UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

ALAN DORAN,
Administrator for the estate of Rachel Hope Doran,
Plaintiff,

v.

GLAXOSMITHKLINE PLC *et al.*,
Defendants.

No. 3:21-cv-1228 (JAM)

ORDER DENYING MOTION TO DISMISS

Rachel Hope Doran died after her doctor prescribed a brand-name drug known as Lamictal and after her pharmacy filled the prescription with a bio-equivalent generic drug known as lamotrigine. The brand-name drug that her doctor prescribed was manufactured and marketed by the defendants in this action—Glaxosmithkline PLC and Glaxosmithkline LLC (collectively, "GSK"). The bio-equivalent generic drug that Rachel received from her pharmacy and that she actually consumed was manufactured and sold by another company.

Rachel's father in his capacity as administrator of her estate has filed this action against GSK under the Connecticut Product Liability Act. The complaint principally alleges claims for design defect, failure to warn, and misleading advertising that caused Rachel's death.

GSK has moved to dismiss. GSK argues that it cannot be liable because it did not manufacture, sell, or otherwise benefit from the drug that Rachel used.

In cases like this, many courts across the country have considered a theory known as "innovator liability" or "warning label liability." *See* Jenny Ange, *Am I My Competitor's Keeper? Innovator Liability in the Fifty States*, 21 COLUM. SCI. & TECH. L. REV. 1 (2019). This theory posits that the inventor and manufacturer of a brand-name drug may be liable under

certain circumstances for harm caused to a consumer by a bio-equivalent generic drug that was manufactured and sold by a different company.

Innovator liability allows a brand-name company to be liable for two main reasons. First, it recognizes that—by operation of federal law—the brand-name company has near-exclusive *control* of the design and warning labels that generic companies must use for bio-equivalent generic drugs. The brand-name company is in the best position to prevent design and warning defects. Innovator liability attributes responsibility to the brand-name company because of this control and possibly as well because of the brand-name company's continuing misleading promotion of its product.

Second, innovator liability recognizes that federal law *preempts* state law claims against generic companies for design defects and failing to warn about the risks of a bio-equivalent generic drug. In light of the broad remedial purposes of product liability laws, innovator liability ensures that a victim of a defective product has a remedy against a brand-name company that defectively designs or fails to warn about the dangers of the drug in the first instance.

Although the Connecticut Supreme Court has yet to address the issue, I predict in light of the text and broad remedial purposes of the Connecticut Product Liability Act that it would adopt innovator liability and conclude that the complaint in this case states a valid claim for relief under Connecticut law. Accordingly, I will deny the motion to dismiss.

BACKGROUND

By way of background, I will first review the allegations of the complaint. Next, I will describe the basic structure and operation of the Connecticut Product Liability Act as well as the relevant federal regulatory framework that governs the duties and liabilities of brand-name and generic drug companies.

The complaint

I accept as true the following facts as alleged in the complaint.[1] Lamotrigine is the active ingredient in a drug originally manufactured and marketed by GSK under the brand name Lamictal.[2] Lamictal and its generic equivalents are approved for the treatment of bipolar disorder.[3]

Among the most serious risks associated with lamotrigine is Hemophagocytic Lymphohistiocytosis ("HLH").[4] HLH describes a wide array of dangerous conditions in which the body's immune system is excessively activated.[5] HLH's symptoms include fever, reduction in the number of mature blood cells, liver injury and swelling, lymph node disease, and impaired blood coagulation.[6] The severe inflammation caused by HLH can lead to hospitalization and death.[7]

Rachel Doran was a sophomore at Cornell University in March 2017 when she began receiving mental health care from the Cornell mental health office.[8] After returning home to Connecticut in December 2017, she met with a local psychiatrist who diagnosed her with a bipolar mood disorder and issued her a prescription for brand-name Lamictal.[9] The pharmacy filled the prescription with a generic version of lamotrigine manufactured by one of GSK's competitors, TEVA Pharmaceuticals.[10]

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[1] *See* Doc. #1 at 13–27.
[2] *Id.* at 15, 17 (¶¶ 20, 39).
[3] *Id.* at 15 (¶¶ 20–21).
[4] *Ibid.* (¶ 24).
[5] *Ibid.* (¶ 25).
[6] *Id.* at 16 (¶ 27).
[7] *Ibid.* (¶ 28).
[8] *Id.* at 22 (¶ 87).
[9] *Ibid.* (¶¶ 88–89).
[10] *Ibid.* (¶ 89).

When Rachel was first prescribed Lamictal in December 2017, the label did not warn of the risk of HLH.[11] But then the FDA issued a warning in April 2018 linking lamotrigine to HLH, and GSK was at the same time required to add a warning about the risk of HLH to its Lamictal label.[12] According to the complaint, GSK knew or should have known of the risk of HLH as of at least December 2017 when Rachel was first prescribed Lamictal.[13]

The complaint describes how Rachel suffered a severe and ultimately fatal reaction to lamotrigine. On July 12, 2018, she went to a clinic in New York City with symptoms of mucosal irritation, including pink eye and a sore throat.[14] Early the next morning, she went to the emergency room at Bridgeport Hospital, where she developed a rash covering much of her body and blistering on her lips.[15] She was released from the hospital but returned later the same day with additional symptoms.[16] Her doctors determined that her symptoms were consistent with Stevens-Johnson Syndrome ("SJS") and Toxic Epidermal Necrolysis ("TEN"), and she was transferred to the hospital's burn unit, where she stayed for several days.[17]

On July 28, 2018, Rachel was transferred from Bridgeport Hospital to Columbia Presbyterian Medical Center, where she suffered from additional symptoms related to HLH.[18] She underwent numerous invasive and painful medical procedures to treat her SJS, TEN, and HLH, but the interventions were unsuccessful.[19] Rachel died on August 17, 2018.[20]

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[11] *Ibid.* (¶ 84).
[12] *Id.* at 16 (¶¶ 30–31).
[13] *Id.* at 16, 22 (¶¶ 32, 84).
[14] *Id.* at 22 (¶90).
[15] *Ibid.* (¶ 91).
[16] *Ibid.* (¶ 92).
[17] *Id.* at 23 (¶ 93).
[18] *Ibid.* (¶ 94).
[19] *Ibid.* (¶¶ 96–97).
[20] *Ibid.* (¶ 97).

Rachel's father as the administrator of her estate has filed this lawsuit against GSK claiming a violation of the Connecticut Product Liability Act. The case was first filed in Connecticut state court before it was removed by GSK to this Court.[21] As noted above, GSK has moved to dismiss on the ground that it may not be liable under the CPLA because it did not manufacture, sell, or benefit from the particular drug that harmed Rachel.[22]

Connecticut Product Liability Act

The Connecticut Product Liability Act ("CPLA") governs all claims arising under Connecticut law for injuries caused by any product. *See* C.G.S. § 52-572m *et seq.* The Act defines a "product liability claim" to include "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." C.G.S. § 52-572m(b). Such claims "shall include, but [are] not limited to, all actions based on the following theories: Strict liability in tort; negligence; breach of warranty, express or implied; breach of or failure to discharge a duty to warn or instruct, whether negligent or innocent; misrepresentation or nondisclosure, whether negligent or innocent." *Ibid.* A "product liability claim" must be asserted "in lieu of all other claims against product sellers, including actions of negligence, strict liability and warranty, for harm caused by a product." C.G.S. § 52-572n(a).

Despite the Act's creation of an exclusive procedural vehicle for the assertion of product liability claims, the Act preserves the substance of an injured plaintiff's rights to recover under

[21] *Id.* at 13.

[22] Doc. #32. GSK has also moved to dismiss for lack of personal jurisdiction. In consultation with counsel, I have deferred consideration of the personal jurisdiction issue until issuing this ruling to address whether the complaint states a plausible claim for relief under the CPLA. *See Ony, Inc. v. Cornerstone Therapeutics, Inc.*, 720 F.3d 490, 498 n.6 (2d Cir. 2013) (proceeding directly to merits question on motion to dismiss where "the personal jurisdictional challenges are based on factual allegations that are, in this early posture, still under development").

the common law. As the Second Circuit has explained, "the CPLA does not preempt all common law theories of product liability," but merely "bars separate common law causes of action in product liability cases." *Densberger v. United Techs. Corp.*, 297 F.3d 66, 70 (2d Cir. 2002) (emphasis omitted).[23]

In addition, "[c]ommon law theories . . . rather than being preempted by the CPLA, are incorporated into the statute unless they are expressly inconsistent with it." *Ibid.* And because "the CPLA was not meant to eliminate common-law substantive rights but does not itself spell out the elements of the types of claims it consolidates," a court must "assess [a plaintiff's] theories of recovery in light of the Connecticut common-law requirements." *LaMontagne v. E.I. Du Pont De Nemours & Co., Inc.*, 41 F.3d 846, 856 (2d Cir. 1994); *see also Leonard v. Gen. Motors L.L.C.*, 504 F. Supp. 3d 73, 92 (D. Conn. 2020) (noting how common law claims "cannot proceed as independent causes of action" but should be construed as "one claim under the CPLA with multiple theories").

Consistent with this framework, the complaint in this case gathers multiple common law theories under a single umbrella for a cause of action under the CPLA. These theories in essence include strict liability and negligence claims for design defects, failure to warn, and misleading promotional statements about the safety of Lamictal.[24]

Federal regulatory framework for brand-name and generic drugs

The state law products liability claim in this case must be understood in the context of federal law standards that govern the manufacture and sale of medical drugs. When a company

[23] Unless otherwise indicated, this opinion omits internal quotation marks, alterations, citations, and footnotes in text quoted from court decisions.

[24] Doc. #1 at 24–26 (¶¶ 100–119). I queried counsel at oral argument whether the arguments for and against dismissal were specific as to any particular common law theory. Doc. #72 at 37–38. Because neither counsel suggested that I differentiate between different theories for present purposes, I have no occasion at this point to examine whether the arguments for dismissal should rise or fall on grounds specific to any particular common law theory of recovery.

like GSK develops a new drug, the Federal Food, Drug, and Cosmetic Act ("FDCA") requires the company to apply for approval of the new drug upon a showing based on extensive clinical studies that it is safe and effective for its intended use. *See* 21 U.S.C. § 355(a)–(b); *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 612 (2011). Such newly approved drugs "are generally referred to as brand-name or brand drugs," and "[a]n approved brand drug enjoys a period of patent exclusivity in the market at the end of which one or more generic drugs, exhibiting the same characteristics as the brand drug, may enter the market at a lower price to compete with the brand drug." *New York ex rel. Schneiderman v. Actavis PLC,* 787 F.3d 638, 643 (2d Cir. 2015).

In 1984, Congress amended the FDCA by passing the "Hatch-Waxman" amendments. Hatch–Waxman was designed to serve the competing goals of "both encouraging generic drug competition in order to lower drug prices" while also "incentivizing brand drug manufacturers to innovate." *Id.* at 644. To enhance innovation, Hatch-Waxman granted brand-name drug companies certain opportunities to extend their standard 20-year periods of patent exclusivity. *Ibid*. At the same time, Hatch-Waxman made it easier upon expiration of the patent for generic drug companies to enter the market on an expedited basis with drugs that are bio-equivalent to a brand-name drug. *Ibid.*

"By enabling generic manufacturers to 'piggy-back' on a brand drug's scientific studies, Hatch–Waxman speeds the introduction of low-cost generic drugs to market, thereby furthering drug competition." *Ibid.* Thus, implicit in Hatch-Waxman is a bargain with brand-name manufacturers: face greater post-patent competition in exchange for the benefit of more generous—and hence, more profitable—patent exclusivity periods.

Because generic drugs are typically less expensive than brand-name drugs, all 50 States in turn have enacted "drug substitution laws" which generally "permit or require pharmacists to

dispense a therapeutically equivalent, lower-cost generic drug in place of a brand drug absent express direction from the prescribing physician that the prescription must be dispensed as written." *Id.* at 645. "These legislative efforts to expand production and consumption of generic drugs have proved wildly successful," and "[n]inety percent of drugs for which a generic version is available are now filled with generics." *PLIVA*, 564 U.S. at 629 (Sotomayor, J., dissenting).[25]

Federal regulation of drugs includes regulation of labeling and the warnings provided to consumers. A brand-name company's new drug application must include an exemplar of the drug's proposed label, describing the drug's indications and usage, contraindications, warnings and precautions, and adverse reactions. *See* 21 U.S.C. § 355(b)(1)(A)(vi); 21 C.F.R. § 201.56(d)-(e). "The FDA's premarket approval of a new drug application includes the approval of the exact text in the proposed label." *Wyeth v. Levine*, 555 U.S. 555, 568 (2009).

After a new drug and label have been approved by the FDA, federal regulations allow a brand-name company to unilaterally update its label warnings if it learns of new adverse risks from its drug. If the brand-name company acquires such new information, then a federal regulation—known as the "changes-being-effected" regulation—allows the brand-name company to change the label in order to strengthen a warning without first obtaining FDA approval to do so. *See PLIVA*, 564 U.S. at 614 (citing 21 C.F.R. § 314.70(c)(6)(iii)); *Gibbons v. Bristol-Myers Squibb Co.*, 919 F.3d 699, 707 (2d Cir. 2019).

As the U.S. Supreme Court has explained, "brand-name and generic drug manufacturers have different federal drug labeling duties." *PLIVA*, 564 U.S. at 613. "A brand-name

[25] "In the United States, 9 out of 10 prescriptions filled are for generic drugs. Increasing the availability of generic drugs helps to create competition in the marketplace, which then helps to make treatment more affordable and increases access to healthcare for more patients." U.S. Food & Drug Administration, *Generic Drugs*, *available at* https://www.fda.gov/drugs/buying-using-medicine-safely/generic-drugs (last accessed June 10, 2022).

manufacturer seeking new drug approval is responsible for the accuracy and adequacy of its label," while "[a] manufacturer seeking generic drug approval, on the other hand, is responsible for ensuring that its warning label *is the same* as the brand name's." *Ibid.* (emphasis added). In this manner, federal law imposes a duty of "sameness" on the generic drug company not only to market a drug that is bio-equivalent to the brand-name drug but also to use the same warning label as the brand-name company. At the same time, a generic company—unlike a brand-name company—may *not* unilaterally change the drug's warning label to account for new information about the risks of the drug. *Id.* at 614–15.

This federal regulatory framework has important implications for plaintiffs who seek relief under state law for injury from a defective drug. Because federal law bars a generic drug company from unilaterally modifying its drug label to include new warnings, the Supreme Court has held that federal law preempts state law failure-to-warn claims against generic drug companies, but not against brand-name companies for the same drug. *See PLIVA*, 564 U.S. at 624. Similarly, because federal law allows a generic drug company to market only a drug that is bio-equivalent to a brand-name drug, the Supreme Court has also ruled that federal law preempts state law design defect claims against generic drug companies for their bio-equivalent drugs. *See Mutual Pharm. Co., Inc. v. Bartlett*, 570 U.S. 472 (2013). The Supreme Court has ruled in this manner in light of "Congress' decision to regulate the manufacture and sale of generic drugs in a way that reduces their cost to patients but leaves generic drug manufacturers incapable of modifying either the drugs' compositions or their warnings." *Id.* at 493.

DISCUSSION

The standard that governs a motion to dismiss under Rule 12(b)(6) is well established. A complaint may not survive unless it alleges facts that, taken as true, give rise to plausible grounds

to sustain a plaintiff's claims for relief. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *Kim v. Kimm*, 884 F.3d 98, 103 (2d Cir. 2018). A court must "accept as true all factual allegations and draw from them all reasonable inferences; but [it is] not required to credit conclusory allegations or legal conclusions couched as factual allegations." *Hernandez v. United States*, 939 F.3d 191, 198 (2d Cir. 2019).

The scope of a cause of action under the CPLA poses a question of state law. Absent a decision from a state's highest court on a question of state law, a federal court's role is to carefully predict how the highest court of the State would rule on the issue presented. *See Haar v. Nationwide Mut. Fire Ins. Co.*, 918 F.3d 231, 233 (2d Cir. 2019). In doing so, the federal court should give proper regard to the relevant rulings of the State's lower courts and may also consider decisions from other jurisdictions on the same or analogous issues. *See In re Thelen LLP*, 736 F.3d 213, 219 (2d Cir. 2013).

GSK argues that it cannot be liable because it did not manufacture, sell, or otherwise benefit from the generic drug that allegedly harmed Rachel. According to GSK, the CPLA imposes no less than a categorical "product identification" requirement—that is, a requirement that a defendant may be liable only if it is the defendant's own product that caused harm rather than the product of one of the defendant's competitors.

This argument has some initial intuitive appeal. Afterall, the vast majority of product liability cases involve claims against a defendant who actually made or sold the product that caused a plaintiff's injury. But to say that a claim is most commonly brought against one type or class of defendant does not necessarily mean that the law is so limited.

To begin, the text of the CPLA lacks a product identification requirement. As noted above, the Act defines a "product liability claim" to include "all claims or actions [for injury] …

caused by the manufacture, construction, design, formula, preparation, assembly, installation, testing, warnings, instructions, marketing, packaging or labeling of *any product*." C.G.S. § 52-572m(b) (emphasis added). And the class of defendants who may be liable under the CPLA are "product sellers," a term that the CPLA defines expansively to mean "any person or entity, including a manufacturer, wholesaler, distributor or retailer who is engaged in the business of selling *such products* whether the sale is for resale or for use or consumption." *Id.* at § 52-572m(a) (emphasis added). Even a company that does not actually manufacture a product qualifies as a "product seller" merely if it "holds itself out as a manufacturer." § 52-572m(e).

Thus, as Judge Haight has recognized, the CPLA "does not, on its face, require that the particular seller have sold the particular product that injured the particular claimant." *Altman v. Motion Water Sports, Inc.*, 722 F. Supp. 2d 234, 238 (D. Conn. 2010). He reasoned that "[i]f such particularity must indeed be proven, it is because elements like proximate causation are now implicitly incorporated into the statutory 'product liability claim,' as elements of the torts that the statute replaced," but that nonetheless "[o]n its face, the statute requires only that the seller have 'engaged in the business' of selling 'such products.'" *Ibid.*

Judge Haight went on to conclude that the CPLA does not preclude a products liability claim against a successor company that purchased and carried on the same line of products of another company that made the product alleged to have injured a plaintiff. *Id.* at 237–48. Although the case before Judge Haight arose in a different factual context than the one before me now, I agree with his core conclusion that the CPLA does not impose a product identification requirement.

Of course, if the Connecticut legislature had wished to impose a product identification requirement, it easily could have done so. At least three other States—Ohio, Nebraska, and Wisconsin—expressly impose a product identification requirement.[26] Connecticut does not.

Rather than pointing to any controlling language of the CPLA or any decision of the Connecticut Supreme Court, GSK relies on state trial court decisions which suggest in dicta that the CPLA imposes a product identification requirement. *See Barbour v. Dow Corning Corp.*, 2002 WL 983346 (Conn. Super. Ct. 2002) (citing out-of-Connecticut decisions concluding that "under product liability law . . . the defendant must be the manufacturer or seller of the specific product that caused the injury"); *Bobryk v. Lincoln Amusements, Inc.*, 1996 WL 24566, at *3 (Conn. Super. Ct. 1996) (stating that the plaintiff in a CPLA action "must plead and prove that the item which caused him harm was in fact the defendant's 'product' within the meaning of the Act"). The problem is that these decisions assume their conclusion and do not explain how the text of the CPLA imposes a product identification requirement or how any such requirement is embedded in any of the common law requirements for product liability claims.[27]

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[26] *See* Ohio Rev. Code Ann. § 2307.73 ("A manufacturer is subject to liability for compensatory damages based on a product liability claim only if the claimant establishes, by a preponderance of the evidence . . . [that t]he manufacturer designed, formulated, produced, constructed, created, assembled, or rebuilt the actual product that was the cause of harm for which the claimant seeks to recover compensatory damages"); Neb. Rev. Stat. Ann. § 25-21,181 ("No product liability action based on the doctrine of strict liability in tort shall be commenced or maintained against any seller or lessor of a product which is alleged to contain or possess a defective condition unreasonably dangerous to the buyer, user, or consumer unless the seller or lessor is also the manufacturer of the product or the part thereof claimed to be defective."); Wis. Stat. § 895.046(3) (product liability plaintiff must prove "in addition to any other elements required to prove his or her claim, that the manufacturer, distributor, seller, or promoter of a product manufactured, distributed, sold, or promoted the specific product alleged to have caused the claimant's injury or harm").

[27] GSK's remaining Connecticut citations—none of which involve prescription drugs, and many of which rely exclusively on *Bobryk*'s product identification language—are no more persuasive. *See Saraceno v. Am. Ladders & Scaffolds*, 2020 WL 3064470, at *2 (Conn. Super. Ct. 2020) (quoting *Bobryk* in dicta and declining to consider whether "the CPLA requires plaintiff to prove that he purchased the [defective product] from the defendant"); *Hammon v. Hess Corp.*, 2014 WL 6764826, at *5–6 (Conn. Super. Ct. 2014) ("the defendant's product must have a direct relation to the alleged defect"); *Estrella v. Sodexho, Inc.*, 2004 WL 2546758, at *1–2 (Conn. Super. Ct. 2004) (quoting *Bobryk* but permitting claim to proceed because "[t]he [CPLA] does not require, as the defendant claims, that the product allegedly causing the injury had been sold by the defendant to the plaintiff"); *Montanaro v. GAF Materials Corp.*, 2002 WL 317947, at *2 (Conn. Super. Ct. 2002) (quoting *Bobryk* but not involving product identification).

GSK also relies on *In re Darvocet, Darvon, & Propoxyphene Prod. Liab. Litig.*, 756 F.3d 917 (6th Cir. 2014), a decision in which the Sixth Circuit reviewed the laws of various States to conclude that they all impose a product identification requirement for product misrepresentation claims. *Id.* at 937–39. With respect to Connecticut, the Sixth Circuit stated that "[b]ecause Plaintiffs bring a personal injury claim allegedly caused by a defective product, their claims are within the scope of the CPLA and require product identification." *Id.* at 942. But the Sixth Circuit cited no authority for this proposition other than a lone Connecticut federal district court decision—*Johannsen v. Zimmer, Inc.*, 2005 WL 756509 (D. Conn. 2005)—which itself makes no mention at all of a product identification requirement under the CPLA. Indeed, the *Johannsen* decision involved a products liability claim against the designer and manufacturer of a hip prothesis, and there was no suggestion that the plaintiff in that case suffered injury because of a hip prothesis that was made by some party other than the named defendant.

GSK cites two more federal cases. *See In re Zantac (Ranitidine) Prod. Liab. Litig.*, 510 F. Supp. 3d 1175, 1207 (S.D. Fla. 2020); *In re Zofran (Ondansetron) Prod. Liab. Litig.*, 2018 WL 2317525, at *4–5 (D. Mass. 2018). But because these rulings rotely rely on the Sixth Circuit's flawed decision without any further effort to analyze Connecticut law, they are not persuasive.

In addition, GSK relies on *Batoh v. McNeil*, 167 F. Supp. 3d 296 (D. Conn. 2016), in which Judge Shea stated in passing that a defendant drug manufacturer "owed no duty under the CPLA to warn [a decedent's] physician about a product that it did not make or sell." *Id.* at 314. This aspect of the court's ruling was not necessary to its conclusion that the defendant was not liable and was not accompanied by analysis of the text of the CPLA. And the case is otherwise factually distinguishable (involving a claim for failure to warn as to a *non*-prescription drug).

At oral argument, GSK cited my prior ruling in *Klorcyzk v. Sears, Roebuck & Co.*, 2019 WL 1433645 (D. Conn. 2019), for the alleged proposition that a defendant may not be liable for a product defect absent evidence that the defendant benefited in some manner from the product that harmed the plaintiff.[28] But the defendant at issue in *Klorcyzk* had no connection at all to the design or marketing of the product that caused the plaintiff's injury, *see id.* at *16, while this case involves a defendant who both designed and dictated the warnings to be issued for the product that injured the plaintiff.

No appellate courts in Connecticut have read into the CPLA a "product identification" requirement that the text does not support. For its part, the Connecticut Supreme Court has outlined the basic elements of a products liability claim in terms that do not address or explicitly require product identification. Setting aside the independent elements of any common law theory of liability on which the plaintiff relies, a plaintiff in a CPLA action must only allege: "(1) the defendant was engaged in the business of selling the product; (2) the product was in a defective condition unreasonably dangerous to the consumer or user; (3) the defect caused the injury for which compensation was sought; (4) the defect existed at the time of the sale; and (5) the product was expected to and did reach the consumer without substantial change in condition." *Bifolck v. Philip Morris, Inc.*, 324 Conn. 402, 434 (2016); s*ee also Ferry v. Mead Johnson & Co., LLC*, 514 F. Supp. 3d 418, 431–32 (D. Conn. 2021).

To be sure, satisfying these elements will ordinarily involve evidence that a plaintiff purchased or used the defendant's own product. But the complaint here alleges that GSK sold Lamictal, that GSK knew or should have known of the risk of HLH posed by Lamictal, that Lamictal was defective by virtue of its inadequate warnings about HLH, and that Lamictal's

[28] Doc. #72 at 17–18.

defective warnings caused Rachel Doran's injuries because they were relied upon by her prescribing physician and copied (just as federal law requires) by the generic drug company whose drug was used to fill the prescription.[29]

That is enough at the least to state a strict liability claim for a failure to warn under the plain language of the CPLA: "A product seller may be subject to liability for harm caused to a claimant who proves by a fair preponderance of the evidence that the product was defective in that adequate warnings or instructions were not provided." C.G.S. § 52-572q(a); *see also Leonard v. Gen. Motors L.L.C.*, 504 F. Supp. 3d 73, 97 (D. Conn. 2020) (interpreting § 52-572q to require warnings about dangers which the manufacturer knew or should have known).

And it is also enough to state a negligence claim. "[T]he essential elements of a cause of action in negligence are well established: duty; breach of that duty; causation; and actual injury." *Mirjavadi v. Vakilzadeh*, 310 Conn. 176, 191 (2013). Under Connecticut law, "the existence of a duty is a question of law and only if such a duty is found to exist does the trier of fact then determine whether the defendant breached that duty." *Demond v. Project Serv., LLC*, 331 Conn. 816, 834 (2019). Although "[f]orseeability is a critical factor in the analysis," Connecticut law makes clear that "foreseeability alone . . . does not automatically give rise to a duty," because "[m]any harms are quite literally foreseeable, yet for pragmatic reasons, no recovery is allowed." *Ibid*.

Instead, as the Connecticut Supreme Court has explained, "[t]he test for the existence of a legal duty entails (1) a determination of whether an ordinary person in the defendant's position, knowing what the defendant knew or should have known, would anticipate that harm of the

[29] Doc. #1 at 16 (¶ 32); 17 (¶ 37); 22 (¶ 84); 25 (¶ 104); 26 (¶ 112). Because Connecticut has adopted the "learned intermediary" doctrine for failure-to-warn claims, a defendant is under no duty to directly warn the end user of a prescription drug. *See Vitanza v. Upjohn Co.*, 257 Conn. 365, 376 (2001).

general nature of that suffered was likely to result, and (2) a determination, on the basis of a public policy analysis, of whether the defendant's responsibility for its negligent conduct should extend to the particular consequences or particular plaintiff in the case." *Ruiz v. Victory Properties, LLC*, 315 Conn. 320, 328–29 (2015). In my view, the Connecticut Supreme Court would find that the facts as alleged here in the complaint satisfy both these foreseeability and public policy requirements.

First, the Connecticut Supreme Court would likely conclude that it would be readily foreseeable to the manufacturer of a brand-name drug that any deficiencies in its own label or marketing materials may result in substantial harm to consumers of a bioequivalent generic drug. Under federal law, a brand-name drug manufacturer "is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market." *Levine*, 555 U.S. at 571. "[I]t has remained a central premise of federal drug regulation that the [brand-name] manufacturer bears responsibility for the content of its label at all times." *Id.* at 570–71.

On the other hand, a generic manufacturer must comply with an "ongoing federal duty of sameness," which requires in part that the generic's warning label match the brand-name label at all times. *PLIVA*, 564 U.S. at 613. Thus, it is not merely foreseeable but a virtual certainty that any deficiency in the brand-name label will likewise compromise the labels of all bioequivalent generic products.[30]

Nor would it come as a surprise to a brand-name manufacturer that the content of the brand-name label will influence the dispensing of not only the brand-name product but also its

[30] Because advertisements for a prescription drug must generally match the information contained in the drug's approved label, *see* 21 C.F.R. 202.1, the negligent misrepresentation claims—to the extent they rely on GSK's marketing of Lamictal—are subject to a similar foreseeability analysis.

bio-equivalent generics. When a physician is selecting among a menu of possible therapies for her patient, a brand-name manufacturer not only foresees but presumably *intends* that the physician will rely upon information contained in the brand-name's warning label and marketing materials. The brand-name manufacturer has succeeded when its warnings and advertisements induce the physician to prescribe drugs belonging to the same class as the brand-name's product. But even then, the brand-name manufacturer should foresee in light of drug substitution laws and prevailing market practices that the patient may ultimately receive a generic equivalent, either because the physician has prescribed the generic or because—as was the case for Rachel Doran—the pharmacist has substituted the brand-name for the generic.

The existence of a duty here is also consistent with a basic requirement of tort law that acknowledges a duty to certain third parties whom a defendant places in danger by means of furnishing false information: "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 (a) to the other, or (b) *to such third persons as the actor should expect to be put in peril by the action taken*." Restatement (Second) of Torts § 311(1) (emphasis added).[31]

The next consideration is whether allowing GSK to be liable in negligence would be consistent with public policy. "Foreseeability notwithstanding, it is well established that Connecticut courts will not impose a duty of care on the defendants if doing so would be inconsistent with public policy." *Monk v. Temple George Assocs., LLC*, 273 Conn. 108, 116 (2005).

[31] Although the Connecticut Supreme Court has not expressly adopted § 311(1), it has cited with approval its companion provision—§ 311(2). *See Doe v. Cochran*, 332 Conn. 325, 336 (Conn. 2019).

Under Connecticut law, "[i]n considering whether public policy suggests the imposition of a duty, we . . . consider the following four factors: (1) the normal expectations of the participants in the activity under review; (2) the public policy of encouraging participation in the activity, while weighing the safety of the participants; (3) the avoidance of increased litigation; and (4) the decisions of other jurisdictions." *Ruiz*, 315 Conn. at 337. I will review all four factors.

As to the first factor, the normal expectations of market participants counsel in favor of recognizing a duty imposed on GSK not to negligently warn or misrepresent its product. For this first factor, a court must give "due consideration to the preexisting common-law and statutory duty" governing the activity in question. *Ibid.* As a general matter, manufacturers of brand-name drugs are under a clear pre-existing duty to design, label, and market their drugs with all reasonable care. Thus, the brand-name manufacturer may reasonably expect that it will face liability in relation to its inadequate or false labeling and marketing of a brand-name drug. If by chance the pharmacy had chosen to fill the prescription with GSK's brand-name product as Rachel Doran's doctor prescribed rather than with the generic product, GSK could have reasonably expected to be liable for any product defects or misrepresentations.

Because of the federally mandated "sameness" requirements and because a brand-name company does not know *ex ante* whether any particular physician or pharmacy will dispense the brand-name product or the generic equivalent, a brand-name company cannot reasonably expect that its duty will extend only to the consumption of its own brand-name product. What the brand-name manufacturer knows and expects in light of the established federal regulatory requirements of "sameness" is that its own drug design and its own label warnings will be relied on by doctors and patients regardless whether the doctor happens to prescribe or the patient happens to consume a generic equivalent.

In addition, it is altogether reasonable for both a physician and her patient to expect that they may safely rely on the labeling and advertisements of a brand-name drug, even when deciding whether to prescribe or consume that drug's generic equivalent. Connecticut law recognizes that "the public has the right to and does expect . . . that reputable sellers will stand behind their goods." *Potter v. Chicago Pneumatic Tool Co.*, 241 Conn. 199, 234–35 (1997). In the case of a prescription drug, that rule may be reasonably extended to give physicians and consumers the right to expect that a brand-name drug manufacturer will stand by the content of its label and advertisements for a product that it continues to market. I conclude that the first public policy factor weighs in favor of imposing a duty of care.

"Because they are analytically related," the second and third public policy factors may be considered together—namely, "the public policy of encouraging participation in the activity, while weighing the safety of the participants," and "the avoidance of increased litigation." *Ruiz*, 315 Conn. at 337; *see also Lawrence v. O & G. Indus., Inc.*, 319 Conn. 641, 658 (2015). While extending a duty of care will almost always have the effect of increasing the pool of potential claimants, it is no less true that the protections of state tort law are critical in the first instance to encouraging participation in the prescription drug market.

As noted above, federal law generally preempts state-law failure-to-warn and design defect claims against generic manufacturers. *See PLIVA*, 564 U.S. at 624; *Bartlett*, 570 U.S. at 476. Thus, absent liability for the brand-name manufacturer, no one—not the generic manufacturers, and not the brand-name manufacturers who control their own warning labels and those of their generic competitors—may face liability for a drug with a defective design or defective warnings. Absent any such legal recourse or remedy, physicians and patients alike may reasonably think twice before deciding to prescribe and consume generic drugs.

On the other hand, by recognizing a brand-name manufacturer's duty of care vis-à-vis prescribers or consumers of generic bio-equivalents, brand-name manufacturers are encouraged to invest in product safety, including through updates to their warning labels. As the U.S. Supreme Court has recognized, "[s]tate tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly." *Wyeth*, 555 U.S. at 579. "They also serve a distinct compensatory function that may motivate injured persons to come forward with information," and "failure-to-warn actions, in particular, lend force to the FDCA's premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times." *Ibid*.

The Connecticut Supreme Court has similarly acknowledged "the public policies informing our product liability law." *Izzarelli v. R.J. Reynolds Tobacco Co.*, 321 Conn. 172, 199 (2016). Thus, in a somewhat different context of developing the rule that governs the standard for consumer expectations with respect to dangerous products, the Connecticut Supreme Court has rejected "a limitation [that] would be to immunize manufacturers even when they readily could have reduced or eliminated the product's danger" and to "immunize manufacturers for design decisions that increase the risk of known dangers." *Ibid.* It noted that "providing such immunity would remove an important incentive to improving product safety," *id.* at 200, and that adopting a broader test "provides a safety incentive that is consonant with our state's public policies," *id.* at 201. Those same policy concerns apply here.

In short, recognition and imposition of a duty of care gives brand-name manufacturers—the *only* private parties with the ability to alter the drug's design or to unilaterally modify a drug formulation or warning label—a reason to invest in product safety to ensure the adequacy of product design and warnings. At the same time, it gives physicians and patients a reason to trust

in the information they receive from drug manufacturers. In my view, the Connecticut Supreme Court would recognize that these benefits well outweigh the potential for increased litigation.

GSK argues that it is unfair to hold it liable for harm caused by the sale of a product manufactured by one of its generic competitors. But this argument is not convincing. It ignores GSK's controlling role over the design and warnings for its competitor's bio-equivalent generic product.[32] Thus, this case is a far cry from a situation in which a consumer seeks to hold a company liable simply because the company happens to sell the same product as the product that actually harmed the consumer.

In addition, GSK's argument ignores the generous benefit that it received from Hatch-Waxman in the form of an extensive period of patent exclusivity. The flip side of the federal regulatory coin is that generic manufacturers are held to a duty of sameness, and, consequently, released from liability for certain products liability claims. A bargain does not become unfair simply because the benefits to one party are front-loaded relative to the benefits to be received by another party.

Finally, the fourth factor, concerning the decisions of other jurisdictions, is not so helpful here, as courts across the country have broadly divided on the question whether a brand-name drug maker may be liable for injury resulting from a patient's use of a generic equivalent. *See Monk*, 273 Conn. at 120 (giving little weight to the fourth factor because "there are multiple ways in which our sister states handle the question of duty"). Still, I am mindful that "only a minority of states have formally adopted innovator liability whereas many states have formally

[32] It may also ignore the continuing market-share benefit that accrues to a brand-name manufacturer even when a particular prescription is filled by a generic equivalent. Whether a particular prescription is filled by a brand-name drug or a generic equivalent, just the fact that the drug itself has been prescribed tends to maintain continuing market share for the product in general vis-à-vis wholly different drugs or therapy for the medical condition at issue. I confirmed with GSK's counsel at oral argument that other classes of drugs were available for the treatment of Rachel's bipolar disorder. *See* Doc. #72 at 5. Likewise, the complaint alleges that there were "other pharmaceutical options to treat bipolar depression that are widely available." Doc. #1 at 25 (¶ 110).

rejected the doctrine." Ange, *supra*, 21 COLUM. SCI. & TECH. L. REV. at 3; *see also Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1284–86 (10th Cir. 2013) (collecting cases).

But many of the jurisdictions that have rejected innovator liability did so before the Supreme Court's decisions in *PLIVA* and *Bartlett* that preempted state law failure-to-warn and related design-defect claims against generic manufacturers. *See, e.g.*, *Foster v. American Home Products Corp.*, 29 F.3d 165, 167 (4th Cir. 1994). While GSK is correct that the U.S. Supreme Court has no authority to modify state common law, where as here the common law turns on an explicit evaluation of public policy factors, it is proper to take into account the background federal regulatory context and how federal law precludes the victim of a defective product from seeking relief against anyone other than the company that designed the drug, that controls the warnings on its labels, and that promotes a continuing market for the drug. For the surviving family of Rachel, their only available remedy is against GSK.

In terms of decisions from other jurisdictions, I predict that the Connecticut Supreme Court would find persuasive the decision of the Supreme Court of California in *T.H. v. Novartis Pharms. Corp.*, 4 Cal. 5th 145 (2017). The issue in that case was whether a brand-name drug manufacturer has a duty of care to a consumer of a bio-equivalent generic drug. And the Supreme Court of California applied a similar analytic framework as discussed above: first, to decide if the harm to the plaintiff was foreseeable, and second to decide if public policy concerns weigh in favor of recognizing a duty of care. *Id.* at 166–74.

As to foreseeability, the Supreme Court of California reasoned that "[w]hat a brand-name manufacturer . . . knows to a legal certainty is that any deficiencies in the label for its drug will be perpetuated in the label for its generic bioequivalent" and that "it is entirely foreseeable that the warnings included (or not included) on the brand-name drug label would influence the

dispensing of the generic drug, either because the generic is substituted by the pharmacist or the insurance company *after* the physician has prescribed the brand-name drug, or because the warning label on the generic drug is legally required to be identical to the label on the brand-name drug." *Id.* at 166–67.

As to public policy concerns, the Supreme Court of California acknowledged the baseline rule that "the overall policy of preventing future harm is ordinarily served, in tort law, by imposing the costs of negligent conduct upon those responsible." *Id.* at 168. It then observed that "[a] brand-name drug manufacturer is not only in the best position to warn of a drug's harmful effects" but "[i]t is also the only manufacturer with the unilateral authority under federal law to issue such a warning for the brand-name drug or its generic bioequivalent." *Id.* at 168–69. "We therefore conclude that warning label liability is likely to be effective in reducing the risk of harm to those who are prescribed (or are exposed to) the brand-name drug or its generic bioequivalent." *Id.* at 170.

The Supreme Court of California went on to consider and reject the brand-name company's arguments why it would be unfair or against public policy to allow it to be liable for injuries caused by bio-equivalent generic drugs. As to the argument that "it is unfair to subject a brand-name drug manufacturer to liability for harm caused by a competitor's product," the court responded that "the alleged fault here lies with [the brand-name company], not with its generic competitors," because it is the brand-name company that controls the warnings that appear on the product labels. *Id.* at 172.

The Supreme Court of California described the numerous exclusivity advantages that federal law affords a brand-name manufacturer over the life of a patent and that "[b]ecause federal law bundles—and indeed, only makes available—those benefits along with the

responsibility to maintain an adequate warning label, it is as logical as it is reasonable for state common law to ensure the brand-name manufacturer holds up its end of the deal." *Ibid*. "The public interest in adequate drug warnings, in short, is just as acute when the brand-name drug manufacturer has an effective monopoly over the *warning label* as it was when the brand-name manufacturer had a monopoly over the *entire market* for the drug." *Id.* at 172–73. All in all, the Supreme Court of California reasoned that "[w]hen it comes to choosing whether the cost of an injury involving prescription medication should be borne by an innocent plaintiff or a negligent defendant, our case law has routinely held that the latter should bear the cost." *Id.* at 173.

I predict that the Connecticut Supreme Court would adopt the same reasoning. Indeed, even for cases where a manufacturer may not foresee the harm from its product, the Connecticut Supreme Court has recognized that "as between injured consumers who lack the ability to protect themselves physically and/or financially from the product's danger and a manufacturer who might not be able to foresee the risk of harm, Connecticut would strike the balance in favor of injured consumers." *Bifolck*, 324 Conn. at 428–29.[33]

I have also considered the contrary reasons advanced by courts that have rejected claims for innovator or warning-label liability. The Tenth Circuit, for example, has identified "three principal rationales" adopted by "courts that have concluded brand-name manufacturers are not liable to consumers of generic drugs." *Schrock*, 727 F.3d at 1285. I will address each of these three reasons in turn.

[33] I note as well a significant ruling of the Supreme Judicial Court of Massachusetts. In *Rafferty v. Merck & Co.*, 479 Mass. 141 (2018), the court approved of a form of innovator liability based on a higher showing of recklessness rather than simple negligence: "We therefore hold that a brand-name manufacturer that controls the contents of the label on a generic drug owes a duty to consumers of that generic drug not to act in reckless disregard of an unreasonable risk of death or grave bodily injury." *Id.* at 157. Because the parties do not focus on the *Rafferty* decision and because the complaint here would survive under the *Rafferty* standard in that it alleges recklessness, *see* Doc. #1 at 25-26 (¶¶ 105, 117, 119), I have no cause at this time to address the *Rafferty* decision other than to note that it persuasively explains the reasons of foreseeability and public policy why it is proper to allow for some form of innovator liability rather than to preclude any remedy at all for victims of drugs that have defective warnings.

First, courts rejecting innovator liability have "based their view on traditional common law tort principles under which a manufacturer is liable for injuries caused by its own product." *Ibid.* I agree that it is "traditional" for a manufacturer to be liable for defects in its own product, but this "tradition" does not shed light on whether a manufacturer should also be liable for another company's product where—as here—the peculiarities of federal law vest the manufacturer with control of the design of and warnings that accompany the other company's product.

To the extent that the Tenth Circuit derides innovator liability as a "novel theory of liability," *id.* at 1286, the same could have been said decades ago when plaintiffs began arguing that the ability of a consumer to recover for a defective product should not be limited by a contractual privity requirement. The novelty of the argument was not reason enough to reject it. Instead, as the Connecticut Supreme Court has recognized, "products liability is a rapidly developing field of law, particularly in the area of manufacturers' liability," and so it has ruled that "where the liability is fundamentally founded on tort rather than contract there appears no sound reason why the manufacturer should escape liability simply because the injured user, a party in the normal chain of distribution, was not in contractual privity with it by purchase and sale." *Garthwait v. Burgio*, 153 Conn. 284, 288, 289 (1965); *see also Potter*, 241 Conn. at 207–15 (describing nationwide evolution of products liability law). The same concerns that counseled against a formalistic *contractual* privity requirement also weigh against a *product* privity requirement of the type that GSK urges here.

Second, courts rejecting innovator liability "reason that brand-name manufacturers' warnings and representations do not create a basis for liability to consumers of competitors' products because brand-name manufacturers only intend to communicate with their customers,

not the customers of their competitors." *Schrock*, 727 F.3d at 1285. But this rationale overlooks that the relevant inquiry for purposes of a negligence claim is one of foreseeability rather than intent. And as explained above, it is flagrantly foreseeable to brand-name producers that consumers will rely on the brand-name producer's design and warnings that invariably accompany a bio-equivalent generic drug.

Third, courts "conclude that public policy considerations weigh against holding name-brand [*sic*] competitors liable for injuries caused by their generic competitor's drug." *Ibid.* But this rationale overlooks the limits of innovator liability which link the potential liability of brand-name companies to those aspects of their competitors' product—the design and labeling of drugs—that the brand-name companies dictate in the first instance. Innovator liability does not render a brand-name company a general insurer or liable for any of its competitors' conduct that the brand-name company does not itself control (*e.g.*, it does not render the brand-name company liable for a competitor's manufacturing defects or for a competitor's false advertising).

And this third rationale also overlooks that, because of federal preemption principles, consumers of generic drugs otherwise have no remedy for the defective design and labeling of bio-equivalent generic drugs. The lack of any remedy would be counter to the "principal purpose" of the CPLA "to protect people from harm caused by defective and hazardous products." *Vitanza v. Upjohn*, 257 Conn. 365, 381 (2001).

In summary, I predict that the Connecticut Supreme Court would conclude that the Connecticut Product Liability Act does not impose a product identification requirement. Accepting as true the facts as alleged in the complaint, I also predict that the Connecticut Supreme Court would recognize that the complaint adequately alleges defective warnings and causation to support a strict liability claim for failure to warn under C.G.S. § 52-572q(a). As to

the negligence claims, I predict that the Connecticut Supreme Court would conclude that the death of Rachel Doran was foreseeable to GSK and that the balance of public policy factors weighs in favor of recognizing that GSK as a brand-name drug company may be liable if the evidence shows that its own conduct foreseeably caused the death of Rachel Doran.

CONCLUSION

For the reasons set forth above, the Court DENIES the defendants' motion to dismiss the complaint (Doc. #32). This ruling is without prejudice to the defendants' filing by **July 8, 2022** of a renewed motion to dismiss on personal jurisdiction grounds and in light of the discovery that the parties have conducted to date. In the event that counsel foresee continued disputes as to the scope of jurisdictional discovery, they are requested to contact chambers for scheduling of a discovery conference.

It is so ordered.

Dated at New Haven this 10th day of June 2022.

/s/ ***Jeffrey Alker Meyer***
Jeffrey Alker Meyer
United States District Judge