SUPREME COURT COPY

No. S233898

IN THE SUPREME COURT OF THE STATE OF CALIFORNIA

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T. H., A MINOR, ETC., ET AL.,

Plaintiffs and Appellants,

v.

NOVARTIS PHARMACEUTICALS CORPORATION

Defendant and Respondent.

SUPREME COURT
FILED
SEP 27 2017
Jorge Navarrete Clerk
Deputy

Review of a Decision of the Court of Appeal
Fourth Appellate District, Division One, Case No. D067839

NOTICE OF ERRATA

Erin M. Bosman, Esq. (SBN 204987)
Julie Y. Park, Esq. (SBN 259929)
MORRISON & FOERSTER LLP
12531 High Bluff Drive
San Diego, California 92130-2040
TEL: (858) 720-5100
FAX: (858) 720-5125
ebosman@mofo.com
juliepark@mofo.com

*Eric G. Lasker, Esq. (*pro hac vice*)
Katharine R. Latimer, Esq. (*pro hac vice*)
HOLLINGSWORTH LLP
1350 I Street NW
Washington, D.C. 20005
TEL: (202) 898-5800
FAX: (202) 682-1639
*elasker@hollingsworthllp.com

Attorneys for Defendant and Respondent,
NOVARTIS PHARMACEUTICALS CORPORATION

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San Diego, California 92130-2040
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ebosman@mofo.com
juliepark@mofo.com

*Eric G. Lasker, Esq. (*pro hac vice*)
Katharine R. Latimer, Esq. (*pro hac vice*)
HOLLINGSWORTH LLP
1350 I Street NW
Washington, D.C. 20005
TEL: (202) 898-5800
FAX: (202) 682-1639
*elasker@hollingsworthllp.com

Attorneys for Defendant and Respondent,
NOVARTIS PHARMACEUTICALS CORPORATION

Novartis Pharmaceuticals Corporation filed a Supplemental Authority Brief on September 22, 2017 and inadvertently omitted attaching the supplemental authority, *In re Zofran (Ondansetron) Prod. Liab. Litig.* (D.Mass. Aug. 4, 2017, No. 1:15-MD-2657-FDS) 2017 WL 3448548. A copy of the supplemental authority is attached hereto as Exhibit A.

Dated: September 26, 2017 Respectfully submitted,

MORRISON & FOERSTER LLP

By: _____
Julie Y. Park

Attorneys for Defendant and Respondent
NOVARTIS PHARMACEUTICALS CORPORATION

Exhibit A

2017 WL 3448548
Only the Westlaw citation is currently available.
United States District Court,
D. Massachusetts.

IN RE: ZOFRAN (ONDANSETRON) PRODUCTS LIABILITY LITIGATION,
This Document Relates To:
Akerman v. GlaxoSmithKline, LLC Case No. 1:16–cv–12471–FDS;
Easterly v. GlaxoSmithKline, LLC Case No. 1:15–cv–13749–FDS;
Green v. GlaxoSmithKline, LLC Case No. 1:16–cv–10665–FDS;
Gulick v. GlaxoSmithKline, LLC Case No. 1:16–cv–12213–FDS;
Perham v. GlaxoSmithKline, LLC Case No. 1:16–cv–10199–FDS;
Rice v. GlaxoSmithKline, LLC Case No. 1:16–cv–11748–FDS.

MDL No. 1:15–md–2657–FDS

Signed 08/04/2017

MEMORANDUM AND ORDER ON DEFENDANT'S CONSOLIDATED MOTION TO DISMISS FOR FAILURE TO PLEAD USE OF ITS PRODUCT; DEFENDANT'S SUPPLEMENTAL CONSOLIDATED MOTION TO DISMISS; AND PLAINTIFFS' MOTION TO CERTIFY QUESTIONS OF LAW TO STATE COURTS

F. Dennis Saylor IV, United States District Judge

*1 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.

GSK has moved to dismiss the claims of various plaintiffs who allege that they ingested only the generic formulation of the drug.[1] Plaintiffs have opposed those motions and, in the alternative, have moved to certify the following question to the highest courts of the relevant states:

> Is a brand-name drug manufacturer immunized from liability under this state's misrepresentation laws even when the brand-name drug manufacturer's misrepresentations created a market for the drug for an unapproved use in an untested population, resulting in injuries to consumers who ingested a generic version of the drug for that unapproved use?

(Pl. Mot. to Certify at 1). For the reasons stated below, defendant's motion to dismiss will be granted, and plaintiffs' motion to certify will be denied.

I. Background

A. Factual Background

1. The Parties and Zofran

GlaxoSmithKline LLC is a pharmaceutical company based in Wilmington, Delaware. (Master Long Form Complaint–Brand Zofran Use ("Compl.") ¶¶ 2–3). It is a subsidiary of GlaxoSmithKline PLC. (*Id.* ¶ 4). Until March 23, 2015, GSK was the sponsor of the new drug applications ("NDAs") for the pharmaceutical Zofran, or ondansetron. (*Id.* ¶ 6).

Zofran is an anti-emetic—that is, a drug that prevents or treats nausea or vomiting. (*Id.* ¶ 17). In 1991, Zofran was approved for marketing in the United States. (*Id.* ¶ 23). It was approved for the prevention of nausea and vomiting induced by chemotherapy or radiation therapy and post-operative nausea and vomiting. (*Id.* ¶ 16). Generic ondansetron became available in the United States in 2007. (Master Long Form Complaint–Generic Use ("Generic Compl.") ¶ 27).

Effective March 23, 2015, Novartis AG, a pharmaceutical

company based in Switzerland, purchased the right to sell Zofran products in the United States. (Compl. ¶ 7). At that time, Novartis Pharmaceuticals Corporation, an American-based subsidiary of Novartis AG, become the NDA holder for Zofran. (*Id.*).

The plaintiffs in this MDL proceeding are parents and guardians of children who allege that they were born with birth defects caused by prenatal exposure to Zofran and/or generic ondansetron. (Compl. ¶ 1).

2. Alleged Effects of Zofran/Ondansetron on Embryonic Development

*2 Zofran is part of a class of anti-emetics referred to as selective serotonin 5–HT3 receptor antagonists. (*Id.* at ¶ 17). Serotonin signaling in the body triggers nausea and vomiting. (*Id.* ¶ 19). The active ingredient in Zofran, ondansetron, is believed to alleviate symptoms of nausea and vomiting by inhibiting the body's serotonin signaling. (*Id.*).

Serotonin signaling regulates developmental processes that are critical to normal embryonic development. (*Id.* ¶ 20). Inhibiting serotonin signaling during embryonic development can therefore increase the risk of birth defects. (*Id.*). According to the complaint, pre-clinical studies conducted by or on behalf of GSK in the 1980s revealed that Zofran ingested by mammals—in particular, rats and rabbits—during pregnancy crosses the placental barrier, exposing the fetus to the drug. (*Id.* ¶ 43). The complaint alleges that subsequent scientific research has confirmed that Zofran also crosses the placental barrier during human pregnancies. (*Id.* ¶ 44).

According to the complaint, animal studies conducted by or on behalf of GSK in the 1980s in Japan revealed clinical signs of toxicity, intrauterine fetal deaths, stillbirths, congenital heart defects, craniofacial defects, impairment of ossification (incomplete bone growth), and other malformations in fetuses exposed to Zofran during gestation. (*Id.* ¶ 45). The complaint also alleges that from 1992 to the present, GSK has received reports—either directly or through studies published in medical literature—of birth defects in children exposed to Zofran or ondansetron during pregnancy. (*Id.* ¶ 46).

3. Alleged Off–Label Marketing of Zofran for Pregnancy–Related Nausea and Vomiting

According to the complaint, beginning around 1997, GSK "launched a marketing scheme to promote Zofran to obstetrics and gynecology healthcare practitioners and consumers as a safe and effective treatment for pregnancy-related nausea and vomiting." (*Id.* ¶ 29). Among other things, GSK's Oncology Division directly created new relationships with obstetricians and gynecologists, and also partnered with GSK's Consumer Health Care Division, which already had established relationships with obstetricians and gynecologists. (*Id.* ¶ 32). The two divisions allegedly entered a "co-marketing agreement" in 2001 to market Zofran to obstetricians and gynecologists for use in treating pregnancy-related nausea and vomiting. (*Id.* ¶¶ 33–34). According to the complaint, "[a]s a result of GSK's fraudulent marketing campaign," by 2002 Zofran had become the most frequently prescribed drug for treating pregnancy-related nausea and vomiting in the United States. (*Id.* ¶ 36).

Since 1993, the prescribing information for Zofran has included the following statement concerning its use during pregnancy:

> Pregnancy: Teratogenic Effects: Pregnancy Category B. Reproduction studies have been performed in pregnant rats and rabbits at I.V. doses of 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.

(*Id.* ¶ 50). The complaint alleges that "[t]his statement is false and misleading because animal studies conducted by or on behalf of GSK outside of the United States have in fact revealed evidence of teratogenic effects due to ondansetron." (*Id.* ¶ 51).[2] It further alleges that the statement is false and misleading "because [d]efendants failed to conduct post-market studies that were properly designed to identify Zofran's true teratogenic risk," and misleading "because it states that Zofran should be used during pregnancy if it is clearly needed, without limiting that representation to situations where it is clearly needed for the prevention of chemotherapy-induced nausea and vomiting, radiation therapy-induced nausea and vomiting, or post-operative nausea and/or vomiting." (*Id.*).

*3 The complaint alleges claims for, among other things, negligence, fraudulent misrepresentation, the violation of state consumer protection laws, wrongful death, and loss of consortium. The crux of all of the claims is that defendants failed to perform an adequate study of the safety of ingesting Zofran during pregnancy and promoted Zofran for use during pregnancy despite knowing of its teratogenic risks. As is particularly relevant here, the generic master complaint alleges that defendants' liability extends to those plaintiffs who ingested only generic ondansetron because it was reasonably foreseeable that promoting Zofran for use during pregnancy would result in patients being prescribed its generic alternative, once available. (*See, e.g.*, Generic Compl. ¶¶ 69, 91, 101, 117).

B. Procedural Background

On October 13, 2015, the Judicial Panel on Multidistrict Litigation transferred individual cases alleging birth defects due to ingestion of Zofran or ondansetron filed across the country to this Court for consolidated pretrial proceedings. In response to this Court's order dated May 18, 2016, plaintiffs filed a brand-name master complaint and a generic master complaint on May 31, 2016. Individual plaintiffs then subsequently filed short-form complaints adopting a master complaint with more detailed individual information concerning their claims.

The brand-name master complaint asserts 13 causes of action against defendants GSK and Novartis: negligence (Count 1); negligent misrepresentation (Count 2); negligent undertaking (Count 3); negligence *per se* (Count 4); failure to warn (Count 5); breach of express warranty (Count 6); breach of implied warranties (Count 7); fraudulent misrepresentation and concealment (Count 8); violation of state consumer protection laws (Count 9); wrongful death (Count 10); survival (Count 11); loss of consortium (Count 12); and punitive damages (Count 13). The generic master complaint is virtually identical, but does not include causes of action for failure to warn, breach of express warranty, or breach of implied warranties.

On October 13, 2016, defendant GSK filed a consolidated motion to dismiss various claims brought by individual plaintiffs who ingested only generic ondansetron.[3] That motion addressed the claims of 27 individual plaintiffs, who asserted claims under the laws of 19 different states. On December 30, 2016, defendants filed a supplemental consolidated motion to dismiss the claims of eight additional plaintiffs.

As a result of voluntary dismissals, the only remaining cases subject to the motions to dismiss are the following:

plaintiff	case number	relevant state
Rice	16-11748	Georgia
Gulick	16-12213	Indiana
Easterly	15-13749	Kentucky
Green	16-10665	Massachusetts
Perham	16-10199	New York
Akerman	16-12471	Oklahoma

Plaintiffs have opposed the motions to dismiss. In addition, and in the alternative, plaintiffs filed a motion to certify the following question to the Supreme Courts of five of the six states (Georgia, Indiana, Kentucky, Massachusetts, and Oklahoma) whose laws are at issue in the motion to dismiss:

> Is a brand-name drug manufacturer immunized from liability under this state's misrepresentation laws even when the brand-name drug manufacturer's misrepresentations created a market for the drug for an unapproved use in an untested population, resulting in injuries to consumers who ingested a generic version of the drug for that unapproved use?

(Pl. Mot. to Certify at 1).

II. Legal Standard

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, 127 S.Ct. 1955, 167 L.Ed.2d 929 (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, 127 S.Ct. 1955 (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, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009) (quoting *Twombly*, 550 U.S. at 556, 127 S.Ct. 1955). 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

A. Introduction

*4 The issues presented by these motions are largely the outgrowth of the operation of two legal principles. The first is the long-settled principle that a manufacturer of a product cannot be held liable for injuries caused by another company's product. *See, e.g., In re Darvocet, Darvon, and Propoxyphene Prods. Liab. Litig.*, 756 F.3d 917, 938 (6th Cir. 2014). The second is the principle, articulated by the Supreme Court in *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 131 S.Ct. 2567, 180 L.Ed.2d 580 (2011), that federal law governing the labeling of generic drugs preempts state tort law. As a result of that preemption finding, the Supreme Court held that generic drug manufacturers are required to use the same label as brand-name manufacturers, and that therefore a plaintiff may not recover against a generic manufacturer based on a state-law claim for failure to provide a different form of warning.[4]

As a practical matter, the result is that 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. *See Mensing*, 564 U.S. at 625, 131 S.Ct. 2567 ("We acknowledge the unfortunate hand that federal drug regulation has dealt [plaintiffs] and others similarly situated"); *id.* at 627, 131 S.Ct. 2567 ("As a result of today's decision, whether a consumer harmed by inadequate warnings can obtain relief turns solely on the happenstance of whether her pharmacist filled her prescription with a brand-name or generic drug.") (Sotomayor, J. dissenting).

Over the years, 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. Most, although not all, of those efforts have been rejected. *See, e.g., In re Darvocet*, 756 F.3d at 938; *but see, e.g, Conte v. Wyeth, Inc.*, 168 Cal.App.4th 89, 85 Cal.Rptr.3d 299 (2008).

Plaintiffs in the six cases at issue here are likewise attempting 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.

*5 None of the highest courts of the six 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.

B. Plaintiffs' Theories of Recovery

The six 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."[5] 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 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 TORTSS § 324 (negligent undertaking).

C. The Court's Ruling Concerning the Misrepresentation Claims

***6** To the extent that plaintiffs' claims rely on a theory of misrepresentation, those claims must satisfy the heightened pleading requirements of Fed. R. Civ. P. 9(b). *See Hayduk v. Lanna*, 775 F.2d 441, 443 (1st Cir. 1985) (noting that Rule 9(b) applies to all cases in "in which fraud lies at the core of the action"). In the First Circuit, to satisfy the requirements of Rule 9(b), plaintiffs must specifically plead "the time, place and content of an alleged false representation." *Id.* at 444.

In an earlier motion to dismiss plaintiff's fraud based claims, this Court ruled that the only claims of misrepresentation set forth in the master complaint that survive scrutiny under Rule 9(b) are those based on alleged misrepresentations in Zofran's product labeling. (*See* Docket No. 685). Plaintiffs' allegations of misrepresentations concerning GSK's marketing materials and statements made to physicians did not adequately plead the time, place, and content of the alleged misrepresentations. Accordingly, any claim of misrepresentation, based on the law of any state, is limited to the alleged misrepresentations or omissions in the product label itself.

D. Overview of State Tort Law

1. The Majority View

The overwhelming majority of courts—including all seven federal circuits to have addressed the issue—have held that the manufacturer of a brand-name drug may not be held liable for injuries caused by ingestion its generic equivalent, regardless of the theory of liability. *See In re Darvocet*, 756 F.3d at 938–39 (affirming dismissal of claims against brand-name manufacturers under the laws of 22 states; "an overwhelming majority of courts ... have rejected 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" (internal quotation marks omitted)); *Moretti v. Wyeth, Inc.*, 579 Fed.Appx. 563, 565 (9th Cir. 2014) (affirming summary judgment for brand-name manufacturer under Nevada law); *Lashley v. Pfizer, Inc.*, 750 F.3d 470, 476–78 (5th Cir. 2014) (affirming summary judgment for brand-name manufacturer under Mississippi and Texas law); *Strayhorn v. Wyeth Pharm., Inc.*, 737

F.3d 378, 406 (6th Cir. 2013) (affirming summary judgment for brand-name manufacturer under Tennessee law; "every federal court of appeals to consider this issue has held that brand-name manufacturers are not liable to plaintiffs who are injured by a generic manufacturer's drug"); *Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1284–86 (10th Cir. 2013) (affirming dismissal of claims against brand-name manufacturer under Oklahoma law; "the courts of other states have overwhelmingly rejected" imposing liability on brand-name manufacturers for generic products); *Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1252 (11th Cir. 2013) (affirming summary judgment for brand-name manufacturer under Florida law; "the overwhelming national consensus—including ... the vast majority of district courts around the country to consider the question—is that a brand-name manufacturer cannot be liable for injuries caused by the ingestion of the generic form of a product"); *Bell v. Pfizer, Inc.*, 716 F.3d 1087, 1092–94 (8th Cir. 2013) (affirming dismissal of claims against brand-name manufacturers under Arkansas law); *Demahy v. Schwarz Pharma, Inc.*, 702 F.3d 177, 183 (5th Cir. 2012) (per curiam) (affirming judgment in favor of brand-name manufacturer under Louisiana law), *rev'd in part on other grounds sub nom. Mensing*, 564 U.S. 604, 131 S.Ct. 2567; *Smith v. Wyeth, Inc.*, 657 F.3d 420, 423–24 (6th Cir. 2011) (affirming dismissal of claims against brand-name manufacturer under Kentucky law); *Foster v. American Home Prods. Corp.*, 29 F.3d 165, 171–72 (4th Cir. 1994) (affirming summary judgment for brand-name manufacturer under Maryland law); *Huck v. Wyeth, Inc.*, 850 N.W.2d 353, 380 (Iowa 2014).

*7 The seminal case adopting the majority view is *Foster*, 29 F.3d at 165. There, plaintiffs brought suit under Maryland law against the manufacturer of a brand-name drug when their daughter died after ingesting the generic equivalent of that drug. *Id.* at 166. Plaintiffs alleged liability under theories of both product liability and negligent misrepresentation. *Id.* at 166–67. The product-liability claim was dismissed early in the litigation, and the Fourth Circuit subsequently affirmed summary judgment on the negligent-misrepresentation claim, holding that "a name brand manufacturer cannot be held liable on negligent misrepresentation theory for injuries resulting from use of another manufacturer's product." *Id.* at 167.

The court in *Foster* rejected plaintiffs' claims for multiple reasons. First, the court was "unable to see any validity in [the] distinction" between a product-liability claim—for which plaintiffs must show that the defendant manufactured the product at issue—and a negligent-misrepresentation claim. *Id.* at 168. The court concluded that plaintiffs were ultimately "attempting to hold [defendant] liable for injuries caused by another manufacturer's product, and we are persuaded that the Maryland courts would reject this effort to circumvent the necessity that a defendant be shown to have manufactured the product that caused an injury prior to being held liable for such injury." *Id.*

The *Foster* court also expressed concerns about the potential unfairness of imposing liability under such circumstances:

> Name brand manufacturers undertake the expense of developing pioneer drugs, performing the studies necessary to obtain premarketing approval, and formulating labeling information. Generic manufacturers avoid these expenses by duplicating successful pioneer drugs and their labels. Name brand advertising benefits generic competitors because generics are generally sold as substitutes for name brand drugs, so the more a name brand drug is prescribed, the more potential sales exist for its generic equivalents. There is no legal precedent for using a name brand manufacturer's statements about its own product as a basis for liability for injuries caused by other manufacturers' products, over whose production the name brand manufacturer had no control. This would be especially unfair when, as here, the generic manufacturer reaps the benefits of the name brand manufacturer's statements by copying its labels and riding on the coattails of its advertising.

29 F.3d at 170.

The court accordingly held that the brand-name manufacturer did not owe a duty of care to individuals who ingested the generic equivalent of its drugs. *Id.* at 171–72. The court reasoned that "to impose a duty in the circumstances of this case would be to stretch the concept of foreseeability too far." *Id.* at 171. Because plaintiffs' daughter was injured by a drug that the defendant did not manufacture, the court concluded that there was no relationship between the parties such that plaintiffs had

the right to rely on the information it provided and it had no duty to give that information to them with care. *Id.*

The *Foster* court also rejected plaintiffs' contention that because federal regulations require generic drugs and their labeling to be identical their brand-name counterparts, it was foreseeable to brand-name manufacturers that plaintiffs may rely on misrepresentations made in their labeling. *Id.* at 169. The court reasoned that generic manufacturers are themselves liable for misrepresentations made on their labels, and that "[a]lthough generic manufacturers must include the same labeling information as the equivalent name brand drug, they are also permitted to add or strengthen warnings and delete misleading statements on labels, even without prior FDA approval." *Id.* at 169–70 (citing 21 C.F.R. § 314.70).

***8** That latter statement is no longer true in light of the Supreme Court's opinion in *Mensing*. *See* 564 U.S. at 624, 131 S.Ct. 2567. Nonetheless, the great majority of courts have continued to follow *Foster*, notwithstanding the *Mensing* decision. Indeed, some courts have held that the federal regulatory framework for pharmaceuticals provides a strong reason not to impose liability on brand-name manufacturers for injuries caused by generic drugs. As the Supreme Court of Iowa observed in *Huck*:

> Through carefully crafted legislation, Congress has made policy choices that impact the economics of prescription drug sales to increase access to medication. Huck cites nothing ... suggesting Congress intended to render brand defendants liable to consumers of generic products. To impose such liability would alter the relationship between generic and brand manufacturers. Specifically, extending liability to brand manufacturers for harm caused by generic competitors would discourage investments necessary to develop new, beneficial drugs by increasing the downside risks.
>
> Economic and public policy analyses strongly disfavor imposing tort liability on brand manufacturers for harm caused by generic competitors.
>
> Huck fails to articulate any persuasive case that public health and safety would be advanced through imposing tort liability on brand defendants for injuries caused by generic products sold by competitors.... [C]ourts are not institutionally qualified to balance the complex, interrelated, and divergent policy considerations in determining labeling and liability obligations of brand and generic pharmaceuticals.

850 N.W.2d at 377 (citations omitted).

2. The Minority View

A handful of courts have rejected the majority view, and held that the manufacturers of brand-name drugs may be liable for injuries caused by ingestion of their brand-name counterparts. The leading case adopting that view is *Conte v. Wyeth, Inc.*, 168 Cal.App.4th 89, 85 Cal.Rptr.3d 299 (2008).

In *Conte*, the First District of the California Appeals Court held that the manufacturer of a brand-name drug has a duty of care in disseminating product information that extends to individuals who are injured by ingestion of the generic version of that drug. *Id.* at 107, 85 Cal.Rptr.3d 299. The court's reasoning was essentially two-fold. First, the court rejected the defendant's contention that the plaintiff's claims for fraud and misrepresentation were really just claims for products liability, noting that there are significant differences between claims based on negligence as compared to strict liability. Second, it relied on the basic principle of tort law that duty follows primarily from foreseeability. *Id.* at 103–04, 85 Cal.Rptr.3d 299. The court concluded that because pharmacists are authorized to fill prescriptions for brand-name drugs with their generic counterparts, and because generic drugs are required by law to be bioequivalent to their brand-name counterparts, it is entirely foreseeable that a patient would ingest a generic drug in reliance on representations made by the brand-name manufacturer about its drug. That is true either because the patient's doctor would prescribe the brand-name drug in reliance on those representations, and the prescription would be filled with the generic equivalent, or because the patient's doctor would rely on the representations concerning the brand-name drug in prescribing the drug's generic equivalent. *Id.* at 105, 85 Cal.Rptr.3d 299. The court also considered various other factors relevant to the existence of a novel duty of care, including "the closeness of the connection between the defendant's conduct and the plaintiff's injury; the moral blame attached to the defendant's conduct; the policy goal of preventing future harm; [and] the burden to the defendant and consequences to the community of imposing a duty of care," *id.* at 105, 85 Cal.Rptr.3d 299. It concluded that, on the summary judgment record before it, those factors did not suggest a result other than finding a duty based on foreseeability. *Id.* at 107, 85 Cal.Rptr.3d 299.

***9** At least three other courts—one state supreme court and two federal district courts—have likewise held that the duty of brand-name manufacturers to exercise due

care in disseminating information about their drugs may, under some circumstances, extend to individuals who ingest the generic versions of their drugs. *See Wyeth, Inc. v. Weeks*, 159 So.3d 649 (Ala. 2014), *superseded by statute*, Ala. Code § 6–5–530(a);[6] *Dolin v. SmithKline Beecham Corp.*, 62 F.Supp.3d 705 (N.D. Ill. 2014); *Kellogg v. Wyeth*, 762 F.Supp.2d 694, 706 (D. Vt. 2010).[7]

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

E. The Law of the Relevant States

1. Georgia (*Rice*)

The *Rice* 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 Northern District of Georgia. (Rice Compl. ¶ 9). The parties agree that the substantive law of Georgia applies to the claims.

Although there is no Georgia Supreme Court authority directly on point, there is a decision on point from the intermediate Georgia Court of Appeals. *See PLIVA, Inc. v. Dement*, 335 Ga.App. 398, 780 S.E.2d 735 (2015), *cert. granted* (Ga. Sept. 6, 2016) (No. S16C0685).

In *Dement*, plaintiffs alleged that they had developed a neurological condition after ingesting the generic version of a drug. *Id.* at 737. They brought claims for negligence, misrepresentation, and breach of warranty against the generic manufacturer as well as the brand-name manufacturer based on the allegedly inadequate warnings each provided regarding the long-term safety of the drug. *Id.* at 737–38. The Georgia Court of Appeals affirmed the grant of summary judgment in favor of the brand-name manufacturer, holding that a brand-name manufacturer does not owe a duty of care under Georgia law to consumers who ingest the generic version of its drug and therefore cannot be held liable for injuries caused by the generic drug. *Id.* at 743.[8]

***10** Two federal courts applying Georgia law—the Sixth Circuit and the Northern District of Georgia—have also held that brand-name manufacturers may not be liable for injuries caused by the ingestion of generic versions of their drugs. *See In re Darvocet*, 756 F.3d at 943; *Swicegood v. Pliva, Inc.*, 543 F.Supp.2d 1351 (N.D. Ga. 2008).

In *Swicegood*, the plaintiff alleged that she developed neurological injuries after ingesting the generic version of a drug and brought various claims against the brand-name manufacturers based on their alleged improper labeling of the brand-name equivalent of the generic drug that she ingested. *Id.* at 1353–54. Applying Georgia law, the court dismissed all claims against the brand-name manufactures, including claims for negligent failure to warn and misrepresentation. *Id.* at 1355–57. The court relied on *Potts v. UAP–GA AG CHEM, Inc.*, 256 Ga.App. 153, 567 S.E.2d 316 (2002) in holding that a defendant could not be liable for failure to warn unless that defendant supplied the product at issue. *Id.* at 1355. Similarly, the court concluded that holding the brand-name manufacturers liable under a theory of misrepresentation would "result in an unprecedented departure from traditional Georgia tort law." *Id.* at 1357 (internal quotation marks omitted). The court rejected plaintiff's contention that a duty of care to consumers of generic versions of the brand-name manufacturers' drug was created by state law (Georgia's "Good Samaritan" doctrine, adopted from § 324A of the Restatement (Second) of Torts) or federal law (the FDCA labeling scheme). *Id.* at 1356–57.

In *In re Darvocet*, the Sixth Circuit reviewed the *Swicegood* opinion (*Darvocet* had not yet been issued) and concluded: "Guided by the Northern District of Georgia's decision, we predict that the Georgia Supreme Court would either construe Plaintiffs' misrepresentation claims as product liability claims that fail for lack of product identification or that Brand Manufacturers did not owe Plaintiffs a duty that could give rise to liability under Georgia law." 756 F.3d at 943.

Based on those cases, and the line of Georgia authority cited by those courts, it appears very likely that the Georgia Supreme Court would adopt the majority view.

2. Indiana (*Gulick*)

The *Gulick* 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 Northern District of Indiana. (Gulick Compl. ¶ 9). The parties agree that the substantive law of Indiana applies to the claims.

There is no Indiana Supreme Court authority directly on point. There is, however, a decision of the Sixth Circuit applying Indiana law. *See In re Darvocet*, 756 F.3d at 945.

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 "predict[ed] that the Indiana Supreme Court would decline to recognize that brand manufacturers owe generic consumers a duty of care that could give rise to liability." *Id.* As to the distinction between products liability and misrepresentation claims, the court noted that the Indiana 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,' " but that the Act explicitly states that it does not govern other claims. *Id.* (quoting Ind. Code Ann. § 34–20–1–1 (2014)). As to duty, the court explained that, under Indiana law, whether a novel duty of care exists is determined by "balanc[ing] three factors: '(1) the relationship between the parties, (2) the reasonable foreseeability of harm to the person injured, and (3) public policy concerns.' " *Id.* (quoting *Webb v. Jarvis*, 575 N.E.2d 992, 995 (Ind. 1991)). Applying those factors, the court reasoned that because (1) the plaintiffs were injured by a drug the brand-name defendants did not produce, (2) "[u]sing federal and Indiana state laws designed to increase the availability of generic drugs as the basis of supplying to duty element for tort liability stretches foreseeability too far," and (3) extending liability could result in "higher priced brand name drugs and fewer innovative drugs," Indiana would likely not extend liability to brand-name manufacturers for injuries caused by ingestion of generic drugs. *Id.*

***11** Indiana 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 Indiana authority suggesting a contrary result.

3. Kentucky (*Easterly*)

The *Easterly* case was originally filed in the Eastern District of Kentucky, and transferred to this Court as part of the MDL proceeding. The parties agree that the substantive law of Kentucky applies to the claims.

There is no Kentucky Supreme Court authority directly on point. However, the Sixth Circuit has twice rejected similar claims under Kentucky law. *See In re Darvocet*, 756 F.3d at 945–46; *Smith v. Wyeth, Inc.*, 657 F.3d 420 (6th Cir. 2011).

In *Smith*, the Sixth Circuit applied Kentucky law to fraud and misrepresentation claims brought against brand-name-drug manufacturers by consumers of the drug's generic equivalent. *Id.* at 422–23. In affirming dismissal of the claims, the court relied primarily on the Kentucky Products Liability Act, Ky. Rev. Stat. §§ 411.300–411.350, which, "[a]s the Kentucky Supreme Court has held, '... applies to all damage claims arising from the use of products, regardless of the legal theory advanced.' " *Id.* at 424 (quoting *Monsanto Co. v. Reed*, 950 S.W.2d 811, 814 (Ky. 1997)). The court concluded that plaintiffs had failed to satisfy the statute's threshold requirement: "that the defendant's product caused the plaintiff's injury." *Id.* (citing *Holbrook v. Rose*, 458 S.W.2d 155, 157 (Ky. 1970)).

The court in *Smith* also rejected plaintiffs' contention that the regulatory structure governing generic drugs makes it foreseeable that physicians and consumers will rely on the brand-name labels in prescribing and ingesting generic versions of the drug. *Id.* at 423–24. Following *Foster* and the majority of courts to have addressed the issue, the Sixth Circuit "reject[ed] 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." *Id.* at 424.[9]

The *Easterly* case was filed in Kentucky, which is in the Sixth Circuit; but for the transfer of the case as part of the MDL proceeding, the *Smith* decision would be binding on the district court.

There is some question as to whether the decisions of the Sixth Circuit interpreting state law are binding on this Court, as a transferee court in an MDL proceeding. *See, e.g., In re General American Life Ins. Co. Sales Practice Litigation*, 391 F.3d 907, 911 (8th Cir. 2004) (stating that an MDL transferee court must apply the law of the circuit in which it is located to issues of federal law, and apply the state law that would have applied had the case not been transferred). But even if *Smith* is not technically binding, it would be highly anomalous for this Court to reject the ruling, and the reasoning, of the Sixth Circuit, as applied to a case properly filed in the Eastern District of Kentucky. Furthermore, and in any event, the *Smith* court followed the majority rule and supported its opinion with ample citation to authority, and there appears to be no Kentucky authority to the contrary.

4. Massachusetts (*Green*)

***12** The *Green* case was filed directly in the District of Massachusetts, as part of the MDL proceeding; it could have been filed in this District regardless, if no such proceeding existed. The parties agree that the substantive law of Massachusetts applies to the claims.

The only two Massachusetts cases directly on point are from the trial-level Superior Court. *See Rafferty v. Merck & Co.*, 2016 WL 3064255 (Mass. Super. Ct. May 23, 2016); *Kelly v. Wyeth*, 2005 WL 4056740 (Mass. Super. Ct. May 6, 2005).

In *Rafferty*, the plaintiff suffered injuries as a result of a generic pharmaceutical. Because the plaintiff was "essentially foreclosed from bringing failure to warn claims against the generic manufacturer," he alleged that the brand-name manufacturer had a duty to maintain the accuracy of the labels for those individuals who would rely on those labels, and that the duty "extend[ed] to individuals who ingest the generic equivalent of [the] brand-name drug." *Rafferty*, 2016 WL 3064255, at *4. The court noted the well-established principle under Massachusetts law that " '[a] plaintiff who sues a particular manufacturer for product liability generally must be able to prove that the item which it is claimed caused the injury can be traced to that specific manufacturer.' " *Id.* (quoting *Mathers v. Midland–Ross Corp.*, 403 Mass. 688, 691, 532 N.E.2d 46 (1989)). It then noted that "while '[a] manufacturer of a product has a duty to warn foreseeable users of dangers in the use of that product[,]' Massachusetts courts 'have never held a manufacturer liable ... for failure to warn of risks created solely in the use or misuse of the product of another manufacturer.' " *Id.* (quoting *Mitchell v. Sky Climber, Inc.*, 396 Mass. 629 631, 487 N.E.2d 1374 (1986)) (alternations in original). The court concluded:

> Reading these legal principles together supports the conclusion that Rafferty cannot hold Merck liable for the harm he allegedly sustained. Merck did not manufacture the [drug], and although Merck did generate the information contained in the label that the generic manufacturer eventually used, it did not affirmatively supply the generic manufacturer with that information.

Id. The court went on to discuss the opinion of the Iowa Supreme Court in *Huck*, setting forth the reasons why public-policy considerations weigh against holding brand-name manufacturers for injuries caused by generic drugs. *Id.* at *5. Finally, it observed that proposed amendments to FDA regulations concerning the labeling of generic drugs might, if adopted, permit recovery against generic manufacturers. *Id.* at *6–7.

Similarly, in *Kelly*, the court held that the manufacturer of a brand-name drug does not owe a duty of care to consumers of that drug's generic equivalent. 2005 WL 4056740, at *4–5. The court relied primarily on *Foster* and *Carrier v. Riddell, Inc.*, 721 F.2d 867 (1st Cir. 1983) in its analysis. In *Carrier*, the First Circuit concluded that Massachusetts tort law barred recovery against a sporting equipment manufacturer for football-related injuries sustained while the plaintiff was wearing a helmet manufactured by another company. 721 F.2d at 868. Plaintiffs (the injured high school student and his mother) contended that the defendant was negligent in not providing a general warning about the limitations of helmets in preventing certain kinds of injuries and that, if it had, the plaintiff-student would have taken additional precautions. *Id.* The First Circuit rejected that argument, reasoning that under basic principles of tort law, for claims involving an alleged omission or failure to act, a defendant's duty not to act negligently extends only "to those who have relied in some special way upon the defendant, to those whom defendants have helped to place in a position where they are likely to depend upon his avoiding negligent omissions." *Id.* at 868–69. The court thus concluded that, as no such special relationship existed, the defendant owned no duty to plaintiffs. *Id.* at 869. The court also noted that its review of Massachusetts law had not found a single case "imposing liability upon a manufacturer (for failure to warn) in favor of one who uses the product of a *different* manufacturer," but that "various Massachusetts 'warning cases' ... [suggest that] a duty of care runs to those who buy or use the product itself, not a different maker's product." *Id.*

***13** In summary, while there is no controlling Massachusetts appellate authority, the only two Massachusetts courts to have considered the question have both adopted the majority view.

5. New York (*Perham*)

The *Perham* case was filed directly in the District of Massachusetts as a part of this proceeding, again as permitted by this Court's MDL Order No. 6; it otherwise would have been filed in the Northern District of New York. (Perham Compl. ¶ 16). The parties agree that the substantive law of New York applies to the claims.

There is no authority from the New York Court of Appeals directly on point. However, two federal courts applying New York law and a New York state trial court have rejected similar claims. *See In re Darvocet*, 756 F.3d at 949; *Goldych v. Eli Lilly & Co.*, 2006 WL 2038436 (N.D.N.Y. July 19, 2006); *Weese v. Pfizer*, 2013 N.Y. Slip. Op. 32563(U), 2013 WL 5691993 (N.Y. Sup. Ct. Oct. 8, 2013).

In *Goldych*, the Northern District of New York, applying New York law, adopted the reasoning of *Foster* and held that "a brand name manufacturer cannot be held liable to a plaintiff allegedly injured by another company's generic bioequivalent." 2006 WL 2038436, at *6. The plaintiff brought claims against defendant Eli Lilly for, among other things, negligence, fraud, fraudulent concealment, and negligent misrepresentation, alleging that it had failed to provide adequate warnings concerning the risks of suicidal ideations and actions associated with taking the anti-depressant Prozac. *Id.* at *1. The court noted that, under New York law, product-liability claims require plaintiffs to prove that the defendant manufactured the product that allegedly caused the injury, and claims of fraud, fraudulent concealment, and negligent misrepresentation are not materially distinct from product-liability claims where the acts underlying fraud-based claims are the same as the acts underlying the negligence and strict products-liability claims. *Id.* at *6 and n.11. The court further reasoned that the brand-name manufacturer did not owe a duty of care to the users of the generic equivalents of its products. *Id.* at *6.

In *Weese*, the plaintiff brought claims against Pfizer for injuries allegedly caused due to ingestion of a generic form of the anti-depressant Zoloft. *Id.* at *1. The court dismissed the claims against Pfizer, concluding that it did not owe a duty to the plaintiff. The court reasoned as follows:

> Pfizer had no intentional role in placing the specific product with the plaintiff. It was not the seller. Indeed, a third party—a competitor—manufactured and sold the product.... It is to be expected that Pfizer had a duty in connection with its own products and labels. However, that duty should not extend to products and labeling over which it has no control, even if those products and labels mirror its own, because it has done nothing toward putting them in the hands of consumers.

Id. at *3–4.

In *In re Darvocet*, the Sixth Circuit reviewed the *Goldych* and *Weese* decisions, and concluded that "the New York Court of Appeals would construe Plaintiffs' misrepresentation claims as a product liability claim that fails for lack of product identification, or alternatively that the Brand Manufacturers did not owe Plaintiffs a duty that could give rise to liability." 756 F.3d at 949.

***14** Thus, the three courts to have addressed the issue have concluded that under New York law a plaintiff may not hold a brand-name manufacturer liable for injuries allegedly caused by ingestion of a generic version of a drug. There appears to be no New York authority to the contrary.

6. Oklahoma (*Akerman*)

The *Akerman* 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 Western District of Oklahoma. (Ackerman Compl. ¶ 9). The parties agree that the substantive law of Oklahoma applies to the claims.

There is no Oklahoma Supreme Court authority directly on point. Two federal circuits, however, have rejected similar claims under Oklahoma law. *See In re Darvocet*, 756 F.3d at 950–51; *Schrock v. Wyeth, Inc.*, 727 F.3d 1273 (10th Cir. 2013).

In *Schrock*, the Tenth Circuit applied Oklahoma law and predicted that "consistent with the trend among courts nationally and Oklahoma tort law in general ... [the Oklahoma Supreme Court] would not recognize a duty flowing from brand-name drug manufacturers to consumers of generic drugs." *Id.* at 1281–82. The court reasoned that Oklahoma courts require "a relationship between the defendant company and the product at issue" to find liability under theories of strict liability as well as others, including negligence, and that no such relationship was present between plaintiffs and the brand-name manufacturer. *Id.* at 1282. Similarly, the court concluded that there was no Oklahoma case law suggesting that Oklahoma courts would impose liability based on theories of misrepresentation, fraud, or failure to warn absent such a relationship. *Id.* at 1283–84. The court also noted that "the courts of other states have overwhelmingly rejected" the theory that manufacturers of brand-name drugs may be liable for injuries caused by the ingestion of their generic equivalents. *Id.* at 1284–85.

In *In re Darvocet*, the Sixth Circuit reviewed the *Schrock* decision, and concluded that "Guided by our sister circuit's analysis of Oklahoma tort law, we predict that the Oklahoma Supreme Court would find that Brand Manufacturers did not owe Plaintiffs a duty that could give rise to liability under Oklahoma law." 756 F.3d at 951.

Oklahoma is in the Tenth Circuit. *See Schrock*, 727 F.3d at 1273. But for the MDL proceeding, the *Schrock* decision would be binding on the district court. As with the *Easterly* case, and for similar reasons, it appears that the appropriate course, if not the binding course, is to follow the Tenth Circuit's decision.

7. Conclusion

In summary, none of the state supreme courts in any of the six relevant states have ruled on precisely the issues presented here. Nonetheless, for each of the jurisdictions, there is case law suggesting, often strongly so, that dismissal is appropriate. Furthermore, there is no authority in any of those jurisdictions, from any court, to the contrary. Under the circumstances, dismissal for failure to state a claim appears to be the appropriate course.

It is true that dismissal would appear to leave consumers injured by generic drugs without any form of remedy. But it is by no means obvious that the minority viewpoint is correct or fair, or even that it is the outcome that best protects consumers. Just as it may be unfair to leave some injured consumers without a remedy, so too it may be unfair or unwise to require brand-name manufacturers to bear 100% of the liability, when they may have only 10%, or less, of the relevant market. *See Mensing*, 564 U.S. at 629, 131 S.Ct. 2567 (Sotomayor, J., dissenting) (noting that, where a generic version is available, 90% of prescriptions are filled with generics). A fair and rational system of tort liability must balance a variety of different factors, including not only providing compensation for injured persons, but also such factors as the appropriate allocation of risk. Congress has apparently decided, at least according to the Supreme Court, to exempt generic drug manufacturers from state-law tort liability. *See Mensing*, 564 U.S. at 624, 131 S.Ct. 2567. It does not clearly follow that brand-name manufacturers should bear all of the potential liability, particularly where it is unclear what the impact of such a potentially enormous shift in liability may have on the development of new drugs.

*15 In any event, the clear majority view is that liability should not be imposed on brand-name manufacturers for injuries caused by generic drugs. As an alternative to outright dismissal, plaintiffs have requested that the Court certify a question to the supreme courts of five of the six states as to whether a drug manufacturer can be held liable on a market misrepresentation theory for sales of generic products.[10]

F. Certification of Questions of Law Generally

"Absent controlling state-law precedent, a federal court sitting in diversity has the discretion to certify a state-law question to the state's highest court." *Nieves v. University of P.R.*, 7 F.3d 270, 274 (1st Cir. 1993). However, before even considering whether to exercise that discretion, a court must first determine whether "the course [the] state [ ] would take is reasonably clear." *Id.* at 274–75 (internal quotation marks omitted) (alterations original). If the course a state court would take is clear, certification would waste judicial resources and is inappropriate. *Armacost v. Amica Mut. Ins. Co.*, 11 F.3d 267, 269 (1st Cir. 1993); *Bi–Rite Enters., Inc. v. Bruce Miner Co.*, 757 F.2d 440, 443 n.3 (1st Cir. 1985). Thus, even absent binding precedent, certification is inappropriate where analogous decisions of a state's highest court or decisions of its lower courts are sufficient to allow a federal court to confidently predict how the state's highest court would resolve the question presented. *See In re Engage, Inc.*, 544 F.3d 50, 55 (1st Cir. 2008). *Cf. id.* at 56 (finding certification appropriate where relevant case law did not provide " 'compelling guidance' on the direction of state law") (quoting *Nicolo v. Philip Morris, Inc.*, 201 F.3d 29, 33 (1st Cir. 2000)).

If the course a state court would take is not clear, a federal court sitting in diversity may either make its best judgment as to what course the state court would take or it may certify the question to the state's highest court. *See In re Engage*, 544 F.3d at 53. A close or difficult legal question alone is not normally enough to warrant certification. *Boston Gas Co. v. Century Indem. Co.*, 529 F.3d 8, 15 (1st Cir. 2008). Rather, certification is generally considered appropriate only when the resolution of the questions presented turns on difficult policy judgments, with conflicting interests, that are better left to state courts and when the interests at stake extend beyond the present parties. *See In re Engage*, 544 F.3d at 53, 57; *Boston Gas*, 529 F.3d at 15; *Brown v. Crown Equip. Corp.*, 501 F.3d 75, 77 (1st Cir. 2007). Other factors that weigh in favor of certification include the lack of a clear consensus among other states to have addressed the issue as well as the complexity and nuance of the questions presented and their possible resolutions. *See Boston Gas*,

529 F.3d at 13, 15; *Brown*, 501 F.3d at 77–78. For example, certification may be appropriate where, among the courts to have addressed the issue, there are not only two general approaches taken but also further divisions within each general approach concerning the details or practicalities of how the issue is resolved. *See Boston Gas*, 529 F.3d at 15.

Furthermore, in order to avoid rendering advisory opinions, all of the state courts relevant here require that certified questions be "determinative" of the case. Ga. Code § 15–2–9; Ind. R. App. P. 64; Ky. R. Civ. P. 76.37; Mass. Sup. Jud. Ct. R. 1:03; 20 Okl. St. § 1602. For the same reason, the state courts require that the questions posed be framed by concrete facts and not sound in hypotheticals. *See Snyder v. King*, 958 N.E.2d 764, 786 (Ind. 2011); *Ball v. Wilshire Ins. Co.*, 184 P.3d 463, 466–67 (Okl. 2007); *Canal Elec. Co. v. Westinghouse Elec. Corp.*, 406 Mass. 369, 371–72, 548 N.E.2d 182 (1990); *Bulloch Cnty. Hosp. Auth. v. Fowler*, 227 Ga. 638, 182 S.E.2d 443, 446 (1971). Where questions may be merely hypothetical, or where they are so broad that they could be answered differently in one set of circumstances than another, state supreme courts may decline to answer questions certified. *See Bulloch Cnty. Hosp. Auth.*, 182 S.E.2d at 446.

G. Whether Certification of a Question Is Appropriate

***16** The question is thus whether this Court should certify the requested question to the supreme courts of the various states.

As to *Perham*, the answer is simple: there is no procedure under New York law for certification of questions to the New York Court of Appeals.

As to *Rice*, there is clear and recent authority from the Georgia Court of Appeals directly on point. *See Dement*, 780 S.E.2d at 735. Although that decision is not from the Georgia Supreme Court, it is presumably binding on trial courts in that state. Under the circumstances, Georgia law is sufficiently clear, and the Court sees no reason to certify the question.

As to *Easterly* and *Akerman*, there is also clear and recent authority from the relevant federal circuits (the Sixth and Tenth Circuits, respectively) directly on point. *See Smith*, 657 F.3d at 424; *Schrock*, 727 F.3d at 1283–84. Presumably, those courts could have employed the certification procedure had they viewed it as necessary or appropriate to do so. This Court sees no reason, under the circumstances, to take a contrary view. A similar approach is appropriate in *Gulick*, notwithstanding the fact that Indiana is not in the Sixth Circuit. *See In re Darvocet*, 756 F.3d at 945.

That leaves *Green*, in which the law of Massachusetts applies. As set forth above, there are two Superior Court decisions on point, as well as opinions from the Supreme Judicial Court setting forth general principles of product identification requirements in tort cases. *See Rafferty*, 2016 WL 3064255; *Kelly*, 2005 WL 4056740. There is not, however, any authority from the SJC or the Massachusetts Appeals Court directly addressing the issue of whether a brand-name manufacturer can be held liable for injuries caused by a drug manufactured by a generic manufacturer. That makes the *Green* case by far the most suitable case of the six available candidates for certification of the question.

There is some superficial appeal to certifying the question to the SJC. Although there is an overwhelming majority view, there is also a minority view, and the correct resolution of the issue is by no means obvious. The issue is one of state law, an area in which a federal district court is not empowered to innovate. The issue also involves a complex set of questions at the intersection of federal drug regulation and state tort law that requires a balancing of multiple considerations of law and policy. Ideally, the balancing of the costs and benefits of different approaches should be left to the political branches, whether at the state or federal level; but it is certainly an exercise that an individual federal district judge, sitting in diversity, is ill-suited to perform.

Nonetheless, there are at least three reasons why certification is inappropriate under the circumstances presented here.

First, this is not a case where the Court cannot make an informed and intelligent prediction as to how the courts of Massachusetts would rule. There is, in fact, an overwhelming and well-reasoned majority view, which has been set out in multiple opinions by a variety of federal and state courts. Furthermore, the issue has been addressed by two associate justices of the Massachusetts Superior Court, both of whom concluded that Massachusetts would follow the majority view.

***17** Second, the question that the plaintiff seeks to certify is not a straightforward question of law. The only federal court to have certified the issue of brand-name manufacturer liability for generic products is the Fourth Circuit, which did so only two months ago. *See McNair v. Johnson & Johnson*, —— Fed.Appx. ——, 2017 WL 2333843 (4th Cir. May 30, 2017) (certifying question to

the West Virginia Supreme Court). The question certified there was as follows:

> Whether West Virginia law permits a claim of failure to warn and negligent misrepresentation against a branded drug manufacturer when the drug ingested was produced by a generic manufacturer.

Id. Here, by contrast, plaintiff seeks to certify the following question:

> Is a brand-name drug manufacturer immunized from liability under this state's misrepresentation laws even when the brand-name drug manufacturer's misrepresentations created a market for the drug for an unapproved use in an untested population, resulting in injuries to consumers who ingested a generic version of the drug for that unapproved use?

That question is centered on a factual allegation—whether GSK's "misrepresentations created a market for the drug for an unapproved use in an untested population"—that may or may not prove to be true. Ultimately, there may be insufficient evidence to support that allegation, or the evidence may support a somewhat different, but relevant, proposition. The question may therefore prove irrelevant, or need to be modified, whether wholesale, only slightly, or otherwise. There is not even a factual record, such as a summary judgment record, as a backdrop for consideration of the question. It is therefore entirely possible that the Court could wind up certifying a purely hypothetical question that has no actual relationship to the evidence. It would be an enormous waste of judicial resources to certify a fact-bound question to the SJC, only to find that the facts as ultimately proved are different.

Third, the proposed question involves alleged misrepresentations, none of which are identified by the plaintiff. This Court has already ruled that the complaint was insufficiently specific, within the meaning of Fed. R. Civ. P. 9(b), as to any alleged misrepresentation other than the product label itself. It is certainly unclear how any alleged misrepresentations in the product label, without more, could have "created a market for the drug for an unapproved use in an untested population." Any answer by the SJC to the proposed question might therefore prove to be entirely advisory.[11]

In summary, under the circumstances, this Court finds that it is inadvisable to certify the requested question in *Green* to the Supreme Judicial Court under Mass. Sup. Jud. Ct. R. 1:03, or to certify that question to any of the four other relevant jurisdictions under their analogous rules.

IV. Conclusion

For the foregoing reasons, the consolidated motion to dismiss of defendant GlaxoSmith Kline, LLC for failure to state a claim upon which relief can be granted is GRANTED as to *Easterly v. GlaxoSmithKline LLC*, 15–cv–13749–FDS; *Akerman v. GlaxoSmithKline LLC*, 16–cv–12471–FDS; *Gulick v. GlaxoSmithKline LLC*, 16–cv–12471–FDS; and *Perham v. GlaxoSmithKline LLC*, 16–cv–10199–FDS; *Rice v. GlaxoSmithKline LLC*, 16–cv–11748–FDS, and *Green v. GlaxoSmithKline LLC*, 16–cv–10665–FDS. The motion of plaintiffs to certify questions of law to state courts is DENIED.

***18 So Ordered.**

All Citations

--- F.Supp.3d ----, 2017 WL 3448548

Footnotes

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*.

2 The complaint specifically alleges that a study conducted in Japan in the 1980s "revealed clinical signs of toxicity, intrauterine fetal deaths, stillbirths, congenital heart defects, craniofacial defects, impairment of ossification (incomplete bone growth), and other malformations" due to ingestion of ondansetron during pregnancy. (*Id.* ¶ 45).

3 On October 26, 2016, plaintiffs filed a motion to strike the motion to dismiss as premature. The Court denied that motion on November 10, and ordered plaintiffs to file an opposition to the motion on or before January 10, 2017.

4 The Supreme Court reasoned that under the Drug Price Competition and Patent Term Restoration Act, often referred to as the Hatch–Waxman Amendments, manufacturers of generic drugs can shortcut lengthy NDA procedures by demonstrating to the FDA that the generic drug is equivalent to an already-approved brand-name drug and that its safety and efficacy labeling is identical to the brand-name drug's labeling. *Id.* at 612, 131 S.Ct. 2567. Thus, under federal law, the labeling duties of a generic-drug manufacturer consist only of "ensuring that its warning label is the same as the brand name's." *Id.* at 613, 131 S.Ct. 2567. Furthermore, the court deferred to the FDA's interpretation of regulations permitting generic-drug manufacturers to "add or strengthen" warnings, holding that generic-drug manufacturers cannot unilaterally add or strengthen warnings, as that would violate federal law requiring that generic and brand-name labels be identical. *Id.* at 614, 131 S.Ct. 2567. Thus, generic manufacturers can only strengthen or add warnings if the brand-name manufacturer makes the same change to its labels. *Id.* at 616, 131 S.Ct. 2567. Given those regulations, the court held that generic manufacturers could not comply with both federal law and state tort-law duties to provide adequate warnings, and that tort-law claims against generic manufacturers alleging failure to warn are therefore preempted. *Id.* at 618, 131 S.Ct. 2567.

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

6 Three justices of the Alabama Supreme Court dissented in *Weeks*. Furthermore, the Alabama legislature reversed *Weeks* by statute within a year of the court's decision. *See* Ala. Code § 6–5–530(a) ("In any civil action for personal injury, death, or property damage caused by a product, regardless of the type of claims alleged or the theory of liability asserted, the plaintiff must prove, among other elements, that the defendant designed, manufactured, sold, or leased the particular product the use of which is alleged to have caused the injury on which the claim is based, and not a similar or equivalent product.").

7 Other lower-court opinions have reached similar conclusions, but have been reversed or superseded by subsequent circuit opinions. *See, e.g., Chatman v. Pfizer, Inc.*, 960 F.Supp.2d 641 (S.D. Miss. 2013); *contra Lashley*, 750 F.3d at 477.

8 The Supreme Court of Georgia granted *certiorari* in *Dement* specifically on the issue of whether the court of appeals "err[ed] in determining that respondents' various claims are not barred as preempted by federal law." Because the issues concerning preemption were raised only as to claims filed against the generic manufacturer, not the brand-name manufacturer, *see id.* at 738–42, it does not appear that the grant of certiorari is likely to affect the holding of the Court of Appeals as to the liability of the brand-name manufacturer.

9 In *In re Darvocet*, the Sixth Circuit affirmed its decision in *Smith* on the ground that it would not overrule the published decision of a prior panel. 756 F.3d at 945–46.

10 Because New York does not have such a certification procedure, that option is not available as to the claim of plaintiff Perham.

11 The question, as framed, applies only to plaintiffs' theories of negligent and intentional misrepresentation; it does not apply to the theory of negligent undertaking.

End of Document

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PROOF OF SERVICE

I declare that I am employed with the law firm of Morrison & Foerster LLP, whose address is 12351 High Bluff Drive, San Diego, California 92130. I am not a party to the within cause, and I am over the age of eighteen years.

I further declare that on September 26, 2017, I served a copy of:

NOTICE OF ERRATA

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Benjamin I. Siminou Kevin F. Quinn Thorsnes, Bartolotta, McGuire LLP 2550 Fifth Avenue, 11th Floor San Diego, California 92103 T: (619) 236-9363 F: (619) 236-9653	Attorneys for Plaintiffs and Appellants
Leslie A. Brueckner Public Justice PC 555 12th Street, Suite 1230 Oakland, California 94607 T: (510) 622-8150 F: (510) 622-8155	Attorneys for Plaintiffs and Appellants
Gregory Herbers Michelle Stilwell Washington Legal Foundation 2009 Massachusetts Ave., NW Washington, DC 20036 T: (202) 588-0302	Counsel for Amicus Curiae Washington Legal Foundation

Fred J. Hiestand Counselor at Law 3418 Third Ave., Suite 1 Sacramento, CA 95817 T: (916) 448-5100	Counsel for Amicus Curiae Civil Justice Association of California
David E. Stanley James M. Beck Reed Smith LLP 355 S. Grand Ave., Suite 2900 Los Angeles, CA 90071 T: (213) 457-8085	Amicus Curiae Product Liability Advisory Council, Inc.
Hugh F. Young Product Liability Advisory Council, Inc. 1850 Centennial Park Drive Suite 510 Reston, VA 20191	Amicus Curiae Product Liability Advisory Council, Inc.
Nance F. Becker Chavez & Gertler LLP 42 Miller Avenue Mill Valley, CA 94925 T: (415) 2381-5599	Amicus Curiae Public Citizen
Allison M. Zieve Public Citizen Litigation Group 1600 20th Street NW Washington, DC 20009 T: (202) 588-1000	Amicus Curiae Public Citizen
Mary-Christine Sungaila Haynes and Boone LLP 600 Anton Blvd., Suite 700 Costa Mesa, CA 92626 T: (949) 202-3000	Amicus Curiae International Association of Defense Counsel and Federation of Defense & Corporate Counsel

Polly Fohn Haynes and Boone LLP 1221 McKinney Street, Suite 2100 Houston, TX 77010 T: (713) 547-2570	Amicus Curiae International Association of Defense Counsel and Federation of Defense & Corporate Counsel
Phil Goldberg Shook Hardy & Bacon LLP 1155 F Street, NW, Suite 20 Washington, DC 20004 T: (202) 783-8400	Amicus Curiae National Association of Manufacturers and American Tort Reform Association
Paul B. La Scala Shook Hardy & Bacon LLP 5 Park Plaza, Suite 1600 Irvine, CA 92614 T: (949) 475-1500	Amicus Curiae National Association of Manufacturers and American Tort Reform Association
Linda E. Kelly Manufacturers' Center For Legal Action 733 10th Street, NW, Suite 700 Washington, DC 20001	Amicus Curiae National Association of Manufacturers and American Tort Reform Association
H. Sherman Joyce American Tort Reform Association 1101 Connecticut Ave., NW Suite 400 Washington, DC 20036	Amicus Curiae National Association of Manufacturers and American Tort Reform Association
Alicia J. Donahue Shook Hardy & Bacon LLP One Montgomery Tower Suite 2700 San Francisco, CA 94104 T: (415) 544-1900	Amicus Curiae Genentech, Inc. and California Life Sciences Association

Kannon K. Shanmugam
Williams & Connolly LLP
725 Twelfth Street, NW
Washington, DC 20005
T: (202) 434-5000

Amicus Curiae Chamber of Commerce of the United States of America

Robert P. Charrow
Greenberg Traurig LLP
2101 L Street, NW
Washington, DC 20037
T: (202) 533-2396

Amicus Curiae Atlantic Legal Foundation

Martin S. Kaufman
Atlantic Legal Foundation
2039 Palmer Avenue
Larchmont, NY 10538
T: (914) 834-3322

Amicus Curiae Atlantic Legal Foundation

Jeffrey M. Davidson
Covington & Burling LLP
One Front Street
San Francisco, CA 94111
T: (415) 591-7021

Amicus Curiae Pharmaceutical Research and Manufacturers of America

Michael X. Imbroscio
Covington & Burling LLP
850 10th Street NW
Washington, DC 20001
T: (202) 662-6000

Amicus Curiae Pharmaceutical Research and Manufacturers of America

William Alvarado Rivera
AARP Foundation Litigation
601 E. Street, NW
Washington, DC 20049
T: (202) 434-3392

Amicus Curiae AARP Foundation

Alan Charles Dell' Ario
1561 Third Street, Suite B
Napa, CA 94559
T: (707) 666-5351

Amicus Curiae Consumer Attorneys of California and American Association for Justice

Jeffrey R. White
777 Sixth Street, NW, Suite 250
Washington, DC 20001
T: (202) 944-2839

Amicus Curiae Consumer Attorneys of California and American Association for Justice

Deborah H. La Ferta
Pacific Legal Foundation
930 G Street
Sacramento, CA 95814
T: (916) 419-7111

Amicus Curiae Pacific Legal Foundation

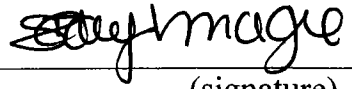
San Diego Superior Court
Hon. Joan M. Lewis
330 West Broadway
San Diego, CA 92101

Clerk of Court
Fourth District Court of Appeal
Division One
750 B Street, Suite 300
San Diego, CA 92101

I declare under penalty of perjury that the foregoing is true and correct.

Executed on this 26th day of September, 2017, at San Diego, California.

Stacy Vinagre
(typed)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