial anomalies, among others.

47. In many instances, GSK received multiple reports in the same month, the same week and even the same day. For example, on or about September 13, 2000, GSK received three separate reports involving Zofran use and adverse events. For two of those incidents, the impact on the baby was so severe that the baby died.

48. From 1992 to the present, GSK has received more than 200 reports of birth defects in children who were exposed to Zofran during pregnancy.

49. The most commonly reported birth defects arising from Zofran use during pregnancy and reported to GSK were congenital heart defects, though multiple other defects such as orofacial defects, intrauterine death, stillbirth and severe malformations in newborns were frequently reported.

50. The number of events actually reported to GSK was only a small fraction of the actual incidents.

Epidemiology Studies Examining the Risk of Congenital Heart Defects in Babies Who Were Exposed to Zofran During Pregnancy

51. Epidemiology is a branch of medicine focused on studying the causes, distribution, and control of diseases in human populations.

52. Three recent epidemiological studies have examined the association between prenatal exposure to Zofran and the risk of congenital heart defects in babies. These studies include: (1) Pasternak, et al., Ondansetron in Pregnancy and Risk of Adverse Fetal Outcomes, New England Journal of Medicine (Feb. 28, 2013) (the "Pasternak Study"); (2) Andersen, et al., Ondansetron Use in Early Pregnancy and the Risk of Congenital Malformations- A Register Based Nationwide Control Study, presented as International Society of Pharmaco-epidemiology,

Montreal, Canada (2013) (the "Andersen Study"); and (3) Danielsson, et al., Ondansetron During Pregnancy and Congenital Malformations in the Infant (Oct. 31, 2014) (the "Danielsson Study").

53. Each of these studies includes methodological characteristics tending to bias its results toward under-reporting the true risk of having a child with a birth defect. Notwithstanding these characteristics biasing the results toward the null hypothesis, all three studies show elevated risk ratios for cardiac malformations, including risk ratios greater than 2.0. In other words, the studies report that a mother exposed to Zofran had more than a doubled risk of having a baby with a congenital heart defect as compared to a mother who did not ingest Zofran during pregnancy.

54. The Pasternak Study included data from the Danish National Birth Registry and examined the use of Zofran during pregnancy and risk of adverse fetal outcomes. Adverse fetal outcomes were defined as: spontaneous abortion, stillbirth, any major birth defect, pre-term delivery, low birth weight, and small size for gestational age. There were 608,385 pregnancies between January 2004 and March 31, 2011 examined. The unexposed group was defined as women who did not fill a prescription for ondansetron during the exposure time window. The exposure time window was defined as the first 12 week gestational period. Notably, the median fetal age at first exposure to Zofran was ten weeks, meaning that half of the cases were first exposed to Zofran after organogenesis (organ formation). This characteristic of the study led to an under-reporting of the actual risk of prenatal Zofran exposure. The study's supplemental materials indicated that women taking Zofran during the first trimester, compared to women who did not take Zofran, were 22% more likely to have offspring with a septal defect, 41% more likely to have offspring with a ventricular septal defect and greater than four-times more likely to have offspring with atrioventricular septal defect.

55. The Andersen Study was also based on data collected from the Danish Medical Birth Registry and the National Hospital Register, the same data examined in the Pasternak Study. The Andersen study examined the relationship between Zofran use during the first trimester and subgroups of congenital malformations. Data from all women giving birth in Denmark between 1997 and 2010 were included in the study. A total of 903,207 births were identified in the study period with 1,368 women filling prescriptions for Zofran during the first trimester. The Andersen Study therefore used a larger data set (13 years) compared to the Pasternak Study (seven years). Exposure to the drug was also defined as filling a prescription during the first trimester, and prescription data were obtained from the National Prescription Registry. The Andersen study

reported that mothers who ingested Zofran during their first- trimester of pregnancy were more likely, than mothers who did not, to have a child with a congenital heart defect, and had a two- to four-fold greater risk of having a baby with a septal cardiac defect.

56. The Danielsson Study investigated risks associated with Zofran use during pregnancy and risk of cardiac congenital malformations from data available through the Swedish Medical Birth Registry. The Swedish Medical Birth Registry was combined with the Swedish Register of Prescribed Drugs to identify 1,349 infants born to women who had taken Zofran in early pregnancy from 1998-2012. The total number of births in the study was 1,501,434 infants, and 43,658 had malformations classified as major (2.9%). Among the major malformations, 14,872 had cardiovascular defects (34%) and 10,491 had a cardiac septum defect (24%). The Danielsson study reported a statistically significantly elevated risk for cardiovascular defects for mothers taking Zofran versus those who did not. The results reported that the mothers who took Zofran during early pregnancy had a 62% increased risk of having a baby with a cardiovascular defect. Further, mothers who took Zofran during pregnancy had a greater than two-fold increased risk of having a baby with a septal cardiac defect, compared to mothers who did not take Zofran during pregnancy.

57. In summary, since at least 1992, GSK has had mounting evidence showing that Zofran presents an unreasonable risk of harm to babies who are exposed to the drug during pregnancy. GSK has been aware that Zofran readily crosses human placental barriers during pregnancy. GSK has also been aware that the animal studies of Zofran cannot reliably support an assertion that Zofran can be used safely or effectively in pregnant women. Since 1992, GSK has received hundreds of reports of major birth defects associated with prenatal Zofran exposure. GSK also has had actual and/or constructive knowledge of the epidemiological studies reporting that prenatal Zofran exposure can more than double the risk of developing congenital heart defects. As alleged below, GSK not only concealed this knowledge from healthcare providers and consumers in the United States, and failed to warn of the risk of birth defects, but GSK also illegally and fraudulently promoted Zofran to physicians and patients specifically for the treatment of morning sickness in pregnancy women.

GSK's Failure to Warn of the Risk of Birth Defects

Associated with Prenatal Exposure to Zofran

58. Under federal law governing GSK's drug labeling for Zofran, GSK was required to "describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur." 21 C.F.R. § 201.57(e).

59. GSK was also required to list adverse reactions that occurred with other drugs in the same class as Zofran. Id. § 201.57(g).

60. In the context of prescription drug labeling, "an adverse reaction is an undesirable effect, reasonably associated with use of a drug,that may occur as part of the pharmacological action of the drug or may be unpredictable in its occurrence." Id.

61. Federal law also required GSK to revise Zofran's labeling "**to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved.**" Id. § 201.57(e) (emphasis added).

62. GSK has received hundreds of reports of birth defects associated with the non-FDA-approved use of Zofran in pregnant women. GSK has failed, however, to disclose these severe adverse events to healthcare providers or expectant mothers, including Ms. Faciane and her prescribing healthcare provider.

63. Under 21 C.F.R. § 314.70(c)(2)(i), pharmaceutical companies were (and are) free to add or strengthen - without prior approval from the FDA - a contraindication, warning, precaution, or adverse reaction.

64. GSK thus had the ability and obligation to add warnings, precautions and adverse reactions to the product labeling for Zofran without prior approval from the FDA. GSK failed to do so.

65. Under 21 C.F.R. § 201.128, "if a manufacturer knows, or has knowledge of facts that would give him notice, that a drug introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a drug which accords with such other uses to which the article is to be put."

66. At least as of 1998, GSK knew well from its off-label promotion and payments to doctors, and its conspicuous increase in revenue from Zofran, and its market analyses of prescription data, that physicians were prescribing Zofran off-label to treat morning sickness in

pregnant women and that such usage was associated with a clinically significant risk or hazard - birth defects.

67. GSK had the ability and obligation to state prominently in the Indications and Usage section of its drug label that there is a lack of evidence that Zofran is safe for the treatment of morning sickness in pregnant women. GSK failed to do so, despite GSK's knowledge that (a) the safety of Zofran for use in human pregnancy has not been established, and (b) there have been hundreds of reports of birth defects associated with Zofran use during pregnancy, and (c) epidemiology studies report an increased risk of birth defects in babies exposed to Zofran during pregnancy.

68. From 1993 to the present, despite mounting evidence of the birth defect risk, GSK's prescribing information for Zofran has included the same statement concerning use of Zofran during pregnancy:

> **"Pregnancy: Teratogenic Effects:** Pregnancy Category B. Reproduction studies have been performed in pregnant rats and rabbits at I.V. doses up to 4 mg/kg per day and have revealed no evidence of impaired fertility or harm to the fetus due to ondansetron. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed."

69. By contrast, the Product Monograph for Zofran in Canada states "the safety of ondansetron for use in human pregnancy has not been established," and that "the use of ondansetron in pregnancy is not recommended."

70. In the United States and in this State specifically, GSK has at all relevant times failed to include any warning disclosing any risks of birth defects arising from Zofran use during pregnancy in Zofran's prescribing information or other product labeling.

71. GSK's inclusion of the phrase "Pregnancy Category B" in Zofran's prescribing information refers to the FDA's pregnancy categorization scheme applicable to prescription drugs in the United States. The FDA has established five categories to indicate the potential of a drug to cause birth defects if used during pregnancy. The current system of pregnancy labeling consists of five letter-categories (A, B, C, D, and X, in order of increasing risk).

72. GSK had the ability, and indeed was required, to update Zofran's label to reflect at best a Pregnancy Category D designation or alternatively a Category X designation for Zofran:

> **Pregnancy Category D. If there is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans**, but the potential benefits from the use of the drug in pregnant women may be acceptable despite its potential risks (for example, if the drug is needed in a life-threatening situation or serious disease for which safer drugs cannot be used or are ineffective), the labeling must state: "Pregnancy Category D. See "Warnings and Precautions" section. Under the "Warnings and Precautions" section**, the labeling must state: "[drug] can cause fetal harm when administered to a pregnant woman.... If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus."**

21 C.F.R. § 201.57(f)(6)(i)(d) (emphasis added).

> **Pregnancy Category X. If studies in animals or humans have demonstrated fetal abnormalities or if there is positive evidence of fetal risk based on adverse reaction reports from investigational or marketing experience, or both**, and the risk of the use of the drug in a pregnant woman clearly outweighs any possible benefit (for example, safer drugs or other forms of therapy are available), the labeling must state: "Pregnancy Category X. See 'Contraindications' section." Under "Contraindications," **the labeling must state: "(Name of drug) may (can) cause fetal harm when administered to a pregnant woman.... (Name of drug) is contraindicated in women who are or may become pregnant. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus."**

ld. § 201.57(f)(6)(i)(e) (emphasis added).

73. Beginning at least in 1992, GSK had positive evidence of human fetal risk posed by Zofran based on more than 200 reports to GSK of birth defects, as well as epidemiology studies, and placental-transfer studies reporting on Zofran's teratogenic risk. GSK has never updated Zofran's labeling to disclose that Zofran can cause fetal harm when administered to a pregnant woman, and GSK has failed to warn of the potential hazards to a fetus arising from Zofran use during pregnancy.

74. The FDA recently promulgated a final rule declaring that, as of June 2015, it will require pharmaceutical manufacturers to remove the current A, B, C, D, or X pregnancy

categorization designation from all drug product labeling and instead summarize the risks of using a drug during pregnancy, discuss the data supporting that summary, and describe relevant information to help health care providers make prescribing decisions and counsel women about the use of drugs during pregnancy and lactation. 79 Fed. Reg. 72064 (Dec. 4, 2014). In promulgating this rule, the FDA "determined that retaining the pregnancy categories is inconsistent with the need to accurately and consistently communicate differences in degrees of fetal risk."

75. In summary, beginning years before Plaintiff was exposed to Zofran, GSK marketed and sold Zofran without adequate warning to healthcare providers and consumers that Zofran was causally associated with an increased risk of birth defects, and that GSK had not adequately tested Zofran to support marketing and promoting it for use in pregnant women. This rendered the warnings accompanying Zofran inadequate and defective.

76. Plaintiff hereby demands that GSK immediately cease the wrongful conduct alleged herein for the benefit of Plaintiff and similarly situated mothers and mothers-to-be, as GSK's wrongful conduct alleged herein is continuing. Plaintiff further demands that GSK fully and fairly comply to remove the Pregnancy Category B designation from its drug product labeling for Zofran and fully and accurately summarize the risks of using Zofran during pregnancy, fully and accurately describe the data supporting that summary, and fully and accurately describe the relevant information to help health care providers make informed prescribing decisions and counsel women about the risks associated with use of Zofran during pregnancy.

GSK's Fraudelent, Off-Label Promotion of Zofran for the Treatment of Morning Sickness in Pregnant Women

77. At all relevant times, GSK has known that the safety of Zofran for use in human pregnancy has not been established.

78. But with more than six million annual pregnancies in the United States since 1991 and an estimated 70-85% incidence of pregnancy-related nausea, the absence of a prescription medication that was approved by the FDA for pregnancy-related nausea presented an extremely lucrative business opportunity for GSK to expand its sales of Zofran. GSK seized that opportunity,

but the effect of its conduct was tantamount to experimenting with the lives of unsuspecting mothers-to-be and their babies in the United States and in this State.

79. After the FDA approved Zofran in 1991, and despite available evidence showing that Zofran presented an unreasonable risk of harm to babies exposed to Zofran prenatally, GSK launched a marketing scheme to promote Zofran to obstetrics and gynecology (Ob/Gyn) healthcare practitioners, among others, as a safe treatment alternative for morning sickness in pregnant women.

80. On March 9, 1999, the FDA's Division of Drug Marketing, Advertising and Communications (DDMAC) notified GSK that the FDA had become aware of GSK's promotional materials for Zofran that violated the Federal Food Drug and Cosmetic Act and its implementing regulations. The FDA reviewed the promotional material and determined that "it promotes Zofran in a manner that is false or misleading because it lacks fair balance." (FDA Ltr. to Michele Hardy, Director, Advertising and Labeling Policy, GSK, Mar. 9 1999.)

81. GSK's promotional labeling under consideration included promotional statements relating the effectiveness of Zofran, such as "Zofran Can," "24-hour control," and other promotional messages. But the promotional labeling failed to present any information regarding the risks associated with use of Zofran.

82. In its March 9, 1999 letter, the FDA directed GSK to "immediately cease distribution of this and other similar promotional materials for Zofran that contain the same or similar claims without balancing risk information."

83. GSK blatantly disregarded this mandate by the FDA. For example, in 2002, GSK's marketing materials to Ob/Gyn practitioners emphasized Zofran's "Pregnancy Category B" designation on the very first page of the marketing material, creating a false impression that the safety of use in pregnancy has been established. GSK's materials failed to disclose any of its internal information concerning the risks of birth defects associated with Zofran treatment during pregnancy.

84. GSK's promotion of Zofran for use in pregnancy eventually led to a federal governmental investigation. On July 2, 2012 the Department of Justice announced that GSK "agreed to plead guilty and pay $3 billion to resolve its criminal and civil liability arising from the company's unlawful promotion of certain prescription drugs," which included Zofran among

numerous others. See DOJ Press Release, GlaxoSmithKline to Plead Guilty and Pay $3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data (July 2, 2012).

85. Part of GSK's civil liability to the government included payments arising from the facts that: (a) GSK promoted Zofran and disseminated false representations about the safety and efficacy of Zofran concerning pregnancy-related nausea and hyperemesis gravidarum, a severe form of morning sickness; and (b) GSK paid and offered to pay illegal remuneration to health care professionals to induce them to promote and prescribe Zofran.

86. GSK knew or should have known that their promotional, advertising, and other information disseminated to the medical community which promoted the off label use of Zofran for morning sickness in pregnant women would influence prescribers of their drug, even when prescriptions for Zofran allowed for generic substitution. Defendant is therefore responsible for the injuries caused to pregnant women's fetuses by ondansetron.

Plaintiff's Exposures to Zofran

87. Plaintiff ASHAE FACIANE is the mother and natural guardian of Z.A.P.

88. To alleviate the symptoms of morning sickness and prevent them from recurring, Plaintiff ASHAE FACIANE was prescribed Zofran and/or ondansetron beginning in her first trimester of pregnancy with Z.A.P.

89. Z.A.P. was born in 2015.

90. Z.A.P. was diagnosed with an atrial septal defect as a direct and proximate result of his prenatal exposures to Zofran and/or ondansetron.

91. There is no history of birth defects in Z.A.P.'s family, and genetic testing has failed to detect a genetic anomaly.

92. Plaintiff ASHAE FACIANE was unaware of the dangerousness of Zofran and/or ondansetron or the fraudulent nature of GSK's marketing of Zofran when she filled her prescriptions and took Zofran and/or ondansetron during pregnancy.

93. Had plaintiff ASHAE FACIANE and/or her healthcare providers known of the increased risk of birth defects associated with Zofran and/or ondansetron, she would not have taken Zofran and/or ondansetron during pregnancy and Z.A.P. would not have been born with congenital malformations.

94. As a direct and proximate result of GSK's conduct, Plaintiff ASHAE FACIANE and her son Z.A.P. have suffered and incurred harm including severe and permanent pain and suffering, mental anguish, medical expenses and other economic and noneconomic damages, and will require more constant and continuous medical monitoring and treatment than had they not been exposed to Zofran.

95. Plaintiff files this lawsuit within the applicable limitations period of first suspecting that Zofran and/or ondansetron caused the appreciable harm sustained by her son, Z.A.P. Plaintiff could not, by the exercise of reasonable diligence, have discovered the wrongful cause of the injuries at an earlier time. Plaintiff did not suspect, nor did Plaintiff have reason to suspect, the tortious nature of the conduct causing the injuries, until a short time before filing of this action. Additionally, Plaintiff was prevented from discovering this information sooner because GSK has misrepresented to the public and to the medical profession that Zofran is safe for use in pregnancy, and GSK has fraudulently concealed facts and information that could have led Plaintiff to discover a potential cause of action. In all events, the statute of limitations is tolled for claims arising from injuries to minors.

FIRST CAUSE OF ACTION
(NEGLIGENCE)

96. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

97. GSK had a duty to exercise reasonable care, and comply with existing standards of care, in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, labeling, sale, testing, and/or distribution of Zofran into the stream of commerce, including a duty to ensure that the product would not cause users to suffer unreasonable, dangerous side effects.

98. GSK failed to exercise ordinary care and failed to comply with existing standards of care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, labeling, sale, testing, quality assurance, quality control, and/or distribution of Zofran into interstate commerce in that GSK knew or should have known that using Zofran created an unreasonable risk of dangerous birth defects, as well as other severe personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished

enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

99. GSK, its agents, servants, and/or employees, failed to exercise ordinary care and failed to comply with existing standards of care in the following acts and/or omissions:

a. Failing to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety risks of Zofran for treating pregnant women while promoting the use of Zofran and providing kickbacks to health care professionals to convince health care professionals to prescribe Zofran for pregnancy-related nausea;

b. Marketing Zofran for the treatment of morning sickness in pregnant women without testing it to determine whether or not Zofran was safe for this use;

c. Designing, manufacturing, producing, promoting, formulating, creating, and/or labeling Zofran without adequately and thoroughly testing it;

d. Selling Zofran without conducting sufficient tests to identify the dangers posed by Zofran to pregnant women;

e. Failing to adequately and correctly warn the Plaintiff, the public, the medical and healthcare profession, and the FDA of the dangers of Zofran for pregnant women;

f. Failing to evaluate available data and safety information concerning Zofran use in pregnant women;

g. Advertising and recommending the use of Zofran without sufficient knowledge as to its dangerous propensities to cause birth defects;

h. Representing that Zofran was safe for treating pregnant women, when, in fact, it was and is unsafe;

i. Representing that Zofran was safe and efficacious for treating morning sickness and hyperemesis gravidarum when GSK was aware that neither the safety nor efficacy for such treatment has been established;

j. Representing that GSK's animal studies in rats and rabbits showed no harm to fetuses, when the data revealed impairment of ossification (incomplete bone growth) and other signs of toxicity;

k. Failing to provide adequate instructions regarding birth defects including cleft palate and cardiac malformations;

l. Failing to accompany Zofran with proper and/or accurate warnings regarding all possible adverse side effects associated with the use of Zofran;

m. Failing to include a black box warning concerning the birth defects associated with Zofran;

n. Failing to issue sufficiently strengthened warnings following the existence of reasonable evidence associating Zofran use with the increased risk of birth defects;

o. Failing to advise Plaintiff, her healthcare providers, FDA, and the medical community that neither the safety nor the efficacy of Zofran for treating pregnancy-related nausea has been established and that the risks of the using the drug for that condition outweigh any putative benefit; and

p. Failing to advise Plaintiff, her healthcare providers, FDA, and the medical community of clinically significant adverse reactions (birth defects) associated with Zofran use during pregnancy;

q. Failing to fully report all known adverse events associated with the maternal use of Zofran and/or ondansetron;

r. Failing to add or strengthen their label with warnings, precautions and adverse reactions.

100. Despite the fact that GSK knew or should have known that Zofran significantly increased the risk of birth defects, GSK continued and continues to negligently and misleadingly market, manufacture, label, distribute and/or sell Zofran to consumers, including Plaintiff.

101. GSK knew or should have known that consumers and their unborn offspring such as Plaintiff would foreseeably suffer injury as a result of GSK's failure to exercise ordinary care, as set forth above.

102. GSK's negligence was the proximate cause of Plaintiff's infant's injuries, harm and economic loss, which Plaintiff's infant suffered and/or will continue to suffer.

103. Had Plaintiff ASHAE FACIANE not taken Zofran, and/or ondansetron, her baby would not have suffered those injuries and damages as described herein with particularity.

104. As a result of the foregoing acts and omissions, Z.A.P. was caused to suffer serious birth defects that are permanent and lasting in nature, physical pain and mental anguish, including

diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

105. Plaintiff ASHAE FACIANE also has sustained severe emotional distress and suffering as a result of GSK's wrongful conduct and the injuries to her child.

106. As a result of the foregoing acts and omissions, Plaintiff requires and will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff ASHAE FACIANE is informed and believes and further alleges that her child will in the future be required to obtain further medical and/or hospital care, attention, and services.

107. By reason of the foregoing, Plaintiff has been damaged by GSK's wrongful conduct. GSK's conduct was willful, wanton, reckless, and, at the very least arose to the level of gross negligence so as to indicate an indifference to, or a reckless disregard of the rights, health and safety of others, justifying an award of punitive damages.

SECOND CAUSE OF ACTION
(NEGLIGENCE PER SE)

108. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

109. GSK had a duty to exercise reasonable care, and comply with existing laws, in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, labeling, sale, testing, and/or distribution of Zofran into the stream of commerce, including a duty to ensure that the product would not cause users to suffer unreasonable, dangerous side effects.

110. GSK failed to exercise ordinary care and failed to comply with existing laws in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, labeling, sale, testing, quality assurance, quality control, and/or distribution of Zofran into interstate commerce in that GSK knew or should have known that using Zofran created an unreasonable risk of dangerous birth defects, as well as other severe and personal injuries which are permanent and

lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

111. GSK, its agents, servants, and/or employees, failed to exercise ordinary care and violated 21 U.S.C. § 331, 352; 42 U.S.C. § 1320a-7b, and 21 C.F.R. §§ 201.57, 201.128, in particular.

112. The laws violated by GSK were designed to protect Plaintiff and similarly situated persons and protect against the risks and hazards that have actualized in this case. Therefore, GSK's conduct constitutes negligence per se.

113. Despite the fact that GSK knew or should have known that Zofran significantly increased the risk of birth defects, GSK continued and continues to negligently and misleadingly market, manufacture, distribute and/or sell Zofran to consumers, including Plaintiff.

114. GSK knew or should have known that consumers such as Plaintiffs would foreseeably use the generic bioequivalent of Zofran and rely upon representations made by GSK as the holder of the NDA for Zofran.

115. GSK knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of GSK's failure to exercise ordinary care, as set forth above.

116. GSK's negligence was the proximate cause of Plaintiff's injuries, harm and economic loss, which Plaintiff suffered and/or will continue to suffer.

117. Had Plaintiff ASHAE FACIANE not taken Zofran, and/or ondansetron her baby would not have suffered those injuries and damages as described herein.

118. As a result of the foregoing acts and omissions, Z.A.P. was caused to suffer serious birth defects that are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

119. ASHAE FACIANE also has sustained severe emotional distress and suffering as a result of GSK's wrongful conduct and the injuries to her child.

120. As a result of the foregoing acts and omissions, Plaintiff requires and will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff ASHAE FACIANE is informed and believes and further alleges that her child will in the future be required to obtain further medical and/or hospital care, attention, and services.

121. By reason of the foregoing, Plaintiff has been damaged by GSK's wrongful conduct. GSK's conduct was willful, wanton, reckless, and, at the very least arose to the level of gross negligence so as to indicate an indifference to, or a reckless disregard of the rights, health and safety of others, justifying an award of punitive damages.

THIRD CAUSE OF ACTION
(STRICT PRODUCTS LIABILITY)

122. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

123. Zofran was designed, formulated, produced, manufactured, sold, marketed, distributed, supplied and/or placed into the stream of commerce by GSK and was defective at the time it left GSK's control in that, and not by way of limitation, the drug was not adequately labeled and failed to include adequate warnings, instructions and directions relating to the dangerous risks associated with the use of Zofran to treat pregnancy-related nausea. Zofran also was defective in its design because the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design. Safe and effective products were available for the purpose for which GSK marketed Zofran in pregnant women, and neither the safety nor the efficacy of Zofran for that purpose had been established.

124. GSK failed to provide adequate warnings to physicians and users, including Plaintiff, of the increased risk of birth defects associated with Zofran and aggressively promoted the product off-label to doctors, to hospitals, and directly to consumers.

125. Prescribing physicians, health care providers and mothers-to-be, neither knew, nor had reason to know at the time of their use of Zofran and/or odansetron of the existence of the aforementioned defects. Ordinary consumers would not have recognized the potential risks or side effects for which GSK failed to include appropriate warnings, and which GSK masked through unbalanced promotion of Zofran specifically for treatment of pregnant women.

126. At all times herein mentioned, due to GSK's off-label marketing of Zofran, the drug was prescribed and used as intended by GSK and in a manner reasonably foreseeable to GSK.

127. GSK knew or should have known that consumers such as Plaintiffs would foreseeably use the generic bioequivalent of Zofran and rely upon representations made by GSK as the holder of the NDA for Zofran.

128. As a direct and proximate result of the defective nature of Zofran, Z.A.P. was caused to suffer serious birth defects that are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

129. Plaintiff ASHAE FACIANE also has sustained severe emotional distress and suffering as a result of GSK's wrongful conduct and the injuries to her child.

130. As a result of the foregoing acts and omissions, Plaintiff requires and will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff ASHAE FACIANE is informed and believes and further alleges that her child will in the future be required to obtain further medical and/or hospital care, attention, and services.

131. By reason of the foregoing, Plaintiff has been damaged by GSK's wrongful conduct. GSK's conduct was willful, wanton, reckless, and, at the very least arose to the level of gross negligence so as to indicate an indifference to, or a reckless disregard of the rights, health and safety of others, justifying an award of punitive damages.

FOURTH CAUSE OF ACTION
(FRAUDULENT MISREPRESENTATION)

132. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

133. GSK falsely and fraudulently represented to the expectant mothers and the medical and healthcare community, including Plaintiff ASHAE FACIANE and her healthcare providers, that:

a) Zofran was safe and effective for treating pregnancy-related nausea;

b) Zofran had been adequately tested and studied in pregnant women;

c) Zofran use during pregnancy did not increase the risk of bearing children with birth defects; and

d) Zofran's "Pregnancy Category B" designation established the safety and efficacy of Zofran for treating pregnancy-related nausea.

134. The representations made by GSK were material, false and misleading.

135. When GSK made these representations, it knew they were false.

136. GSK made these representations with the intent of defrauding and deceiving the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, including Plaintiff and her providers, to recommend, prescribe, dispense and/or purchase Zofran to treat pregnancy-related nausea, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of Plaintiff herein.

137. At the time the aforesaid representations were made by GSK and, at the time Plaintiff used Zofran and/or ondansetron, she was unaware of the falsity of said representations and reasonably believed them to be true.

138. In reliance upon said representations, Plaintiff's prescriber was induced to prescribe Zofran to her, and Plaintiff ASHAE FACIANE was induced to and did use Zofran and/or ondansetron to treat pregnancy-related nausea.

139. GSK knew that Zofran had not been sufficiently tested for pregnancy-related nausea and that it lacked adequate warnings.

140. GSK knew or should have known that Zofran and/or ondansetron increases the risk of birth defects in the offspring of expectant mothers.

141. GSK knew or should have known that consumers such as Plaintiffs would foreseeably use the generic bioequivalent of Zofran and rely upon representations made by GSK as the holder of the NDA for Zofran.

142. As a result of the foregoing acts and omissions, Z.A.P. was caused to suffer birth defects that are permanent and lasting in nature, as well as physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

143. Plaintiff ASHAE FACIANE also has sustained severe emotional distress and suffering as a result of GSK's wrongful conduct and the injuries to her child.

144. As a result of the foregoing acts and omissions, Plaintiff requires and will require more health care and services and did incur medical, health, incidental and related expenses.

Plaintiff ASHAE FACIANE is informed and believes and further alleges that her child will in the future be required to obtain further medical and/or hospital care, attention, and services.

145. By reason of the foregoing, Plaintiff has been damaged by GSK's wrongful conduct. GSK's conduct was willful, wanton, reckless, and, at the very least arose to the level of gross negligence so as to indicate an indifference to, or reckless disregard of the rights, health and safety of others, justifying an award of punitive damages.

FIFTH CAUSE OF ACTION
(FRAUDULENT CONCEALMENT)

146. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

147. In representations to Plaintiff's healthcare providers, expectant mothers including Plaintiff and the FDA, GSK fraudulently concealed and intentionally omitted the following material facts:

a) GSK was illegally paying and offering to pay doctors remuneration and/or gifts of food, tickets and other items of value to promote and prescribe Zofran;
b) Zofran had not (and has not) been tested or studied in pregnant women at all;
c) in utero Zofran exposure increases the risk of birth defects;
d) the risks of birth defects associated with the consumption of Zofran and/or ondansetron by pregnant women were not adequately tested prior to GSK's marketing of Zofran and/or ondansetron;
e) the safety and efficacy of Zofran for treating pregnancy-related nausea has not been established;
f) Zofran is not safe and effective for treating pregnancy-related nausea; and
g) GSK's internal data and information associated Zofran use during pregnancy with birth defects.

148. GSK's concealment and omissions of material facts concerning, among other things, the safety and efficacy of Zofran for pregnancy-related nausea was made purposefully, willfully, wantonly, and/or recklessly, to mislead physicians, hospitals and healthcare providers, and expectant mothers including Plaintiff ASHAE FACIANE into reliance, continued use of Zofran and/or ondansetron, and to cause them to promote, purchase, prescribe, and/or dispense Zofran.

149. GSK knew that physicians, hospitals, healthcare providers and expectant mothers such as Plaintiff had no way to determine the truth behind GSK's concealment and material omissions of facts surrounding Zofran, as set forth herein.

150. Plaintiff and her providers reasonably relied on GSK's promotional statements concerning Zofran's asserted safety and efficacy in pregnant women, from which GSK negligently, fraudulently and/or purposefully omitted material facts.

151. As a result of the foregoing acts and omissions, Z.A.P. was caused to suffer serious birth defects, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

152. Plaintiff ASHAE FACIANE also has sustained severe emotional distress and suffering as a result of GSK's wrongful conduct and the injuries to her child.

153. As a result of the foregoing acts and omissions, Plaintiff requires and will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff ASHAE FACIANE is informed and believes and further alleges that her child will in the future be required to obtain further medical and/or hospital care, attention, and services.

154. By reason of the foregoing, Plaintiff has been damaged by GSK's wrongful conduct. GSK's conduct was willful, wanton, reckless, and, at the very least arose to the level of gross negligence so as to indicate an indifference to, or reckless disregard of the rights, health and safety of others, justifying an award of punitive damages.

SIXTH CAUSE OF ACTION
(NEGLIGENT MISREPRESENTATION)

155. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

156. GSK falsely and negligently represented to the medical community and expectant mothers, including Plaintiff and her providers, that:

a) Zofran was safe and effective for treating pregnancy-related nausea;

b) Zofran had been adequately tested and studied in pregnant women;

c) Zofran use during pregnancy did not increase the risk of bearing children with birth defects; and

d) Zofran's "Pregnancy Category B" designation established the safety and efficacy of Zofran for treating pregnancy-related nausea.

157. The representations made by GSK were, in fact, false and misleading.

158. Plaintiff ASHAE FACIANE and her providers reasonably relied upon GSK's expertise, skill, judgment, and knowledge and upon their express and/or implied warranties that their product was safe, efficacious, adequately tested, of merchantable quality and fit for the use during pregnancy. In justifiable reliance upon these misrepresentations, Plaintiff ASHAE FACIANE and her providers were induced to prescribe and use Zofran and/or ondansetron, its generic bioequivalent.

159. Had GSK not made express and implied false statements, or revealed all material information about Zofran, Plaintiff ASHAE FACIANE's providers would not have prescribed it and Plaintiff ASHAE FACIANE would not have used Zofran and/or ondansetron, its generic bioequivalent.

160. As a result of the foregoing acts and omissions, Z.A.P. has suffered serious birth defects, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

161. As a result of the foregoing acts and omissions, Z.A.P. requires and will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff ASHAE FACIANE is informed and believes and further alleges that Z.A.P. will in the future be required to obtain further medical and/or hospital care, attention, and services.

162. Plaintiff ASHAE FACIANE also has sustained severe emotional distress and suffering as a result of GSK's wrongful conduct and the injuries to her child.

163. By reason of the foregoing, Plaintiff has been damaged by GSK's wrongful conduct. GSK's conduct was willful, wanton, reckless, and, at the very least arose to the level of gross negligence so as to indicate an indifference to, or reckless disregard of the rights, health and safety of others, justifying an award of punitive damages.

SEVENTH CAUSE OF ACTION
(BREACH OF EXPRESS WARRANTY)

164. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

165. Defendants expressly warranted that:

a) Zofran was safe and effective for treating pregnancy–related nausea;

b) Zofran had been adequately tested and studied in pregnant women;

c) Zofran use during pregnancy did not increase the risk of bearing children with birth defects; and

d) Zofran's "Pregnancy Category B" designation established the safety and efficacy of Zofran for treating pregnancy-related nausea.

166. Zofran does not conform to these express representations because Zofran is not safe and presents an unreasonable risk of serious side effects, including birth defects and intrauterine death, which were not warned about by GSK. As a direct and proximate result of the breach of said warranties, Plaintiff suffered and will continue to suffer severe and permanent personal injuries, harm, mental anguish and economic loss.

167. Plaintiff and her healthcare providers did rely on the express warranties of the GSK herein.

168. Members of the medical community, including physicians and other healthcare professionals, relied upon the representations and warranties of GSK for use of Zofran in recommending, prescribing, and/or dispensing Zofran and/or ondansetron to treat morning sickness.

169. GSK knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that Zofran was not safe and fit for the use promoted,

expressly warranted and intended by GSK, and, in fact, it produced serious injuries to the pregnant women and their babies, which injuries were not accurately identified and disclosed by GSK.

170. As a result of the foregoing acts and omissions, Z.A.P. was caused to suffer serious and dangerous side effects including, life-threatening birth defects, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

171. Plaintiff ASHAE FACIANE also sustained severe emotional distress and suffering as a result of GSK's wrongful conduct and the injuries to her child.

172. As a result of the foregoing acts and omissions, Z.A.P. requires and will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff ASHAE FACIANE is informed and believes and further alleges that Z.A.P. will in the future be required to obtain further medical and/or hospital care, attention, and services.

173. By reason of the foregoing, Plaintiff has been damaged by GSK's wrongful conduct. GSK's conduct was willful, wanton, reckless, and, at the very least arose to the level of gross negligence so as to indicate an indifference to, or reckless disregard of the rights, health and safety of others, justifying an award of punitive damages.

EIGHTH CAUSE OF ACTION
(BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY AND FITNESS FOR PARTICULAR USE)

174. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

175. GSK is a merchant with respect to goods of the kind Plaintiff received. GSK impliedly warranted that its product was merchantable. Plaintiff and her health care providers relied on GSK's skill and judgment when deciding to use GSK's product.

176. GSK impliedly warranted that its product was fit for the particular purpose of being used safely in the treatment of pregnancy-related nausea. Plaintiff and her health care providers relied on GSK's skill and judgment when deciding to use GSK's product.

177. GSK's product was not fit for the ordinary purpose for which such goods were used. It was defective in design and its failure to provide adequate warnings and instructions, and was

unreasonably dangerous. GSK's product was dangerous to an extent beyond the expectations of ordinary consumers with common knowledge of the product's characteristics, including Plaintiff and her medical providers.

178. GSK breached its implied warranties because the product was not safe, not adequately packaged and labeled, did not conform to representations GSK made, and was not properly usable in its current form according to the labeling and instructions provided.

179. By reason of the foregoing, Plaintiff has been damaged by GSK's wrongful conduct. GSK's conduct was willful, wanton, reckless, and, at the very least arose to the level of gross negligence so as to indicate a disregard of the rights and safety of others, justifying an award of punitive damages.

NINTH CAUSE OF ACTION
(LOSS OF CONSORTIUM)

180. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

181. Z.A.P. is a minor child who is dependent upon his biological parent, Ms. Faciane, for support.

182. As a direct and proximate result of Defendant’s negligence, Ms. Faciane has been deprived of the society, love, affection, companionship, care and services, of her child, Z.A.P., and is entitled to recovery for said loss.

183. Plaintiff seeks all damages available against GSK on account of her loss of her son’s consortium.

DEMAND FOR JURY TRIAL

Plaintiff demands trial by jury pursuant to Rule 38 of the Federal Rules of Civil Procedure and the Seventh Amendment of the U.S. Constitution.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against GSK on each of the above-referenced claims and Causes of Action and as follows:

a) For general damages in a sum in excess of the jurisdictional minimum of this Court;

b) For medical, incidental and hospital expenses according to proof;

c) For pre-judgment and post-judgment interest as provided by law;

d) For full refund of all purchase costs of Zofran and/or ondansetron;

e) For consequential damages in excess of the jurisdictional minimum of this Court;

f) For compensatory damages in excess of the jurisdictional minimum of this Court;

g) For punitive damages in an amount in excess of any jurisdictional minimum of this Court in an amount sufficient to deter similar conduct in the future and punish the Defendant for the conduct described herein;

h) For attorneys' fees, expenses and costs of this action; and

i) For such further and other relief as this Court deems necessary, just and proper.

Dated: January 13, 2016

GURFEIN DOUGLAS, LLP

By: /s Richard A. Gurfein
Richard A. Gurfein
11 Park Place, Suite #1100
New York, NY 10007
Tel: (212) 406-1600
Fax: (212) 406-4779

JS 44 (Rev. 12/12)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

Ashae Faciane Individually and as Parent and Natural Guardian of Z.A.P. a Minor

(b) County of Residence of First Listed Plaintiff _____
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, Email and Telephone Number)*
Richard A. Gurfein
Gurfein Douglas, LLP
11 Park Place, Suite 1100, New York, NY 10007

DEFENDANTS

GlasoSmithKline LLC

County of Residence of First Listed Defendant Newcastle, DE
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*
Shook, Hardy & Bacon L.L.P.
1155 F Street NW, Suite 200
Washington, D.C. 20004

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ❒ 1 U.S. Government Plaintiff
- ❒ 3 Federal Question *(U.S. Government Not a Party)*
- ❒ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	❒ 1	❒ 1	Incorporated *or* Principal Place of Business In This State	❒ 4	❒ 4
Citizen of Another State	☒ 2	❒ 2	Incorporated *and* Principal Place of Business In Another State	❒ 5	☒ 5
Citizen or Subject of a Foreign Country	❒ 3	❒ 3	Foreign Nation	❒ 6	❒ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

CONTRACT
- ❒ 110 Insurance
- ❒ 120 Marine
- ❒ 130 Miller Act
- ❒ 140 Negotiable Instrument
- ❒ 150 Recovery of Overpayment & Enforcement of Judgment
- ❒ 151 Medicare Act
- ❒ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ❒ 153 Recovery of Overpayment of Veteran's Benefits
- ❒ 160 Stockholders' Suits
- ❒ 190 Other Contract
- ❒ 195 Contract Product Liability
- ❒ 196 Franchise

TORTS

PERSONAL INJURY
- ❒ 310 Airplane
- ❒ 315 Airplane Product Liability
- ❒ 320 Assault, Libel & Slander
- ❒ 330 Federal Employers' Liability
- ❒ 340 Marine
- ❒ 345 Marine Product Liability
- ❒ 350 Motor Vehicle
- ❒ 355 Motor Vehicle Product Liability
- ❒ 360 Other Personal Injury
- ❒ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ❒ 365 Personal Injury - Product Liability
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ❒ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ❒ 370 Other Fraud
- ❒ 371 Truth in Lending
- ❒ 380 Other Personal Property Damage
- ❒ 385 Property Damage Product Liability

REAL PROPERTY
- ❒ 210 Land Condemnation
- ❒ 220 Foreclosure
- ❒ 230 Rent Lease & Ejectment
- ❒ 240 Torts to Land
- ❒ 245 Tort Product Liability
- ❒ 290 All Other Real Property

CIVIL RIGHTS
- ❒ 440 Other Civil Rights
- ❒ 441 Voting
- ❒ 442 Employment
- ❒ 443 Housing/ Accommodations
- ❒ 445 Amer. w/Disabilities - Employment
- ❒ 446 Amer. w/Disabilities - Other
- ❒ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ❒ 463 Alien Detainee
- ❒ 510 Motions to Vacate Sentence
- ❒ 530 General
- ❒ 535 Death Penalty

Other:
- ❒ 540 Mandamus & Other
- ❒ 550 Civil Rights
- ❒ 555 Prison Condition
- ❒ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ❒ 625 Drug Related Seizure of Property 21 USC 881
- ❒ 690 Other

LABOR
- ❒ 710 Fair Labor Standards Act
- ❒ 720 Labor/Management Relations
- ❒ 740 Railway Labor Act
- ❒ 751 Family and Medical Leave Act
- ❒ 790 Other Labor Litigation
- ❒ 791 Employee Retirement Income Security Act

IMMIGRATION
- ❒ 462 Naturalization Application
- ❒ 465 Other Immigration Actions

BANKRUPTCY
- ❒ 422 Appeal 28 USC 158
- ❒ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ❒ 820 Copyrights
- ❒ 830 Patent
- ❒ 840 Trademark

SOCIAL SECURITY
- ❒ 861 HIA (1395ff)
- ❒ 862 Black Lung (923)
- ❒ 863 DIWC/DIWW (405(g))
- ❒ 864 SSID Title XVI
- ❒ 865 RSI (405(g))

FEDERAL TAX SUITS
- ❒ 870 Taxes (U.S. Plaintiff or Defendant)
- ❒ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ❒ 375 False Claims Act
- ❒ 400 State Reapportionment
- ❒ 410 Antitrust
- ❒ 430 Banks and Banking
- ❒ 450 Commerce
- ❒ 460 Deportation
- ❒ 470 Racketeer Influenced and Corrupt Organizations
- ❒ 480 Consumer Credit
- ❒ 490 Cable/Sat TV
- ❒ 850 Securities/Commodities/ Exchange
- ❒ 890 Other Statutory Actions
- ❒ 891 Agricultural Acts
- ❒ 893 Environmental Matters
- ❒ 895 Freedom of Information Act
- ❒ 896 Arbitration
- ❒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ❒ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

❒ 1 Original Proceeding ❒ 2 Removed from State Court ❒ 3 Remanded from Appellate Court ❒ 4 Reinstated or Reopened ❒ 5 Transferred from Another District *(specify)* ☒ 6 Multidistrict Litigation

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 U.S.C. 1332

Brief description of cause:
Defective Drug

VII. REQUESTED IN COMPLAINT:

❒ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ❒ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE F. Dennis Saylor IV. DOCKET NUMBER MDL No. 1:15-md-2657-FDS

DATE
01/13/2016

SIGNATURE OF ATTORNEY OF RECORD
/s/Richard A. Gurfein

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) **County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) **Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. **Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

III. **Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. **Nature of Suit.** Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerk(s) in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. **Origin.** Place an "X" in one of the six boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

VI. **Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

VII. **Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. **Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.