UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

EUGENIA NETO, Representative for Manuel F. Neto (Deceased)
Plaintiff,

v.

BRISTOL-MYERS SQUIBB AND UPSHER SMITH LABORATORIES,
Defendants.

No. 3:22-cv-1344 (VAB)

RULING AND ORDER ON MOTION TO DISMISS

Eugenia Neto ("Plaintiff"), Representative for Manuel F. Neto (Deceased), appearing *pro se*, has sued Bristol Myers Squibb Company (or "BMS"), Upsher Smith Laboratories (or "USL") (collectively, "Defendants") alleging that Defendants failed to adequately warn of the hemorrhaging suffered by the decedent, and subsequent death by taking brand name prescription, generic, and/or Coumadin in violation of the Connecticut Products Liability Act (or "CPLA"), Conn. Gen. Stat. § 52-572m, *et seq.* Notice of Removal at 5, ECF No. 1-1 (Oct. 25, 2022) ("Compl.").

Defendants have filed a motion to dismiss Plaintiff's Complaint for failure to state a claim upon which relief can be granted. Defs.' Mot. to Dismiss at 2, ECF No. 8 (Nov. 1, 2022) ("Mot.").

For the following reasons, the motion to dismiss is **GRANTED.**

To the extent the deficiencies identified in this Complaint can be remedied, Plaintiff may move for leave to file an Amended Complaint by **July 7, 2023**. Failure to file an Amended Complaint by that date will result in the dismissal of this case with prejudice.

I. FACTUAL AND PROCEDURAL BACKGROUND

A. Factual Allegations

Manuel Neto allegedly used Coumadin, a product allegedly manufactured and sold by Defendants, including the Bristol Myers Squibb entities, during all relevant times. Compl. ¶ 124.

Mr. Neto allegedly took the Coumadin without any warnings from Defendants regarding the symptoms of hemorrhaging, or in turn, death from taking Coumadin. *Id*. ¶ 125. In addition, Mr. Neto allegedly would not have taken Warfarin had he known of or been fully and adequately informed by Defendants, or by physicians of Mr. Neto, regarding the increased risks and serious dangers of taking Warfarin. *Id.*

B. Procedural History

On October 25, 2022, Eugenia Neto, the appointed representative of Mr. Neto, now deceased, filed this lawsuit. *See* Compl.

On November 1, 2022, Bristol Myers Squibb Company filed a notice regarding the notice of removal stating that USL has not been served. *See* Notice re Notice of Removal at 1, ECF No. 7 (Nov. 1, 2022) ("Notice").

On that same day, Bristol Myers Squibb Company filed their motion to dismiss the Complaint. Mot.

Plaintiff have not filed an opposition to Defendants' motion to dismiss, and the deadline for responding to the motion has passed. *See* D. Conn. L. Civ. R. 7(a)2 (providing twenty-one days for the filing of a responsive pleading).

II. STANDARD OF REVIEW

To survive a motion to dismiss under 12(b)(6), a complaint must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a). Any claim that fails "to state a claim upon which relief can be granted" will be dismissed. Fed. R. Civ. P. 12(b)(6). In reviewing a complaint under Rule 12(b)(6), a court applies a "plausibility standard" guided by "[t]wo working principles." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

First, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.*; *see also Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) ("While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations . . . a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." (internal citations omitted)). Second, "only a complaint that states a plausible claim for relief survives a motion to dismiss." *Iqbal*, 556 U.S. at 679. Thus, the complaint must contain "factual amplification . . . to render a claim plausible." *Arista Records LLC v. Doe 3*, 604 F.3d 110, 120 (2d Cir. 2010) (quoting *Turkmen v. Ashcroft*, 589 F.3d 542, 546 (2d Cir. 2009)).

When reviewing a complaint under Federal Rule of Civil Procedure 12(b)(6), the court takes all factual allegations in the complaint as true. *Iqbal*, 556 U.S. at 678. The court also views the allegations in the light most favorable to the plaintiff and draws all inferences in the plaintiff's favor. *Cohen v. S.A.C. Trading Corp.*, 711 F.3d 353, 359 (2d Cir. 2013); *see also York v. Ass'n of the Bar of N.Y.*, 286 F.3d 122, 125 (2d Cir. 2002) ("On a motion to dismiss for failure to state a claim, we construe the complaint in the light most favorable to the plaintiff, accepting the complaint's allegations as true.").

A court considering a motion to dismiss under Rule 12(b)(6) generally limits its review "to the facts as asserted within the four corners of the complaint, the documents attached to the complaint as exhibits, and any documents incorporated in the complaint by reference." *McCarthy v. Dun & Bradstreet Corp.*, 482 F.3d 184, 191 (2d Cir. 2007). A court may also consider "matters of which judicial notice may be taken" and "documents either in plaintiffs' possession or of which plaintiffs had knowledge and relied on in bringing suit." *Brass v. Am. Film Techs., Inc.*, 987 F.2d 142, 150 (2d Cir. 1993); *Patrowicz v. Transamerica HomeFirst, Inc.*, 359 F. Supp. 2d 140, 144 (D. Conn. 2005).

A plaintiff's "[f]actual allegations must be enough to raise a right to relief above the speculative level" and assert a cause of action with enough heft to show entitlement to relief and "enough facts to state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 555, 570. A claim is facially plausible if "the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678.

Although the Federal Rules of Civil Procedure do not require "detailed factual allegations," a complaint must offer more than "labels and conclusions," "a formulaic recitation of the elements of a cause of action," or "naked assertion[s]" devoid of "further factual enhancement." *Twombly*, 550 U.S. at 555–57. Plausibility at the pleading stage is nonetheless distinct from probability, and "a well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof of [the claim] is improbable, and . . . recovery is very remote and unlikely." *Id*. at 556 (internal quotation marks omitted).

III. DISCUSSION[1]

Defendants raise two arguments in their motion to dismiss: (1) that Plaintiff fails to allege properly a products liability claim; and (2) even if Plaintiff does adequately allege such a claim, any such claim fails as a matter of law.

The Court will address each argument in turn.

A. The Alleged Failure to State a Product Liability Claim

Courts evaluating a Connecticut Products Liability Act claim engage in a three-step analysis. *See Karavitis v. Makita U.S.A., Inc.*, 243 F. Supp. 3d 235, 252–53 (D. Conn. 2017).

First, a plaintiff must satisfy the five elements governing all product liability claims. *See id.* at 252. Plaintiff must allege the following: "(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." *Schulz v. Medtronic, Inc.*, No. 3:21-CV-00414 (MPS), 2022 WL 503960, at *3 (D. Conn. Feb. 18, 2022) (quoting *Bifolck v. Philip Morris, Inc.*, 324 Conn. 402, 434 (2016)); *see also Phila. Indem. Ins. Co. v. Lennox Insu., Inc.*, No. 3:18-cv-217 (CSH), 2019 WL 1258918, at *3 (D. Conn. Mar. 18, 2019) ("[T]he plaintiff must plead and prove that the product was defective and that the defect was the proximate cause of the plaintiff's injuries [to succeed on a products liability claim]." (quoting *Haesche v. Kissner*,

[1] Plaintiff has not filed an opposition to Defendants' motion to dismiss, and the deadline for responding to the motion has passed. *See* D. Conn. L. Civ. R. 7(a)2. Thus, the Court will consider the merits of Defendants' motion based on the motion itself and Plaintiff's Complaint. *See id.* ("Failure to submit a memorandum in opposition to a motion may be deemed sufficient cause to grant the motion, except where the pleadings provide sufficient grounds to deny the motion.").

229 Conn. 213, 218 (1994))).

Second, the Court must determine whether the product instructions or warnings "were required and, if required, whether they were adequate." *Schulz*, 2022 WL 503960, at *4 (internal quotation marks omitted). In that determination, the following factors are relevant: "(1) [t]he likelihood that the product would cause the harm suffered by the claimant; (2) the ability of the product seller to anticipate at the time of manufacture that the expected product user would be aware of the product risk, and the nature of the potential harm; and (3) the technological feasibility and cost of warnings and instructions." *Karavitis*, 243 F. Supp. 3d at 252–53 (citing Conn. Gen. Stat. § 52-572q(b)).

Third, a plaintiff must establish that "if adequate warnings or instructions had been provided, the claimant would not have suffered the harm." *Id.* at 253 (quoting Conn. Gen. Stat. § 52-572q(c)); *see also Ferry v. Mead Johnson & Co., LLC*, 514 F. Supp. 3d 418, 432 (D. Conn. 2021).

Defendants argue that "Plaintiff fails to allege the required elements of a product liability claim," and "Plaintiff pleads no facts that show the Coumadin taken by the decedent was in a defective condition unreasonable or dangerous to the consumer or user." Mot. at 7. In addition, Defendants argue that "Plaintiff also fails to plead any facts that any defect existed at the time the decedent purchased the Coumadin he ingested" and "the Complaint is silent as to whether BMS provided any warnings to the decedent's physician and how such a warning was purportedly inadequate." *Id.* Defendants also argue that Plaintiff fails to show causation by providing sufficient facts within the Complaint. *See id.* Moreover, Defendants argue that "Plaintiff fails to allege the required elements of a product liability claim" and "Plaintiff pleads no facts that show the Coumadin taken by the decedent was in a defective condition

unreasonable or dangerous to the consumer or user." *Id.* at 7. Finally, Defendants argue that "Plaintiff also fails to plead any facts that any defect existed at the time the decedent purchased the Coumadin he ingested." *Id.*

The Court agrees in part.

First, the Plaintiff sufficiently alleges that Defendants were engaged in selling Coumadin. *See* Compl. ¶ 124 ("Plaintiffs regularly took brand name prescription, genenc, and/or Coumadin. Upon information and belief, these products were manufactured and sold by Defendants, including the Bristol Myers Squibb entities, during all relevant times."). But Plaintiff fails to provide any facts within the Complaint that shows the Coumadin taken was defective. *See Karazin v. Wright Med. Tech., Inc.*, No. 3:17CV823 (JBA), 2018 WL 4398250, at *4 (D. Conn. Sept. 14, 2018) ("Pointing to the entirety of the device in question, without more, is not sufficient to state a claim of design defect."). In addition, Plaintiff fails to show that the condition of the Coumadin was defective at the time of purchase. *Id.* Moreover, there are no facts provided within the Complaint that show BMS providing any warnings to the decedent's physician, which, in turn, could show that the provided warning was purportedly inaccurate.

Second, the Complaint fails to allege facts sufficient to determine whether there is causation. Under the learned intermediary doctrine, "prescribing physicians act as learned intermediaries between a manufacturer and consumer and, therefore, stand in the best position to evaluate a patient's needs and assess [the] risks and benefits of a particular course of treatment." *Schulz*, 2022 WL 503960, at *4 (citation omitted). Consistent with this doctrine, a plaintiff therefore must plead that an adequate warning would have changed a doctor's decision to prescribe Coumadin to the decedent. *See id.* But Plaintiff fails to allege any reason for the decedent's doctor to prescribe Coumadin to him or provide the reason why any warning would

change the prescriber's decision. *Id.* at *3–5 (dismissing *pro se* plaintiff's product liability claims for "[plaintiff] fail[ing] to plead sufficient facts to establish a design defect or a failure to warn claim").

Accordingly, Plaintiff's Complaint fails to state a plausible Connecticut Products Liability Act claim.

B. Any Alleged Product Liability Claim Failing as a Matter of Law

Even if the Plaintiff has adequately pled a Connecticut Products Liability Act claim, this claim still may fail as a matter of law. Defendants argue that this is the case for two reasons: (1) Defendants' product provided the warnings required under applicable federal law; and (2) to the extent that the Connecticut Products Liability Act can be construed to require more than the current warning label, any such viable state law claim would be preempted by federal law.

The Court will address each of these issues in turn.

1. The adequacy of the warning labels

In this Circuit, courts have deemed warnings for a prescription drug sufficient where the label described the side effects allegedly caused by the prescription. *See, e.g.*, *Hunte v. Abbott Lab'ys, Inc.*, 569 F. Supp. 3d 115, 121–122 (D. Conn. 2021) ("The [learned intermediate doctrine] provides that adequate warnings to prescribing physicians obviate the need for manufacturers of prescription products to warn ultimate consumers directly. . . . [C]ourts have applied the [learned intermediate doctrine] in cases involving prescription products . . . ." (emphasis omitted) (internal quotation marks omitted)); *Fane v. Zimmer, Inc.*, 927 F.2d 124, 130 (2d Cir. 1991) (affirming directed verdict in favor of defendant on failure to warn claim because warnings included information on the risks associated with the use of the key-free prescription device at issue, including the risk that materialized for plaintiff); *Becker v. Cephalon, Inc.*, No.

14 Civ. 3864 (NSR), 2015 WL 5472311, at *7 (S.D.N.Y. Sept. 15, 2015) (dismissing strict liability and negligence claims because "a products liability claim simply cannot lie" where the prescription "label clearly and adequately warn[ed] of the very side effects suffered by the [d]ecedent"); *Alston v. Caraco Pharm.*, Inc., 670 F. Supp. 2d 279, 287 (S.D.N.Y. 2009) (dismissing failure to warn claim on summary judgment motion because "all of the alleged side effects described by [plaintiff were] specifically indicated as potential side effects in [the medication's] package insert").

"Plaintiff alleges that '[h]ad any Defendant warned that Coumadin could lead to hemorrhaging or, in turn, death,' the decedent would not have taken Coumadin, a prescription anticoagulant." Mot. at 8 (quoting Compl. ¶ 125). But Defendants argue that "the Coumadin labels during the time decedent allegedly took the two medications, from 2015 to 2020, clearly state in a black box warning that 'major' or even 'fatal' bleeding is a potential side effect." *Id.* In the Defendants' view, "the labels warned that the '[m]ost common adverse reactions' to warfarin are 'fatal and nonfatal hemorrhage from any tissue or organ.' *See, e.g.*, 2011 Coumadin Label (Ex. A) (emphasis added); 2017 Coumadin Label (Ex. B) (emphasis added)." *Id.* at 8–9. And "[t]hese risks are precisely the maladies that the decedent allegedly suffered, and the drug labels squarely contradict Plaintiff's allegations that BMS failed to warn of these risks." *Id.* at 9.

The Court agrees.

Here, the prescription "label clearly and adequately warn[ed] of the very side effects suffered by the [d]ecedent," *Becker*, 2015 WL 5472311, at *7. Coumadin labels during the time decedent allegedly took the two medications, from 2015 to 2020, clearly state in a black box warning that "major" or even "fatal" bleeding is a potential side effect. In addition, the labels warned that the "[m]ost common adverse reactions" to warfarin are "fatal and nonfatal

hemorrhage from any tissue or organ." *See, e.g.*, 2011 Coumadin Label (Ex. A) (emphasis added); 2017 Coumadin Label (Ex. B) (emphasis added). In the Complaint, Plaintiff alleges that the decedent experienced these precise risks; thus, the Coumadin labels contradict the allegations made by Plaintiff that BMS failed to warn of these risks. *See* Compl. ¶¶124–125 ("Plaintiffs regularly took brand name prescription, generic, and/or Coumadin. Upon information and belief, these products were manufactured and sold by Defendants, including the Bristol Myers Squibb entities . . . . Had any Defendant warned that Coumadin could lead to hemorrhaging or, in turn, death, Plaintiffs would not have taken Coumadin. Plaintiffs would not have taken Warfarin had Plaintiffs known of or been fully and adequately informed by Defendants, or by Plaintiffs' physicians of the true increased risks and serious dangers of taking the drug."); *cf. Becker*, 2015 WL 5472311, at *5 ("Plaintiff's allegations that Cephalon failed to warn of the risk of SJS/TEN when taking TREANDA, particularly in conjunction with allopurinol, are squarely contradicted by the TREANDA label.").

Accordingly, the Coumadin label is adequate as a matter of law.

2. Preemption

The Supremacy Clause of the U.S. Constitution establishes that federal law "shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const., art. VI, cl. 2. Accordingly, "[w]here state and federal law directly conflict, state law must give way." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 617 (2011) (internal quotations omitted). "[S]tate and federal law conflict where it is 'impossible for a private party to comply with both state and federal requirements.'" *Id.* at 618 (quoting *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995)).

In *PLIVA*, the Supreme Court held the doctrine of "impossibility" preemption applies to

state law claims that impose additional duties on drug manufacturers after a drug has been approved by the Food and Drug Administration ("FDA"). *Id.* at 620. The Second Circuit has ruled that the Food, Drug, and Cosmetics Act ("FDCA") limits a drug manufacturer's "ability to unilaterally change the labels on their products." *Gibbons v. Bristol-Myers Squibb Co.*, 919 F.3d 699, 707 (2d Cir. 2019). "Specifically, to make a change on their own, a manufacturer must comply with the 'changes being effected' ('CBE') regulation, set forth in 21 C.F.R. § 314.70(c)(6)(iii)." *Id.* In accordance with this regulation, once the FDA has approved the warning label for a drug, the manufacturer may only "add or strengthen a contradiction, warning, precaution or adverse reaction, or add or strengthen an instruction about dosing and administration that is intended to increase the safe usage of the drug product in order to reflect newly acquired information." *Id.* (citations and internal quotation marks omitted).[2]

"Because manufacturers may unilaterally update a drug's label if the change complies with the CBE regulation, a state law failure-to-warn claim that depends on newly acquired information – information that Defendants could have added to their label without FDA approval – is not preempted." *Gibbons*, 919 F.3d at 708. Therefore, "to state a claim for failure-to-warn that is not preempted by the FDCA, a plaintiff must plead a labeling deficiency that [Defendants] could have corrected using the CBE regulation." *Id.* (alteration in original) (internal quotation

[2]As one Circuit Court has delineated it, a change under the changes being effected regulation "must be for the purpose of accomplishing at least one of the five following objectives:

(A) To add or strengthen a contraindication, warning, precaution, or adverse reaction for which the evidence of a causal association satisfies the standard for inclusion in the labeling . . . ;

(B) To add or strengthen a statement about drug abuse, dependence, psychological effect, or overdosage;

(C) To add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product;

(D) To delete false, misleading, or unsupported indications for use or claims for effectiveness; or

(E) Any labeling change normally requiring a supplement submission and approval prior to distribution of the drug product that FDA specifically requests be submitted under this provision." *In re Celexa & Lexapro Mktg. & Sales Pracs. Litig.*, 779 F.3d 34, 37 (1st Cir. 2015) (quoting 21 C.F.R. § 314.70(c)(6)(iii)).

marks omitted). "If the plaintiff meets that standard, the burden shifts to the party asserting a preemption defense to demonstrate that there is clear evidence that the FDA would not have approved a change to the [prescription drug's] label." *Id.* at 708 (alteration in original) (internal quotations omitted).

Defendants argue that "[t]o the extent Plaintiff claims that the Coumadin label should have contained different or stronger warnings regarding the risk of fatal hemorrhaging, that argument is preempted by federal law." Mot. at 14.

The Court agrees.

To avoid preemption, the Plaintiff must show that the Bristol Myers Squibb Company could have added more content to the Coumadin label through the changes being effected regulation. *See Gibbons*, 919 F.3d at 708 (recognizing that "a state law failure-to-warn claim that depends on newly acquired information . . . that Defendants could have added to their label without FDA approval . . . is not preempted"). To do so, the Plaintif must "plausibly allege the existence of newly acquired information that could have justified Defendants' revising [the Coumadin label] through the CBE regulation." *Id.* Here, the FDA-approved Coumadin label already included a black box warning regarding the risk of "major or fatal bleeding," Mot. at 8; *see* Defs. Mot., Ex. A., 2011 Coumadin Label ("COUMADIN can cause major or fatal bleeding."), and, just as in *Gibbons*, Plaintiff has not alleged that the risk of fatal hemorrhaging was "of a different type or greater severity or frequency" than that already included in the FDA-approved label. *Gibbons*, 919 F.3d at 708 ("[F]or these reports and studies to constitute newly acquired information, as the term is defined in 21 C.F.R. § 314.3(b), they must have reveal[ed] risks of a different type or greater severity or frequency than previously included in submissions to the FDA." (second alteration in original) (internal quotation marks omitted)).

Indeed, there must be "new information" with "some degree of scientific validity and conclusiveness to constitute 'newly acquired information' under the CBE regulation." *Roberto v. Boehringer Ingelheim Pharms., Inc.*, No. CPL-HHD-CV16-6068484-S, 2019 WL 5068452, at *14 (Conn. Super. Ct. Sept. 11, 2019). This newly acquired information "'must provide reasonable evidence of a causal association of a clinically significant adverse reaction linked to a drug.' A clinically significant adverse reaction 'ha[s] a significant impact on therapeutic decision-making, such as a risk that is potentially fatal or otherwise serious.'" *McGrath v. Bayer HealthCare Pharms. Inc.*, 393 F. Supp. 3d 161, 167 (E.D.N.Y. 2019) (alteration in original) (emphasis omitted) (quoting 21 C.F.R. § 201.57(c)(6)(i)). The FDA imposes that standard because it "recognize[s] that exaggeration of risk, or inclusion of speculative or hypothetical risks, could discourage appropriate use of a beneficial drug . . . or decrease the usefulness and accessibility of important information by diluting or obscuring it. Indeed, labeling that includes theoretical hazards not well-grounded in scientific evidence can cause meaningful risk information to lose its significance." *Id*. (alteration in original) (quoting *Utts v. Bristol-Myers Squibb Co*., 251 F. Supp. 3d 644, 659 (S.D.N.Y. 2017), *aff'd sub nom. Gibbons v. Bristol-Myers Squibb Co*., 919 F.3d 699 (2d Cir. 2019)).

Here, the Complaint lacks any suggestion of "newly acquired information" whatsoever; it does not identify any "data, analysis, or other information" regarding the risk of fatal hemorrhaging. *See, e.g.*, *McGrath*, 393 F. Supp. 3d at 168–71 (E.D.N.Y. 2019) (dismissing as preempted failure to warn claim against brand name drug manufacturer because plaintiff's complaint failed to plead a plausible causal association between medication at issue and risk of clinically significant adverse reaction).

Accordingly, to the extent that Plaintiff alleges a Connecticut Products Liability Act

claim that the currently FDA-approved label is insufficient, any such claim is preempted by federal law, and thus must be dismissed.

IV. CONCLUSION

For the foregoing reasons, Defendants' motion to dismiss is **GRANTED**.

To the extent the deficiencies identified in this Complaint can be remedied, Plaintiff may move for leave to file an Amended Complaint by **July 7, 2023**. Failure to file an Amended Complaint by that date will result in the dismissal of this case with prejudice.

SO ORDERED at Bridgeport, Connecticut, this 26th day of May, 2023.

/s/ Victor A. Bolden
VICTOR A. BOLDEN
UNITED STATES DISTRICT JUDGE