UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: ZOFRAN (ONDANSETRON) PRODUCTS LIABILITY LITIGATION,	)	**MDL No. 1:15-md-2657-FDS**
This Document Relates To:	)	
***Buker v. GlaxoSmithKline, LLC,* Case No. 1:17-cv-10062-FDS;**	)	
***Farrington v. GlaxoSmithKline, LLC,* Case No. 1:16-12290-FDS; and**	)	
***Varrichione v. GlaxoSmithKline, LLC,* Case No. 1:15-cv-13899-FDS.**	)	

MEMORANDUM AND ORDER ON DEFENDANT'S
MOTION FOR JUDGMENT ON THE PLEADINGS

SAYLOR, J.

This is a multi-district litigation ("MDL") proceeding arising out of claims that the use of the drug Zofran by pregnant women caused birth defects. Plaintiffs allege, among other things, that defendant GlaxoSmithKline LLC ("GSK") negligently and fraudulently promoted Zofran to treat pregnancy-related nausea and vomiting despite its knowledge of risks associated with taking the drug during pregnancy and its failure to adequately study and warn of that risk.

Certain plaintiffs also allege that GSK should be liable for injuries caused by the ingestion of the generic formulation of Zofran, due to the widespread off-label promotion of Zofran by GSK for use to treat morning sickness. In other words, those plaintiffs allege that GSK may be held liable even though it did not manufacture or sell the product that caused their injuries.

Defendant has moved for judgment on the pleadings to dismiss the claims of three

plaintiffs who allege that they ingested only the generic formulation of the drug.[1] On August 4, 2017, the Court granted a motion to dismiss six individual complaints based on similar arguments. For the reasons stated below, the present motion to dismiss will also be granted.

I. Background

On October 13, 2016, GSK filed a motion to dismiss the claims of six individual plaintiffs who alleged that they ingested only the generic formulation of the drug. Plaintiffs opposed those motions and, in the alternative, moved to certify a question to the highest courts of the relevant states. On August 4, 2017, the Court granted the motion to dismiss, finding that the relevant states, which included Oklahoma, would not impose liability on a brand-name manufacturer for injuries caused by ingestion of generic drugs. It also denied the request for certification.

On October 27, 2017, GSK moved for judgment on the pleadings on the claims of seven additional plaintiffs who alleged that they ingested the generic version of the drug. As a result of voluntary dismissals, only three cases subject to the motion remain:

Plaintiff	Case Number	Relevant State
Buker	17-10062	Connecticut
Farrington	16-12290	New Jersey
Varrichione	15-13899	Oklahoma

II. Legal Standard

A Rule 12(c) motion for judgment on the pleadings "is treated much like a Rule 12(b)(6) motion to dismiss." *Perez-Acevedo v. Rivero-Cubano*, 520 F.3d 26, 29 (1st Cir. 2008). It differs from a Rule 12(b)(6) motion primarily because it is filed after the close

[1] For the sake of convenience, this opinion will refer to plaintiffs having "ingested" the drug, although of course only the pregnant mothers did so; the plaintiffs who are children were exposed *in utero*.

of pleadings and "implicates the pleadings as a whole." *Aponte-Torres v. Univ. of P.R.*, 445 F.3d 50, 54-55 (1st Cir. 2006). Because a Rule 12(c) motion "calls for an assessment of the merits of the case at an embryonic stage, the court must view the facts contained in the pleadings in the light most favorable to the nonmovant and draw all reasonable inferences therefrom to the nonmovant's behoof." *R.G. Financial Corp. v. Vergara-Nunez*, 446 F.3d 178, 182 (1st Cir. 2006).

On a motion to dismiss, the Court "must assume the truth of all well-plead[ed] facts and give . . . plaintiff the benefit of all reasonable inferences therefrom." *Ruiz v. Bally Total Fitness Holding Corp.*, 496 F.3d 1, 5 (1st Cir. 2007) (citing *Rogan v. Menino*, 175 F.3d 75, 77 (1st Cir. 1999)). To survive a motion to dismiss, the complaint must state a claim that is plausible on its face. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). That is, "[f]actual allegations must be enough to raise a right to relief above the speculative level, . . . on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Id.* at 555 (citations omitted). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 556). Dismissal is appropriate if the facts as alleged do not "possess enough heft to show that plaintiff is entitled to relief." *Ruiz Rivera v. Pfizer Pharm., LLC*, 521 F.3d 76, 84 (1st Cir. 2008) (alterations omitted) (internal quotation marks omitted).

III. Analysis

As discussed in the Court's opinion of August 4, 2017, a person injured by a generic drug cannot normally sue either the manufacturer of the product (that is, the generic manufacturer) or the creator of the label (that is, the brand-name manufacturer). Such a person therefore may not

have a legal remedy. (August 4, 2017 Mem. at 8-9).

As the Court also noted, plaintiffs have sought to avoid that result by proceeding under a variety of theories, under the laws of different states, under which brand-name drug manufacturers could be held liable for injuries caused by generic drugs manufactured by a different company. (*Id.* at 9). Most, although not all, of those efforts have been rejected. The majority view is that plaintiffs injured by generic products cannot recover against brand-name manufacturers. *See, e.g., In re Darvocet*, 756 F.3d at 938. The minority view permits recovery, at least under some circumstances. *See, e.g., Conte v. Wyeth*, 168 Cal. App. 4th 89 (2008).

Since the issuance of the Court's opinion on August 4, 2017, three state supreme courts (in California, Massachusetts, and West Virginia) have issued opinions on that topic. *See T.H. v. Novartis Pharm. Corp.*, 4 Cal. 5th 145 (2017); *Rafferty v. Merck & Co., Inc.*, 479 Mass. 141 (2018); *McNair v. Johnson & Johnson*, 2018 WL 2186550 (W. Va. May 11, 2018). Two of those opinions (California and Massachusetts) follow the minority view, and one (West Virginia) follows the majority view.

Plaintiffs in the three cases at issue here are likewise seeking to impose liability on a brand-name manufacturer for injuries caused by a generic product. As set forth below, plaintiffs seek to proceed on what is essentially a theory of intentional or negligent misrepresentation or negligent undertaking. The theory is based on the allegation that GSK "created a market" for the drug's use to treat pregnancy-related nausea that led to the use of generic alternatives, and therefore should be liable for all injuries created by those products.

None of the highest courts of the three states in question have issued rulings directly on point, and therefore this Court must endeavor to predict how those courts might rule. The analysis begins with a description of the claims asserted by plaintiffs.

A. Plaintiffs' Theories of Recovery

The three plaintiffs whose claims are at issue have sued GSK, the brand-name manufacturer, despite the fact that they allege only that they ingested a generic product manufactured by another company. The theory of recovery that they assert is set out in the "Master Long Form Complaint and Jury Demand – Generic Ondansetron Use."[2] That "generic brand" master complaint alleges that GSK developed, and obtained FDA approval for, the drug Zofran, which it improperly promoted and sold to treat pregnancy-related nausea.

The "generic brand" complaint makes clear that the claims against GSK are based on a misrepresentation theory:

> Plaintiffs' claims against Defendants are not based on Defendants' manufacture or sale of a defective product. Instead, Plaintiffs' claims against Defendants are based on Defendants' misrepresentations and suppression of material information resulting in Plaintiffs' injuries in connection with ingestion of generic versions of Defendants' branded drugs to treat a condition that the generic drugs would not have been prescribed to treat in the absence of Defendants' misrepresentations and suppression.

(Compl. ¶ 16).

The complaint goes on to allege that GSK knew "that a substantial number of pregnant patients, whose prescribers consider product information for Zofran, are highly likely to have generic ondansetron dispensed to them," and "that all fifty states allow pharmacies to substitute generic versions of branded drugs, and that healthcare insurers strongly encourage this practice to save costs." (*Id.* ¶ 17).

It then alleges:

> GSK intended for its false and misleading promotional campaign alleged herein to create a market for the use of branded ondansetron for the treatment of pregnancy-related nausea. GSK also knew that, once its promotional scheme proved effective and once branded ondansetron's patents expired, GSK's scheme

[2] The claims against GSK by plaintiffs who ingested a GSK product are set out in a separate master complaint.

> would induce prescribers to prescribe, and patients to ingest, generic ondansetron to treat pregnancy-related nausea.
>
> As the holders of the New Drug Application (NDA) for Zofran and the patents for Zofran, Defendants knew that any generic drug manufacturer would be required by law to use the same labeling as Zofran's, and that any inadequacies in the labeling of generic ondansetron could be corrected by Defendants only.

(*Id.* ¶¶ 18–19).

Plaintiffs contend that they are not proceeding under a novel theory of liability, and that they seek to hold GSK liable under traditional tort-law principles of misrepresentation and negligent undertaking. First, they contend that they seek to hold GSK liable for its alleged misrepresentations concerning the safety and efficacy of ingesting Zofran during pregnancy, which, according to plaintiffs, created a market for Zofran use during pregnancy that foreseeably led to the prescription and/or ingestion of generic ondansetron to treat morning sickness and which, in turn, foreseeably led to the alleged injuries. *See* RESTATEMENT (SECOND) OF TORTS § 310 (intentional misrepresentation); RESTATEMENT (SECOND) OF TORTS § 311 (negligent misrepresentation). They further contend that by promoting Zofran for off-label use, GSK voluntarily undertook a duty to communicate to doctors and patients the dangers associated with ingesting ondansetron during pregnancy and failed to exercise reasonable care in fulfilling that duty. *See* RESTATEMENT (SECOND) OF TORTS § 324 (negligent undertaking).

B. Recent Developments

As noted, since the issuance of the Court's August 4, 2017 opinion, three state supreme courts have addressed the issue of liability of brand-name manufacturers for generic products.

In *T.H. v. Novartis Pharm. Corp.*, 4 Cal. 5th 145 (2017), the California Supreme Court held that a brand-name drug manufacturer has a duty "to warn of the risks about which it knew or reasonably should have known, regardless of whether the consumer is prescribed the brand-

name drug or its generic 'bioequivalent.'" *Id.* at 165. The court's reasoning was essentially two-fold. First, the court relied on the basic principle of tort law that duty follows primarily from foreseeability. *Id.* at 166-68. Second, it concluded that as a matter of public policy, a brand-name drug manufacturer was the proper party to bear the costs of harm suffered by innocent plaintiffs. *Id.* at 168-74. In making that conclusion, the court placed particular emphasis on federal regulations, which vest exclusive authority to change drug warning labels on brand-name manufacturers. *Id.* at 169-70 ("If the policy of preventing harm has special relevance to any particular endeavor, surely prescription drug labeling is one.").

In *Rafferty v. Merck & Co., Inc.*, 479 Mass. 141, 157 (2018), the Massachusetts Supreme Judicial Court held that brand-name drug manufacturers could be held responsible for "reckless," but not "negligent," conduct in failing to update labels resulting in "an unreasonable risk of death or grave bodily injury." In its opinion, the SJC attempted to reconcile the policy goals of providing injured plaintiffs recourse for harm caused by generic drugs and avoiding burdening brand-name manufacturers with total legal liability, in light of the fact that generics constitute approximately 90% of the prescription drug market. *Id.* at 152.

Finally, in *McNair v. Johnson & Johnson*, 2018 WL 2186550 (W. Va. May 11, 2018), the West Virginia Supreme Court of Appeals rejected innovator liability. In doing so, it stated that, "[f]inding the brand manufacturer liable for the ingestion of a generic drug would sever the connection between risk and reward." *Id.* at *11 (citation and quotation marks omitted). The court hewed closely to the traditional tort doctrine that liability for a product that causes injury can be imposed only "on the party who profits from its manufacture and sale." *Id.* (citing *Huck v. Wyeth*, 850 N.W. 2d 353, 378 (Iowa 2014)). It further cautioned that "[i]f brand manufacturers become liable for injuries allegedly caused by generic drugs, significant litigation

costs would be added to the price of new drugs to the disadvantage of consumers," and stated that the "proper remedy for consumers harmed by generic drugs rests with Congress or the FDA." *Id.* at *11-12.

With that as background, the analysis shifts to the claims at issue here.

C. Case Law in the Relevant States

1. Oklahoma (*Varrichione*)

The Court previously determined that under Oklahoma law, GSK could not be held liable for injuries sustained by a plaintiff who ingested generic Zofran. Plaintiffs seek reconsideration of this ruling, but have not pointed to any new Oklahoma-related authority that would change the Court's interpretation of Oklahoma law. While it is true that the minority view has gained ground in the last year with the California and Massachusetts opinions, that is not sufficient under the circumstances to tip the balance. Accordingly, for the reasons stated in the Court's August 4, 2017 memorandum and order, the claims of plaintiff Varrichione (15-13899) will be dismissed.

2. Connecticut (*Buker*)

The *Buker* case was filed directly in the District of Massachusetts as a part of this proceeding, as permitted by this Court's MDL Order No. 6; it otherwise would have been filed in the District of Connecticut. The parties agree that the substantive law of Connecticut applies to the claims.

There is no Connecticut Supreme Court authority directly on point. There is, however, a decision of the Sixth Circuit applying Connecticut law. *See In re Darvocet*, 756 F.3d at 942.

In *In re Darvocet*, the Sixth Circuit considered misrepresentation claims brought against brand-name-drug manufacturers by consumers of the drug's generic equivalent and predicted

that the Connecticut Supreme Court "would find that Plaintiffs' claims are product liability claims within the scope of the [Connecticut Product Liability Act, or CPLA] that do not survive under [the Connecticut Unfair Trade Practices Act]." *Id.* As to the distinction between products liability and misrepresentation claims, the court noted that the CPLA provides the exclusive remedy for consumers bringing claims for "personal injury, death, or property damage caused by the manufacture, construction, design, formula, preparation, assembly, installation, testing, warnings, instructions, marketing, packaging or labeling of any product." *Id.* (citing Conn. Gen. Stat. § 52-572m(b)). *See also Winslow v. Lewis-Shepard, Inc.*, 562 A.2d 517, 519 (Conn. 1989).

The court also concluded that "[b]ecause plaintiffs bring a personal injury claim allegedly caused by a defective product, their claims are within the scope of the CPLA" and cannot survive under another statute, the Connecticut Unfair Trade Practices Act ("CUTPA"). *In re Darvocet*, 756 F.3d at 942. ("[T]he purported CUTPA would be revealed to be nothing more than a product liability act claim dressed in the robes of CUTPA.") (quoting *Gerrity v. R.J. Reynolds Tobacco, Co.*, 818 A.2d 769, 775 (Conn. 2003)).

Connecticut is not in the Sixth Circuit, and therefore that decision would not have been binding, even in the absence of the MDL proceeding. Nonetheless, *In re Darvocet* is a 2014 decision by a federal appellate court that addresses the issue in comprehensive terms, and there appears to be no Connecticut authority suggesting a contrary result. Therefore, the claims of plaintiff Buker (16-12290) will be dismissed.

3. New Jersey (*Farrington*)

The *Farrington* case was filed directly in the District of Massachusetts as a part of this proceeding, as permitted by this Court's MDL Order No. 6; it otherwise would have been filed in the District of New Jersey. The parties agree that the substantive law of New Jersey applies to

the claims.

There is no authority from the New Jersey Supreme Court directly on point. However, a federal court applying New Jersey law and four New Jersey state trial courts have rejected similar claims. *See In re Darvocet, Darvon and Propoxyphene Prod. Liab. Litig.*, 856 F. Supp. 2d 904 (E.D. Ky. 2012); *Coundouris v. Wyeth, Inc.*, 2012 WL 2401776 (N.J. Super. Ct. Law Div. Jun 26, 2012); *Westerlund v. Wyeth, Inc.*, 2008 WL 5592753 (N.J. Super. Ct. Law Div. Oct. 20, 2008); *Rossi v. Hoffmann-LaRoche*, 2007 WL 7632318 (N.J. Super. Ct. Law Div. Jan. 3, 2007); *Sloan v. Wyeth, Inc.*, 2004 WL 5767103 (N.J. Super. Ct. Law Div. Oct. 13, 2004).

The New Jersey trial courts have all declined to impose liability on brand-name manufacturers for harm caused by generic products. *See, e.g., Coundouris*, 2012 WL 2401776 at *1-2 (stating that the New Jersey Product Liability Act ("PLA") "reflected the legislature's intent to limit liability to specific parties—namely the manufacturer or seller of a product"); *see also id.* ("As the New Jersey Supreme Court has explained, "[t]he language chosen by the legislature in enacting the PLA is both expansive and inclusive, encompassing virtually all possible causes of action relating to harms caused by consumer and other products.") (quoting *Sinclair v. Merck & Co., Inc.*, 195 N.J. 51, 66 (2008); *In re Lead Paint Litig.*, 191 N.J. 405, 435-37 (2007)).

The sole federal court to apply New Jersey law on this issue similarly declined to apply innovator liability. In *Darvocet*, the Eastern District of Kentucky concluded that plaintiffs' misrepresentation claims were product liability claims. *See In re Darvocet*, 856 F. Supp. 2d at 911 (citing *DeBendetto v. Denny's, Inc.*, 23 A.3d 496, 499 (N.J. Super. Ct. Law Div. 2010)). The court noted that New Jersey's PLA provides the exclusive remedy for consumers harmed by a product that "was not reasonably fit, suitable or safe for its intended purpose." N.J. Stat. Ann. § 2A:58C-2. Cautioning that "federal court[s] should hesitate to expand the scope of state law

without guidance from that state's highest court," the court concluded that a brand-name manufacturer could not be held liable to a plaintiff who consumed a generic drug. *In re Darvocet*, 856 F. Supp. 2d at 913.[3]

Thus, the five courts to have addressed the issue have concluded that under New Jersey law a plaintiff may not hold a brand-name manufacturer liable for injuries allegedly caused by ingestion of a generic version of a drug. Because there is no New Jersey authority to the contrary, the claims of plaintiff Farrington (16-12290) will be dismissed.

IV. Conclusion

For the foregoing reasons, defendant's motion for judgment on the pleadings is GRANTED as to *Buker v. GlaxoSmithKline LLC*, 17-cv-10062-FDS; *Farrington v. GlaxoSmithKline LLC*, 16-12290-FDS, and *Varrichione v. GlaxoSmithKline LLC*, 15-cv-13899-FDS.

So Ordered.

/s/ F. Dennis Saylor IV
F. Dennis Saylor IV
United States District Judge

Dated: May 21, 2018

[3] To the extent plaintiffs rely on *Knipe v. SmithKline Beecham*, 583 F. Supp. 2d 602 (E.D. Pa. 2008) and *Wendling v. Pfizer. Inc.*, 2008 WL 833549 (N.J. App. Div. Mar, 31, 2008) for the proposition that Farrington's claims are not subsumed under the New Jersey PLA, those cases are inapposite. The Court has dismissed the claims of fraud based on marketing activities for failure to comply with Fed. R. Civ. P. 9(b). The remaining claims allege that the product's consumption, not its misleading promotion, caused plaintiffs harm. *See McDonough v. Bayer Healthcare, LLC*, 2011 WL 2119107, at *3 (D.N.J. May 26, 2011).