UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

IN RE: ZANTAC (RANITIDINE) PRODUCTS LIABILITY LITIGATION

MDL NO. 2924
20-MD-2924

JUDGE ROBIN L. ROSENBERG
MAGISTRATE JUDGE BRUCE E. REINHART

_____/

ORDER GRANTING BRAND-NAME MANUFACTURER DEFENDANTS' MOTION TO DISMISS PLAINTIFFS' INNOVATOR-LIABILITY CLAIMS

This matter is before the Court upon Brand-Name Manufacturer Defendants' ("Defendants") Rule 12 Motion to Dismiss Plaintiffs' Innovator-Liability Claims ("Motion to Dismiss"). DE 1585. The Court held a hearing on the Motion to Dismiss on December 14, 2020 (the "Hearing"). DE 2498. The Court has carefully considered the Motion to Dismiss, Plaintiffs' Opposition thereto [DE 1973], Defendants' Reply [DE 2132], the parties' supplemental briefing [DE 2307; DE 2335], the arguments that the parties made during the Hearing, and the record and is otherwise fully advised in the premises. For the reasons set forth below, the Motion to Dismiss is **GRANTED**.

I. Factual Background[1]

This case concerns the pharmaceutical product Zantac and its generic forms, which are widely sold as heartburn and gastric treatments. The molecule in question—ranitidine—is the active ingredient in both Zantac and its generic forms.

[1] A court must accept a plaintiff's factual allegations as true at the motion–to–dismiss stage. *West v. Warden*, 869 F.3d 1289, 1296 (11th Cir. 2017) ("When considering a motion to dismiss, we accept as true the facts as set forth in the complaint and draw all reasonable inferences in the plaintiff's favor." (quotation marks omitted)). Plaintiffs have set forth their factual allegations in three "master" complaints: the Master Personal Injury Complaint ("MPIC"), the Consolidated Consumer Class Action Complaint ("CCCAC"), and the Consolidated Third Party Payor Class Complaint ("CTPPCC") (collectively "Master Complaints"). DE 887, 888, 889.

Zantac has been sold since the early 1980's, first by prescription and later as an over-the-counter medication. In 1983, the U.S. Food and Drug Administration ("FDA") approved the sale of prescription Zantac. MPIC ¶¶ 226, 231, 432. GlaxoSmithKline ("GSK") first developed and patented Zantac. *Id.* ¶ 230. Zantac was a blockbuster—the first drug in history to reach $1 billion annually in sales. ¶ 231.

GSK entered into a joint venture with Warner-Lambert in 1993 to develop an over-the-counter ("OTC") form of Zantac. *Id.* ¶ 233. Beginning in 1995, the FDA approved the sale of various forms of OTC Zantac. *Id.* ¶¶ 233, 237. The joint venture between GSK and Warner-Lambert ended in 1998, with Warner-Lambert retaining control over the sale of OTC Zantac in the United States and GSK retaining control over the sale of prescription Zantac in the United States. *Id.* ¶ 234. Pfizer acquired Warner-Lambert in 2000 and took control of the sale of OTC Zantac in the United States. *Id.* ¶ 235. The right to sell OTC Zantac in the United States later passed to Boehringer Ingelheim Pharmaceuticals and then to Sanofi. *Id.* ¶¶ 239-40, 242-44. When the patents on prescription and OTC Zantac expired, numerous generic drug manufacturers began to produce generic ranitidine products in prescription and OTC forms. *Id.* ¶¶ 249-51.

Scientific studies have demonstrated that ranitidine can transform into a cancer-causing molecule called N-nitrosodimethylamine ("NDMA"), which is part of a carcinogenic group of compounds called N-nitrosamines. *Id.* ¶¶ 253, 321, 324, 331. Studies have shown that these compounds increase the risk of cancer in humans and animals. *Id.* ¶¶ 253, 264-72. The FDA, the Environmental Protection Agency, and the International Agency for Research on Cancer consider NDMA to be a probable human carcinogen. *Id.* ¶¶ 254, 258. The FDA has set the acceptable daily intake level for NDMA at 96 nanograms. *Id.* ¶¶ 4, 263.

Valisure LLC and ValisureRX LLC, a pharmacy and testing laboratory, filed a Citizen Petition on September 9, 2019, calling for the recall of all ranitidine products due to high levels of NDMA in the products. *Id.* ¶ 285. The FDA issued a statement on September 13 warning that some ranitidine products may contain NDMA. *Id.* ¶ 286. On November 1, the FDA announced that testing had revealed the presence of NDMA in ranitidine products. *Id.* ¶ 296. The FDA recommended that drug manufacturers recall ranitidine products with NDMA levels above the acceptable daily intake level. *Id.* Six months later, on April 1, 2020, the FDA requested the voluntary withdrawal of all ranitidine products from the market. *Id.* ¶ 301.

II. Procedural Background

After the discovery that ranitidine products may contain NDMA, Plaintiffs across the country began initiating lawsuits related to their purchase and/or use of the products. On February 6, 2020, the United States Judicial Panel on Multidistrict Litigation created this multi-district litigation ("MDL") pursuant to 28 U.S.C. § 1407 for all pretrial purposes and ordered federal lawsuits for personal injury and economic damages from the purchase and/or use of ranitidine products to be transferred to the undersigned. DE 1. Since that time, hundreds of Plaintiffs have filed lawsuits in, or had their lawsuits transferred to, the United States District Court for the Southern District of Florida. In addition, this Court has created a Census Registry where thousands of claimants who have not filed lawsuits have registered their claims. *See* DE 547.

Plaintiffs filed three Master Complaints on June 22, 2020. DE 887, 888, 889. Plaintiffs contend that the ranitidine molecule is unstable, breaks down into NDMA, and has caused thousands of consumers of ranitidine products to develop various forms of cancer. MPIC ¶¶ 1, 6, 19. Plaintiffs allege that "a single pill of ranitidine can contain quantities of NDMA that are hundreds of times higher" than the FDA's allowable limit. *Id.* ¶ 4. Plaintiffs are pursuing federal

claims and state claims under the laws of all 50 U.S. states, Puerto Rico, and the District of Columbia. *See generally* CCCAC. The entities named as defendants are alleged to have designed, manufactured, tested, marketed, distributed, labeled, packaged, handled, stored, and/or sold ranitidine products. MPIC ¶¶ 20, 225.

The Court has entered numerous Pretrial Orders to assist in the management of this MDL. In Pretrial Order # 30, the Court set a case management schedule that is intended to prepare the MDL for the filing of *Daubert* motions on general causation and class certification motions in December 2021. DE 875; *see generally Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993). In Pretrial Order # 36, the Court set a schedule for the filing and briefing of motions to dismiss under Federal Rule of Civil Procedure 12 directed to the Master Complaints. DE 1346. Defendants filed the instant Motion to Dismiss pursuant to that schedule.

III. The Master Personal Injury Complaint

For the purposes of this Order, the Court's references to "Plaintiffs" are to only those Plaintiffs who allegedly were injured solely by generic ranitidine products, not by brand-name ranitidine products. While there are fifteen counts asserted against Defendants in the MPIC, Plaintiffs acknowledged at the Hearing that the only substantive counts they are pursuing against Defendants are Counts VII and VIII. DE 2498 at 209; MPIC ¶¶ 542–73. Count VII is a claim for general negligence. MPIC ¶¶ 542–61. Plaintiffs allege that Defendants "breached their duty of reasonable care and failed to exercise ordinary care in the design, manufacture, testing, marketing, labeling, packaging, handling, distribution, storage, and/or sale of ranitidine-containing products." *Id.* ¶ 551. Count VIII is a claim for negligent misrepresentation. *Id.* ¶¶ 561–73. Plaintiffs allege that Defendants "owed a duty to Plaintiffs to make accurate and truthful representations regarding ranitidine-containing products" and breached that duty. *Id.* ¶ 564. In this Order, the Court refers

to Counts VII and VIII as Plaintiffs' "negligence-based claims." Additionally, Counts XIII-XV are derivative claims and include: loss of consortium, survival actions, and wrongful death. *Id.* ¶¶ 637–56.

It is undisputed that all of Plaintiffs' claims against Defendants are based on a theory of liability that is currently only recognized under California and Massachusetts law. DE 1585 at 6;[2] DE 1973 at 15; *see also Rafferty v. Merck & Co.*, 92 N.E.3d 1205, 1219–20 (Mass. 2018) (holding that, under Massachusetts law, brand-name manufacturers owe a duty to generic drug consumers not to act in reckless disregard of an unreasonable risk of death or grave bodily injury and allowing common law claims against brand-name manufacturers for recklessness but not for ordinary negligence); *T.H. v. Novartis Pharm. Corp.*, 407 P.3d 18, 47–48 (Cal. 2017) (holding that, under California law, brand-name manufacturers owe a duty to use ordinary care in warning about the safety risks of their drugs, regardless of whether the injured party consumed the brand or generic drug, and allowing claims of general negligence and negligent misrepresentation against brand-name manufacturers). This theory of liability has been referred to as "innovator liability." *See* Allen Rostron, *Prescription for Fairness: A New Approach to Tort Liability of Brand–Name and Generic Drug Manufacturers*, 60 Duke L.J. 1123, 1176 (2011). Under this theory of liability, the consumers of a generic drug product may hold a brand-name drug manufacturer liable for failing to warn of a defect in the product—a product that the brand-name drug manufacturer did not itself make, sell, or distribute. *See id.* The theory is based on a principle articulated in Section 311 of the Restatement (Second) of Torts, which provides in relevant part:

> One who negligently gives false information to another is subject to liability for physical harm caused by action taken by the other in reasonable reliance upon such information, where such harm results. . . to such third persons as the actor should expect to be put in peril by the action taken.

[2] Unless noted otherwise, all page number references herein are to the page numbers generated by CM/ECF in the header of each document.

Restatement (Second) of Torts § 311(1)(b) (Am. Law Inst. 1965).

Here, Plaintiffs have pled that Defendants are liable for their alleged misrepresentations concerning the safety of ingesting brand-name ranitidine products which, according to Plaintiffs, created the market for generic ranitidine products, foreseeably led to the ingestion of generic ranitidine products, and, in turn, foreseeably led to generic consumers' injuries.

IV. Summary of the Parties' Arguments

Defendants filed the instant Motion to Dismiss seeking the dismissal of all claims asserted against them under Plaintiffs' theory of liability in all individual complaints, the MPIC, and Short Form Complaints adopting the MPIC. DE 1585 at 20.[3] Defendants' Motion to Dismiss has three primary arguments. First, claims brought in jurisdictions other than California and Massachusetts fail as a matter of law because those jurisdictions have yet to recognize Plaintiffs' theory of liability under their tort regimes. *Id.* at 13. Second, although California and Massachusetts recognize Plaintiffs' theory of liability under their respective tort regimes, Plaintiffs cannot assert their claims in the courts of those states because neither state has personal jurisdiction over Defendants.[4] *Id.* at 14. Lastly, Plaintiffs' claims fail even in those states in which Defendants are subject to general jurisdiction because those states are constrained by the Due Process Clause from applying the law of California or Massachusetts to Plaintiffs' claims. *Id.* at 17.

Plaintiffs argue that, in order to determine whether their theory of liability is viable under the laws of the jurisdictions that have not explicitly accepted or rejected it, the Court must make

[3] "Individual complaints" are personal injury complaints that plaintiffs to this litigation have filed in their individual cases. "Short Form Complaints" are complaints that plaintiffs to this litigation have filed in their individual cases using the form attached to the MPIC. *See* DE 887-1.

[4] Defendants argue that lack of personal jurisdiction is an independent ground for dismissal of all of Plaintiffs' claims in all jurisdictions. DE 1585 at 14 n.3. However, they focus on the lack of personal jurisdiction in California and Massachusetts because they argue that those are the only states that recognize Plaintiffs' theory of liability. *Id.*

an *Erie* prediction by examining the law of each jurisdiction. DE 1973 at 15. These jurisdictions are likely to find Plaintiffs' theory of liability viable. *Id*. California and Massachusetts courts have specific personal jurisdiction over Defendants because of Defendants' alleged targeted marketing and labeling activities in those states. *Id.* at 24. And, because California and Massachusetts courts have specific personal jurisdiction over Defendants, California and Massachusetts courts also have legislative jurisdiction in other states and territories with personal jurisdiction over Defendants. *Id.* at 26.

The Court ordered supplemental briefing from Plaintiffs and responsive supplemental briefing from Defendants on the issue of whether Plaintiffs' theory of liability may be viable under the laws of each jurisdiction that has yet to accept or reject the theory. DE 2228.[5] Thus, the parties provided briefing for the 35 remaining jurisdictions. DE 2307; DE 2335.

V. Summary of the Court's Rulings

The Court undertook the requisite *Erie* predictions, as set forth in Appendix A to this Order, and concludes that none of the 35 jurisdictions that the Court analyzed would recognize Plaintiffs' theory of liability under which Defendants may be held liable for injuries sustained by Plaintiffs' ingestion of a product that Defendants did not manufacture, sell, or distributed. *See Erie R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938). Additionally, the Court concludes that Plaintiffs failed to allege a prima facie case of specific personal jurisdiction as to any Defendant in California or Massachusetts and that California and Massachusetts do not have legislative jurisdiction within those states that have general personal jurisdiction over Defendants. Therefore, the Court grants

[5] Defendants acknowledged in the Motion to Dismiss that California and Massachusetts have recognized Plaintiffs' theory of liability [DE 1585 at 6], and Plaintiffs acknowledged in their Opposition that their theory of liability is not viable under the laws of Alabama, Iowa, West Virginia, or Florida [DE 1973 at 11]. Therefore, the Court did not require supplemental briefing on those states. In their supplemental briefing, Plaintiffs apprised the Court that they are not pursuing claims under their theory of liability in the following additional eleven jurisdictions: Georgia, Idaho, Indiana, Kansas, Kentucky, Louisiana, New Jersey, Ohio, Tennessee, Texas, and Washington. DE 2307 at 25.

the Motion to Dismiss. Plaintiffs' claims are dismissed without prejudice and with leave to amend to plead a prima facie case of personal jurisdiction in California and Massachusetts.

VI. Standards of Review

Defendants did not cite to any Federal Rule of Civil Procedure in their Motion to Dismiss. *See generally* DE 1585. However, Defendants informed the Court at the Hearing that they are moving to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(2) for lack of personal jurisdiction and Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim. DE 2498 at 191.

A. Rule 12(b)(2)

A court may grant a motion to dismiss a pleading for lack of personal jurisdiction. Fed. R. Civ. P. 12(b)(2). At the pleading stage, the burden is on the plaintiff to establish a prima facie case of personal jurisdiction over the nonresident defendant. *See Consol. Dev. Corp. v. Sherritt, Inc.*, 216 F.3d 1286, 1291 (11th Cir. 2000). A prima facie case of personal jurisdiction is established if a plaintiff presents sufficient facts, entitled to the assumption of truth and viewed in the light most favorable to the plaintiff, to withstand a motion for directed verdict. *Id.* Non-specific statements providing "labels and conclusions" or "a formulaic recitation of the elements of [jurisdiction]" are not accepted as true and are insufficient to establish a prima facie case of jurisdiction. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007); *see, e.g.*, *Snow v. DirecTV, Inc.*, 450 F.3d 1314, 1318 (11th Cir. 2006) (holding that the plaintiff's "vague and conclusory allegations" presented in his complaint were insufficient to establish a prima facie case of personal jurisdiction over a defendant).

B. Rule 12(b)(6)

A court may grant a motion to dismiss a pleading if the pleading fails to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). A court ruling on a motion to dismiss accepts the well-pled factual allegations as true and views the facts in the light most favorable to the plaintiff. *Jones v. Fransen*, 857 F.3d 843, 850 (11th Cir. 2017). But the court need not accept legal conclusions couched as factual allegations. *Diverse Power, Inc. v. City of LaGrange, Ga.*, 934 F.3d 1270, 1273 (11th Cir. 2019). "Under Rule 12(b)(6), dismissal is proper when, on the basis of a dispositive issue of law, no construction of the factual allegations will support the cause of action." *Allen v. USAA Cas. Ins. Co.*, 790 F.3d 1274, 1278 (11th Cir. 2015) (quotation marks omitted).

VII. Analysis

A. Plaintiffs' Theory of Liability Against Defendants

1. Arguments and Allegations

Defendants argue that this Court should align itself with the majority view that Plaintiffs' theory of liability—holding a brand-name manufacturer liable for injuries from a product it did not make, sell, or distribute—is invalid. DE 1585 at 13. Courts often reject the theory of liability because it ignores a fundamental principle of products liability law that requires a plaintiff to show that the product that caused injury was sold, manufactured, or distributed by the defendant. *Id.* at 10; *see In re Darvocet, Darvon & Propoxyphene Prod. Liab. Litig.*, 856 F. Supp. 2d 904, 908 (E.D. Ky. 2012) ("[I]t is well-settled law that a 'threshold requirement of any products liability claim is that the plaintiff assert that the defendant's product caused the plaintiff's injury.'") (quoting *Smith v. Wyeth*, 657 F.3d 420, 423 (6th Cir. 2011)), *aff'd*, 756 F.3d 917 (6th Cir. 2014); *In re Aredia & Zometa Prod. Liab. Litig.*, No. 3-06-MD-1760, 2010 WL 5136142, at *2 (M.D. Tenn. Dec. 7,

2010) (holding that traditional principles of products liability law require that the plaintiff prove the defendant supplied the product which caused the injury). As no Plaintiff was injured by a Defendant's product, the claims against them fail. DE 1585 at 10. Additionally, even if the fact that Plaintiffs were not injured by Defendants' products is ignored, Plaintiffs' negligence-based claims fail because courts have routinely held that a brand-name manufacturer owes no duty to generic consumers. *Id.* at 11.

Plaintiffs argue that Defendants' liability turns on whether they owe a duty to generic consumers. DE 1973 at 14. Defendants "intended for Plaintiffs and their physicians to reasonably and foreseeably rely on their misrepresentations about ranitidine-containing products in prescribing or recommending the drug to Plaintiffs, leading to their injuries." *Id.* at 16. Holding "brand-manufacturers liable for injuries caused by generic versions of their drugs is consistent with the long-standing rule that those who disseminate misinformation to the public are liable for physical harm to third parties resulting from foreseeable reliance on those misrepresentations." *Id.* at 17.

2. Law on *Erie* Prediction

A federal court sitting in diversity must apply state substantive law. *Erie*, 304 U.S. at 78. Where the highest state court has spoken on a topic, the federal court must follow its rule. *Molinos Valle Del Cibao, C. por A. v. Lama*, 633 F.3d 1330, 1348 (11th Cir. 2011). Where the highest state court has not spoken on the topic, the federal court must follow the decisions of intermediate appellate courts unless persuasive evidence demonstrates that the highest court would conclude otherwise. *Id.* If there is no explicit state law on an issue, "a federal court attempting to forecast state law must consider whatever might lend it insight, including 'relevant state precedents, analogous decisions, considered dicta, scholarly works, and any other reliable data tending

convincingly to show how the highest court in the state would decide the issue at hand.'" *Guideone Elite Ins. Co. v. Old Cutler Presbyterian Church, Inc.*, 420 F.3d 1317, 1326 n.5 (11th Cir. 2005) (quoting *McKenna v. Ortho Pharm. Corp.*, 622 F.2d 657, 663 (3d Cir. 1980)). It is "generally presume[d] that [state] courts would adopt the majority view on a legal issue in the absence of indications to the contrary." *Bobo v. Tennessee Valley Auth.*, 855 F.3d 1294, 1304 (11th Cir. 2017) (citing *Wammock v. Celotex Corp.*, 835 F.2d 818, 820 (11th Cir. 1988)).

However, when a federal court is called upon to recognize a cause of action under a state's laws that the state itself has yet to recognize, "considerations of comity and federalism counsel that [the federal court] proceed gingerly when venturing into uncharted waters of state substantive law." *Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1251 (11th Cir. 2013) (declining to "manufacture" a law making brand-name manufacturers liable for the injuries of generic consumers "out of whole cloth," in part, because no Florida state court had adopted such law); *see also City of Miami v. Bank of Am. Corp.*, 800 F.3d 1262, 1289 (11th Cir. 2015) (declining "to invent a novel basis for unjust enrichment under Florida law" because the Florida Supreme Court had not yet ruled on whether such law existed and because of "the complete lack of supporting Florida caselaw").

3. Analysis and Conclusion

The Court has the task of making an *Erie* prediction as to whether the highest courts of 35 jurisdictions would recognize Plaintiffs' theory of liability.[6] In making its *Erie* predictions, the Court follows the *Erie* analysis steps set forth by the Eleventh Circuit. In addition to its own research, the Court relies upon the supplemental briefing provided by the parties. DE 2307; DE 2335. The Court's *Erie* predictions for the 35 jurisdictions are included in Appendix A.

[6] The 35 jurisdictions are: Alaska, Arizona, Arkansas, Colorado, Connecticut, Delaware, the District of Columbia, Hawaii, Illinois, Maine, Maryland, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oklahoma, Oregon, Pennsylvania, Puerto Rico, Rhode Island, South Carolina, South Dakota, Utah, Vermont, Virginia, Wisconsin, and Wyoming.

As an initial matter, the Court recognizes that "the overwhelming national consensus—including the decisions of every [federal] court of appeal and 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." *Guarino*, 719 F.3d at 1253 (finding no liability under Florida law of a brand-name manufacturer for injuries caused by ingestion of a generic drug); *see In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, 756 F.3d 917, 941–54 (6th Cir. 2014) (holding that brand-name manufacturers cannot be held liable for damages caused by ingestion of generic drugs under negligent misrepresentation law of 22 states).[7] A small minority of federal and state courts have found that brand-name manufacturers owe a duty to generic consumers, reasoning that brand-name manufacturers know or should know that doctors foreseeably rely upon information relayed to them by brand-name manufacturers and foreseeably prescribe generic versions of the drug, which foreseeably causes injuries to generic consumers.[8]

[7] *See also Johnson v. Teva Pharm. USA, Inc.*, 758 F.3d 605, 616 & n.3 (5th Cir. 2014) (finding no liability under Louisiana law of a brand-name manufacturer for injuries caused by ingestion of a generic drug and observing that "[o]ur decision is consistent with other circuit decisions that have held (under the laws of several different states) that brand-name manufacturers are not liable for injuries caused by a plaintiffs ingestion of generic products"); *Eckhardt v. Qualitest Pharms., Inc.*, 751 F.3d 674, 681–82 (5th Cir. 2014) (finding no liability under Texas Law); *Lashley v. Pfizer, Inc.*, 750 F.3d 470, 476–78 (5th Cir. 2014) (finding no liability under Mississippi and Texas law); *Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1281–86 (10th Cir. 2013) (finding no liability under Florida law); *Strayhorn v. Wyeth Pharms.*, Inc., 737 F.3d 378, 401–06 (6th Cir. 2013) (finding no liability under Tennessee law); *Bell v. Pfizer, Inc.*, 716 F.3d 1087, 1093 (8th Cir. 2013) (finding no liability under Arkansas law); *Demahy v. Schwarz Pharma, Inc.*, 702 F.3d 177, 183 (5th Cir. 2012) (per curiam) (finding no liability under Louisiana law); *Smith*, 657 F.3d at 423–24 (finding no liability under Kentucky law); *Foster v. Am. Home Prod. Corp.*, 29 F.3d 165, 171 (4th Cir. 1994) (finding no liability under Maryland law).

[8] *See Rafferty*, 92 N.E.3d at 1219 (recognizing a duty to refrain from acting recklessly under Massachusetts law); *T.H. v. Novartis*, 407 P.3d at 47 (recognizing a duty of ordinary care under California law); *Wyeth, Inc. v. Weeks*, 159 So. 3d 649, 676 (Ala. 2014) (recognizing a duty of ordinary care under Alabama law), *superseded by statute*, Ala. Code § 6-5-530(a); *Dolin v. SmithKline Beecham Corp.*, 62 F. Supp. 3d 705, 714 (N.D. Ill. 2014) (recognizing a duty of ordinary care under Illinois law), *rev'd on other grounds sub nom. Dolin v. GlaxoSmithKline LLC*, 901 F.3d 803 (7th Cir. 2018); *Garner v. Johnson & Johnson, Janssen Rsch. & Dev. LLC*, No. 116-CV-01494, 2017 WL 6945335, at *7 (C.D. Ill. Sept. 6, 2017) (recognizing a duty of ordinary care under Illinois law); *Kellogg v. Wyeth*, 762 F. Supp. 2d 694, 708–09 (D. Vt. 2010) (recognizing a duty of ordinary care under Vermont law).

As the Sixth Circuit explained,

> There are two analytical avenues by which a state's highest court would determine whether Plaintiffs have stated viable [negligence and negligent misrepresentation] claims against Brand Manufacturers under applicable state law: (1) Plaintiffs' claims may be construed as strict "product liability" claims under the state's tort regime regardless of whether they are articulated as sounding in negligence [and negligent misrepresentation], or (2) even if they are seen as distinct and separate from product liability claims under a state's law, whether a duty exists between Brand Manufacturers and users of generic drugs that can give rise to liability.

In re Darvocet, 756 F.3d at 937. If the plaintiff's claims are construed as products liability claims, a threshold requirement is "product identification": for a plaintiff's claim to survive, the plaintiff must allege that she was injured by the defendant's product. *Id.* at 938.; *see also* Am. L. Prod. Liab. 3d § 5:1 (2020) ("[A] threshold requirement for a products liability action is that the plaintiff identify the manufacturer or supplier responsible for placing the injury-causing product into the stream of commerce; this is the traditional requirement that plaintiff establish causation.").

Although Plaintiffs argue that they are not pursing products liability claims against Defendants, as explained in Appendix A, the laws of some jurisdictions do not treat claims related to products that are pursued under a theory of negligence as distinct from products liability claims. Thus, if Plaintiffs' negligence-based claims are construed as products liability claims under state law, then for those claims to be viable under the laws of jurisdictions that require product identification, Plaintiffs must allege that the drugs that caused their injuries were made, sold, or distributed by Defendants. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (explaining that "[a] claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged"). For Plaintiffs' negligence-based claims viewed under state law as distinct from products liability claims to be viable, Plaintiffs must establish that Defendants owed Plaintiffs a duty sufficient to trigger liability.

The Court predicts that the highest courts of all 35 jurisdictions examined would hold that it is settled law that product identification must exist for a products liability claim to succeed. *See* Appendix A. The Court further predicts that the highest courts of Arizona, Arkansas, Colorado, Connecticut, Mississippi, North Carolina, and Oregon would hold that Plaintiffs' negligence-based claims are, in reality, products liability claims because all of Plaintiffs' claims stem from an injury caused by a product. The negligence-based claims are not distinct from products liability claims under the laws of these jurisdictions. Thus, because these states require product identification and Plaintiffs have not pled product identification, Plaintiffs' claims against Defendants of general negligence (Count VII) and negligent misrepresentation (Count VIII) fail under the laws of these jurisdictions.

Lastly, the Court predicts that the highest courts of Alaska, Delaware, the District of Columbia, Hawaii, Illinois, Maine, Maryland, Michigan, Minnesota, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Dakota, Oklahoma, Pennsylvania, Puerto Rico, Rhode Island, South Carolina, South Dakota, Utah, Vermont, Virginia, Wisconsin, and Wyoming could hold that Plaintiffs' negligence-based claims are distinct from products liability claims. Consequently, the Court undertook further analysis to predict whether the highest courts of those jurisdictions would recognize a duty owed by Defendants to Plaintiffs that gives rise to liability. Based on the Court's review of each jurisdiction's analysis of when a duty is owed, the Court predicts that the highest courts of each of these jurisdictions would determine that Defendants do not owe a duty to Plaintiffs. This prediction comports with the principles of comity and federalism, which counsel federal courts to "proceed gingerly when venturing into uncharted waters of state substantive law." *Guarino*, 719 F.3d at 1251–53; *see also Douglas Asphalt Co. v. QORE, Inc.*, 657 F.3d 1146, 1154 (11th Cir. 2011) ("It is not the function

of federal courts to expand state tort doctrine in novel directions absent state authority suggesting the propriety of doing so."); *City of Miami*, 800 F.3d at 1289 (declining "to invent a novel basis for unjust enrichment under Florida law" because the Florida Supreme Court had not yet ruled on whether such a claim existed and because of "the complete lack of supporting Florida caselaw"). Furthermore, this prediction is consistent with the majority view and is appropriate given the absence of any strong evidence that these jurisdictions would join the minority view. *See Bobo*, 855 F.3d at 1304 (holding that it is "generally presume[d] that [state] courts would adopt the majority view on a legal issue in the absence of indications to the contrary"). Plaintiffs' claims of general negligence (Count VII) and negligent misrepresentation (Count VIII) against Defendants fail under the laws of these jurisdictions.

In conclusion, the Court predicts that none of the highest courts of the 35 jurisdictions would recognize Plaintiffs' theory of liability. Thus, Counts VII and VIII of the MPIC by Plaintiffs against Defendants fail under the laws of the 35 jurisdictions for failure to state a claim. And because Plaintiffs' substantive claims fail, so do their derivative claims, Counts XIII, XIV, and XV. *See In re Darvocet*, 756 F.3d at 936 (affirming a district court's dismissal of "derivative claims for wrongful death, survivorship, unjust enrichment, loss of consortium, and punitive damages" when the district court had dismissed all "underlying claims" because the derivative claims "stand or fall with the underlying claims on which they rest").

B. Personal Jurisdiction

1. Arguments and Allegations

Defendants argue that Plaintiffs have failed to establish specific personal jurisdiction in any state but focus their arguments on California and Massachusetts as the only two states that have explicitly recognized Plaintiffs' theory of liability. DE 1585 at 15. As to California and

Massachusetts, personal jurisdiction over Defendants exists if Plaintiffs' claims "'arise out of or relate to' actions" that Defendants took or directed to those states. DE 2132 at 10–11 (quoting *Bristol-Myers Squibb Co. v. Superior Ct. of Cal., S.F. Cty.*, 137 S. Ct. 1773, 1780 (2017)). Further, "there must be an affiliation between the forum and the underlying controversy, principally, an activity or an occurrence that takes place in the forum State and is therefore subject to the State's regulation." DE 1585 at 15 (quoting *Bristol–Myers Squibb Co.*, 137 S. Ct. at 1780). The "controversy" in this case concerns the content of the label for generic ranitidine products and, thus, "the only conduct by the Brand-Name Manufacturers relevant to the innovator-liability claims" is "the labeling decisions," which "did not take place in California and Massachusetts." *Id.* at 16. Additionally, it makes no difference whether Defendants marketed their brand-name ranitidine products in California or Massachusetts because, to establish personal jurisdiction, Plaintiffs would have to allege "that such marketing of [brand-name ranitidine products] somehow caused them to take generic ranitidine" or "that the Brand-Name Manufacturers should have foreseen that their marketing of [brand-name ranitidine products] in California or Massachusetts would expose them to product-liability suits based on generic ranitidine." *Id.* at 12–13. Plaintiffs have not made either allegation, nor could they plausibly make such allegations. *Id.*

Plaintiffs argue that the jurisdictional allegations in the MPIC are "enough" to show personal jurisdiction over Defendants in California and Massachusetts. DE 1973 at 24. Specifically, Plaintiffs allege in the MPIC "labeling and marketing efforts within the states of California and Massachusetts (and elsewhere), which is where the [D]efendants 'targeted the consumer market.'" *Id.* (citing MPIC ¶ 221). Defendants' labeling and marketing efforts within California and Massachusetts "created the market for generic ranitidine and are thus 'affiliated' with the generic prescription and over-the-counter purchases that led to Plaintiffs' injuries." *Id.* at

25. "At the very least, Plaintiffs must be allowed to seek jurisdictional discovery into Defendants' labeling, sales, and advertising practices to disprove their denials of any connection to" California and Massachusetts. *Id.* at 26.

2. Law on Personal Jurisdiction

There are two types of personal jurisdiction: general and specific. *Goodyear Dunlop Tires Operations, S.A. v. Brown*, 564 U.S. 915, 919 (2011). "A court may assert general jurisdiction over foreign (sister-state or foreign-country) corporations to hear any and all claims against them when their affiliations with the State are so 'continuous and systematic' as to render them essentially at home in the forum State." *Id.* (quoting *Int'l Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945)). Absent exceptional circumstances, general personal jurisdiction over a corporation exists only in its place of incorporation and principal place of business. *See Daimler AG v. Bauman*, 571 U.S. 117, 138–39 & n.19 (2014).

Specific personal jurisdiction over a defendant is established when a plaintiff's claims arise out of or relate to the defendant's contacts with the forum, the defendant purposefully availed itself of the privilege of conducting activities in the forum, and the exercise of personal jurisdiction comports with traditional notions of fair play and substantial justice. *Louis Vuitton Malletier, S.A. v. Mosseri*, 736 F.3d 1339, 1355 (11th Cir. 2013) (citing *Burger King Corp. v. Rudzewicz*, 471 U.S. 462 (1985)). Importantly, "a tort 'arise[s] out of or relate[s] to' the defendant's activity in a state only if the activity is a 'but-for' cause of the tort." *Waite v. Union Carbide Corp.*, 901 F.3d 1307, 1314 (11th Cir. 2018) (quoting *Oldfield v. Pueblo De Bahia Lora, S.A.*, 558 F.3d 1210, 1223 (11th Cir. 2009)).

> Whether specific or general, the exercise of personal jurisdiction over a defendant must comport with due process. The touchstone of this analysis is whether the defendant has certain minimum contacts with [the state] such that the maintenance of the suit does not offend traditional notions of fair play and substantial justice.

Id. at 1312 (quoting *Int'l Shoe Co.*, 326 U.S. at 316). Traditional notions of fair play and substantial justice are not offended if "the defendant could reasonably foresee that it would cause harm within the forum and thereby had fair warning that it could be subject to suit . . . based on the harm caused." *Oldfield*, 558 F.3d at 1223.

The minimum contacts analysis examines "the relationship among the defendant, the forum, and the litigation." *Walden v. Fiore*, 571 U.S. 277, 284 (2014) (quotation marks omitted). "[The] unilateral activity of another party or a third person is not an appropriate consideration when determining whether a defendant has sufficient contacts with a forum State to justify an assertion of jurisdiction." *Helicopteros Nacionales de Columbia, S.A. v. Hall*, 466 U.S. 408, 417 (1984).

The burden is on the plaintiff to establish a prima facie case of personal jurisdiction over the non-resident defendant. *See Consol. Dev. Corp.*, 216 F.3d at 1291. A prima facie case of personal jurisdiction is established if a plaintiff presents sufficient facts, entitled to the assumption of truth and viewed in the light most favorable to the plaintiff, to withstand a motion for directed verdict. *Id.* Non-specific statements providing "labels and conclusions" or "a formulaic recitation of the elements of [jurisdiction]" are not accepted as true and are insufficient to establish a prima facie case of jurisdiction. *Bell Atl. Corp.*, 550 U.S. at 555; *see, e.g.*, *Snow*, 450 F.3d at 1318 (holding that the plaintiff's "vague and conclusory allegations" presented in his complaint were insufficient to establish a prima facie case of personal jurisdiction over a defendant); *In re Takata Airbag Prods. Liab. Litig.*, 396 F. Supp. 3d 1101, 1148–49 (S.D. Fla. 2019) (concluding that plaintiffs failed to establish a prima facie case of personal jurisdiction over foreign defendants where the "generalized allegations [were] devoid of specificity, and thereby fail[ed] to establish

that the Foreign Defendants 'purposefully availed' themselves of the privileges of conducting activity" in the states at issue).

3. Analysis and Conclusion

Plaintiffs allege in the MPIC the states in which Defendants are incorporated and have their principal places of business and thus are subject to general personal jurisdiction. MPIC ¶¶ 21–36. The Court accepts these allegations as true at this stage in the litigation. *See Consol. Dev. Corp.*, 216 F.3d at 1291. At the Hearing, Plaintiffs acknowledged that each Defendant is subject to general personal jurisdiction only in the states in which it is incorporated and has its principal places of business. DE 2498 at 210; *see* MPIC ¶¶ 21–36.

Yet, Plaintiffs allege that all of the defendants in the MPIC are subject to specific personal jurisdiction in all U.S. states and territories. Specifically, Plaintiffs allege that:

> 220. Defendants have significant contacts with the federal judicial district identified in each Plaintiff's [Short Form Complaint] such that they are subject to the personal jurisdiction of the courts in each of those districts.
>
> 221. At all relevant times, Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold ranitidine-containing products within the judicial district listed in the [Short Form Complaints] and targeted the consumer market within those districts.
>
> 222. At all times alleged herein, Defendants were authorized to conduct or engage in business within each of the States and Territories of the United States and supplied ranitidine-containing products within each of the States and Territories of the United States. Defendants received financial benefit and profits as a result of designing, manufacturing, testing, marketing, labeling, packaging, handling, distributing, storing, and/or selling ranitidine-containing products within each of the States and Territories of the United States.
>
> 223. Defendants each have significant contacts in each of the States and Territories of the United States, such that personal jurisdiction would be proper in any of them. Defendants have derived revenue from the sale of their ranitidine-containing products in each of the States and Territories of the United States.

MPIC ¶¶ 220–23.

These allegations, however, do not establish a prima facie case of personal jurisdiction over Defendants in any identifiable state or territory. The allegations do not plead facts with sufficient specificity and are not tailored to any of the dozens of defendants named in the MPIC, nor are the allegations tailored to any particular state or territory. *See, e.g.*, *Snow*, 450 F.3d at 1318; *In re Takata*, 396 F. Supp. 3d at 1148–49.

Plaintiffs fail to allege specific, non-conclusory facts demonstrating that any of Defendants' actions, including marketing and labeling decisions, took place in any state or territory, including California or Massachusetts, the only two states that recognize Plaintiffs' theory of liability. To establish specific personal jurisdiction based on Defendants' activities in a particular state, Plaintiffs must allege that those activities were the "but-for" cause of Plaintiffs' ingestion of generic ranitidine products and injuries. *See Waite*, 901 F.3d at 1314 (holding that a tort arises out of or relates to a defendant's activity only if the activity is a but-for cause of the tort). Plaintiffs have failed to do so. Additionally, Plaintiffs must allege that Defendants should have foreseen that their activities regarding their brand-name ranitidine products in that state could expose them to liability for injuries sustained from the ingestion of generic ranitidine products. *See Oldfield*, 558 F.3d at 1223. Again, Plaintiffs have failed to do so.

In conclusion, Plaintiffs have sufficiently alleged general personal jurisdiction for each Defendant only in the states in which the Defendant is at home, that is, the states in which it is incorporated and has its principal place of business. Plaintiffs have failed to allege a prima facie case of specific personal jurisdiction for Defendants in any U.S. state or territory. Accordingly,

Counts VII, VIII, XIII, XIV, and XV of the MPIC by Plaintiffs against Defendants outside of Defendants' home states are dismissed without prejudice.[9]

C. Legislative Jurisdiction

1. Arguments and Allegations

Defendants' final argument is that, "[f]or the same reasons that Plaintiffs cannot establish specific jurisdiction over Defendants in California or Massachusetts courts, California or Massachusetts law cannot be extended to apply to claims brought in Defendants' home states where the courts have general jurisdiction." DE 1585 at 17. Plaintiffs respond that, "[i]f Defendants' *home states* would apply foreign law, that cannot be unconstitutional. For a Defendant's home state has the constitutional freedom—and territorial sovereignty—to borrow the rule of decision from any place it wishes." DE 1973 at 27.

2. Law on Legislative Jurisdiction

Legislative jurisdiction is a type of jurisdiction "relevant to determining the extraterritorial reach of a statute." *Hartford Fire Ins. Co. v. California*, 509 U.S. 764, 813 (1993) (Scalia, J., dissenting) (explaining that legislative jurisdiction refers to "the authority of a state to make its laws applicable to persons or activities" beyond its borders). A state's legislative jurisdiction is limited by the Due Process Clause. *See Gerling Glob. Reinsurance Corp. of Am. v. Gallagher*, 267 F.3d 1228, 1236–37 (11th Cir. 2001). Courts "inquire not only into the contacts between the regulated *party* and the state, but also into the contacts between the regulated *subject matter* and

[9] As Plaintiffs have failed to plead a prima facie case of personal jurisdiction and have not moved for jurisdictional discovery, their request for jurisdictional discovery within their Opposition is denied at this stage. *See Butler v. Sukhoi Co.*, 579 F.3d 1307, 1313–15 (11th Cir. 2009) (concluding that a complaint failed to plead a prima facie case of subject matter jurisdiction and stating that, "[i]nasmuch as the complaint was insufficient as a matter of law to establish a prima face case that the district court had jurisdiction, the district court abused its discretion in allowing the case to proceed and granting discovery on the jurisdictional issue"); *Hinkle v. Cirrus Design Corp.*, 775 F. App'x 545, 550 (11th Cir. 2019) (upholding the district court's decision to deny "requests" for jurisdictional discovery when the party buried such requests in its briefs instead of presenting them in a motion).

the state." *Id.* at 1236 (emphasis in original). "There must be at least some minimal contact between a State and the regulated subject before it can, consistently with the requirements of due process, exercise legislative jurisdiction." *Hellenic Lines Ltd. v. Rhoditis*, 398 U.S. 306, 314 n.2 (1970) (Harlan, J., dissenting). To determine whether a state has legislative jurisdiction, a court must look to personal jurisdiction *and* choice-of-law analyses. *Gerling Glob.*, 267 F.3d at 1235.

Typically, a choice-of-law analysis will resolve any questions about whether a foreign state possesses legislative jurisdiction. This is so for two reasons. First, if a choice-of-law analysis results in the application of the forum's state law in lieu of a foreign state's law, the question of whether a foreign state possessed legislative jurisdiction becomes moot. Second, if a choice-of-law analysis results in the application of the law of a foreign state, such an analysis necessarily requires a consideration of fairness and due process—the precise question that must be considered in a due process challenge to legislative jurisdiction; a choice-of-law analysis requires "that [a] State must have a significant contact or significant aggregation of contracts, creating state interests, such that its choice of law is neither arbitrary nor fundamentally unfair." *Am. Charities for Reasonable Fundraising Reg., Inc. v. Pinellas Cnty.*, 221 F.3d 1211, 1216 (11th Cir. 2000) (citing *Allstate Ins. Co. v. Hague*, 449 U.S. 302 (1981)).

3. Analysis and Conclusion

As the Court must conduct both a personal jurisdictional analysis and a choice-of-law analysis to consider legislative jurisdiction, the Court turns first to personal jurisdiction. Plaintiffs concede that "the same personal jurisdiction analyses apply to Defendants' due process arguments directed to legislative jurisdiction." DE 1973 at 26. Thus, for the same reasons that Plaintiffs failed to establish a prima facie case of specific personal jurisdiction over Defendants in any state or territory, the Court similarly holds that Plaintiffs have not established sufficient minimum contacts

between Defendants and the states of Massachusetts or California, such that neither state may apply their substantive law extraterritorially in accordance with the Due Process Clause. Thus, Counts VII, VIII, XIII, XIV, and XV of the MPIC brought by Plaintiffs against Defendants outside of California and Massachusetts to which Plaintiffs seek to have California and Massachusetts law apply fail and are dismissed without prejudice. Because of this dismissal, a choice-of-law analysis is unnecessary as to all Defendants except one: Patheon Manufacturing Services, LLC ("Patheon").

As alleged, Patheon is a brand-name manufacturer subject to general personal jurisdiction in Massachusetts. MPIC ¶ 35. Therefore, at least as to Pantheon, the Court concludes that Plaintiffs have met their burden to allege a basis for personal jurisdiction and the Court must conduct a choice-of-law analysis for the State of Massachusetts. The Court is nonetheless unable to do so because this issue has received minimal attention in the parties' briefing. Plaintiffs merely contend, in a conclusory fashion, that any choice-of-law analysis will favor them, and Defendants, for their part, make the equally conclusory assertion that a choice-of-law analysis will favor them. Neither party has addressed or argued Massachusetts choice of law. The Court therefore expresses no opinion on Massachusetts choice-of-law principles and declines to dismiss Patheon on legislative-jurisdiction grounds at this juncture. In the event this issue is raised by either party in the future, the parties must argue the appropriate choice-of-law factors and must apply those factors to the facts of this case.

VIII. Conclusion

For the foregoing reasons, it is **ORDERED AND ADJUDGED** that Brand-Name Manufacturer Defendants' Motion to Dismiss [DE 1585] is **GRANTED**.

1. All claims brought by Plaintiffs against Defendants in California courts fail for lack of personal jurisdiction and are **DISMISSED WITHOUT PREJUDICE AND WITH LEAVE TO AMEND** consistent with this Order.
2. All claims brought by Plaintiffs against Defendants, with the exception of Patheon Manufacturing Services, LLC, in Massachusetts courts fail for lack of personal jurisdiction and are **DISMISSED WITHOUT PREJUDICE AND WITH LEAVE TO AMEND** consistent with this Order.
3. All claims brought by Plaintiffs against Defendants in courts outside of California and Massachusetts are **DISMISSED WITHOUT PREJUDICE AND WITH LEAVE TO AMEND** consistent with this Order.
4. Leave to amend is granted as to the MPIC. At this time, the Court is not requiring any individual complaints or Short Form Complaints to be amended.
5. Under Pretrial Order # 36, Plaintiffs' repled Master Complaints are due 30 days after the Court issues its Order on Article III standing. DE 1346 at 4. The Court **AMENDS** that requirement in Pretrial Order # 36. Plaintiffs' repled Master Complaints are due 30 days after the Court issues its forthcoming Order on Branded Defendants' Rule 12 Partial Motion to Dismiss Plaintiffs' Three Complaints as Preempted by Federal Law. DE 1580. All other requirements in Pretrial Order # 36 remain in place.

DONE and ORDERED in Chambers, West Palm Beach, Florida, this 31st day of December, 2020.

Robin L. Rosenberg

ROBIN L. ROSENBERG
UNITED STATES DISTRICT JUDGE

Copies furnished to Counsel of Record

Appendix A

1. Alaska

The Alaska Supreme Court and the Alaska intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under Alaska law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the Alaska Supreme Court would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See Guideone Elite*, 420 F.3d at 1326 n.5.

There is no Alaska caselaw that explicitly addresses the issue of product identification. However, Alaska law dictates that a manufacturer "is strictly liable in tort when an article *he places* on the market, knowing that it is to be used without inspection for defects, proves to have a defect that causes injury to a human being." *Shanks v. Upjohn Co.*, 835 P.2d 1189, 1194 (Alaska 1992) (quoting *Clary v. Fifth Ave. Chrysler Ctr.*, 454 P.2d 244, 247 (Alaska 1969)) (emphasis added). Under Alaska law, therefore, product identification must be alleged in order to maintain a products liability claim. However, Alaska does not have a products liability statute that would subsume Plaintiffs' negligence-based claims. And, the Court is unaware of any Alaska caselaw indicating that those claims would be construed as products liability claims. The Alaska Supreme Court could consider Plaintiffs' negligence-based claims as distinct from products liability claims. Thus, the Court must predict whether the Alaska Supreme Court would hold that Defendants owe a duty to Plaintiffs.

To determine whether a claim presents an actionable duty of care, Alaska courts look to:

> The foreseeability of harm to the plaintiff, the degree of certainty that the plaintiff suffered injury, the closeness of the connection between the defendant's conduct and the injury suffered, the moral blame attached to the defendant's conduct, the policy of preventing future harm, the extent of the burden to the defendant and

> consequences to the community of imposing a duty to exercise care with resulting liability for breach, and the availability, cost and prevalence of insurance for the risk involved.

D. S. W. v. Fairbanks N. Star Borough Sch. Dist., 628 P.2d 554, 555 (Alaska 1981) (quotation omitted). Alaska courts have stated that "[t]he most important single criterion for imposing a duty of care is foreseeability" and that "the legal relationship between individuals" is the overall focus of the duty question. *Bolieu v. Sisters of Providence in Wash.*, 953 P.2d 1233, 1235-36 (Alaska 1998).

After weighing these factors, the Court predicts that the Alaska Supreme Court would follow the majority view and hold that Defendants do not owe a duty to Plaintiffs. First, generic consumers' injuries are not the foreseeable result of brand-name drug manufacturers' conduct. Rather, the injuries are the foreseeable result of "the laws over which the brand manufacturers have no control." *In re Darvocet*, 756 F.3d at 944 (citing Victor E. Schwartz et al., *Warning: Shifting Liability to Manufacturers of Brand-Name Medicines When the Harm Was Allegedly Caused by Generic Drugs Has Severe Side Effects*, 81 Fordham L. Rev. 1835, 1865 (2013) (hereinafter "Schwartz et al."). To impose a duty under Alaska law "would be to stretch the concept of foreseeability too far." *Foster*, 29 F.3d at 171.

Further, the Court finds that the connection between Defendants' alleged conduct and Plaintiffs' alleged injuries is attenuated, given the absence of a relationship between the parties. Additionally, the burden to Defendants and the consequences to the community of imposing a duty of care are great. As other courts have concluded, many public policy considerations weigh against holding brand-name manufacturers liable for injuries caused by their generic competitors' drugs. *See, e.g.*, *Huck v. Wyeth, Inc.*, 850 N.W.2d 353, 377 (Iowa 2014) (noting that "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"); *McNair v. Johnson & Johnson*, 818 S.E.2d 852, 866 (W. Va. 2018) (explaining 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 "the increase in litigation . . . could stifle the development of new drugs").

In sum, the Court predicts that the Alaska Supreme Court would hold that Plaintiffs' claims against Defendants fail for lack of product identification and for lack of a duty giving rise to liability under Alaska Law.

2. Arizona

The Arizona Supreme Court and the Arizona intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under Arizona law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the Arizona Supreme Court would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See Guideone Elite*, 420 F.3d at 1326 n.5.

Arizona products liability law defines a "products liability action" as:

> [*A*]*ny action* brought against a manufacturer or seller of a product for damages for bodily injury, death or property damage caused by or resulting from the manufacture, construction, design, formula, installation, preparation, assembly, testing, packaging, labeling, sale, use or consumption of any product, the failure to warn or protect against a danger or hazard in the use or misuse of the product or the failure to provide proper instructions for the use or consumption of any product.

Ariz. Rev. Stat. Ann. § 12-681 (2020) (emphasis added). Further, product identification is a "fundamental tenet" of Arizona products liability law. *Winsor v. Glasswerks PHX, L.L.C.*, 63 P.3d 1040, 1049 (Ariz. Ct. App. 2003) (noting that Arizona law construes the reach of products liability to those involved in the chain of production or distribution of the product, but that Arizona courts

have never "expanded liability to those entities who bear no causal connection to the production or distribution of the product").

Given the plain language of § 12-681, the Court predicts that the Arizona Supreme Court would find all of Plaintiffs' claims to be products liability claims, regardless of how they are characterized, and that such claims require product identification to be viable. For this reason, the Court predicts that the Arizona Supreme Court would hold that Plaintiffs' claims against Defendants fail for lack of product identification.[10]

3. Arkansas

The Arkansas Supreme Court and the Arkansas intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under Arkansas law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the Arkansas Supreme Court would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See Guideone Elite*, 420 F.3d at 1326 n.5.

In *Bell v. Pfizer, Inc.*, the Eighth Circuit predicted that the Arkansas Supreme Court would hold that Arkansas law does not support imposing liability on a brand-name manufacturer for a generic manufacturer's product. 716 F.3d at 1094. The court held that the plaintiffs' negligence-based claims for injuries caused by a product fell within the Arkansas Product Liability Act's broad definition of a "product liability action," making them products liability claims. *Id.* at 1092; *see*

[10] The Eastern District of Kentucky has twice predicted that the Arizona Supreme Court would hold that Arizona law does not support imposing liability on a brand-name defendant for a generic manufacturer's product due to lack of product identification. *See In re Darvocet, Darvon & Propoxyphene Products Liability Litigation*, 2012 WL 3842045, at *7–8 (E.D. Ky. Sept. 5, 2012) (holding that the plaintiffs' claims failed for lack of product identification), *aff'd on other grounds*, 756 F.3d 917 (6th Cir. 2014); *In re Darvocet, Darvon & Propoxyphene Products Liability Litigation*, 2012 WL 4831632, at *2–3 (E.D. Ky. Oct. 10, 2012) (same), *aff'd on other grounds*, 756 F.3d 917 (6th Cir. 2014). However, the court cited to no Arizona caselaw or statute in support of its prediction, and, because no Arizona plaintiff appealed, the Sixth Circuit did not analyze the claims under Arizona law as it did for twenty-two other states. Thus, while the Court takes note of these cases, the Court does not end its analysis of Arizona law there.

Ark. Code Ann. § 16-116-102(5) (2020) (defining "product liability action" as "all actions brought for or on account of personal injury, death, or property damage caused by or resulting from the manufacture, construction, design, formula, preparation, assembly, testing, service, warning, instruction, marketing, packaging, or labeling of any product"). The court also noted that a basic requirement of a products liability action under Arkansas law is product identification. *Bell*, 716 F.3d at 1093. Thus, the court held the plaintiffs' claims against brand-name manufacturers failed for lack of product identification. *Id.* And for the sake of argument, the court held that even if the requirement of product identification was ignored, the claims would fail for lack of a duty as there was no Arkansas authority that supported extending "a duty of care to the customer of a competitor using a competing product." *Id.*

While the Court is not bound by the decisions of federal courts of appeals outside of the Eleventh Circuit in making its *Erie* prediction, the Court finds the Eighth Circuit's reasoning to be "reliable data tending convincingly to show" whether the Arkansas Supreme Court would find the theory of liability at issue to be viable. *See Guideone Elite*, 420 F.3d at 1326 n.5.[11] The Court therefore predicts that the Arkansas Supreme Court would hold that Plaintiffs' claims fail for lack of product identification and for lack of a duty giving rise to liability under Arkansas law.

4. Colorado

The Colorado Supreme Court and the Colorado intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under Colorado law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the Colorado Supreme Court would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See id.*

[11] The Sixth Circuit also predicted that the Arkansas Supreme Court would reject this theory of liability, relying upon the Eighth Circuit's reasoning in *Bell*. *See In re Darvocet*, 756 F.3d at 941.

In *Sheeks v. American Home Products Corporation*, a Colorado District Court held that Colorado law does not support imposing liability on a brand-name defendant for a generic manufacturer's product. No. 02CV337, 2004 WL 4056060, at *2 (Colo. Dist. Ct. Oct. 15, 2004). The court held that the plaintiffs' misrepresentation claims fell within the Colorado Product Liability Act's broad definition of a "product liability action," making them products liability claims. *See id.* at *1; *see also* Colo. Rev. Stat. Ann. § 13-21-401 (West 2020) (defining "[p]roduct liability action" as "*any action* brought against a manufacturer or seller of a product, *regardless of the substantive legal theory or theories upon which the action is brought*, for or on account of personal injury, death, or property damage caused by or resulting from . . . [a] product") (emphasis added)).

Further, the court noted that, "[u]nder Colorado statutory law, products liability is imposed on a 'manufacturer' of the product," which includes "those entities involved in the production of the product or otherwise in control [of] the production process." *Sheeks*, 2004 WL 4056060, at *1 (quoting *Yoder v. Honeywell, Inc.*, 900 F. Supp. 240, 246 (D. Colo. 1995), *aff'd*, 104 F.3d 1215 (10th Cir. 1997)). In other words, product identification is a requirement of a products liability action under Colorado law. Thus, the court held that the plaintiffs' claims failed for lack of product identification. *Id.*

The court declined to look at the plaintiffs' claim of negligent misrepresentation as distinct from their products liability claims. *Id.* at *2. The court noted for the sake of argument that even if it disregarded Colorado law and viewed the negligence misrepresentation claim as distinct, the claim would still fail because a brand-name manufacturer owed no duty to plaintiffs "to warn of a drug that it did not manufacture or supply." *Id.* The Court came to this conclusion after analyzing the factors used to determine whether a duty exists under Colorado law. *See id.*; *see also Bailey v.*

Huggins Diagnostic & Rehab. Ctr., Inc., 952 P.2d 768, 772 (Colo. App. 1997) (listing the factors that Colorado courts consider to determine whether a duty exists as "whether harm is a reasonably foreseeable result of the act or omission under consideration" in addition to "the social utility of the defendant's activity; the magnitude of the burden guarding against the harm; the consequences of placing that burden on the defendant; and all other factors that would be relevant in weighing the competing individual and societal").

While the Court is not bound by the decisions of state district courts in making its *Erie* prediction, the Court finds the Colorado District Court's reasoning to be "reliable data tending convincingly to show" whether the Colorado Supreme Court would find the theory of liability at issue to be viable. *See Guideone Elite*, 420 F.3d at 1326 n.5. The Court therefore predicts that the Colorado Supreme Court would hold that Plaintiffs' claims against Defendants fail for lack of product identification and would otherwise fail for lack of a duty giving rise to liability under Colorado law.

5. Connecticut

The Connecticut Supreme Court and the Connecticut intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under Connecticut law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the Connecticut Supreme Court would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See id.*

The Sixth Circuit predicted that the Connecticut Supreme Court would hold that Connecticut law does not support imposing liability on a brand-name defendant for a generic manufacturer's product. *See In re Darvocet*, 756 F.3d at 942. The court found that the plaintiffs' negligence-based claims were encompassed by the Connecticut Products Liability Act, making

them products liability claims. *Id*; *see* Conn. Gen. Stat. § 52–572m(b) (defining a "product liability claim" as " all claims or actions brought 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"). The court also noted that a requirement of a product liability action under Connecticut law is product identification. *In re Darvocet*, 756 F.3d at 942. Thus, the court held that the plaintiffs' claims failed for lack of product identification. *Id.*

While the Court is not bound by the decisions of federal courts of appeals outside of the Eleventh Circuit in making its *Erie* prediction, the Court finds the Sixth Circuit's reasoning to be "reliable data tending convincingly to show" whether the Connecticut Supreme Court would find the theory of liability at issue to be viable. *See Guideone Elite*, 420 F.3d at 1326 n.5. The Court therefore predicts that the Connecticut Supreme Court would hold that Plaintiffs' claims against Defendants fail for lack of product identification.

6. Delaware

The Delaware Supreme Court and the Delaware intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under Delaware law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the Delaware Supreme Court would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See id.*

In *Trower v. Janssen Pharmaceuticals, Inc.*, the federal District of Delaware predicted that the Delaware Supreme Court would hold that Delaware law does not support imposing liability on a brand-name defendant for a generic manufacturer's product. No. 1:16-CV-00135-RGA, 2019 WL 1571834, at *4 (D. Del. Apr. 11, 2019). In its analysis, the court first noted that Delaware

courts had held that Delaware products liability law requires product identification. *Id.* at *3 (citing *In re Benzene Litig.*, No. CIV.A.05C-09-020-JRS, 2007 WL 625054, at *6 (Del. Super. Ct. Feb. 26, 2007)). As to the question of whether brand-name manufacturers owe a generic consumer a duty, the court held that no Delaware law supports such a duty, and the court highlighted that "at least one Delaware court has expressed hesitation when pressured to make changes to traditional tort law in the product liability space." *Id.* (citing *Nutt v. A.C. & S. Co.*, 517 A.2d 690, 694 (Del. Super. Ct. 1986) (choosing to defer to the legislature rather than judicially expand the scope of liability)). Additionally, the court held that, "even if Delaware law provided some basis for imposing liability for failure to warn on brand name manufacturers, it would be imprudent [for the federal court] to extend Delaware's law to that point while sitting in diversity." *Id.* at *4.

While the Court is not bound by the decisions of federal district courts in making its *Erie* prediction, the Court finds the *Trower* court's reasoning to be "reliable data tending convincingly to show" whether the Delaware Supreme Court would find the theory of liability at issue to be viable. The Court therefore predicts that the Delaware Supreme Court either would construe all of Plaintiffs' claims as products liability claims that fail for lack of product identification or would rule that Plaintiffs' claims otherwise fail for lack of a duty giving rise to liability under Delaware law.

7. District of Columbia

The D.C. Court of Appeals and the D.C. intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under D.C. law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the D.C. Court of Appeals would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See Guideone Elite*, 420 F.3d at 1326 n.5.

D.C. products liability law requires product identification. *See Claytor v. Owens-Corning Fiberglas Corp.*, 662 A.2d 1374, 1381 (D.C. 1995) ("It is, of course, incumbent on the plaintiff in any product liability action to show that the defendant's product was the cause of his or her injuries."). However, D.C. does not have a products liability statute that would subsume Plaintiffs' negligence-based claims. Additionally, the Court is unaware of any D.C. caselaw indicating that those claims would be construed as products liability claims. The D.C. Court of Appeals could consider Plaintiffs' negligence-based claims as distinct from products liability claims under D.C. law. As a result, the Court must predict whether the D.C. Court of Appeals would find that Defendants owe a duty to Plaintiffs.

In determining whether a duty is owed, D.C. courts primarily look to the foreseeability of the harm, which is largely determined by the nature of the relationship between the parties. *See Hedgepeth v. Whitman Walker Clinic*, 22 A.3d 789, 794 (D.C. 2011). Whether a duty exists is "essentially a question of whether the policy of the law will extend the responsibility for the conduct to the consequences which have in fact occurred." *District of Columbia v. Cooper*, 483 A.2d 317, 321 (D.C. 1984) (quotation marks omitted).

After weighing the requisite factors, the Court predicts that the D.C. Court of Appeals would follow the majority view and hold that Defendants do not owe a duty to Plaintiffs. First, the generic consumers' injuries are not the foreseeable result of brand-name drug manufacturers' conduct. *See In re Darvocet*, 756 F.3d at 944. Rather, the injuries are the foreseeable result of "the laws over which the brand manufacturers have no control." *Id.* (citing Schwartz et al. at 1865). Additionally, the Court views the relationship between the brand-name manufacturers and generic consumers to be, at best, "at arms' length." *See Hedgepeth*, 22 A.3d at 794 (noting that generally "there is only a minimal duty—if any—owed to a party who is at arms' length"). The Court

predicts that the D.C. Court of Appeals would not recognize a duty owed by Defendants to Plaintiffs. In sum, the Court predicts that D.C. Court of Appeals would hold that Plaintiffs' claims against Defendants fail for lack of product identification and for lack of a duty giving rise to liability under D.C. law.

8. Hawaii

The Supreme Court of Hawaii and the Hawaii intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under Hawaii law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the Supreme Court of Hawaii would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See Guideone Elite*, 420 F.3d at 1326 n.5.

In *Acoba v. General Tire, Inc.*, the Supreme Court of Hawaii stated that, under Hawaii products liability law, there is a "principle" that "a manufacturer owes a duty to warn regarding its *own product*, not regarding products it did not produce, sell, or control." 986 P.2d 288, 305 (Haw. 1999). While Hawaii has no products liability statute that would subsume Plaintiffs' negligence-based claims, the court's meaning in *Acoba* is clear: a manufacturer owes no duty to consumers of products it did not produce, sell, or control. Therefore, the Court predicts that the Supreme Court of Hawaii would not recognize a duty owed by Defendants to Plaintiffs. In sum, the Court predicts that the Supreme Court of Hawaii would hold that Plaintiffs' claims against Defendants fail for lack of a duty giving rise to liability under Hawaii Law.

9. Illinois

The Supreme Court of Illinois and the Illinois intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for

injuries under Illinois law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the Supreme Court of Illinois would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See Guideone Elite*, 420 F.3d at 1326 n.5.

Three federal courts have predicted whether the Supreme Court of Illinois would hold that Illinois law supports imposing liability upon brand-name manufacturers. In *Dolin v. SmithKline Beecham Corp.*, the Northern District of Illinois held that the plaintiff's common-law negligence claims were distinct from her products liability claims. 62 F. Supp. 3d at 713. Consequently, the court analyzed the four *Simpkins* factors used to determine whether a duty is owed by brand-name manufacturers to generic consumers: "(1) the reasonable foreseeability of the injury; (2) the likelihood of the injury; (3) the magnitude of the burden guarding against the injury; and (4) the consequences of placing that burden on the defendant." *Id.* at 714–15 (quoting *Simpkins v. CSX Transportation, Inc.*, 965 N.E.2d 1092, 1097 (Ill. 2012)). The court held that it was "entirely foreseeable" that negligence on the part of the brand-name manufacturer regarding the brand-name label could result in injury to generic consumers because the labels were required by law to be identical and defects later discovered could only be remedied by the brand-name manufacturer. *Id.* at 714.

The court further held that there was a strong likelihood that the brand-name manufacturer's negligence in the design or warning label of the drug would cause injury, that guarding against the injury alleged was "as simple as updating the warning label," and that there was nothing in the record to suggest the consequences of placing the burden on the defendant were large. *Id.* at 715. Thus, the court predicted that the Supreme Court of Illinois would conclude that the brand-name manufacturer owed a duty to the generic consumer giving rise to liability under

Illinois law, and, as a result, the plaintiff's general negligence claim, negligent misrepresentation claim, and negligence-based products liability claims were deemed viable. *Id.* at 723–24. The Central District of Illinois, relying upon the *Dolin* court's reasoning, came to the same conclusion. *See Garner*, 2017 WL 6945335, at *6–9.

In *In re Darvocet*, the Sixth Circuit explicitly rejected the *Dolin* court's reasoning. 756 F.3d at 944. The court explained that, while Illinois has no products liability statute that encompassed the plaintiffs' negligence-based claims, Illinois caselaw dictated that the claims "would be construed as products liability claims and fail for lack of product identification." *Id*; *see York v. Lunkes*, 545 N.E.2d 478, 480 (Ill. App. Ct. 1989) (holding that, under Illinois law, a plaintiff must "identify the supplier of the product and establish a causal connection between the injury and the product"); *Smith v. Eli Lilly & Co*., 560 N.E.2d 324, 328 (Ill. 1990) ("[I]t is obvious that to hold a producer, manufacturer, or seller liable for injury caused by a particular product, there must first be proof that the defendant produced, manufactured, sold, or was in some way responsible for the product") (quotation marks omitted).

The Sixth Circuit further held that, even if the Supreme Court of Illinois construed the plaintiffs' misrepresentation claims as distinct from products liability claims, the *Simpkins* duty factors do not support recognizing a duty owed by brand-name manufacturers to generic consumers. *In re Darvocet*, 756 F.3d at 944. In applying the factors, the court found that the generic consumers' injuries were "not the foreseeable result of the brand manufacturers' conduct, but of the laws over which the brand manufacturers have no control," and that using "these laws as the basis of supplying the duty element for tort liability stretches foreseeability too far." *Id.*; *see* Schwartz et al. at 1865. The Sixth Circuit also held that the *Dolin* court "failed to properly account for the magnitude of the brand manufacturers' burden of guarding against the injury; and the

consequences of placing that burden on the brand manufacturers." *In re Darvocet*, 756 F.3d at 944. The court reasoned that "[c]ourts in the majority note the traditional reticence against imposing liability on a manufacturer for injuries caused by their competitor's products." *Id.* And the court highlighted the "grave health policy consequences associated with recognizing brand manufacturer liability in these situations including higher brand name drugs and fewer innovative drugs." *Id.*

The Court finds the reasoning of the Sixth Circuit in *In re Darvocet* to be sound and more persuasive than the reasoning of the *Dolin* and *Garner* courts. While the Court is not bound by the decisions of federal courts of appeals outside of the Eleventh Circuit in making its *Erie* prediction, the Court finds the Sixth Circuit's reasoning to be "reliable data tending convincingly to show" whether the Supreme Court of Illinois would find the theory of liability at issue to be viable. *See Guideone Elite*, 420 F.3d at 1326 n.5. The Court therefore predicts that the Supreme Court of Illinois would hold that Plaintiffs' claims fail for lack of product identification and for lack of a duty giving rise to liability under Illinois law.

10. Maine

The Maine Supreme Judicial Court and the Maine intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under Maine law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the Maine Judicial Supreme Court would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See id.*

The Maine Supreme Judicial Court has noted that there is "no authority" to suggest that "the supplier of a safe product has a duty to warn against another supplier's dangerous product." *Bouchard v. Am. Orthodontics*, 661 A.2d 1143, 1145 (Me. 1995). Further, the federal District Court of Maine held that, under Maine law, "[a] manufacturer or seller owes a duty to exercise

reasonable care to foreseeable users of its products." *Doe v. Solvay Pharm., Inc.*, 350 F. Supp. 2d 257, 263 (D. Me. 2004), *aff'd*, 153 F. App'x 1 (1st Cir. 2005). Pursuant to this caselaw and the fact that, given there are no indications to the contrary, it is presumed that Maine would adopt the majority view requiring product identification for products liability claims.

However, Maine does not have a products liability statute that would subsume Plaintiffs' negligence-based claims. Nor is the Court aware of any caselaw indicating that Maine courts would construe those claims as products liability. The Maine Supreme Judicial Court could consider Plaintiffs' negligence-based claims distinct from products liability claims under Maine law. However, based on the same caselaw the Court relied upon in holding that the Maine Supreme Judicial Court would require product identification, the Court also predicts that the Maine Supreme Judicial Court would not recognize a duty owed by brand-name manufacturers to generic consumers. *See Bouchard*, 661 A.2d at 1145 (holding that "the supplier of a safe product has no duty to warn against another supplier's dangerous product"); *Doe*, 350 F. Supp. 2d at 263 (explaining that "[a] manufacturer or seller owes a duty to exercise reasonable care to foreseeable users of its products").

In sum, the Court predicts that the Maine Supreme Judicial Court would hold that Plaintiffs' claims against Defendants fail for lack of product identification and for lack of a duty giving rise to liability under Maine law.

11. Maryland

The Maryland Court of Appeals and the Maryland intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under Maryland law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the Maryland Court of Appeals would find Plaintiffs'

theory of liability viable for any of their claims against Defendants. *See Guideone Elite*, 420 F.3d at 1326 n.5.

In *Foster v. American Home Products Corp.*, the Fourth Circuit predicted that the Maryland Court of Appeals would hold that Maryland law does not support imposing liability on a brand-name defendant for a generic manufacturer's product. 29 F.3d 165, 172 (4th Cir. 1994). Specifically, the court held that, under Maryland law, a plaintiff must plead product identification and that the plaintiffs brought negligence-based claims merely as an attempt 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.* at 168; *see also Lee v. Baxter Healthcare Corp.*, 721 F. Supp. 89, 92 (D. Md. 1989) (noting that it is "axiomatic" that the plaintiff must "prove that the defendant manufacturer made the product that caused plaintiff's injury"); *Jensen v. Am. Motors Corp.*, 437 A.2d 242, 247 (Md. Ct. Spec. App. 1981) ("*Regardless of the recovery theory*, the plaintiff in product litigation must satisfy three basics from an evidentiary standpoint: (1) the existence of a defect; (2) the attribution of the defect to the seller; and (3) a causal relation between the defect and the injury.") (emphasis added). The Fourth Circuit, thus, predicted that that the Maryland Court of Appeals would construe all of the plaintiffs' claims as products liability claims that failed for lack of product identification. *Foster*, 29 F.3d at 168.

Further, the court held that, even if it disregarded Maryland law and construed the plaintiffs' negligence-based claims as distinct from products liability claims, Maryland law would not support recognizing a duty owed by brand-name manufacturers to generic consumers. *Id.* at 171. The court explained that "to impose a duty… would be to stretch the concept of foreseeability too far" considering the complete absence of a relationship between brand-name manufacturers and generic consumers. *See id.*

While the Court is not bound by the decisions of federal courts of appeals outside of the Eleventh Circuit in making its *Erie* prediction, the Court finds the Fourth Circuit's reasoning to be "reliable data tending convincingly to show" whether the Maryland Court of Appeals would find the theory of liability at issue to be viable. *See Guideone Elite*, 420 F.3d at 1326 n.5.[12] In sum, the Court therefore predicts that the Maryland Court of Appeals would hold that Plaintiffs' claims fail for lack of product identification and for lack of a duty giving rise to liability under Maryland law.

12. Michigan

The Michigan Supreme Court and the Michigan intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under Michigan law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the Michigan Supreme Court would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See id.*

The Sixth Circuit predicted that the Michigan Supreme Court would hold that Michigan law does not support imposing liability on a brand-name defendant for a generic manufacturer's product. *See In re Darvocet*, 756 F.3d at 946–47. In making this prediction, the Sixth Circuit first held that Michigan products liability law requires product identification. *See id.*; *see also Abel v. Eli Lilly & Co.*, 343 N.W.2d 164, 170 (Mich. 1984) (holding that "the threshold requirement of any products liability action is identification of the injury-causing product and its manufacturer"). The court also found that Michigan products liability law does not clearly "foreclose or permit common law negligence actions against non-manufacturers for misrepresentations based on injuries from products"; thus, the court had to predict whether brand-name manufacturers owed

[12] The Sixth Circuit and the federal District Court of Maryland also predicted that the Maryland Court of Appeals would reject this theory of liability, relying upon the Fourth Circuit's reasoning in *Foster*. *See In re Darvocet*, 756 F.3d at 946; *Gross v. Pfizer, Inc.*, No. 10-CV-00110-AW, 2010 WL 4485774, at *2–3 (D. Md. Nov. 9, 2010).

generic consumers a duty of care giving rise to liability for their alleged misrepresentations. *In re Darvocet*, 756 F.3d at 947.

The court explained that whether a defendant owes a plaintiff a duty under Michigan law depends on "the relationship between the parties, the nature and foreseeability of the risk, and any other considerations that may be relevant on the issue." *Id.* (quoting *Buczkowski v. McKay*, 490 N.W.2d 330, 333 (Mich. 1992)). In analyzing these factors, the court found that the parties had no relationship, that the generic consumers' injuries were "not the foreseeable result of the brand manufacturers' conduct, but of the laws over which the brand manufacturers have no control," and that there were "grave health policy consequences associated with recognizing brand manufacturer liability in these situations, including high priced brand name drugs and fewer innovative drugs." *Id.* (quoting Schwartz et al. at 1870–71). Thus, the court predicted that the Michigan Supreme Court would not recognize a duty owed by brand-name manufacturers to the generic consumers. *Id.*

While the Court is not bound by the decisions of federal courts of appeals outside of the Eleventh Circuit in making its *Erie* prediction, the Court finds the Sixth Circuit's reasoning to be "reliable data tending convincingly to show" whether the Michigan Supreme Court would find the theory of liability at issue to be viable. *See Guideone Elite*, 420 F.3d at 1326 n.5. In sum, the Court therefore predicts that the Michigan Supreme Court would hold that Plaintiffs' claims fail for lack of product identification and for lack of a duty giving rise to liability under Michigan law.

13. Minnesota

The Minnesota Supreme Court and the Minnesota intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under Minnesota law. Therefore, the Court must make a prediction using all "reliable data

tending convincingly to show" whether the Minnesota Supreme Court would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See id.*

The Minnesota Court of Appeals case of *Flynn v. America Home Products Corp.*, 627 N.W.2d 342, 344 (Minn. App. 2001) is instructive. In *Flynn*, a generic drug consumer brought misrepresentation claims against brand-name drug manufacturers. 627 N.W.2d at 344. The court held that the brand-name manufacturers did not owe the generic consumers a duty because "Minnesota common law… requires a stronger relationship and a direct communication" between a defendant and a plaintiff in order to find that a duty exists. *Id.* at 350. As the plaintiff "did not purchase or use [the brand-name manufacturers'] product . . . there was no direct relationship between them, let alone a fiduciary relationship that gave rise to a duty." *Id.*

Further, the Eighth Circuit has predicted, relying upon the reasoning in *Flynn*, that generic consumers' products liability claims against brand-name manufacturers fail for lack of product identification and legal duty. *See Mensing v. Wyeth, Inc.*, 588 F.3d 603, 612-14 (8th Cir. 2009), *rev'd sub nom. PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011), *and opinion vacated in part, reinstated in part*, 658 F.3d 867 (8th Cir. 2011); *see also Magnuson v. Rupp Mfg., Inc.*, 171 N.W.2d 201, 206 (Minn. 1969) (noting that Minnesota products liability law requires the plaintiff to prove that the "dangerous condition of the defendant's product" caused the plaintiff's injuries).

While the Court is not bound by the decisions of federal courts of appeals outside of the Eleventh Circuit in making its *Erie* prediction, the Court finds the reasoning of the Eighth Circuit, as well as that of the Minnesota Court of Appeals in *Flynn*, to be "reliable data tending convincingly to show" whether the Minnesota Supreme Court would find the theory of liability at issue to be viable. *See Guideone Elite*, 420 F.3d at 1326 n.5. The Court therefore predicts that the

Minnesota Supreme Court would hold that Plaintiffs' claims fail for lack of product identification and for lack of a duty giving rise to liability under Minnesota law.

14. Mississippi

The Supreme Court of Mississippi and the Mississippi intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under Mississippi law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the Supreme Court of Mississippi would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See id.*

The Fifth Circuit predicted that the Supreme Court of Mississippi would hold that Mississippi law does not support imposing liability on a brand-name defendant for a generic manufacturer's product. *See Lashley*, 750 F.3d at 476. The court noted that that Mississippi products liability claims require product identification and, additionally, that the Mississippi Products Liability Act ("MLPA") applies "in any action for damages caused by a product." *Id.* at 476–77 (quoting Miss. Code Ann. § 11–1–63 (2020)); *see also Monsanto Co. v. Hall*, 912 So. 2d 134, 136–37 (Miss. 2005) (holding that a required element of a products liability claim under Mississippi law is product identification). Thus, the Fifth Circuit construed all of the plaintiff's negligence-based claims as products liability claims under the MLPA that failed for lack of product identification. *Lashley*, 750 F.3d at 476-77.

While the Court is not bound by the decisions of federal courts of appeals outside of the Eleventh Circuit in making its *Erie* prediction, the Court finds the Fifth Circuit's reasoning to be "reliable data tending convincingly to show" whether the Supreme Court of Mississippi would

find the theory of liability at issue to be viable. *See Guideone Elite*, 420 F.3d at 1326 n.5.[13] The Court therefore predicts that the Supreme Court of Mississippi would hold that Plaintiffs' claims fail for lack of product identification.

15. Missouri

The Supreme Court of Missouri and the Missouri intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under Missouri law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the Supreme Court of Missouri would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See id.*

Missouri products liability law requires product identification. *See Ford v. GACS, Inc.*, 265 F.3d 670, 680 (8th Cir. 2001) (holding that "[t]he common thread among Missouri products liability cases is that an entity must have 'plac[ed] a defective product in the stream of commerce'") (quoting *Bailey v. Innovative Mgmt. & Inv., Inc*., 916 S.W.2d 805, 807-08 (Mo. Ct. App. 1995)); *In re Darvocet, Darvon & Propoxyphene Prod. Liab. Litig.*, No. 2:11-MD-2226-DCR, 2012 WL 3610237, at *2 (E.D. Ky. Aug. 21, 2012) (finding that, under Missouri law, "[t]here is no theory of product liability under which a defendant can be held liable for an injury caused by a product it did not sell, manufacture, or otherwise supply to the plaintiff"), *aff'd on other grounds*, 756 F.3d 917 (6th Cir. 2014); *Johnson v. Auto Handling Corp.*, 523 S.W.3d 452, 466 (Mo. 2017) (en banc) (holding that, in negligent manufacture, design, or warning products liability cases, Missouri law "requires the jury to consider whether the defendant manufactured the product"); *City of St. Louis*

[13] The Sixth Circuit and two federal Mississippi federal district courts have also predicted that the Supreme Court of Mississippi would reject this theory of liability, relying upon the Fifth Circuit's reasoning in *Lashley*. *See In re Darvocet*, 756 F.3d at 947–48; *Truddle v. Wyeth, LLC*, No. 2:11-CV-00207-GHD, 2015 WL 160696, at *4 (N.D. Miss. Jan. 12, 2015); *Chatman v. Pfizer, Inc.*, No. 5:11-CV-69 DCB MTP, 2014 WL 4546042, at *3 (S.D. Miss. Sept. 11, 2014).

v. Benjamin Moore & Co., 226 S.W.3d 110, 115 (Mo. 2007) (holding that, "where the plaintiff seeks to hold the defendants liable on the basis that their products caused harm to the plaintiff, the identification requirement must be satisfied").

However, Missouri does not have a products liability statute that would subsume Plaintiffs' negligence-based claims. Additionally, the Court is unaware of any Missouri caselaw indicating that those claims would be construed as products liability claims. The Supreme Court of Missouri could consider Plaintiffs' negligence-based claims as distinct from products liability claims under Missouri law. As a result, the Court must predict whether the Supreme Court of Missouri would hold that Defendants owe a duty to Plaintiffs.

In determining whether a duty is owed, Missouri courts weigh "the foreseeability of the injury, the likelihood of the injury, the magnitude of the burden of guarding against it, and the consequences of placing that burden on the defendant." *Bunker v. Ass'n of Mo. Elec. Coops.*, 839 S.W.2d 608, 611 (Mo. Ct. App. 1992). "The common denominator that must be present is the existence of a relationship between the plaintiff and defendant that the law recognizes as the basis of a duty of care." *Id.* Further, Missouri courts look "to the body of statutes, rules, principles and precedents which make up the law." *Kopoian v. George W. Miller & Co.*, 901 S.W.2d 63, 68 (Mo. Ct. App. 1995) (quotation marks omitted). "Where no duty is indicated by Missouri statute, case law, or otherwise, a fundamental prerequisite to establishing negligence is absent." *Ford*, 265 F.3d at 682.

After weighing the requisite factors, the Court predicts that the Supreme Court of Missouri would follow the majority view and hold that Defendants do not owe a duty to Plaintiffs. First, generic consumers' injuries are not the foreseeable result of brand-name drug manufacturers' conduct. *See In re Darvocet*, 756 F.3d at 944. Rather, the injuries are the foreseeable result of "the

laws over which the brand manufacturers have no control." *Id.* (citing Schwartz et al. at 1865). To impose a duty under Missouri law "would be to stretch the concept of foreseeability too far." *Foster*, 29 F.3d at 171.

Further, the Court finds that the burden to Defendants and the consequences to the community of imposing a duty of care are great. As other courts have concluded, many public policy considerations weigh against holding brand-name competitors liable for injuries caused by their generic competitors' drugs. *See, e.g.*, *Huck*, 850 N.W.2d at 377 (finding that "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"); *McNair*, 818 S.E.2d at 866 (explaining 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 "the increase in litigation . . . could stifle the development of new drugs").

In sum, the Court predicts that the Supreme Court of Missouri would hold that Plaintiffs' claims against Defendants fail for lack of product identification and for lack of a duty giving rise to liability under Missouri law.

16. Montana

The Montana Supreme Court and the Montana intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under Montana law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the Montana Supreme Court would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See Guideone Elite*, 420 F.3d at 1326 n.5.

Montana products liability law requires product identification. *See Schelske v. Creative Nail Design, Inc.*, 933 P.2d 799, 803 (Mont. 1997) (holding that, to proceed with a prima facie claim of products liability, the plaintiff must allege product identification and that, further, the "the defect existed when it left the hands of the defendant"). However, Montana does not have a products liability statute that would subsume Plaintiffs' negligence-based claims. Additionally, the Court is unaware of any Montana caselaw indicating that those claims would be construed as products liability claims. The Montana Supreme Court could consider Plaintiffs' negligence-based claims as distinct from products liability claims under Montana law. As a result, the Court must predict whether the Montana Supreme Court would hold that Defendants owe a duty to Plaintiffs.

In determining whether a duty is owed, Montana courts consider whether the injuries were "reasonably foreseeable" as well as various policy factors, including "the moral blame attributable to the defendant's conduct; the prevention of future harm; the extent of the burden placed on the defendant; the consequences to the public of imposing such a duty; and the availability of insurance for the risk involved." *Hinkle v. Shepherd Sch. Dist. No. 37*, 93 P.3d 1239, 1244 (Mont. 2004).

After weighing the requisite factors, the Court predicts that the Montana Supreme Court would follow the majority view and hold that Defendants do not owe a duty to Plaintiffs. First, generic consumers' injuries are not the foreseeable result of brand-name drug manufacturers' conduct. *See In re Darvocet*, 756 F.3d at 944. Rather, the injuries are the foreseeable result of "the laws over which the brand manufacturers have no control." *Id.* (citing Schwartz et al. at 1865). To impose a duty under Montana law "would be to stretch the concept of foreseeability too far." *Foster*, 29 F.3d at 171. Further, the Court finds that the burden to Defendants and the consequences to the community of imposing a duty of care are great. As other courts have concluded, many public policy considerations weigh against holding brand-name competitors

liable for injuries caused by their generic competitors' drugs. *See, e.g.*, *Huck*, 850 N.W.2d at 377 (concluding that "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"); *McNair*, 818 S.E.2d at 866 (explaining 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 "the increase in litigation . . . could stifle the development of new drugs").

In sum, the Court predicts that the Supreme Court of Montana Supreme Court would hold that Plaintiffs' claims against Defendants fail for lack of product identification and for lack of a duty giving rise to liability under Montana law.

17. Nebraska

The Nebraska Supreme Court and the Nebraska intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under Nebraska law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the Nebraska Supreme Court would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See Guideone Elite*, 420 F.3d at 1326 n.5.

The Sixth Circuit predicted that the Nebraska Supreme Court would hold that Nebraska law does not support imposing liability on a brand-name defendant for a generic manufacturer's product. *See In re Darvocet*, 756 F.3d at 948–49. The court determined that the plaintiffs' negligence-based claims were encompassed by Nebraska's products liability statute, making them products liability claims. *Id.* at 948; *see also* Neb. Rev. Stat. § 25-21,180 (2020) (defining a "product liability action" as "any action brought against a manufacturer, seller, or lessor of a

product, regardless of the substantive legal theory or theories upon which the action is brought, for or on account of personal injury [or] death"). The court also noted that a requirement of a product liability action under Nebraska law is product identification. *In re Darvocet*, 756 F.3d at 948; *see* Neb. Rev. Stat. § 25-21,180 (2020) (limiting liability to "the manufacturer of the product or part thereof claimed to be defective"). Thus, the court predicted that the Nebraska Supreme Court would construe all of the plaintiffs' claims as products liability claims that failed for lack of product identification. *In re Darvocet*, 756 F.3d at 948.

The court also predicted that, even if the Nebraska Supreme Court characterized the plaintiffs' negligence-based claims as distinct from products-liability claims, the Nebraska Supreme Court would not recognize a duty owed by the defendants to the plaintiffs. *Id.* The court explained that, in order to determine whether a defendant owes a duty, Nebraska courts look to the Restatement (Third) of Torts. *Id* (citing Restatement (Third) of Torts § 7 (Am. Law Inst. 2010)). The court further explained that, "[u]nder that regime, actors must 'exercise reasonable care' when their conduct creates a risk of harm, but courts may decide a defendant has 'no duty' in exceptional cases, when a countervailing policy warrants denying or limiting liability." *Id.* (quoting *A.W. v. Lancaster Cty. Sch. Dist. 0001*, 784 N.W.2d 907, 918 (Neb. 2010)). The court determined that the brand-name manufacturers' conduct "did not create the risk of harm that caused plaintiffs' injuries, rather the Congressional and Nebraska state laws designed to increase the availability of generic drugs did." *Id.*; *see* Schwartz et al., at 1870–71. The court further determined that there were "grave health policy consequences associated with recognizing brand manufacturer liability in these situations, including high priced brand name drugs and fewer innovative drugs." *In re Darvocet*, 756 F.3d at 948. The court concluded that "the potential ramifications for Nebraskans' health and welfare" made the case exceptional and warranted denying liability. *Id.*

While the Court is not bound by the decisions of federal courts of appeals outside of the Eleventh Circuit in making its *Erie* prediction, the Court finds the Sixth Circuit's reasoning to be "reliable data tending convincingly to show" whether the Nebraska Supreme Court would find the theory of liability at issue to be viable. *See Guideone Elite*, 420 F.3d at 1326 n.5. In sum, the Court therefore predicts that the Nebraska Supreme Court would hold that Plaintiffs' claims fail for lack of product identification and duty giving rise to liability under Nebraska Law.

18. Nevada

The Supreme Court of Nevada and the Nevada intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under Nevada law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the Supreme Court of Nevada would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See id.*

The federal District Court of Nevada has twice predicted that the Supreme Court of Nevada would hold that Nevada law does not support imposing liability on a brand-name defendant for a generic manufacturer's product. *See Baymiller v. Ranbaxy Pharm., Inc*., 894 F. Supp. 2d 1302, 1310 (D. Nev. 2012); *Moretti v. Wyeth, Inc.*, No. 2:08-CV-00396-JCMGWF, 2009 WL 749532, at *3 (D. Nev. Mar. 20, 2009). In *Moretti*, the court determined that, under Nevada products liability law, a plaintiff must allege product identification. *Moretti*, 2009 WL 749532, at *5; *see Allison v. Merck & Co., Inc.*, 878 P.2d 948, 952 (Nev. 1994) (holding that a plaintiff must establish that his injury was "caused by a defect in the product, and that such defect existed when the product left the hands of the defendant"). Thus, the court predicted that the Supreme Court of Nevada would hold that plaintiff's products liability claims would fail for lack of product identification. *Moretti*, 2009 WL 749532, at *5.

The district court also noted that, for a duty to exist, Nevada law "requires, at a minimum, some form of relationship between the parties." *Id.* at *3. The court found that no such relationship existed between the plaintiff who had consumed a generic drug and the brand-name manufacturer defendant. *Id*. Thus, the court predicted that, even if the Supreme Court of Nevada characterized the plaintiffs' fraud and negligence-based claims as distinct from products-liability claims, the Supreme Court would not recognize a duty owed by the defendant to the plaintiff. *Id.*; *see Baymiller*, 894 F. Supp. 2d at 1309 (holding that the brand-name manufacturer did not owe the plaintiff a duty of care because the brand-name manufacturer did not manufacture the drug that purportedly injured the plaintiff).

While the Court is not bound by the decisions of federal district courts in making its *Erie* prediction, the Court finds the District Court of Nevada's reasoning to be "reliable data tending convincingly to show" whether the Supreme Court of Nevada would find the theory of liability at issue to be viable. *See Guideone Elite*, 420 F.3d at 1326 n.5. In sum, the Court therefore predicts that the Supreme Court of Nevada would hold that Plaintiffs' claims fail for lack of product identification and for lack of a duty giving rise to liability under Nevada Law.

19. New Hampshire

The New Hampshire Supreme Court and the New Hampshire intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under New Hampshire law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the New Hampshire Supreme Court would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See id.*

New Hampshire law requires product identification. *See Univ. Sys. of N.H. v. U.S. Gypsum Co.*, 756 F. Supp. 640, 653 (D.N.H. 1991) (explaining that the "imposition of liability depends

upon the plaintiff[] proving that the defendant manufacturer made the product that caused the plaintiff's injury"); *cf. MacCleery v. T.S.S. Retail Corp.*, 882 F. Supp. 13, 16 (D.N.H. 1994) (holding that a manufacturer who was not involved in the design, manufacture, or distribution of the product that caused the plaintiff's injury "has not . . . engaged in any conduct for which, as a matter of law, it could be directly liable"). However, New Hampshire does not have a products liability statute that would subsume Plaintiffs' negligence-based claims. And, the Court is unaware of any New Hampshire caselaw indicating that those claims would be construed as products liability claims. The New Hampshire Supreme Court could consider Plaintiffs' negligence-based claims as distinct from products liability claims under New Hampshire law. As a result, the Court must predict whether the New Hampshire Supreme Court would hold that Defendants owe a duty to Plaintiffs.

In determining whether a duty exists, New Hampshire courts balance "the societal interest involved, the severity of the risk, the burden upon the defendant, the likelihood of occurrence and the relationship between the parties." *Williams v. O'Brien*, 669 A.2d 810, 813 (N.H. 1995). Further, "the balance weighs in favor of the plaintiff only when a special relationship indicating heightened reliance exists" or other "special circumstances" are present. *Id.*

Defendants and Plaintiffs have no relationship, let alone the required "special relationship," and the Court is unaware of any other "special circumstances" in this case that would warrant imposing liability upon Defendants. Therefore, the Court predicts that the New Hampshire Supreme Court would follow the majority view and hold that Defendants do not owe a duty to Plaintiffs.

In sum, the Court predicts that the New Hampshire Supreme Court would hold that Plaintiffs' claims against Defendants fail for lack of product identification and for lack of a duty giving rise to liability under New Hampshire law.

20. New Mexico

The New Mexico Supreme Court and the New Mexico intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under New Mexico law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the New Mexico Supreme Court would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See Guideone Elite*, 420 F.3d at 1326 n.5.

New Mexico products liability law requires product identification. *See Huber v. Armstrong World Indus., Inc.*, 930 F. Supp. 1463, 1465 (D.N.M. 1996) (holding that the plaintiff failed to produce sufficient evidence that he was injured by a product manufactured by any of the defendants); *see also Tenney v. Seven-Up Co.*, 584 P.2d 205, 206 (N.M. 1978) (holding that, in a products liability case, a plaintiff must prove "the product was defective when it left the *hands of the defendants*") (emphasis added). However, New Mexico does not have a products liability statute that would subsume Plaintiffs' negligence-based claims. Additionally, the Court is unaware of any New Mexico caselaw indicating that those claims would be construed as products liability claims. The New Mexico Supreme Court could consider Plaintiffs' negligence-based claims as distinct from products liability claims under New Mexico law. As a result, the Court must predict whether the New Mexico Supreme Court would hold that Defendants owe a duty to Plaintiffs.

When determining the existence of a duty, New Mexico courts "must articulate specific policy reasons, unrelated to foreseeability considerations, when deciding whether a defendant does or does not have a duty or that an existing duty should be limited." *Rodriguez v. Del Sol Shopping Ctr. Assocs., L.P.*, 326 P.3d 465, 474 (N.M. 2014). "Only '[i]n exceptional cases, when an articulated countervailing principle or policy warrants denying or limiting liability in a particular class of cases, a court may decide that the defendant has no duty or that the ordinary duty of reasonable care requires modification.'" *Id.* at 471 (quoting Restatement (Third) of Torts § 7(b) (Am. Law Inst. 2010)).

The Court predicts that the New Mexico Supreme Court would follow the majority view and determine that Defendants do not owe Plaintiffs a duty of care. As the Sixth Circuit explained when interpreting Nebraska law, which also adheres to the Restatement (Third) of Torts, the brand-name manufacturers' conduct "did not create the risk of harm that caused plaintiffs' injuries, rather the Congressional and Nebraska state laws designed to increase the availability of generic drugs did." *See In re Darvocet*, 756 F.3d at 948; *see also* Schwartz et al., at 1870–71. Additionally, there are "grave health policy consequences associated with recognizing brand manufacturer liability in these situations, including high priced brand name drugs and fewer innovative drugs." *See In re Darvocet*, 756 F.3d at 948. The potential health and welfare ramifications of recognizing such a duty make the case "exceptional" and warrant denying liability. *Id.*

In sum, the Court predicts that the New Mexico Supreme Court would hold that Plaintiffs' claims against Defendants fail for lack of product identification and for lack of a duty giving rise to liability under New Mexico law.

21. New York

The New York Court of Appeals and the New York intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under New York law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the New York Court of Appeals would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See Guideone Elite*, 420 F.3d at 1326 n.5.

Six federal courts and two New York state trial courts have held that Plaintiffs' theory of liability is inconsistent with New York law because a generic consumer's claims against brand-name manufacturers fail for lack of product identification or a duty triggering liability. *See In re Darvocet*, 756 F.3d at 949; *Montero v. Teva Pharm. USA Inc.*, No. 19 CIV. 9304 (AKH), 2019 WL 6907467, at *1 (S.D.N.Y. Dec. 4, 2019); *Rosser v. Sanofi-Aventis*, No. 17-CV-2396 (VSB), 2018 WL 4080351, at *4 (S.D.N.Y. Aug. 26, 2018); *In re Zofran*, 261 F. Supp. 3d 62, 78–79 (D. Mass. 2017); *Coleson v. Janssen Pharm., Inc.*, 251 F. Supp. 3d 716, 720-23 (S.D.N.Y. 2017); *Goldych v. Eli Lilly & Co.*, No. 5:04CV1477(GLS/GJD), 2006 WL 2038436, at *6 (N.D.N.Y July 19, 2006); *Preston v. Janssen Pharm., Inc.*, No. 158570/17, 2018 WL 5017045, at *3 (N.Y. Sup. Ct. Oct. 12, 2018); *Weese v. Pfizer, Inc.*, No. No. 153742/12, 2013 WL 5691993, at *2–3 (N.Y. Sup. Ct. Oct. 08, 2013).

In *Goldych v. Eli Lilly & Co.*, the Northern District of New York explained that New York law "requires a plaintiff seeking recovery for an injury caused by a defective product to prove that the defendant manufactured the product." 2006 WL 2038436, at *6; *see also Rastelli v. Goodyear Tire & Rubber Co.*, 591 N.E.2d 222, 225 (N.Y. 1992) (holding that "a plaintiff may recover in strict products liability or negligence when a manufacturer fails to provide adequate warnings

regarding the use of *its* product") (emphasis added). The court reasoned that, although the plaintiff asserted alternative theories, she had effectively brought a products liability suit and could not "circumvent the requirements of product liability law." *Goldych*, 2006 WL 2038436, at *6. Thus, the court predicted that the New York Court of Appeals would hold that the plaintiff's products liability claims failed for lack of product identification. *Id.*

Additionally, in *Weese v. Pfizer, Inc*., a New York trial court explained that "[i]t is to be expected that [the brand-name manufacturer] has a duty in connection with its own products and labels." 2013 WL 5691993, at *2. However, the court further held that the "duty should not extend to products and labeling over which it has no control, even if those products and labels mirrors its own, because it has done nothing toward putting them in the hands of consumers." *Id.* Thus, the court held that the brand-name manufacture owed no duty to generic consumers. *Id.* at *3.

While the Court is not bound by the decisions of federal district courts or state trial courts in making its *Erie* prediction, the Court finds the reasoning in *Goldych* and *Weese* to be "reliable data tending convincingly to show" whether the New York Court of Appeals would find the theory of liability at issue to be viable. *See Guideone Elite*, 420 F.3d at 1326 n.5.[14] In sum, the Court therefore predicts that the New York Court of Appeals would hold that Plaintiffs' claims fail for lack of product identification or duty giving rise to liability under New York Law.

22. North Carolina

The North Carolina Supreme Court and the North Carolina intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under North Carolina law. Therefore, the Court must make a prediction using

[14] The Sixth Circuit, the District of Massachusetts, and the Southern District of New York also predicted that the New York Court of Appeals would reject this theory of liability, relying upon the reasoning in *Goldych* and *Weese*. *See In re Darvocet*, 756 F.3d at 949; *Coleson*, 251 F. Supp. 3d at 721–22; *In re Zofran*, 261 F. Supp. 3d at 78–79.

all "reliable data tending convincingly to show" whether the North Carolina Supreme Court would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See id.*

Four federal courts have held that Plaintiffs' theory of liability is inconsistent with North Carolina law because a generic consumer's claims against brand-name manufacturers fail for lack of product identification. *See In re Darvocet*, 756 F.3d at 949–950; *Perdue v. Wyeth Pharm., Inc.*, 209 F. Supp. 3d 847, 854 (E.D.N.C. 2016); *Couick v. Wyeth, Inc.*, 691 F. Supp. 2d 643, 646 (W.D.N.C. 2010); *Stoddard v. Wyeth, Inc.*, 630 F. Supp. 2d 631, 634 (E.D.N.C. 2009). In *Couick v. Wyeth, Inc.*, the Western District of North Carolina held that, although the plaintiff's claims were "masked in various legal theories," they were "premised on a single claim of product liability" and clearly fell within North Carolina's definition of a "product liability action." 691 F. Supp. 3d at 645; *see* N.C. Gen. Stat. Ann. § 99B-1 (2020) (defining a "product liability action" to include "any action brought for or on account of personal injury, death or property damage caused by or resulting from… any product"). The court also noted that North Carolina products liability law requires product identification. *See Couick*, 691 F. Supp. 3d at 645; *see also Stoddard*, 630 F. Supp. 2d at 634 ("[U]nder North Carolina law a manufacturer of a brand name pharmaceutical may not be held liable for injuries stemming from the use of another manufacturer's generic bioequivalent."). Thus, the court held that the plaintiff's claims failed for lack of product identification. *Couick*, 691 F. Supp. 3d at 645.

The court also held that the plaintiff's claims failed for lack of a duty owed by the brand-name manufacturers to generic consumers. *See id.* at 646. In making this determination, the court reasoned that "[i]mposing a duty upon the name-brand manufacturers for alleged injuries sustained by a product they did not manufacturer would 'stretch the concept of foreseeability too far.'" *Id.* (quoting *Foster*, 29 F.3d 165 at 171).

While the Court is not bound by the decisions of federal district courts in making its *Erie* prediction, the Court finds the district court's reasoning in *Couick* to be "reliable data tending convincingly to show" whether the North Carolina Supreme Court would find the theory of liability at issue to be viable. *See Guideone Elite*, 420 F.3d at 1326 n.5.[15] In sum, the Court therefore predicts that the North Carolina Supreme Court would hold that Plaintiffs' claims fail for lack of product identification or, alternatively, for lack of a duty giving rise to liability under North Carolina Law.

23. North Dakota

The North Dakota Supreme Court and the North Dakota intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under North Dakota law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the North Dakota Supreme Court would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See id.*

North Dakota products liability law requires product identification. *See Reagan v. Hi-Speed Checkweigher Co.*, 30 F.3d 947, 948 (8th Cir. 1994) (explaining that "a plaintiff must prove that there was a defect in the defendant's product or its design that was a proximate cause of his or her injuries"); *Morrison v. Grand Forks Hous. Auth.*, 436 N.W.2d 221, 224 (N.D. 1989) (stating that, to recover under a products liability action, "the plaintiff must prove there was a 'defect' in the defendant's product"). However, North Dakota law considers Plaintiffs' negligence-based claims distinct from products liability claims. *See Mauch v. Mfrs. Sales & Serv., Inc.*, 345 N.W.2d 338, 345 (N.D. 1984) (holding that "recovery sought under a negligent failure-to-warn theory and recovery sought under a products-liability theory… are two separate and distinct theories of

[15] The Sixth Circuit relied upon the reasoning in *Couick* in making its prediction that the North Carolina Supreme Court would reject this theory of liability. *See In re Darvocet*, 756 F.3d at 949.

recovery"). As a result, the Court must predict whether the North Dakota Supreme Court would hold that Defendants owe a duty to Plaintiffs.

In determining whether a duty is owed, North Dakota courts "have focused on either the foreseeability of the injury or the nature of the relationship between the parties." *Palmer v. 999 Quebec, Inc.*, 874 N.W.2d 303, 309 (N.D. 2016). In this case, regardless of whether the Court focuses on the foreseeability of Plaintiffs' injuries or the nature of the relationship between Plaintiffs and Defendants, the Court predicts that the North Dakota Supreme Court would not recognize a duty owed by Defendants to Plaintiffs. There is no relationship between the parties. Additionally, generic consumers' injuries are not the foreseeable result of brand-name drug manufacturers' conduct. *See In re Darvocet*, 756 F.3d at 944. Rather, the injuries are the foreseeable result of "the laws over which the brand manufacturers have no control." *Id.* (citing Schwartz et al. at 1865). To impose a duty under North Dakota law "would be to stretch the concept of foreseeability too far." *Foster*, 29 F.3d at 171.

In sum, the Court predicts that the North Dakota Supreme Court would hold that Plaintiffs' claims against Defendants fail for lack of product identification and for lack of a duty giving rise to liability under North Dakota law.

24. Oklahoma

The Supreme Court of Oklahoma and the Oklahoma intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under Oklahoma law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the Supreme Court of Oklahoma would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See Guideone Elite*, 420 F.3d at 1326 n.5.

Federal courts have consistently held that Plaintiffs' theory of liability is not viable under Oklahoma law. *See Schrock*, 727 F.3d at 1281–82; *accord In re Darvocet*, 756 F.3d 917, 950–51 (6th Cir. 2014); *In re Zofran*, 261 F. Supp. 3d 79-80 (D. Mass. 2017). The Tenth Circuit noted that Oklahoma law requires "a relationship between the defendant company and the product at issue" for products liability claims based on theories of strict liability and negligence. *Schrock*, 727 F.3d at 1281; *see also Kirkland v. Gen. Motors Corp.*, 521 P.2d 1353, 1363 (Okla. 1974) (holding that, to prevail on a strict liability claim for a defective product, a plaintiff must show that the product was defective when it left the defendant's "possession and control"); *Spence v. Brown–Minneapolis Tank, Co.*, 198 P.3d 395, 401 (Okla. Civ. App. 2008) (rejecting a plaintiff's negligence claim because the defendant "had nothing to do with the manufacture" of the product at issue and did not "occupy a relationship which gives rise to a legal obligation . . . for the benefit of the" plaintiff). Without such a relationship, there can be no duty to warn triggering liability on the part of brand-name manufacturers. *Schrock*, 727 F.3d at 1282-83. The court found no recognized relationship between the generic consumers and brand-name manufacturers. *Id.* at 1283. Based on that determination and the fact that every federal circuit court to address the plaintiffs' theory of liability had rejected it, the court predicted that Supreme Court of Oklahoma would hold that the plaintiffs' claims failed for lack of a duty owed by brand-name manufacturers to generic consumers. *Id.* at 1285-86.

While the Court is not bound by the decisions of federal courts of appeals outside of the Eleventh Circuit in making its *Erie* prediction, the Court finds the Tenth Circuit's reasoning to be "reliable data tending convincingly to show" whether the Supreme Court of Oklahoma would find the theory of liability at issue to be viable. *See Guideone Elite*, 420 F.3d at 1326 n.5. In sum, the

Court therefore predicts that the Supreme Court of Oklahoma would hold that Plaintiffs' claims fail for lack of a duty.

25. Oregon

The Oregon Supreme Court and the Oregon intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under Oregon law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the Oregon Supreme Court would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See id.*

The federal District of Oregon predicted that the Oregon Supreme Court would hold that Oregon law does not support imposing liability on a brand-name defendant for a generic manufacturer's product. *See Phelps v. Wyeth, Inc*., 857 F. Supp. 2d 1114, 1120 (D. Or. 2012). The court held that Oregon's products liability statute "includes all theories a plaintiff may bring in an action based on a product defect." *Id*. at 1121; *see* Or. Rev. Stat. Ann. § 30.900 (2020) (defining "product liability civil action" as "a civil action brought against a manufacturer, distributor, seller, or lessor of a product for damages for personal injury, death, or property damage arising out of . . . any defect, failure to warn, or failure to properly instruct in the use of a product"). The court also noted that, "[u]nder Oregon's product liability law, the name-brand defendants cannot be found liable for plaintiffs' injuries because plaintiffs cannot show that their injuries resulted from the use of the name-brand manufacturers' product." *Phelps*, 857 F. Supp. 2d at 1120 (citing *McEwen v. Ortho Pharm. Corp*., 528 P.2d 522, 538 (Or. 1974) (holding that the manufacturer owed a duty to disclose risks inherent in the use of its product)). Thus, the court held that all of the plaintiff's claims, whether based in a theory of negligence or strict liability, were products liability claims that failed for lack of product identification. *Id.* at 1122.

While the Court is not bound by the decisions of federal district courts in making its *Erie* prediction, the Court finds the district court's reasoning in *Phelps* to be "reliable data tending convincingly to show" whether the Oregon Supreme Court would find the theory of liability at issue to be viable. *See Guideone Elite*, 420 F.3d at 1326 n.5. In sum, the Court therefore predicts that the Oregon Supreme Court would hold that Plaintiffs' claims fail for lack of product identification.

26. Pennsylvania

The Supreme Court of Pennsylvania and the Pennsylvania intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under Pennsylvania law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the Supreme Court of Pennsylvania would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See id.*

The Eastern District of Pennsylvania predicted that the Supreme Court of Pennsylvania would hold that Pennsylvania law does not support imposing liability on a brand-name defendant for a generic manufacturer's product. *See Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 539 (E.D. Pa. 2006), *aff'd*, 521 F.3d 253 (3d Cir. 2008), *vacated and remanded on other grounds*, 556 U.S. 1101 (2009). The court noted that "an essential and elementary characteristic" of Pennsylvania products liability law is that it requires "that the defendant manufacture or sell the product in question." *Id.* at 541 (citing *Hahn v. Richter*, 673 A.2d 888, 891 (Pa. 1996) (holding that a products liability claim can only be brought against "a manufacturer" of the drug in question)). Further, after considering the factors that Pennsylvania courts examine to determine whether a duty exists, the court predicted that the Supreme Court of Pennsylvania would not recognize a duty owed by brand-name manufacturers to generic consumers. *Id.*; *see Althaus v.*

Cohen, 756 A.2d 1166, 1169 (Pa. 2000) (listing the factors as: "(1) the relationship between the parties; (2) the social utility of the actor's conduct; (3) the nature of the risk imposed and foreseeability of the harm incurred; (4) the consequences of imposing a duty upon an actor; and (5) the overall public interest in the proposed solution"). The court held that to impose a duty "'would be to stretch the concept of foreseeability too far,' as [the brand-name manufacturer] cannot reasonably expect that consumers will rely on information they provide when actually ingesting another company's drug." *Colacicco*, 432 F. Supp. 2d at 541 (quoting *Foster*, 29 F.3d at 171). The court also held that it would be unfair to impose a duty upon the brand-name manufacturer when it did benefit from the sale of the generic drug and had "no control over the manufacturing or labeling" of the drug, "yet it bore the expense of developing the [brand-name drug] from which the [generic manufacturer] materially benefits." *Id.* (citing *Foster*, 29 F.3d at 170). Additionally, the court highlighted the importance of not "unduly burden[ing] the pharmaceutical industry with unfettered liability" so as to avoid hindering innovation. *Id.* at 542.

While the Court is not bound by the decisions of federal district courts in making its *Erie* prediction, the Court finds the district court's reasoning in *Colacicco* to be "reliable data tending convincingly to show" whether the Supreme Court of Pennsylvania would find the theory of liability at issue to be viable. *See Guideone Elite*, 420 F.3d at 1326 n.5. In sum, the Court therefore predicts that the Supreme Court of Pennsylvania would hold that Plaintiffs' claims fail for lack of a duty triggering liability under Pennsylvania law.

27. Puerto Rico

The Supreme Court of Puerto Rico and the Puerto Rico intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under Puerto Rico law. Therefore, the Court must make a prediction using all "reliable

data tending convincingly to show" whether the Supreme Court of Puerto Rico would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See id.*

Puerto Rico products liability law requires product identification. *See Rivera Santana v. Superior Packaging Inc*., 132 D.P.R. 115, 125–26 (P.R. 1992) (explaining that "[a] manufacturer is strictly liable in tort when an article he places on the market, knowing that it is to be used without inspection for defects, proves to have a defect that causes injury to a human being") (quotations omitted). However, Puerto Rico does not have a products liability statute that would subsume Plaintiffs' negligence-based claims. And, the Court is unaware of any Puerto Rico caselaw indicating that those claims would be construed as products liability claims. The Supreme Court of Puerto Rico could consider Plaintiffs' negligence-based claims as distinct from products liability claims under Puerto Rico law. As a result, the Court must predict whether the Supreme Court of Puerto Rico would find that Defendants owe a duty to Plaintiffs.

Under Puerto Rico law, a duty of care may arise: "(1) by statute or regulation; (2) 'as the result of a special relationship between the parties that has arisen through custom; or (3) as the result of a traditionally recognized duty of care particular to the situation.'" *Baum-Holland v. Hilton El Con Mgmt., LLC* (1st Cir. 2020) (quoting *De Jesús-Adorno v. Browning Ferris Indus. of P.R., Inc.*, 160 F.3d 839, 842 (1st Cir. 1998)). There is no Puerto Rico statute or regulation that imposes a duty on brand-name manufacturers to generic consumers. Nor is there a "special relationship between the parties" from which a duty of care may be recognized; in fact, there is no relationship between brand-name manufacturers and generic consumers. Further, there exists no "traditionally recognized duty of care" requiring a brand-name manufacturer to go beyond ensuring the safety of its own product. Thus, the Court predicts that the Supreme Court of Puerto

Rico would not recognize a duty owed by Defendants to Plaintiffs triggering liability under Puerto Rico law.

In sum, the Court predicts that the Supreme Court of Puerto Rico would hold that Plaintiffs' claims against Defendants fail for lack of product identification and for lack of a duty giving rise to liability under Puerto Rico law.

28. Rhode Island

The Rhode Island Supreme Court and the Rhode Island intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under Rhode Island law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the Rhode Island Supreme Court would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See Guideone Elite*, 420 F.3d at 1326 n.5.

Rhode Island products liability law requires product identification. *See Clift v. Vose Hardware, Inc.*, 848 A.2d 1130, 1132 (R.I. 2004) (per curiam) (noting that "it is axiomatic that a plaintiff must prove that the proximate cause of his or her injuries was the defendant's product") (quotation omitted). However, Rhode Island does not have a products liability statute that would subsume Plaintiffs' negligence-based claims. Additionally, the Court is unaware of any Rhode Island caselaw indicating that those claims would be construed as products liability claims. The Rhode Island Supreme Court could consider Plaintiffs' negligence-based claims as distinct from products liability claims under Rhode Island law. As a result, the Court must predict whether the Rhode Island Supreme Court would hold that Defendants owe a duty to Plaintiffs.

In determining whether a duty exists, Rhode Island courts consider "all relevant factors, including the relationship between the parties, the scope and burden of the obligation to be imposed

upon the defendant, [and] public policy considerations," *Volpe v. Gallagher*, 821 A.2d 699, 705 (R.I. 2003). Courts also consider "the foreseeability of harm to the plaintiff." *Banks v. Bowen's Landing Corp.*, 522 A.2d 1222, 1225 (R.I. 1987).

After weighing these factors, the Court predicts that the Rhode Island Supreme Court would follow the majority view and hold that Defendants do not owe a duty to Plaintiffs. There is no relationship between brand-name drug manufacturers and generic consumers, and the burden to Defendants and the consequences to the community of imposing a duty of care are great. As other courts have concluded, many public policy considerations weigh against holding brand-name competitors liable for injuries caused by their generic competitors' drugs. *See, e.g.*, *Huck*, 850 N.W.2d at 377 (reasoning that "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"); *McNair*, 818 S.E.2d at 866 (explaining 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 "the increase in litigation . . . could stifle the development of new drugs"). Additionally, generic consumers' injuries are not the foreseeable result of brand-name drug manufacturers' conduct. *See In re Darvocet*, 756 F.3d at 944. Rather, the injuries are the foreseeable result of "the laws over which the brand manufacturers have no control." *Id.* (citing Schwartz et al. at 1865).

In sum, the Court predicts that the Rhode Island Supreme Court would hold that Plaintiffs' claims against Defendants fail for lack of product identification and for lack of a duty giving rise to liability under Rhode Island law.

29. South Carolina

The South Carolina Supreme Court and the South Carolina intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under South Carolina law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the South Carolina Supreme Court would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See Guideone Elite*, 420 F.3d at 1326 n.5.

The federal District of South Carolina has predicted that the South Carolina Supreme Court would hold that South Carolina law does not support imposing liability on a brand-name defendant for a generic manufacturer's product. *See Fisher v. Pelstring*, No. 4:09-CV-00252-TLW, 2010 WL 2998474, at *10 (D.S.C. July 28, 2010). In making this predication, the court relied on the reasoning of analogous federal court decisions that this Court has already deemed persuasive. *See id.* at *4-5 (citing *Foster*, 29 F.3d at 167-71 and *Couick*, 691 F. Supp.2d at 645-56). The court also cited to several instructive decisions within the state of South Carolina, which "indicated that the courts of South Carolina would apparently not allow a tort recovery against a defendant for injuries caused by a product manufactured, distributed, and sold by a third party to which the plaintiff has no connection." *Id.* at *6; *see also Ryan v. Eli Lilly & Co.*, 514 F. Supp. 1004, 1006-07 (D.S.C. 1981) (applying South Carolina law and noting that "[t]he defendant manufacturer must be identified with the specific instrumentality that allegedly caused the injury" and that "[p]roof connecting the defendant with the instrumentality of the alleged defect is necessary regardless of the theory upon which plaintiff relies"); *Baughman v. Gen. Motors Corp.*, 627 F. Supp. 871, 878 (D.S.C. 1985) (holding that "[b]ecause plaintiff cannot show that the defendant exercised dominion over the allegedly defective [product], defendant may not be held liable under any tort

theory"). Thus, because the plaintiffs could not establish that the brand-name manufacturer defendants manufactured or sold the products allegedly responsible for their injuries, the court held that the plaintiffs' claims, whether based in theories of strict liability or negligence, failed for lack of product identification and a duty. *Fisher*, 2010 WL 2998474, at *8.

While the Court is not bound by the decisions of federal district courts in making its *Erie* prediction, the Court finds the district court's reasoning in *Fisher* to be "reliable data tending convincingly to show" whether the South Carolina Supreme Court would find the theory of liability at issue to be viable. *See Guideone Elite*, 420 F.3d at 1326 n.5. In sum, the Court therefore predicts that the South Carolina Supreme Court would hold that Plaintiffs' claims fail for lack of a duty triggering liability under South Carolina law.

30. South Dakota

The South Dakota Supreme Court and the South Dakota intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under South Dakota law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the South Dakota Supreme Court would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See id.*

South Dakota products liability law requires product identification. *See Bradley v. Firestone Tire & Rubber Co.*, 590 F. Supp. 1177, 1179 (D.S.D. 1984) (explaining that "[i]t is a fundamental principle that a plaintiff must prove, as an essential element of his case, that the defendant manufacturer actually made the particular product in question"). However, South Dakota does not have a products liability statute that would subsume Plaintiffs' negligence-based claims. Additionally, the Court is unaware of any South Dakota caselaw indicating that those claims would be construed as products liability claims. The South Dakota Supreme Court could

consider Plaintiffs' negligence-based claims as distinct from products liability claims under South Dakota law. As a result, the Court must predict whether the South Dakota Supreme Court would hold that Defendants owe a duty to Plaintiffs.

In determining whether a duty exists, South Dakota courts look to "whether a 'relationship exists between the parties such that the law will impose upon the defendant a legal observation of reasonable conduct for the benefit of the plaintiff.'" *Zerfas v. AMCO Ins. Co.*, 873 N.W.2d 65, 69 (S.D. 2015) (quoting *First Am. Bank & Tr., N.A. v. Farmers State Bank*, 756 N.W.2d 19, 26 (S.D. 2008). Additionally, foreseeability of injury to the plaintiff and public policy play "major" roles in identifying a legal duty. *Englund v. Vital*, 838 N.W.2d 621, 632 (S.D. 2013) (Konenkamp, J., concurring) (citing *Kirlin v. Halverson*, 758 N.W.2d 436, 453 (S.D. 2008)).

The Court predicts that the South Dakota Supreme Court would hold that a generic consumer's negligence claims against a brand-name manufacturer fail for lack of a duty triggering liability. As previously discussed, the Court finds there to be a complete absence of a relationship between a generic consumer and a brand-name manufacturer. Further, generic consumers' injuries are not the foreseeable result of brand-name manufacturers' conduct. *See In re Darvocet*, 756 F.3d at 944. Rather, the injuries are the foreseeable result of "the laws over which the brand manufacturers have no control." *Id.* (citing Schwartz et al. at 1865). Additionally, as other courts have concluded, many public policy considerations weigh against holding brand-name competitors liable for injuries caused by their generic competitors' drugs. *See, e.g.*, *Huck*, 850 N.W.2d at 377 (finding that "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") (citing Schwartz et al. at 1870–72); *McNair*, 818 S.E.2d at 866 (explaining 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 "the increase in litigation . . . could stifle the development of new drugs").

In sum, the Court predicts that the South Dakota Supreme Court would hold that Plaintiffs' claims against Defendants fail for lack of product identification and for lack of a duty giving rise to liability under South Dakota law.

31. Utah

The Utah Supreme Court and the Utah intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under Utah law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the Utah Supreme Court would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See Guideone Elite*, 420 F.3d at 1326 n.5.

Utah products liability law requires product identification. *Bylsma v. R.C. Willey*, 416 P.3d 595, 604 (Utah 2017) (explaining that liability may only be imposed on parties "involved in the product's chain of distribution"). However, Utah does not have a products liability statute that would subsume Plaintiffs' negligence-based claims. Additionally, the Court is unaware of any Utah caselaw indicating that those claims would be construed as products liability claims. The Utah Supreme Court could consider Plaintiffs' negligence-based claims as distinct from products liability claims under Utah law. As a result, the Court must predict whether the Utah Supreme Court would find that Defendants owe a duty to Plaintiffs.

In determining whether a duty exists, Utah courts consider: "(1) the extent that the manufacturer could foresee that its actions would cause harm; (2) the likelihood of injury; (3) the magnitude of the burden of guarding against it; and (4) the consequences of placing the burden on the defendant." *Slisze v. Stanley-Bostitch*, 979 P.2d 317, 320 (Utah 1999). After weighing these

factors, the Court predicts that the Utah Supreme Court would follow the majority view and hold that brand-name manufacturers do not owe a duty to generic consumers. As previously discussed, generic consumers' injuries are not the foreseeable result of brand-name manufacturers' conduct. *See In re Darvocet*, 756 F.3d at 944. Rather, the injuries are the foreseeable result of "the laws over which the brand manufacturers have no control." *Id.* (citing Schwartz et al. at 1865). Additionally, as other courts have concluded, many public policy considerations weigh against holding brand-name competitors liable for injuries caused by their generic competitors' drugs. *See, e.g.*, *Huck*, 850 N.W.2d at 377 (finding that "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"); *McNair*, 818 S.E.2d at 866 (explaining 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 "the increase in litigation . . . could stifle the development of new drugs").

In sum, the Court predicts that the Utah Supreme Court would hold that Plaintiffs' claims against Defendants fail for lack of product identification and for lack of a duty giving rise to liability under Utah law.[16]

32. Vermont

The Vermont Supreme Court and the Vermont intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under Vermont law. Therefore, the Court must make a prediction using all "reliable data

[16] A Utah state trial court held that brand-name manufacturers owe no duty to generic drug consumers, relying heavily upon the Fourth Circuit's decision in *Foster*. *See Beutella v. A.H. Robins Co.*, No. 980502372, 2001 WL 35669202, at *3 (Utah Dist. Ct. Dec. 10, 2001). However, "in light of the huge caseloads carried by the trial courts," the court opted not to draft a detailed ruling and did not analyze Utah law in any depth. *Id.* at *3 n.4. Thus, the Court does not find the decision particularly persuasive.

tending convincingly to show" whether the Vermont Supreme Court would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See Guideone Elite*, 420 F.3d at 1326 n.5.

Vermont products liability law requires product identification. *Farnham v. Bombardier, Inc.*, 640 A.2d 47, 48 (Vt. 1994) (holding that "a plaintiff must show that the defendant's product… caused injury to the consumer because of its defective design"). As for Plaintiffs' negligence-based claims, the District of Vermont has predicted that the Vermont Supreme Court would recognize a duty owed by brand-name manufacturers to generic consumers. *See Kellogg*, 762 F. Supp. 2d at 709. In reaching this conclusion, the court began by noting that "[n]either the Vermont courts nor the Vermont legislature have collapsed negligence actions into strict liability actions where products are involved." *Id.* at 704. Thus, the court found the plaintiff's negligence-based claims were distinct from products liability claims and proceeded to determine whether a duty was owed by brand-name manufacturers to generic consumers. The court explained that, in determining whether a duty is owed, Vermont courts primarily consider the foreseeability of the risk, but also look to "the relationship of the parties, the nature of the risk, and the public interest at stake." *Id.* at 705 (quoting *Hamill v. Pawtucket Mut. Ins. Co.*, 892 A.2d 226, 228 (Vt. 2005)); *see also Langle v. Kurkul*, 510 A.2d 1301, 1305 (Vt. 1986). The court held that because

> [a] pharmacist is required by law to substitute the lowest priced generic equivalent when filling a prescription for a drug, unless otherwise instructed by the prescriber . . . it is routine . . . and entirely foreseeable, that a physician will prescribe a drug in reliance upon information disseminated by the brand name manufacturer, and that the patient with receive and ingest a generic equivalent.

Kellogg, 762 F. Supp. 2d at 705-06. The court further held imposing a duty would not be unfair to brand-manufacturers. *Id.* at 706.

The Court agrees with the District of Vermont insofar as the Court concludes that the Vermont Supreme Court could view Plaintiffs' negligence-based claims as distinct from products liability claims under Vermont law. However, the Court disagrees with the District of Vermont's reasoning and conclusion regarding whether the Vermont Supreme Court would recognize a duty owed by brand-name manufacturers to generic consumers. Generic consumers' injuries are "not the foreseeable result of the brand manufacturers' conduct, but of the [Vermont and federal] laws over which the brand manufacturers have no control," and to use "these laws as the basis of supplying the duty element for tort liability stretches foreseeability too far." *In re Darvocet*, 756 F.3d at 944; *see also* Schwartz et al. at 1865. Additionally, the District of Vermont failed to account for the "grave health policy consequences associated with recognizing brand manufacturer liability in these situations including higher brand name drugs and fewer innovative drugs" and the complete absence of any relationship between brand-name manufacturers and generic consumers. *In re Darvocet*, 756 F.3d at 944; *see also McNair*, 818 S.E.2d at 864 n.11 (finding the reasoning in *Kellogg* unpersuasive and declining to recognize a duty owed by brand-manufacturers to generic consumers).

In sum, the Court predicts that the Vermont Supreme Court would hold that Plaintiffs' claims fail either for lack of product identification and a duty giving rise to liability under Vermont law.

33. Virginia

The Supreme Court of Virginia and the Virginia intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under Virginia law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the Supreme Court of Virginia would find Plaintiffs'

theory of liability viable for any of their claims against Defendants. *See Guideone Elite*, 420 F.3d at 1326 n.5.

The Northern District of Illinois has predicted that the Supreme Court of Virginia would hold that Virginia law does not support imposing liability on a brand-name defendant for a generic manufacturer's product. *See Colas v. Abbvie, Inc.*, No. 14 C 1452, 2014 WL 2699756, at *2 (N.D. Ill. June 13, 2014). In making this determination, the court noted that, under Virginia law, only "one who supplies directly or through a third person a chattel for another to use is subject to liability to those whom the supplier should expect to use the chattel." *Id.* (quoting Restatement (Second) of Torts § 388 (Am. Law Inst. 1965)); *see also Featherall v. Firestone Tire & Rubber Co.*, 252 S.E.2d 358, 366 (Va. 1979) (adopting § 388 and stating that "[t]he duty to warn stems from the view that the manufacturer should have superior knowledge of his product"). Because the brand-name manufacturer defendant was not the supplier of the drug that the plaintiff ingested, the plaintiff's negligent failure to warn claim failed. *Colas*, 2014 WL 2699756, at *2; *see also Baker v. Poolservice Co.*, 636 S.E.2d 360, 365 (Va. 2006) (stating that the plaintiff's "reliance on *Featherall* and § 388 of the Restatement (Second) of Torts to argue [that a spa repair service] owed a duty to warn [was] . . . misplaced" because the repair service "was not the manufacturer of the spa"). The court held that "the Virginia failure to warn decisions, and the weight of authority from other jurisdictions, suggests that the Virginia Supreme Court would not recognize such duty." *Colas*, 2014 WL 2699756, at *2.

While the Court is not bound by the decisions of federal district courts in making its *Erie* prediction, the Court finds the district court's reasoning in *Colas* to be "reliable data tending convincingly to show" whether the Supreme Court of Virginia would find the theory of liability at issue to be viable. *See Guideone Elite*, 420 F.3d at 1326 n.5. In sum, the Court therefore predicts

that the Supreme Court of Virginia would hold that Plaintiffs' claims fail for lack of a duty triggering liability under Virginia law.

34. Wisconsin

The Wisconsin Supreme Court and the Wisconsin intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under Wisconsin law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the Wisconsin Supreme Court would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See id.*

Wisconsin products liability law requires product identification. *See Green v. Smith & Nephew AHP, Inc.*, 629 N.W.2d 727, 746 (Wis. 2001) (holding that "strict products liability holds that manufacturer responsible for injuries caused by that product"). However, Wisconsin does not have a products liability statute that would subsume Plaintiffs' negligence-based claims. Additionally, the Court is unaware of any Wisconsin caselaw indicating that those claims would be construed as products liability claims. The Wisconsin Supreme Court could consider Plaintiffs' negligence-based claims as distinct from products liability claims under Wisconsin law. As a result, the Court must predict whether the Wisconsin Supreme Court would find that Defendants owe a duty to Plaintiffs.

A Wisconsin appellate court has made clear that "a manufacturer only owes a duty to warn regarding its own products, not products it did not manufacture, sell, or otherwise place in the stream of commerce." *Screiner v. Wieser Concrete Prods. Inc.*, 720 N.W.2d 525, 531 (Wis. Ct. App. 2006). Additionally, when determining the existence of a duty, Wisconsin courts look to whether "it was foreseeable that the defendant's act or omission could harm or injure another person." *Morden v. Cont'l AG*, 611 N.W.2d 659, 674 (Wis. 2000). As discussed, generic

consumers' injuries are not the foreseeable result of brand-name drug manufacturers' conduct. *See In re Darvocet*, 756 F.3d at 944. Rather, the injuries are the foreseeable result of "the laws over which the brand manufacturers have no control." *Id.* (citing Schwartz et al. at 1865). Thus, given the appellate court's holding in *Screiner* and the lack of foreseeability of generic consumers' injuries, the Court predicts that the Wisconsin Supreme Court would not impose a duty on brand-name drug manufacturers to generic consumers.

In sum, the Court predicts that the Wisconsin Supreme Court would hold that Plaintiffs' claims against Defendants fail for lack of product identification and for lack of a duty giving rise to liability under Wisconsin law.

35. Wyoming

The Wyoming Supreme Court and the Wyoming intermediary appellate courts have not determined whether generic drug consumers may hold brand-name drug manufacturers liable for injuries under Wyoming law. Therefore, the Court must make a prediction using all "reliable data tending convincingly to show" whether the Wyoming Supreme Court would find Plaintiffs' theory of liability viable for any of their claims against Defendants. *See Guideone Elite*, 420 F.3d at 1326 n.5.

Wyoming products liability law requires product identification. *See Ogle v. Caterpillar Tractor Co.*, 716 P.2d 334, 342 (Wyo. 1986) (adopting the Restatement (Second) Torts § 402A, which explains that "[o]ne who sells any product . . . is subject to liability for physical harm thereby caused if . . . the seller is engaged in the business of selling such a product"). However, Wyoming does not have a products liability statute that would subsume Plaintiffs' negligence-based claims. Additionally, the Court is unaware of any Wyoming caselaw indicating that those claims would be construed as products liability claims. The Wyoming Supreme Court could consider Plaintiffs'

negligence-based claims as distinct from products liability claims. As a result, the Court must predict whether the Wyoming Supreme Court would hold that Defendants owe a duty to Plaintiffs.

In determining whether a duty is owed, Wyoming courts look to:

> (1) the foreseeability of harm to the plaintiff, (2) the closeness of the connection between the defendant's conduct and the injury suffered, (3) the degree of certainty that the plaintiff suffered injury, (4) the moral blame attached to the defendant's conduct, (5) the policy of preventing future harm, (6) the extent of the burden upon the defendant, (7) the consequences to the community and the court system, and (8) the availability, cost and prevalence of insurance for the risk involved.

Gates v. Richardson, 719 P.2d 193, 196 (Wyo. 1986).

After weighing these factors, the Court predicts that the Wyoming Supreme Court would follow the majority view and hold that brand-name drug manufacturers do not owe a duty to generic consumers. First, generic consumers' injuries are not the foreseeable result of brand-name manufacturers' conduct. *See In re Darvocet*, 756 F.3d at 944, Rather, the injuries are the foreseeable result of "the laws over which the brand manufacturers have no control." *Id.* (citing Schwartz et al. at 1865). To impose a duty under Wyoming law "would be to stretch the concept of foreseeability too far." *Foster*, 29 F.3d at 171.

Further, the Court finds that the connection between brand-name manufacturers' conduct and generic consumers injuries is attenuated, given the absence of a relationship between the them. And the burden to brand-name manufacturers and the consequences to the community of imposing a duty of care are great. As other courts have concluded, many public policy considerations weigh against holding brand-name manufacturers liable for injuries caused by their generic competitors' drugs. *See, e.g.*, *Huck*, 850 N.W.2d at 377 (finding that "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"); *McNair*, 818 S.E.2d at 866 (explaining 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 "the increase in litigation . . . could stifle the development of new drugs").

In sum, the Court predicts that the Wyoming Supreme Court would hold that Plaintiffs' claims against Defendants fail for lack of product identification and for lack of a duty giving rise to liability under Wyoming law.