UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

KRISTOPHER SCHULZ EXECUTOR OF THE ESTATE OF ALEXANDRA MORAN, *Plaintiff,* v. MEDTRONIC, INC. *Defendant*	No. 3:21-cv-00414 (MPS)

RULING ON MOTION TO DISMISS

Plaintiff Kristopher Schulz, the executor of Alexandra Moran's estate, has brought this action against Medtronic, Inc, ("Medtronic") alleging that Medtronic's tracheostomy tube was defective and caused Moran's death. Schulz asserts a claim for product liability with multiple theories under the Connecticut Product Liability Act ("CPLA") and a claim for wrongful death. Medtronic moves to dismiss Schulz's complaint for failure to state a claim. ECF No. 12. For the reasons below, I grant Medtronic's motion to dismiss but grant Schulz leave to amend his Complaint.

I. BACKGROUND

The following facts are taken from Schulz's Complaint, ECF No. 1-2, and are accepted as true for the purposes of this ruling.

On November 28, 2018, Dr. Fischbach referred Alexandra Moran to Dr. Mehra, an ear, nose, and throat ("ENT") physician, for an evaluation. ECF No. 1-2 ¶ 9. Dr. Mehra evaluated Moran and recommended a tracheostomy. *Id.* "Moran refused based on the lack of evidence it

would improve her breathing, [and] that adding more medical intervention would only complicate her already complex condition." *Id.* Dr. Mehra noted in his records that refusing the tracheostomy was "not unreasonable." *Id.* Then on December 5, 2018, "Moran saw Dr. Ayala for the first time in [two] years." *Id.* ¶ 10. Despite Moran's ability to carry out her daily activities, Dr. Ayala "insisted she immediately be seen by [an] ENT for an [e]mergency [t]racheostomy at Bridgeport Hospital." *Id.* Moran waited at the Bridgeport Hospital for nine hours but there was "no in house surgeon … to perform the procedure." *Id.* She was then transferred to Yale New Haven Hospital where Dr. Mehra saw her and advised her that "she could die if she doesn't do this." *Id.* On December 7, 2018, Dr. Earles performed the tracheostomy on Moran at Yale New Haven Hospital, *id.*, implanting the Shiley #6, Tracheostomy Tube, # 18D0688JZX ("Shiley 6 CFS"), manufactured by Medtronic, *see id.* ¶ 2 (noting that the tracheostomy tube "worn/used" by Moran when she died was the Shiley CFS 6).

On February 20, 2019, Dr. Ayala evaluated Moran and stated her that "'she could develop respiratory failure and die…' if she didn't go back to the emergency room." *Id.* ¶ 11. In the same report, Dr. Ayala noted that Moran had "[n]o difficulty with activities of daily living." *Id.* Moran was then "admitted to the Bridgeport Hospital for evaluation of airway and possibility of PE and pleural effusion."[1] *Id.* ¶ 12. At 9:17 PM, Nurse Bridgette Dolio noted blood in the trach tube, and at 10:26 PM, "Respiratory [was] paged to evaluate bleeding from [the trachea]." *Id.* "CT scan of the neck and CTA scan of the chest [were] recommended, [and a] small anterior tracheal diverticulum [was] identified." *Id.* On March 7, 2019, Dr. Mehra evaluated Moran and performed both a tracheobronchoscopy and laryngoscopy on her without incident. *Id.* ¶ 13. Moran wanted to remove the tracheostomy tube because it had not improved her breathing but

[1] It is not clear from the Complaint if Moran was admitted to the hospital on the same day that she was evaluated by Dr. Ayala.

Dr. Mehra advised her that "he [did] not recommend removal and [would] re-evaluate in [three] months." *Id.* Moran's close friend, Robert Winkler, and Schulz stated that the tracheostomy tube did not improve Moran's breathing. *Id.*

On March 23, 2019, "Moran suffered a massive hemorrhage while in her sitting room" and she "was found dead of 'Exsanguination' on her back porch by … Winkler." *Id.* ¶¶ 6–7. On June 12, 2019, "the State of Connecticut Medical Examiner determined the cause of [d]eath to be 'Exsanguination due to Tracheo-Brachiocephalic Artery Fistula Complicating Squamous Cell Carcinoma of the Lung,'" and classified the manner of death as a "therapeutic condition." *Id.* ¶ 8 (emphasis omitted). Schulz alleges that "the trach tube Shiley 6 CFS … worn by … Moran[] abraded her Trachea and ruptured her Cephalic Artery causing a massive hemorrhage inside her throat leading to a horrific and violent death," *id.* ¶ 14, and that the Shiley 6 CFS "directly" caused Moran's death "as identified by the State of Connecticut Medical Examiner," *id.* ¶ 29. Further, Schulz alleges that (1) Medtronic's "trach tube design (Shiley 6 CFS) failed because the shape … caused a Tracheoinnominate Fistula rupturing the Cephalic artery and kill[ing]" Moran; and (2) Medtronic "failed to identify the specific patient populations [that] may not be ideal candidates for a rigid trach tube, and failed to identify clinical use cases where patients have an elevated risk to Tracheoinnominate Fistulas (TIF) caused by trach tubes." *Id.* ¶¶ 16–17. The Complaint states that "[i]t is undetermined if the Shily 6 CFS trach tube was faulty or damaged in any way[] [a]s it was destroyed by the Connecticut State [M]edical Examiner." *Id.* ¶ 18.

II. PROCEDURAL HISTORY

On March 23, 2021, Shulz, filed this lawsuit against Medtronic Corporation[2] and Yale New Haven Health Services Corporation in state court. *See* ECF No. 1-3 at 2. On March 25,

[2] Medtronic states that it was incorrectly identified as "Medtronic Corporation" in the Complaint. ECF No. 12-1 at 1.

2021, Medtronic removed the case to federal court. ECF No. 1. On September 7, 2021, I ordered Schulz "to show cause by September 14, 2021 why the claims against Defendant Yale New Haven Health Services Corp. should not be dismissed for lack of service within 90 days as required under Fed. R. Civ. P. 4(m)." ECF No. 20 (emphasis omitted). On September 16, 2021, I dismissed the claim against Yale New Haven Health Services Corp. because Schulz had "not shown cause nor indicated that [Yale New Haven Health Services Corp.] was properly served." ECF No. 21.

III. LEGAL STANDARD

In assessing a Rule 12(b)(6) motion to dismiss, the Court must determine whether the plaintiff has alleged "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "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." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). While the Court must "accept as true all allegations in the complaint and draw all reasonable inferences in favor of the non-moving party," *Vietnam Ass'n for Victims of Agent Orange v. Dow Chem. Co.*, 517 F.3d 104, 115 (2d Cir. 2008), it must grant the moving party's motion if "a complaint is based solely on wholly conclusory allegations and provides no factual support for such claims." *Scott v. Town of Monroe*, 306 F. Supp. 2d 191, 198 (D. Conn. 2004); *Ashcroft*, 556 U.S. at 678 ("The tenet that a court must accept as true all of the allegations in a complaint is inapplicable to legal conclusions."). In addition, for a plaintiff proceeding *pro se*, "his or her pleadings must be considered under a more lenient standard than that accorded to 'formal pleadings drafted by lawyers.'" *Bellamy v. Mount Vernon Hosp.*, No. 07 CIV. 1801 (SAS), 2009 WL 1835939, at *3 (S.D.N.Y. June 26, 2009), aff'd, 387 F. App'x 55 (2d Cir. 2010) (quoting *Haines v. Kerner*, 404

U.S. 519, 520 (per curiam)). "[C]ourts must construe [the *pro se* plaintiff's complaint] broadly, and interpret [it] to raise the strongest arguments that [it] suggest[s]." *Cruz v. Gomez*, 202 F.3d 593, 597 (2d Cir. 2000) (internal quotation marks omitted). *Pro se* status, however, "does not exempt a party from compliance with relevant rules of procedural and substantive law." *Traguth v. Zuck*, 710 F.2d 90, 95 (2d Cir. 1983) (citation omitted).

IV. DISCUSSION

Medtronic moves to dismiss the Complaint on the grounds that (1) Schulz's product liability claim fails to state a claim under the Connecticut Products Liability Act (the "CPLA"), Conn. Gen. Stat. § 52-572m, *et seq.*, and that (2) Schulz's wrongful death claim is time-barred, subsumed by the exclusive remedies under CPLA, and not an independent cause of action under Connecticut law. ECF No. 12-1 at 4. In response, Schulz submitted an opposition brief describing additional facts not found in the Complaint.[3] *See* ECF No. 15. But on a motion to dismiss, I may not consider facts outside of the Complaint. *See Nechis v. Oxford Health Plans, Inc.*, 421 F.3d 96, 100 (2d Cir. 2005) (limiting "consideration [on a motion to dismiss] to facts stated in the complaint or documents attached to the complaint as exhibits or incorporated by reference"); *see Weir v. City of New York*, No. 05 Civ. 9268 (DFE), 2008 WL 3363129, at *9 (S.D.N.Y. Aug. 11, 2008) ("[I]t is axiomatic that the Complaint cannot be amended by the briefs in opposition to a motion to dismiss." (citation omitted)). Therefore, in deciding the motion to dismiss, I consider only the facts in Schulz's Complaint and, after doing so, I conclude that

[3] On April 13, 2021, Medtronic filed its motion to dismiss. ECF No. 12. Afterwards, on April 14, 2021, I entered an order stating the following: "On or before May 4, 2021**,** Plaintiff shall either file a response to the motion or file an amended complaint pleading as many facts as possible, consistent with Rule 11 of the Federal Rules of Civil Procedure, to address the alleged defects discussed in Defendant's memorandum of law. The Court will not allow further amendments after May 4, 2021**.** If Plaintiff chooses to amend and if Defendant then renews the motion to dismiss, Defendant may incorporate by reference any prior briefing." ECF No. 14 (emphasis omitted). On May 3, 2021, Schulz filed his opposition to the motion to dismiss. ECF No. 15.

Schulz has failed to state a claim for both product liability and wrongful death. However, for the reasons discussed below, I also grant Schulz leave to amend his Complaint.

A. Product Liability

"Manufacturers in Connecticut are strictly liable for defective products under § 402A of the Restatement (Second) of Torts. A product may be defective due to a flaw in the manufacturing process, a design defect or because of inadequate warnings or instructions." *Breen v. Synthes-Stratec, Inc.*, 108 Conn. App. 105, 110 (2008). For any products liability claim under Connecticut law, whether a design defect, manufacturing defect, or failure to warn claim, the 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." *Bifolck v. Philip Morris, Inc.*, 324 Conn. 402, 434 (2016). When broadly construed, Schulz's Complaint appears to assert two theories under the CPLA: design defect and failure to warn. I will address each theory below.

i. Design Defect

A plaintiff bringing a design defect claim may establish the second element—that the product was in a defective condition unreasonably dangerous to the consumer or user—under the "risk-utility" test, which governs most cases, or the "consumer expectation" test. *Id.* The risk-utility test provides that

> [A] product is in a defective condition unreasonably dangerous to the consumer or user if:
>
> (1) A reasonable alternative design was available that would have avoided or reduced the risk of harm and the absence of that alternative design renders the product unreasonably dangerous. In considering whether there is a reasonable

> alternative design, the jury must consider the feasibility of the alternative. Other relevant factors that a jury may consider include, but are not limited to, the ability of the alternative design to reduce the product's danger without unreasonably impairing its usefulness, longevity, maintenance, and esthetics, without unreasonably increasing cost, and without creating other equal or greater risks of danger; or
>
> (2) The product is a manifestly unreasonable design in that the risk of harm so clearly exceeds the product's utility that a reasonable consumer, informed of those risks and utility, would not purchase the product. The factors that a jury may consider include, but are not limited to, the magnitude and probability of the risk of harm, the instructions and warnings accompanying the product, the utility of the product in relation to the range of consumer choices among products, and the nature and strength of consumer expectations regarding the product, including expectations arising from product portrayal and marketing.

Id. at 434–35. "Under the consumer expectation test, our secondary test, a product is in a defective condition unreasonably dangerous to the consumer or user only if it is 'dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics.'" *Id.* (citing Restatement (Second) § 402A, comment (i), p. 352).

Medtronic argues that Schulz's design defect claim fails because he "fails to identify any defect in the tracheostomy tube." ECF No. 12-1 at 7. Further, Medtronic argues that Schulz's statement that the tracheostomy tube "failed because of the shape" is a bare and conclusory allegation. *Id.* at 8. I agree.

Schulz fails to plead any facts that "the product was in a defective condition unreasonably dangerous to the consumer or user" under either the risk-utility or consumer expectation test. Schulz does not identify how the tube was allegedly defectively designed. In addition, he does not identify any reasonable alternative design, facts suggesting that the "product is a manifestly unreasonable design," or how the product is dangerous "beyond that which would be contemplated by the ordinary consumer." Schulz's only possible allegation of defect is that the

tube "failed because [of] the shape." ECF No. 1-2 ¶ 16. But, as Medtronic points out, that allegation is conclusory and vague and, even when drawing all reasonable inferences in favor of Schulz, I cannot infer how the shape was "unreasonably dangerous." *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."). Because Schulz fails to point to any defect in the tube, he also fails to plausibly plead that the "the defect caused the injury." Schulz alleges that the tube "abraded [Moran's] [t]rachea and ruptured her Cephalic Artery causing a massive hemorrhage inside her throat." *Id.* ¶ 14. This allegation does not suggest that the defect itself caused the abrasion leading to the hemorrhage and Moran's death.

Further, Schulz fails to plead any facts indicating that the "defect existed at the time of the sale" and that the tube "reach[ed] the consumer without substantial change in condition." Instead, the Complaint states that "[i]t is undetermined if the Shiley 6 CFS trach tube was faulty or damaged in any way[] [a]s it was destroyed by the Connecticut State [M]edical Examiner." ECF No. 1-2 § 18. When drawing all reasonable inferences in favor of Schulz, I infer from this allegation that he did not know the condition of the tube upon Moran's death and whether the tube had been altered after Medtronic sold it, but neither of those inferences plausibly suggest that any defect existed at the time of sale or reached the consumer without change.

ii. Failure to Warn

In addition to the product liability test described above, Conn. Gen. Stat. § 52-572q provides other requirements for a failure to warn claim. Under Conn. Gen. Stat. § 52-572q(a), 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." Conn. Gen. Stat. § 52-572q(a). "In determining whether instructions or warnings were required and, if required, whether they were adequate, the trier of fact may consider: (1) The 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." Conn. Gen. Stat. § 52-572q(b). The plaintiff must also allege that "if adequate warnings or instructions had been provided, the claimant would not have suffered the harm." Conn. Gen. Stat. § 52-572q(c). Further, under the "learned intermediary doctrine," the manufacturer is not required to provide a warning to the ultimate consumers. Instead, the "doctrine provides that adequate warnings to prescribing physicians obviate the need for manufacturers of prescription products to warn ultimate consumers directly. The doctrine is based on the principle that 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." *Breen*, 108 Conn. App. 105, 110–12 (2008). Connecticut courts also apply the doctrine to prescription implantable medical devices. *Id.* at 112–13.

Medtronic argues that the Complaint fails to state a failure to warn claim because there are no allegations indicating if there were any warnings associated with the tube and if so, why those warnings were inadequate. ECF No. 12-1 at 9. Medtronic also argues that Schulz fails to allege that "if adequate warnings or instructions were provided, the Decedent would not have suffered the alleged harm." *Id.* I agree.

Schulz fails to state a claim for failure to warn for the same reasons as described above in the design defect section and because he does not allege that Medtronic failed to give any

warnings or that Medtronic's warnings to either the physicians or Moran were inadequate. In fact, he does not identify any warnings in the Complaint. The Complaint only states that Medtronic "failed to identify the specific patient populations which may not be ideal candidates for a rigid trach tube, and failed to identify clinical use cases where patients have an elevated risk to Tracheoinnominate Fistulas (TIF) caused by trach tubes." ECF No. 1-2 ¶ 17. Based on this allegation, it is not clear whether Medtronic has provided any warnings and instructions at all, let alone instructions about the appropriate patient population or the risk for TIF. *See Philadelphia Indem. Ins. Co. v. Lennox Indus., Inc.*, No. 3:18-CV-00217 (CSH), 2019 WL 1258918, at *3 (D. Conn. Mar. 18, 2019) (Absent even basic factual support for [the failure to warn] claim—for example, whether the blower motor was accompanied with any warnings or instructions at all and, if so, what they stated and why they were inadequate—Plaintiff's claim is nothing more than a conclusory assertion that the Court must disregard."). This allegation alone is insufficient to state a claim for failure to warn—it does not indicate, nor can it be inferred, why any warnings (or lack thereof) were inadequate or that Moran would not have suffered the harm if adequate warnings were provided. *See Mals v. Smith & Nephew, Inc.*, No. 3:19-CV-01770 (VLB), 2020 WL 3270835, at *6 (D. Conn. June 17, 2020) (dismissing plaintiff's failure to warn claim because he "failed to specify what warnings he did receive about the product and how they were deficient").

I conclude that Schulz has failed to plead sufficient facts to establish a design defect or a failure to warn claim and, therefore, I grant the motion to dismiss as to Count One.

B. Wrongful Death

Conn. Gen. Stat. § 52-555 governs wrongful death actions and provides that "[i]n any action surviving to or brought by an executor or administrator for injuries resulting in death,

whether instantaneous or otherwise, such executor or administrator may recover from the party legally at fault for such injuries just damages together with the cost of reasonably necessary medical, hospital and nursing services, and including funeral expenses."

Medtronic argues that the wrongful death claim should be dismissed because (1) it is time-barred, (2) CPLA is the exclusive remedy for the alleged harm, and (3) wrongful death is a derivative action. Because I find that the CPLA is the exclusive remedy for Schulz's claim and that wrongful death is a derivative action, I grant the motion to dismiss as to Count Three[4] and decline to address whether the claim is time-barred.

Under Connecticut law, the CPLA is the "exclusive remedy for claims falling within its scope," *Winslow v. Lewis-Shepard, Inc.*, 212 Conn. 462, 471 (1989), and provides that "[a] *product liability claim* … may be asserted and shall be in lieu of all other claims against product sellers, including actions of negligence, strict liability and warranty, for *harm* caused by a product," Conn. Gen. Stat. § 52-572n(a) (emphases added). "Product liability claims" 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." Conn. Gen. Stat. § 52-572m(b). Further, "harm" is defined as "damage to property, including the product itself, and personal injuries including *wrongful death*." Conn. Gen. Stat. § 52-572m(d) (emphasis added). Here, Schulz's wrongful death claim arises from Moran's death allegedly caused by the tracheostomy tube. *See* ECF No. 1-2 ¶ 30. The statutory language makes clear that the CPLA provides the exclusive remedy for claims falling within its scope and encompasses harms

[4] Count Two is directed at Yale New Haven Health Services Corporation, as to which, as noted above, I have already dismissed all claims.

resulting from "personal injuries including wrongful death." Therefore, Schulz cannot assert a separate cause of action for wrongful death premised on his CPLA claim.

Further, "Connecticut's wrongful death statute does not create a new cause of action, independent of any claims that the decedent might have had during his or her life. Rather, the wrongful death statute merely allows the administrator of an estate to append to an already valid claim an additional element of damages consisting of costs associated with the decedent's death." *Soto v. Bushmaster Firearms Int'l, LLC*, 331 Conn. 53, 104 (2019). A cause of action for wrongful death "will lie only insofar as the decedent, had he or she survived, could have satisfied all of the essential elements" of the underlying claim. *Id.* Thus, wrongful death is not an independent cause of action and cannot be asserted as such. And because I found that Schulz failed to state a claim for products liability, the underlying claim, the wrongful death action also fails.

C. Leave to Amend

i. Schulz's Opposition Brief

As stated above, Schulz's opposition brief contains facts not found in the Complaint. In its reply brief, Medtronic notes that the Court offered Schulz "the option to 'file a response *or* file an amended complaint pleading as many facts as possible'" and the Court stated that it "will not allow further amendments after May 4, 2021." ECF No. 16 at 3 (quoting ECF No. 14 (emphasis added)). Therefore, Medtronic argues, Schulz should not be allowed any more opportunities to amend his complaint because he failed do so by May 4, 2021. Because that position is not consistent with Second Circuit precedent, I must disagree.

Under Federal Rules of Civil Procedure 15(a)(2), a court "should freely give leave [to amend] when justice so requires." "The permissive standard of Rule 15 is consistent with [the

Second Circuit's] strong preference for resolving disputes on the merits." *Loreley Fin. (Jersey) No. 3 Ltd. v. Wells Fargo Sec., LLC*, 797 F.3d 160, 190 (2d Cir. 2015) (internal quotations marks and citation omitted). The Second Circuit has held that district courts should grant plaintiffs leave to amend after a ruling on a motion to dismiss if the plaintiffs satisfy Rule 15. *See Loreley*, 797 F.3d at 169, 189–90 ("hew[ing] to the liberal standard set forth in Rule 15" and finding that the district court improperly denied the plaintiffs' request for leave to amend when the district court asked the plaintiffs to choose either to amend their complaint in response to the defendants' three-page letter describing their motion to dismiss or forfeit the opportunity to replead and the plaintiffs declined to amend but later requested leave to amend in their opposition to the defendants' motion to dismiss); *see id.* at 190 ("Without the benefit of a ruling, many a plaintiff will not see the necessity of amendment or be in a position to weigh the practicality and possible means of curing specific deficiencies."). *Loreley* interprets Rule 15 alone, and does not address a situation in which a proposed amendment postdates a "no further amendments" deadline in a scheduling order issued under Rule 16. The Second Circuit has suggested that *Loreley* does not apply when courts enter a scheduling order setting a deadline after which all amendments are prohibited. *See Sacerdote v. New York Univ.*, 9 F.4th 95, 115 (2d Cir. 2021) (describing "three standards for amending pleadings," which "depend on when the amendment is sought": (1) "[a]t the outset of a litigation, a plaintiff may freely amend her pleadings pursuant to Rule 15(a)(1) as of right without court permission"; (2) "upon the expiration of a specified period [for amendment as of right] in a scheduling order or upon expiration of the default period set forth in Rule 15(a)(1)(A), [] the plaintiff must move the court for leave to amend, but the court should grant such leave 'freely … when justice so requires'" under Rule 15(a)(2) unless there is a showing of "undue delay, bad faith, dilatory motive, [or] futility" (citing *Loreley*); and (3) after "the district

court issues a scheduling order setting a date after which no amendment will be permitted," the "period of 'liberal' amendment ends" and the plaintiff may amend only if he or she satisfies the "'good cause' [standard] that is required to modify a scheduling order under Rule 16(b)(4)"); *see also Sec. & Exch. Comm'n v. Rio Tinto plc*, No. 17cv7994(AT)(DF), 2020 WL 2504008, at *8 (S.D.N.Y. Mar. 9, 2020), *objections overruled*, No. 17CIV7994ATDCF, 2021 WL 807020 (S.D.N.Y. Mar. 3, 2021) (stating that *Loreley* discussed Rule 15, not the applicability of Rule 16); *id.* at *9, *15 (denying the plaintiff's motion for leave to amend because the plaintiff failed to meet the amendment deadline in the scheduling order and Rule 16's "good cause" standard for amendments). Here, however, the scheduling order does not set a deadline for amendments. *See* ECF No. 19. Further, because the plaintiff is pro se, the court must err on the side of permitting amendment. *See Elder v. McCarthy*, 967 F.3d 113, 132 (2d Cir. 2020) ("Where a district court cannot rule out any possibility, however unlikely it might be, that an amended complaint would succeed in stating a claim, a pro se complaint should not be dismissed without granting leave to amend at least once."). Still, under Rule 15, a court "has discretion to deny leave for good reason, including futility, bad faith, undue delay, or undue prejudice to the opposing party." *McCarthy v. Dun & Bradstreet Corp.*, 482 F.3d 184, 200 (2d Cir. 2007).

Construing Schulz's opposition brief liberally, I interpret the introduction of new factual allegations as a request for leave to amend his Complaint. *See Roda v. Comm. of Social Sec.*, 338 F. App'x 39, 41 (2d Cir. 2009) ("[D]istrict courts are obligated to construe pro se submissions liberally."). So even though I ordered Schulz to amend his Complaint by May 4, 2021, because that date was not incorporated into the scheduling order, I find whether he is allowed to amend is governed by Rule 15.

ii. Amendment of the Complaint Would Not Be Futile

Medtronic appears to argue that Schulz's proposed amendment would be futile and states that even with the additional facts, Schulz still fails to plead a claim.[5] *See* ECF No. 16 at 7–10. I disagree. When considering the new allegations in Schulz's opposition brief with the allegations in the Complaint, I conclude that the proposed amendment for the design defect and the failure to warn claims would not be futile but that the proposed amendment for the wrongful death claim would be futile. Therefore, I grant Schulz leave to amend his Complaint as to the product liability claim.

"An amendment to a pleading is futile if the proposed claim could not withstand a motion to dismiss pursuant to [Fed. R. Civ. P.] 12(b)(6)." *Lucente v. Int'l Bus. Machs. Corp.*, 310 F.3d 243, 258 (2d Cir. 2002). "If the problems with a claim are 'substantive' rather than the result of an 'inadequately or inartfully pleaded' complaint, an opportunity to replead would be 'futile' and 'should be denied.'" *Jordan v. Chase Manhattan Bank*, 91 F. Supp. 3d 491, 510 (S.D.N.Y. 2015) (quoting *Cuoco v. Moritsugu*, 222 F.3d 99, 112 (2d Cir. 2000)). If, however, "the underlying facts or circumstances relied upon by a plaintiff may be a proper subject of relief, he ought to be afforded an opportunity to test his claim on the merits." *Foman v. Davis*, 371 U.S. 178, 182 (1962).

a. Schulz's Additional Allegations

The following facts are taken from Schulz's opposition brief and the attached exhibits, *see* ECF Nos. 15, 15-1, and are accepted as true for the purposes of the futility analysis.

The Shiley 6 CFS is "designed, manufactured[,] and sold by Medtronic." ECF No. 15 ¶ 5. "The design of the rigid [tracheostomy tube] had a sharp distal end"—located at "the tip" of

[5] There are no facts suggesting that Schulz made this request in bad faith or after undue delay. He responded to Medtronic's motion to dismiss with his opposition brief on May 3, 2021. In addition, because this case is at the motion to dismiss stage, an amendment would not unduly prejudice Medtronic.

the tube inserted "inside" the trachea—which, Schulz alleges, "abraded [Moran's] tracheal wall rupturing the Cephalic artery." *Id.* ¶ 6. "This is a known complication of a Tracheotomy." *Id.* ¶ 6. Schulz alleges that the "sharp distal end" is a "design defect" because it "is unreasonably sharp and puts the patient at risk of damaging the trachea." *Id.* ¶¶ 6–7; *see also* ECF No. 15-1 at 15 (image of the distal end of the tracheostomy tube). "[T]he device most likely reached the patient in [its] intended condition," ECF No. 15 ¶ 14. Schulz's opposition brief alleges that Medtronic has had "at least two FDA CLASS I medical device recalls for the 'design' of [its] tracheostomy tubes" and alleges that "Medtronic has a history of designing faulty [t]racheostomy [t]ubes." *Id.* ¶¶ 13–14; *see* ECF No. 15-1 at 40 (recall notice for "Medtronic Shiley Neonatal and Pediatric Tracheostomy Tubes"); *id.* at 46 (recall notice for "Shiley Reusable Cannula Low Pressure Cuffed Tracheostomy Tubes").

Schulz also alleges that the tracheostomy tube "was unreasonably safe to be used in patients who had previously received or are currently undergoing radiation treatment to the throat or … upper chest/trachea area" because radiation "compromises trachea tissue making it more sensitive [and] susceptible to injury." ECF No. 15 ¶ 8. "Given that lung cancer patients are a targeted market segment being served by the Shiley 6[]CFS, … [Medtronic] should [have] design[ed] the tracheostomy tube to be more sensitive to the trachea tissue knowing [of the] possible risk" to patients undergoing radiation. *Id.* In 2019, "Medtronic launched a new line of flexible tracheostomy tubes … to mitigate risks such as Tracheoinnominate Fistulas, False Passage and other known complications of tracheostomy tubes." *Id.* (emphasis omitted).

Further, Schulz alleges that the Instructions for Use ("Instructions") included with the tracheostomy tube "failed to properly warn the physicians or patients of the less than obvious risks or the known complications of a Tracheoinnominate Fistula even though it is a known

complication in the Otolaryngology [field.]." *Id.* ¶ 9; *see* ECF No. 15-1 at 17–26 (instructions for the tracheostomy tube). Schulz also alleges that the Instructions "failed to properly warn the patient" of the "proper head and neck alignment/position while the Tracheostomy Tube is in use." ECF No. 15 ¶ 10. Improper "[n]eck position can put the trachea tissue at risk of being abraded if head and neck are positioned in a chin to chest position." *Id.* ¶ 10.

Schulz's opposition brief also attaches the autopsy report for Moran, *see* ECF No. 15-1 at 2–13, in which the Chief Medical Examiner for the State of Connecticut determined that Moran's cause of death was "Exsanguination due to Tracheo-Brachiocephalic Artery Fistula Complicating Tracheostomy Tube Placement for Management of Vocal Cord Paralysis Complicating Squamous Cell Carcinoma of the Lung," *id.* at 5. The manner of death was classified as "Therapeutic Complication." *Id.* Based on the autopsy report, Schulz alleges that the tracheostomy tube "was directly responsible for abrading and rupturing her Cephalic Artery causing [Moran's] unfortunate and horrific death." ECF No. 15 ¶¶ 5, 11.

b. Futility Analysis

Medtronic argues that the design defect claim still fails because Schulz's allegation that the distal end of the tube is too sharp is conclusory and because Schulz failed to include facts that the tracheostomy tube is unreasonably dangerous. ECF No. 16 at 7–9. When considering the additional allegations along with the Complaint, I disagree and find that Schulz's design defect and failure to warn claims are plausible.

Contrary to Medtronic's argument, Schulz plausibly pleads that the Shiley 6 CFS is "unreasonably dangerous" under either the risk-utility test or the consumer expectation test. Schulz alleges that the "sharp distal end" "is unreasonably sharp" putting "the patient at risk of damaging the trachea," and further, that the "sharp distal end" "abraded [Moran's] tracheal wall

rupturing [her] Cephalic artery." When all reasonable inference are drawn in Schulz's favor, the allegations suggest that the tracheostomy tube "is a manifestly unreasonable design," *i.e.*, the sharp distal end is too dangerous to be inserted safely into tracheas,[6] and that the tracheostomy tube is "dangerous to an extent beyond that which would be contemplated by the ordinary consumer," *i.e.*, a person receiving a tracheostomy to improve his or her breathing would not expect the tracheostomy tube to abrade or injure his or her trachea. Schulz also plausibly alleges the other elements of a design defect claim: (1) Medtronic manufactures and sells the Shiley 6 CFS; (2) the sharp distal end of the tracheostomy tube abraded Moran's tracheal wall, causing the Cephalic artery to rupture and leading to her death; and (3) the tracheostomy tube "most likely" reached the consumer in its "intended condition," from which, when drawing all reasonable inferences in favor of Schulz, I can infer that the "sharp distal end" existed at the time of sale and reached the consumer without "substantial change."

The allegations in Schulz's brief also plausibly state a claim for failure to warn. Schulz alleges that the Instructions fail to (1) inform physicians and patients of the "complications of a Tracheoinnominate Fistula," which is "a known complication in the Otolaryngology [field]," and (2) inform patients of the "proper head and neck alignment/position while the Tracheostomy

[6] Medtronic argues that the "flexible tracheostomy tubes" referred to as a possible alternative design in Schulz's brief were not a "reasonable alternative design" because they were not available to Moran's physicians when they implanted the Shiley 6 CFS in December 2018 since Medtronic did not release them until 2019. ECF No. 16 at 9. But this argument does not address whether the flexible tracheostomy tube was *available* as an alternative design to Medtronic when it designed and manufactured the Shiley 6 CFS. *See* Restatement (Third) of Torts § 2(b) ("A product is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor …."). In any event, Connecticut courts do not require plaintiffs to prove "the existence of a reasonable alternative design in order to prevail on a design defect claim." *Potter v. Chicago Pneumatic Tool Co.*, 241 Conn. 199, 215–17 (1997); *see also Mals v. Smith & Nephew, Inc*, No. 3:19-CV-01770 (VLB), 2020 WL 3270835, at *5 (D. Conn. June 17, 2020) ("Requiring Plaintiff to identify a specific alternative design places too great a burden on him to meet pleading requirements, and courts instead require that Plaintiffs establish the dangerous condition of the product as evidence of a design defect.").

Tube is in use." Schulz attaches a copy of the Instructions, which does not mention Tracheoinnominate Fistula or the proper head and neck alignment. In addition, Schulz alleges that Moran died from a Tracheoinnominate Fistula. It is not clear that Moran can sufficiently plead a failure to warn claim for the lack of warning for the proper neck and head position because Schulz does not explain how the lack of those warnings contributed to the harm suffered by Moran. I find, however, that Schulz does plausibly state a claim for failure to warn for the lack of warnings for the risk of Tracheoinnominate Fistula. When all reasonable inferences are drawn in favor of Schulz, these allegations suggest that Medtronic provided the Instructions to physicians and/or patients,[7] that the Instructions failed to include any warnings about the risk of Tracheoinnominate Fistula, that Medtronic should have known of this complication because "it is a known complication in the Otolaryngology [field]," and that the lack of warnings about this complication rendered the Instructions deficient and contributed to Moran's death. Schulz does not need to allege what instructions should have been provided. *See Karazin*, 2018 WL 4398250, at *5 (rejecting that the plaintiff needed to provide "detailed factual allegations regarding exactly what instructions should have been provided"). Therefore, I find that Schulz's failure to warn claim is plausible.

Schulz's proposed amendment for his wrongful death claim, however, is futile. Schulz argues that the filing of his Complaint was timely for the wrongful death claim. ECF No. 15 ¶ 3. But, as discussed above, Schulz's wrongful death claim is substantively flawed "rather than the result of an 'inadequately or inartfully pleaded' complaint." No amendments to the Complaint

[7] Medtronic argues that Schulz "fails to include any facts on what instructions or warnings were provided to [Moran's] physicians, or how or why such warnings and/or instructions were inadequate." ECF No. 16 at 9. As explained above, a fair reading of Schulz's opposition brief suggests that the Instructions were the "warnings" provided to the physicians and/or patients and that the Instructions were inadequate because the document did not mention the risk of Tracheoinnominate Fistula.

can render the wrongful death claim valid because none would change the conclusion that, under Connecticut law, wrongful death is not an independent claim and CPLA provides the exclusive remedy for Schulz's alleged harm.

Therefore, I grant Schulz leave to amend his Complaint for his design defect and failure to warn claims but deny leave to amend for his wrongful death claim.

V. CONCLUSION

For the reasons stated above, I grant the motion to dismiss (ECF No. 12) and grant Schulz leave to amend his Complaint for his product liability claim. Schulz shall file an Amended Complaint setting forth the product liability claim described in his brief within 14 days of this order.

IT IS SO ORDERED.

/s/

Michael P. Shea, U.S.D.J.

Dated: Hartford, Connecticut
February 18, 2022