IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

IN RE: PHILIPS RECALLED CPAP, BI-LEVEL PAP, AND MECHANICAL VENTILATOR PRODUCTS LIABILITY LITIGATION This Document Relates to: All Actions	Master Docket: No. 21-mc-1230-JFC MDL No. 3014

MEMORANDUM OF LAW IN SUPPORT OF PHILIPS DEFENDANTS' MOTION TO ADJOURN REMAND MOTION BRIEFING SCHEDULE IN LIGHT OF CONTINUED FILING OF STATE COURT ACTIONS AND PROPOSED CLASS SETTLEMENT AND RELEASE OF ECONOMIC LOSS CLAIMS

Defendants Philips RS North America LLC ("Respironics"), Koninklijke Philips N.V., Philips North America LLC, Philips Holding USA Inc., and Philips RS North America Holding Corporation (together, the "Philips Defendants") respectfully move to adjourn the schedule for briefing remand motions, and to defer the Court's consideration of and ruling on such motions. Two developments justify this relief: *first*, the universe of remand motions is not yet complete as there continue to be filed state court actions that cover the subject matter of the MDL; and *second*, Plaintiffs' recently-filed unopposed motion for preliminary approval of the proposed class settlement and release of economic loss claims (the "Proposed Settlement") necessitates additional time to evaluate the settlement's impact on the pending remand motions and the remand plaintiffs' claims more generally. The Philips Defendants request that the deadline to oppose remand motions be set for 30 days after the deadline to opt out of the Proposed Settlement, with reply briefs (if any) due 30 days later. The Plaintiffs' Steering Committee does not oppose this request.

Under Pretrial Order No. 22, as amended, remand motions were due to be filed on August 31, 2023, responses are due on October 31, 2023, and replies, if any, are due on November 30,

2023. *See* ECF No. 1901. Six remand motions were timely filed by the August 31 deadline.[1] But state court actions and remand motions continue to be filed in courts across the country. Since the current remand motion briefing schedule was established on May 17, 2023, sixteen more cases have been removed from state courts and transferred to this MDL. Remand motions continue to be filed in these and other removed actions. Indeed, a new remand motion was filed in the Western District of New York just days ago in the recently-removed *Lis* action.[2] The Philips Defendants anticipate that matter will be transferred to this MDL, like every other removed case to date, so that this Court may rule on remand issues. The Philips Defendants further expect additional cases will be filed in state court and removed in the coming months, mirroring the likelihood of ongoing waves of remand motion practice. It would waste this Court's valuable resources to consider the current slate of remand motions while additional remand motions continue to be filed that raise overlapping issues more efficiently resolved in a consolidated, rather than piecemeal, fashion.

Moreover, the economic loss claims of any plaintiffs seeking remand are subject to the Proposed Settlement. If the Proposed Settlement receives preliminary Court approval, then these members of the settlement class will be enjoined from further litigating their economic loss claims and should be provided an opportunity to evaluate Court-approved notice and consider their options, including whether they would like to participate in the settlement, if approved. Certain current and/or future claims that are the subject of remand motions may be resolved, in whole or in part, by the Proposed Settlement. Remand motion briefing should therefore be adjourned to

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[1] *See* ECF Nos. 1842 (*Traversa* Remand Motion), 2127 (*Trueblood* Remand Motion); 2194 (*Graham* Remand Motion), 2195 (*Dobbs* Remand Motion); *see also Murray v. Koninklijke Philips N.V., et al.*, No. 2:23-cv-00627-JFC (W.D. Pa.) (ECF No. 2); *Papsun, et al. v. B. Braun Medical, Inc., et al.*, No. 2:23-cv-01211-JFC (W.D. Pa.) (ECF No. 7).

[2] *See* Plaintiffs' Notice of Motion to Remand, *Lis v. Koninklijke Philips N.V., et al.*, No. 1:23-ccv-00907 (W.D.N.Y. Sept. 11, 2023) (ECF No. 9) ("*Lis* Remand Motion").

allow Plaintiffs time to consider Court-approved notice of the Proposed Settlement and to make informed decisions about whether to participate in the settlement and resolve certain claims without further litigation.

BACKGROUND

On August 25, 2022, the Court entered Pretrial Order No. 22, which established a schedule for the filing and briefing of remand motions. *See* ECF No. 701. On April 18, 2023, the parties jointly moved to extend the remand motion deadlines in light of the continued filing of state court cases and related removals and remand motions. *See* ECF 1807. On May 17, 2023, the Court granted the parties' motion and issued an order modifying Pretrial Order No. 22 and establishing the current remand briefing schedule. *See* ECF No. 1901. Pursuant to the modified schedule, remand motions were due on August 31, 2023, with responses due by October 31, 2023, and replies, if any, due by November 30, 2023. *Id.* Plaintiffs in six actions (the "Remand Actions") filed remand motions by the August 31, 2023 deadline. *See supra* n.1.

Since the August 31, 2023 deadline, further state court actions have been filed and removed. In fact, one additional remand motion was filed on September 11, 2023, in the *Lis* action, which is currently proceeding in the Western District of New York pending transfer to this Court.

On September 7, 2023, Plaintiffs filed an unopposed motion for preliminary approval of a class action settlement of the economic loss claims pending in this MDL. *See* ECF No. 2212. The Proposed Settlement releases all economic loss claims brought against the "Released Parties" by any person or entity who purchased, leased, rented, paid for (in whole or in part), or was prescribed a recalled device. *See* ECF No. 2213 at 1. "Released Parties" include, among others, the Philips Defendants and "all current, former or future distributors, sellers, insurers, reinsurers, resellers, lessors, retail dealers, and DME providers for the Recalled Devices." *See* ECF No. 2213-1 at 8.

In addition to seeking preliminary approval of the Proposed Settlement, Plaintiffs' motion requests that the Court "stay and enjoin the continued pursuit of all Economic Loss Claims" until the Court has determined whether to finally approve the Proposed Settlement. *See* ECF No. 2212 at 1. Under the Proposed Settlement, notice of the settlement will be disseminated to class members within 60 days after entry of the preliminary approval order, and class members will have 120 days from entry of that order to opt out of or object to the settlement. A preliminary approval hearing is scheduled for September 18, 2023. *See* ECF No. 2218.

ARGUMENT

I. REMAND MOTION BRIEFING SHOULD BE ADJOURNED IN LIGHT OF THE CONTINUED FILING OF STATE COURT ACTIONS AND REMAND MOTIONS.

As noted above, per modified Pretrial Order No. 22, existing actions in the MDL were required to file remand motions by August 31, 2023, responses are due on October 31, 2023, and replies are due on November 30, 2023. *See* ECF No. 1901. Despite these deadlines, recall-related state court actions and remand motions continue to be filed with regularity in courts across the country. Indeed, since the Court established the current remand motion briefing schedule on May 17, 2023, sixteen recall-related cases have been removed to federal court and transferred to this MDL. Two of those cases were removed after the August 31, 2023 deadline for filing remand motions, and in one of those cases (*Lis*), a remand motion has already been filed in the transferor court while the matter is pending transfer. *See supra* n.2. The Philips Defendants expect that additional state court actions, removals, and remand motions will be filed in the coming months. This is particularly so in light of the Proposed Settlement, as those who wish to opt out of the settlement but who have not yet filed suit may initiate state court actions, thereby leading to more removals and remand motions.

Adjournment of the remand motion briefing schedule is warranted given the continued

filing of state court cases and related removals and remand motions, and the overlapping nature of many removal and remand arguments. For example, the remand motion filed on September 11, 2023 in the *Lis* action—which is pending in the Western District of New York and has been tagged for transfer to the MDL—makes fraudulent joinder arguments substantially similar to those being made in the Remand Actions.[3] It would waste the Court's resources to consider those and other remand issues now, only to be faced with the same issues and engage in duplicative analysis after *Lis* is transferred and yet again months from now after more state court cases are filed, removed, and transferred to this Court. Deferring remand motion briefing until the landscape is more settled will more efficiently use party and judicial resources and avoid redundant motion practice.

II. REMAND MOTION BRIEFING SHOULD BE ADJOURNED IN LIGHT OF THE PROPOSED SETTLEMENT AND RELEASE OF ECONOMIC LOSS CLAIMS.

Adjournment of the current remand motion briefing schedule is further warranted in light of Plaintiffs' recently-filed and unopposed motion for preliminary approval of the Proposed Settlement of economic loss claims.

Certain currently-pending (and/or potentially future-filed) claims that will be the subject of remand motions may be resolved, in whole or in part, by the Proposed Settlement. For example, plaintiffs in at least four of the six pending Remand Actions—the *Murray*, *Trueblood*, *Papsun*,

[3] *Compare Lis* Remand Motion at 1 (arguing that "diversity jurisdiction does not exist" because "the company that distributed and sold the harm-causing product" was not "fraudulently joined"), *with Graham* Remand Motion (ECF No. 2194-1) at 1 ("Defendants' contention diversity jurisdiction exists because Gould's was fraudulently joined is without merit.") *and Traversa* Remand Motion (ECF No. 1824) at 12 ("Montgomery Medical is rightly joined as a party in this matter and was not fraudulently joined for the purposes of defeating diversity.").

and *Traversa* Plaintiffs—assert claims for economic loss.[4] Such claims may be resolved, in whole or in part, by the Proposed Settlement should those plaintiffs choose not to opt out. The release of such claims may impact the nature of those plaintiffs' remand arguments and/or their desire to continue litigating their remaining claims. Remand motion briefing should therefore be adjourned so that these plaintiffs may review Court-approved notice of the Proposed Settlement and consider whether to participate in or opt out of the settlement, as well as its impact, if any, on their claims and/or any jurisdictional issues raised or to be raised in their remand motions.

Moreover, the pending motion for preliminary approval of the Proposed Settlement seeks to stay and enjoin all litigation of economic loss claims pending final approval of the Proposed Settlement, and courts regularly grant such relief so that class members may review the settlement terms and consider their options under the settlement. *See, e.g.*, *Q+ Food, LLC v. Mitsubishi Fuso Truck of Am., Inc.*, No. 14-CV-06046-DEA, 2016 WL 7213278, at *4 (D.N.J. Oct. 26, 2016) (preliminarily approving class action settlement and staying all proceedings pending settlement approval process in order to "conserve the parties' and various courts' resources" and "preserve the Settlement for a short period of time while class members receive notice and evaluate their options"); *Bisch v. Bontempo*, No. 2:13-CV-01392, 2014 WL 12596984, at *3 (W.D. Pa. Mar. 3,

[4] *See, e.g.*, **Exhibit A** (*Trueblood* Remand Motion (ECF No. 2127-1)) at 2 (stating "Plaintiff has not experienced any health issues, cancer, or other physical consequences of using the device," "is not claiming medical damages, lost earnings, or loss of consortium," and "has lost only the money he paid for the device, and the money he expended buying a new device"); **Exhibit B** (*Murray* Complaint) ¶ 56 (alleging that Plaintiff suffered "damages and ***economic loss*** and will continue to suffer such harm, damages and ***economic loss***"); **Exhibit C** (*Papsun* Complaint) ¶ 269 (alleging Plaintiff has suffered "***economic loss*** and will continue to suffer such harm, damages and ***economic loss*** in the future"); *id.* ¶ 285 (alleging plaintiff suffered "physical, mental and emotional injuries and harm, and ***economic*** loss"); *id.* ¶ 305 (alleging plaintiff "has suffered serious physical injury, harm damages and ***economic loss*** and will continue to suffer such harm, damages and ***economic loss***"); *id.* ¶ 310 (same); **Exhibit D** (*Traversa* Complaint) ¶ 122 (alleging plaintiff "suffered damages in the form of lost income; hospital bills; lost quality of life; pain and suffering; emotional distress; and ***other damages of both an economic and non-economic nature***.").

2014) (preliminarily approving class action settlement and staying "[a]ll proceedings in the Action, other than proceedings as may be incident to carry out the terms and conditions of the [settlement]"). Briefing of remand motions should likewise be deferred so that the remand plaintiffs may review the settlement documentation, understand the relief provided therein, and make informed decisions about whether to participate in the Proposed Settlement and resolve their claims without further litigation, and whether and to what extent the Proposed Settlement affects their remand position.

CONCLUSION

The Philips Defendants respectfully request that the Court enter an order (i) adjourning the schedule for briefing remand motions, and deferring the Court's consideration of and ruling on such motions, and (ii) setting the deadline to oppose remand motions for 30 days after the deadline to opt out of the Proposed Settlement, with reply briefs (if any) due 30 days later.

Dated: September 18, 2023

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on September 18, 2023, the foregoing document was electronically filed with the Clerk of the Court and served upon counsel of record through the Court's ECF system.

/s/ John P. Lavelle, Jr.
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Exhibit A

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UNITED STATES DISTRICT COURT

WESTERN DISTRICT OF PENNSYLVANIA

ALEXANDER TRUEBLOOD, Plaintiff, vs. PHILIPS NORTH AMERICA LLC, KONINKLIJKE PHILIPS ELECTRONICS N.V., and DOES 1-25, Defendants.	Case No: 2:23-CV-01304-JFC MDL Case No: 21-MV-1230 **MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF MOTION TO REMAND ACTION TO STATE COURT** Date: TBD Time: TBD Courtroom: 5A

I. INTRODUCTION

A. Factual Background

This is a products liability action against a medical device manufacturer, concerning the Phillips Bi-Level Positive Airway Pressures device, with the tradename Dreamstation. This device regulates breathing pressure via positive airflow delivered through tubing and a mask, and is used to treat sleep apnea during the sleep cycle. Plaintiff has sleep apnea, and purchased the product. Phillips subsequently recalled the product in June, 2021, advising the public that the device contains polyurethane foam which degrades, and can cause health consequences, including respiratory issues and cancer.

B. Procedural History

Plaintiff filed this action in the Los Angeles Superior Court on May 30, 2023. The complaint alleges claims for negligence, strict products liability, and breach of warranty, all of which arise exclusively under state law. There is no federal claim and the complaint does not allege damages exceeding $75,000. The complaint merely states that the Los Angeles Superior Court has jurisdiction because the amount in controversy exceeds $25,000. Complaint, ¶ 6. Plaintiff has not sought non-monetary remedies or punitive damages. Complaint, Prayer for Relief, p. 5. There are no claims in the complaint under which either party could claim attorneys fees, and plaintiff has not sought them. Id.

Plaintiff has not yet served any defendant with the state court complaint. However, defendant Phillips North America, LLC ("Phillips") apparently learned of the complaint from the state court docket, and removed the case to United States District Court, Central District of California, on June 28, 2023, alleging diversity jurisdiction. Defendant Koninklijke Philips Electronics N.V. ("Royal Philips") did not join in the removal. Defendant Phillips served the removal petition on plaintiff on June 28, 2023 by mail, and plaintiff's statutory deadline to move to remand was therefore July 31, 2023. Trueblood Decl., ¶ 2.

After removal, defendant Phillips filed a motion to stay the case in the Central District of California, pending transfer to the MDL, styled Philips Recalled CPAP, Bi-Level PAP, And Mechanical Ventilator Products Litigation (MDL No. 3014, W.D. Pa.). On July 17, 2023, the MDL Panel issued a conditional order transferring this case into the MDL. The transfer to the MDL became effective on or about July 20, 2023, when the Western District of Pennsylvania accepted the transfer. Plaintiff opposed the motion to stay, because of his intent to move for a remand, which would render the stay issue moot. Defendant Phillips subsequently informed the Central District of California that its motion to stay was withdrawn as moot, due to the MDL transfer.

B. Present Motion To Remand

There is a "strong presumption" against removal jursidiction. Gaus v. Miles, Inc., 980 F.2d 564, 566 (9th Cir. 1992). Accordingly, the removal statute is strictly construed against removal. Schmitt v. Ins. Co. of North America, 845 F.2d 1546, 1551 (9th Cir. 1988). A case must be remanded if there is any doubt at all about the propriety of removal. Gaus v. Miles, 980 F.2d at 566;; Libhart v. Santa Monica Dairy Co., 592 F.2d 1062, 1064 (9th Cir. 1979). The removing defendant bears the burden of proof to show that all procedural requirements of removal have been met. Gaus, supra, 980 F.2d at 566.

Defendant cannot meet its burden to show that removal was proper in this case. The amount in controversy in this matter does not exceed $75,000. Plaintiff has not experienced any health issues, cancer, or other physical consequences of using the device, and is not claiming medical damages, lost earnings, or loss of consortium. Plaintiff has lost only the money he paid for the device, and the money he expended buying a new device after the recall, and seeks compensation for future medical monitoring, and a modest sum of emotional distress damages. Plaintiff seeks no punitive damages or attorneys fees. Plaintiff's total damages do not exceed $75,000, and this Court therefore has no diversity jurisdiction.

The removal petition is also defective in that it fails to properly allege complete diversity of citizenship. The notice of removal fails to allege what type of entity defendant Koninklijke Philips Electronics N.V. is, i.e. a corporation, a limited liability company, or some other unincorporated association. The "N.V." in this defendant's name suggests it is a foreign limited liability company, but defendant has not alleged the citizenship of all members of the foreign LLC, as required by well-settled law. Moreover, even if this entity were a corporation formed in the Netherlands, defendant failed to allege whether it is also incorporated in any U.S. state. Each such U.S. state counts toward the diversity analysis.

Finally, defendant failed to allege complete diversity of citizenship both at the time of removal, and the time of filing of the complaint, which is another defect in the removal petition requiring a remand.

II. ARGUMENT

A. The Amount In Controversy Does Not Exceed $75,000

The court does not have diversity jurisdiction because the amount in controversy is $75,000 or less. Plaintiff's complaint alleges only that the amount in controversy exceeds $25,000. Complaint, ¶ 6. The complaint does not allege anywhere that plaintiff suffered any physical injury from the device, only that he was generally "harmed" by the defective product. Complaint, ¶ 14. The removal petition speculates that plaintiff suffered severe physical injury or impairments, but that is not in the complaint, and is not the reality.

Plaintiff was not physically injured by the device to his knowledge,[1] and is claiming no bodily injury, medical expenses, loss of work, reduced earning capacity, or loss of consortium. Trueblood Decl., ¶ 3. Plaintiff is claiming damages for certain harms, but they do not add up to more than $75,000. Plaintiff seeks only

[1] At least at this time, plaintiff is not aware of any physical damage or bodily injury caused by the device. The amount in controversy is measured at the time of the complaint and removal, not in the future. Strotek v. Air Trasnp. Ass's of America, 300 F.3d 1129, 1131 (9th Cir. 2002); Reece v. Bank of New York Mellon, 760 F.3d 771, 777-778 (8th Cir. 2014).

the original cost of the now worthless device (approximately $1,800), the replacement cost for a new device from another manufacturer (approximately $1,000), 16 future years of medical monitoring expenses in the amount of $16,000, and emotional distress in a sum which does not exceed $35,000. Trueblood Decl., ¶ 3. The complaint does not seek punitive damages. Accordingly, the amount in controversy is about $53,800 at the most. The removing defendant bears the burden of proof on the amount in controversy, and defendant has not met that burden. McPhail v. Deere & Co., 529 F.3d 947, 954 (10th Cir. 2008).

The removal petition wrongly asserts that attorneys fees and costs may be counted as part of the amount in controversy. The diversity jurisdiction statute specifically states that the amount in controversy must exceed $75,000, "exclusive of interest and costs." 28 U.S.C. § 1332(a). Attorneys fees can be added to the amount in controversy only if a statute authorizes the successful plaintiff to recover them. Suber v. Kontinental Koaches, Inc., 104 F.3d 578, 585 (3rd Cir. 1997); Galt G/S v. JSS Scandinavia, 142 F.3d 1150, 1155 (9th Cir. 1988)("[W]hen there is no direct legal authority for an attorney's fee, a request for a fee cannot be included in the computation or the jurisdictional amount"). In this ordinary products liability case, there is no statute or contract authorizing attorneys fees, and plaintiff has not sought attorneys fees in the complaint.

B. The Notice of Removal Fails To Allege The Citizenship Of Defendant Royal Philips

Complete diversity of citizenship between the plaintiff and each defendant is required to establish federal diversity jurisdiction. 28 U.S.C. § 1332(a). The citizenship of unserved defendants must be considered when determining if complete diversity exists. Pechaski v. General Motors Corp., 636 F.2d 1156, 1160 (8th Cir. 1981); Pullman v. Jenkins, 305 U.S. 534, 541 (1939).

The notice of removal fails to properly allege the jurisdictional facts needed to prove the citizenship of defendant Royal Philips. The notice of removal fails to

allege whether this entity is a corporation or some other type of entity. Plaintiff alleged that "Defendant Koninklijke Philips Electronics N.V. is a foreign entity *of unknown form* based in Amsterdam, the Netherlands." Complaint, ¶ 10. Thus, plaintiff did not allege whether Royal Philips is a traditional corporation or something else.

The notice of removal only alleges that Royal Philips is "a foreign entity" but does not state whether it is a corporation, a limited liability company, or some other type of unincorporated association. Notice of Removal, ¶¶ 30 and 32. The Notice of Removal does state that Royal Philips is generically "incorporated" in the Netherlands, but not whether it was incorporated as a traditional corporation, or as a limited liability company, or some other form of entity. Notice of Removal, ¶ 31. Moreover, Exhibit D to the Notice of Removal, an SEC Form 20-F, states nothing about the form of the Royal Philips entity, either.

The actual legal form of Royal Philips is relevant to diversity of citizenship, for two reasons. First, if Royal Philips is not a corporation, but an LLC or other non-corporation, which appears to be the case based on its name, the removal petition had to identify the citizenship of all of its members, and establish complete diversity as to all of those members, but did not. Secondly, if Royal Philips is a corporation, the removal petition fails to state in which U.S. states it is incorporated.

Koninklijke Philips Electronics N.V. appears to be a limited liability company, based on the term "N.V." in its name. According to Investopedia, the term N.V. "is an acronym for Naamloze Vennootschap, a public limited liability company in the Netherlands and other Dutch-influenced nations." Plaintiff requests that the court take judicial notice of Investopedia's website page on this topic, which is https://www.investopedia.com/terms/n/nv-nv-or-naamloze-vennootschap.asp.

There is no statutory rule governing the citizenship of non-corporations, such

as an LLC. The principal place of business of an entity other than a corporation, is irrelevant to diversity jurisdiction. Lincoln Property Co. v. Roch, 546 U.S. 81, 84 n.1 (2005). That is because the citizenship of an LLC (and other non-corporations) is determined by the citizenship of *each of its members*, all of whom are part of the diversity analysis. Americold Realty Trust v. Conagra Foods, Inc., 577 U.S. 378, 379 (2016)("While humans and corporations can assert their own citizenship, other entities take the citizenship of their members"); Carden v. Arkoma Assocs., 494 U.S. 185, 195 (1990)(citizenship of entities other than corporations is determined by the individual citizenships of all of their members); D.B. Zwirn Special Opportunities Fund, L.P. v. Mehrotra, 661 F.3d 124, 125 (1st Cir. 2011)(limited liability company); Bayerische Landesbank, New York Branch v. Aladdin Capital Management LLC, 692 F.3d 42, 49 (2d Cir. 2012)(limited liability company).

Thus, the removing party must identify and allege the citizenship of all members of a limited liability company party, to establish complete diversity. However, defendant Philips failed to do this in its removal petition as to Royal Philips.

Moreover, even if Royal Philips is a corporation – a fact unknowable by reading the removal notice -- it is a citizen of both the Netherlands and any U.S. state in which it is also incorporated. 28 U.S.C. § 1332(c)(1). However, the Notice of Removal is silent about whether Royal Philips is incorporated in any U.S. state, including California, and therefore the petition does not adequately allege complete diversity.

Accordingly, there is no removal jurisdiction here, because complete diversity of citizenship has not been properly alleged. The burden is on the removing defendant to allege and prove the jurisdictional facts supporting removal jurisdiction. Geographic Expeditions, Inc. v . Estate of Lhotka, 599 F.3d 1102, 1107 (9th Cir. 2010). If the complaint does not disclose the citizenship of each party, the notice of removal must do so, or the case must be remanded. Rolling

Greens MHP, L.P. vc. Comcast SCH Holdings, L.L.C., 374 F.3d 1020, 1021-22 (11th Cir. 2004); Barnhill v. Ins. Co. of North America, 130 FRD 36 (D. SC. 1990).

C. The Notice of Removal Fails To Allege Diversity At The Time Of Filing and The Time of Removal

The removal petition must allege diversity both at the time the action was filed, and at the time of removal. Reece v. Bank of New York Mellon, 760 F.3d 771, 777 (8th Cir. 2014)("Mellon's notice of removal is defective because it fails to specify Reece's citizenship when the suit was commenced"); Strotek v. Air Trasnp. Ass's of America, 300 F.3d 1129, 1131-1132 (9th Cir. 2002).

Defendant's removal petition alleges the citizenship of the parties only at the time of removal, not at the time suit commenced, and is therefore defective. Notice of Removal, ¶¶ 26, 27, 31.

III. CONCLUSION

For all of the foregoing reasons, plaintiff respectfully requests that the case be remanded to the Superior Court of the State of California, County Of Los Angeles.

Dated: July 28, 2023

Respectfully Submitted,
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Exhibit B

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SUPERIOR COURT FOR THE STATE OF CALIFORNIA

FOR THE COUNTY OF SANTA BARBARA

NORTH COUNTY

ROBERT MURRAY, Plaintiff vs. KONINKELIJKE PHILIPS N.V.; PHILIPS NORTH AMERICA LLC; PHILIPS HOLDING USA, INC.; PHILLIPS DS NORTH AMERICA LLC; PHILIPS RS NORTH AMERICA LLC; and DR. JEFFREY R. POLITO, MD, Does 1 to 25, inclusive Defendants	No. **COMPLAINT – PRODUCT LIABILITY, FAILURE TO WARN**

Robert Murray ("Plaintiff" herein), by and through his undersigned counsel, hereby submits the following Complaint and Demand for Jury Trial against Defendants Koninkelijke Philips N.V. ("Royal Philips" herein), Philips North America LLC ("Philips NA" herein), Philips Holding USA, Inc. ("PHUSA" herein), Philips RS North America LLC ("Philips RS" herein) (collectively referred to as "Philips" herein) and Dr. Jeffrey R. Polito, MD ("Polito"

herein) cumulatively referred to as "Defendants" herein, alleges the following on personal knowledge, information and belief as follows:

ALEGATIONS COMMON TO ALL CAUSES OF ACTION

1. Plaintiff is a 66-year-old individual. At all times relevant, Plaintiff has been a resident domiciliary of the city of Lompoc, Santa Barbara County, California.
2. Defendant Koninklijke Philips N.V. ("Royal Philips") is a public limited liability company established under the laws of The Netherlands, having its principal executive offices at Philips Center, Amstelpein 2, 1096 BC Amsterdam, The Netherlands. Royal Philips is the parent company of Philips NA, Phillips USA LLC, Phillips DS and Philips RS.
3. Defendant Philips North America LLC ("Philips NA") is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Floor 3, Cambridge, MA 02141. Philips NA is a wholly-owned subsidiary of Royal Philips. Upon information and belief, Philips NA manages the operation of Royal Philips' various lines of business, including Philips RS, in North America. Philips NA may be served through its registered agent, Corporation Service Company dba CSC-Lawyers Incorporating Service, 2710 Gateway Oaks Drive, Suite 150N, Sacramento CA 95833
4. Defendant Philips Holding USA, Inc. ("PHUSA") is a Deleware corporation with its principal place of business located at 222 Jacobs Street, Floor 3, Cambridge, MA 02141. PHUSA is a holding company that is the sole member of Philips NA. PHUSA may be served through its registered agent, Corporation Service Company dba CSC-Lawyers Incorporating Service, 2710 Gateway Oaks Drive, Suite 150N, Sacramento CA 95833
5. Defendant Philips RS North America LLC ("Philips RS") is a Delaware limited liability company with its principal place of business located at 6501 Living Place, Pittsburgh, PA 15206. Philips RS was formerly operated under the business name Respironics, Inc. ("Respironics"). Royal Philips acquired Respironics in 2008. Philips

RS may be served through its California registered agent, Corporation Service Company dba CSC-Lawyers Incorporating Service, 2710 Gateway Oaks Drive, Suite 150N, Sacramento CA 95833

6. Phillips DS North America LLC ("Phillips DS") is also a Delaware LLC with its principal place of business in121251 Research Parkway, Orlando, FL 32826 and it may be served through its California registered agent, Corporation Service Company dba CSC-Lawyers Incorporating Service, 2710 Gateway Oaks Drive, Suite 150N, Sacramento CA 95833
7. Royal Philips, Philips NA, PHUSA, Phillips DS and Philips RS are hereinafter collectively referred to as to as "Philips."
8. Defendant Jeffrey R. Polito, MD is a medical doctor specializing in internal medicine and sleep medicine. Polito's place of business is 5333 Hollister Ave., Suite 225, Goleta, CA 93111. All Polito's interactions with Plaintiff took place in Santa Barbara County, California.
9. Plaintiff does not know the names or capacities of the defendants sued herein as DOES and he therefor sues such defendants by those fictitious names. Each of these defendants is legal responsible to Plaintiff on account of the acts and facts set forth herein by reason of its conduct or its agency and /or employment by the other defendants, or any of them.
10. At all times relevant to this Complaint, Philips were and are in the business of designing, manufacturing, marketing, promoting, advertising and selling devices for the treatment of Obstructive Sleep Apnia ("OSA" herein), including the device prescribed by Polito for Plaintiff.
11. At all times relevant to this Complaint, Philips were the mere alter egos or instrumentalities of each other. There is such a unity of interest and ownership between and amongst Philips that the separate personalities of their entities ceased to exist. Philips operated as a single enterprise, equally controlled each other's business affairs, commingled their assets and funds, disregarded corporate formalities and used

each other as a corporate shield to defeat justice, perpetuate fraud and evade contractual and/or tort liability.

12. At all times relevant to this Complaint, Philips acted in all respects as agents or apparent agents of one another.

13. At all times relevant to this Complaint, Philips acted in concert in the designing, manufacturing, marketing, promoting, advertising and selling of devices for the treatment of OSA, including the Phillips device purchased and used by Plaintiff. Philips combined their property and labor in joint undertaking for profit, with rights of mutual control over each other, rendering them jointly liable to Plaintiff.

14. Philips regularly transacts business in California that includes marketing, advertising, promoting and selling devices for the treatment of OSA, derive substantial revenue from their business transactions in California, and have purposely availed themselves of the privilege of doing business in California. Phillips shipped or participated in shipping the CPAP device purchased and used by Plaintiff and other devices with the reasonable expectation that the devices could or would find their way to California through the stream of commerce.Philips' actions in marketing and selling their devices in California should have led them to reasonably anticipate being subject to the jurisdiction of Courts in California.

Philips have sufficient "minimum contacts" with California that subjecting them to personal jurisdiction in California does not offend traditional notions of fair play and substantial justice. This Court has personal jurisdiction over Philips because of its systematic and continuous contacts with California

15. As detailed below, Plaintiff suffered injuries in Santa Barbara County, California from the subject device that Philips negligently designed and/or manufactured. Philips tortious conduct caused injuries in California, and the Court has personal jurisdiction over Philips under California's Long Arm Statute. This Court has personal jurisdiction over Philips because of their systematic and continuous contacts with California, as well as their maintenance of a registered agent for service of process in California.

16. This Court is the proper venue for this case as the events giving rise to Plaintiff's claims occurred in Santa Barbara County, California.

17. At all relevant times, Philips manufactured, marketed, sold and distributed a line of CPAP, BPAP and ventilator devices under its "Sleep & Respiratory Care" portfolio. These devices are designed to assist individuals with a number of sleep, breathing and other respiratory conditions, including OSA.

18. Polito is a sleep specialist, who regularly prescribes CPAP machines to his patients with OSA, including plaintiff.

19. In or about 2015, Polito prescribed a "Respironics" brand CPAP "Pro" machine manufactured and distributed by Phillips to Plaintiff for control of his OSA and Plaintiff purchased such machine. This will be referred to as "the subject device."

20. Philips had sought and obtained Food and Drug Administration ("FDA") approval to market the various CPAP devices, including the subject device prescribed by Polito and used by Plaintiff, under §510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act. §510(k) allows marketing of medical devices if the device is deemed substantially equivalent to tother legally marketed predicate devices marketed prior to May 28, 1976. No formal review for safety or efficacy was required.

21. Continuous Positive Airway Pressure ("CPAP") therapy is a common non-surgical treatment primarily used to treat OSA. CPAP therapy typically involves the use of a facemask through which the device pushes a constant flow of air into an individual's trachea during sleep.

22. OSA is a common sleep disorder characterized by repeated interruptions in breathing throughout an individual's sleep cycle. These interruptions, called "apneas," are caused when the soft tissue in an individual's airway closes. The airway closure prevents oxygen from reaching the individual's kidneys, which can cause a buildup of carbon dioxide.

23. Philips utilized polyester-based polyurethane (PE-PUR) sound abatement to dampen device vibration and sound on the Phillips CPAP device purchased and used by Plaintiff.

24. On April 26, 2021, as part of its Quarterly Report for the first quarter of the 2021 fiscal year, Philips disclosed for the first time, under a section entitled "Regulatory Update," that device user reports had led to a discovery that the type of PE-PUR "sound abatement" foam Philips used to minimize noise in several CPAP and BPAP devices, including the devise prescribed by Polito and purchased and used by Plaintiff nightly posed health risks to its users. Specifically, Philips disclosed that "the [PE-PUR] foam may degrade and release carcinogens into the sleeping user's body.

25. On June 14, 2021, as a result of extensive ongoing review following the announcement on April 26, 2021, Philips issued a recall notification for specific affected devices[1] including the CPAP device prescribed by Polito in 2015 and owned and used continuously by Plaintiff since 2015 (herein sometimes "the Recalled Devices"). In its recall notification, Philips reported that, based on lab testing and evaluations, it was possible that these potential health risks of the use of the CPAP machine containing PE-PUR sound abatement foam could result in a wide range of potential patient impacts, from transient potential injuries, symptoms and complications, as well as possibly serious injury which can be life-threatening or cause permanent impairment, or require medical intervention to preclude permanent impairment,[2] including but not limited to the risk of suffering from "headache, irritation [skin, eye and respiratory tract], inflammation, respiratory issues, and possible toxic and carcinogenic effects" whereas the "potential risks of chemical exposure due to off-gassing include headache, irritation, hypersensitivity, nausea/vomiting, and possible toxic and carcinogenic effects."[3] The carcinogenic effects were kidney cancer and other possible cancers.

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[1] *Medical Device recall notification* (U.S.only)/*field safety notice* (international markets), PHILIPS RESPIRONICS (June 14, 2021), https://www.usa.philips.com/healthcare/e/sleep/communications/src-update#section_2 (accessed September 19, 2022)

[2] Id.

[3] *Philips issues recall notification*, PHILIPS RESPIRONICS (June 14, 2021), https://www.usa.philips.com/a-w/about/news/archive/standard/news/press/2021/20210614-philips-issues-recall-notification-to-mitigate-potential-health-risks-related-to-the-sound-abatement-foam-component-in-certain-sleep-and-respiratory-care-devices.html (accessed September 19, 2022)

26. On June 14, 2021, Philips also issued a brief report entitled "Clinical Information for Physicians." In this report, Philips disclosed that "lab analysis of the degraded foam reveals the presence of potentially harmful chemicals including: Toluene Diamine, Toluene Diisocyanate, Diethylene Glycol." Philips also disclosed that laboratory testing performed by and for Philips has also identified the presence of Volatile Organic Compounds (VOCS) which may be emitted from the sound abatement foam component of the affected devices. "VOCs are emitted as gases from the foam included in the [affected devices] and may have short- and long-term health effects. Standard testing identified two compounds of concern may be emitted from the foam that are outside of safety thresholds. The compounds identified are the following: Dimethyl Diazine, Phenol, 2,6-bis (1,1,-demethylethyl)-4-(1-methylpropyl)."[4]

27. Philips issued the following advice to patients using an of the recalled devices: "For patients using BiLevel Pap and CPAP devices: Discontinue use of affected units and consult with physicians to determine the benefits of continuing therapy and potential risks."[5]

28. Philips did not contact end users of the Recalled Devices and inform them of the recall.

29. At some point after the recall was issued by Philips, Polito became aware of it. Polito knew that he had prescribed Recalled Devices. Polito did not inform Plaintiff of the Philips recall.

30. Plaintiff Robert Murray is a southern California native. Plaintiff graduated from the University of California, Santa Barbara. Plaintiff has lived and worked in Santa Barbara County since 1972. Plaintiff and his wife of 46 years raised three children (two daughters and a son) all of whom served in the United States military.

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[4] https://www.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/philips-recall-clinical-information-for-physicians-and-providers.pdf

[5] *Medical Device recall notification* (U.S.only)/*field safety notice* (international markets), PHILIPS RESPIRONICS (June 14, 2021), https://www.usa.philips.com/healthcare/e/sleep/communications/src-update#section_2 (accessed September 19, 2022)

31. In 2015, Plaintiff sought treatment from Polito for difficulty sleeping. Plaintiff underwent a sleep study, after which Polito determined Plaintiff had sleep apnea.
32. To treat Plaintiff's OSA, Polito prescribed the Philips/Respironics "Pro" CPAP device. Polito ordered Plaintiff to use the device every night.
33. Plaintiff purchased and used the device routinely and continuously for 7 years.
34. Plaintiff only used the device as instructed, in the manner prescribed by Phillips and Polito.
35. Plaintiff would clean the hose portion of the device from time to time (approximately once every few weeks) with tap water. Plaintiff never cleaned the device with anything other than water.
36. At all times Plaintiff used the subject device, he did so for a purpose for which the subject device was marketed, designed and intended.
37. As a result of using the subject device, Plaintiff has suffered personal injuries including harm to his respiratory system, cellular damage, metastatic disease and kidney cancer.
38. But for Plaintiff's use of the subject device, Plaintiff's injuries would not have occurred.
39. Plaintiff's use of the subject device caused or significantly contributed to his development of metastatic disease and kidney cancer, which has permanently changed and probably shortened his life.
40. By reason of the foregoing, Plaintiff had to undergo significant treatment, including but not limited to the removal of one kidney, and he will be required to undergo further significant treatment in the future. Plaintiff has developed lesions in his kidneys and elsewhere throughout his body.
41. Due to the defective nature of Philips' subject device, Plaintiff has suffered, and will continue to suffer in the future.
42. Plaintiff only became aware of the recall of the subject device after seeing an advertisement by a law firm for a class action lawsuit against Philips for their CPAP devices. Neither Philips nor Polito ever informed Plaintiff of the recall. As a result,

Plaintiff continued to use subject device after being diagnosed with metastatic disease and having a kidney removed.

43. Philips and Polito's failure to inform Plaintiff of the subject device recall contributed to Plaintiff continuing to use the subject device for one year and two months after the recall was issued.

44. As a result of the aforesaid conduct by Phillips in the manufacture, design, sale, distribution, advertisement, and promotion of the CPAP "Pro" device purchased and used by Plaintiff, Plaintiff was injured, resulting in severe mental and physical pain and suffering. As a result of such injuries, Plaintiff has suffered damages for which compensatory damages should be awarded.

45. As a result of Phillips and Polito's oppressive, recklessness and wanton disregard for Plaintiff's health and safety for placing such an unsafe and dangerous product in the stream of commerce and of failing to notify Plaintiff of the subject device recall, Plaintiff is entitled to punitive damages.

COUNT I
STRICT PRODUCTS LIABILITY – DESIGN DEFECT

46. This claim is timely as Plaintiff has two years from the time he knew or should have known of the design defect. Philips issued its recall on June 14, 2021.

47. At all times mentioned herein, Philips were involved in researching, designing, developing, manufacturing, testing, selling and/or distributing the CPAP device purchased and used nightly by Plaintiff, which was defective and unreasonably dangerous.

48. The subject device is defective in its design and/or formulation in that it is not reasonably fit, suitable or safe for its intended purpose. The subject device is defective in design because it causes headaches, irritation of the skin, eye, and respiratory tract, inflammation respiratory issues, asthma, adverse effect to organs (including the kidneys and liver), hypersensitivity, nausea, vomiting, and toxic and carcinogenic effects. It is more dangerous than other available devices indicated for similar conditions and uses, and the utility of the device does not outweigh its risks.

49. The defective condition of the subject device rendered it unreasonably dangerous and/or not reasonably safe, and the device was in this defective condition at the time it left the hands of Phillips. The subject device was expected to and did reach Plaintiff and Polito without substantial change in the condition in which it was designed, manufactured, labeled, sold, distributed, marketed, promoted, supplied, and otherwise released into the stream of commerce. The subject device was used for its intended purposes by Plaintiff and the subject device was not materially altered or modified prior to its use. The subject device is and was being used in a way which the Defendants intended at the time it was prescribed to Plaintiff.

50. The subject device is defective in design because the PE-PUR foam comprising part of the device can degrade into particles that enter the device's air pathway and can off-gas certain chemicals. These characteristics cause, among other problems, kidney cancer.

51. At or before the time the subject device was released on the market and/or sold to Plaintiff, Philips could have designed the product to make it less prone to causing the above listed health harms, a technically feasible safer alternative design that would have prevented the harm Plaintiff suffered without substantially impairing the function of the device.

52. Plaintiff was not able to discover, nor could he have discovered through the exercise of reasonable diligence, the defective nature of the subject device. Further, in no way could Plaintiff have known that Philips had designed, developed, and manufactured the subject device in a way as to create a risk of harm or injury.

53. Philips had a duty to create a device that was not unreasonably dangerous for its normal, intended use and breached this duty.

54. Philips knew or should have known that the recalled devices, including the subject device, would be prescribed to patients and that physicians and patients were relying on them to furnish a suitable device. Further, Philips knew or should have known that patients for whom the recalled devices would be used, such as Plaintiff, could be and would be affected by the defective design and composition of the devices.

55. Philips researched, designed, manufactured, tested, advertised, promoted, marketed, sold, and distributed a defective device which, when used in its intended or reasonably foreseeable manner, created an unreasonable risk to the health of consumers, such as Plaintiff, and Philips are therefore strictly liable for the injuries sustained by Plaintiff.

56. As a direct and proximate result of Philips' placement of the subject device into the stream of commerce and Plaintiff's use of the product as designed, manufactured, sold, supplied, and introduced into the stream of commerce by Defendants, Plaintiff suffered serious physical and mental injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

COUNT II
STRICT PRODUCTS LIABILITY – FAILURE TO WARN

57. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

58. At all times herein mentioned, Philips designed, developed, researched, tested, and knew or should have known about significant cancer risks with subject device.

59. At all times herein mentioned, Philips advertised, promoted, marketed, sold, and distributed the subject device that was used by the Plaintiff.

60. The subject device was expected to and did reach the usual consumers, handlers, and persons coming into contact with said device without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Philips.

61. Philips had an independent duty and continuing duty to warn its customers (patients), the medical community and Plaintiff's physicians about the significance of the risks of cancer and other health harms with the subject device.

62. Plaintiff used the subject device in a manner intended and foreseeable by Defendants.

63. The subject device was defective due to inadequate warnings because Philips knew or should have known that the product created a significantly increased risk of cancer, among other health impacts, and failed to warn the medical community and Plaintiff's

physician of the nature of such risks. Plaintiffs omitted and downplayed the significantly increased risks of cancer and other health risks with the subject device that Plaintiffs knew or should have known from previous testing and research even prior to subject device's FDA approval.

64. The subject device's labeling and warnings were defective because they omitted and inadequately warned of the device's risk of cancer and other health risks.

65. Although physicians are supposed to weigh the risks and benefits before prescribing a medical device, Plaintiffs knew that their deliberate omissions would cause physicians, including Polito, to prescribe the subject device without being able to adequately weigh the risk of device's risk of cancer and other health risks

66. If Philips would have properly warned about the subject device's cancer risk and/or other health harms, no reasonable physician, including Polito, would have recommended or prescribed the subject device because the potential benefits are significantly outweighed by the risk of cancer and/or other harms.

67. Had Philips reasonably provided adequate warnings of cancer, such warnings would have been heeded and no healthcare professional, including Polito, would have prescribed the subject device and no consumer, including Plaintiff, would have purchased and/or used the subject device.

68. As a direct and proximate result of the subject device's defects as described herein, Plaintiff developed cancer, suffered permanent and continuous injuries, pain and suffering, disability and impairment. Plaintiff has further suffered emotional trauma, harm and injuries that will continue into the future. Plaintiff has lost his ability to live a normal life and will continue to be so diminished in the future.

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COUNT III
STRICT LIABILITY – MANUFACTURING DEFECT

Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

69. The subject device was expected and did reach Plaintiff without a substantial change in its condition.

70. The subject device deviated, in terms of construction and quality, from the specifications or planned output in a manner that made it unreasonably dangerous.

71. The subject device was defectively and improperly manufactured and designed by Philips.

72. Philips continued to supply customers with defective and improperly manufactured and designed devices, including the subject device, despite having full knowledge that the devices posed substantial and avoidable bodily injury, including cancer.

73. The foreseeable risks posed by the use of the subject device were known to Philips and could have been avoided.

74. The subject device was defectively manufactured by Philips in that its design and formulation is more dangerous than what an ordinary consumer would expect when used as intended in a reasonably foreseeable manner.

75. The subject device was defectively manufactured in the PE-PUR foam comprising part of the device can degrade into particles that the device's air pathway and can off-gas certain chemicals known to be harmful to humans. These characteristics cause, among other problems, cancer in humans. Plaintiff was unknowingly subjected to receiving different doses of toxins, carcinogens and other deleterious components and contaminants when using the subject device.

76. As a direct and proximate result of the defective manufacture of the subject device, Plaintiff suffered and will continue to suffer damages for the rest of his life, for which he is entitled to recovery.

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COUNT IV
NEGLIGENT DESIGN

77. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

78. At all times relevant to this Complaint, Philips manufactured, designed, marketed, tested, promoted, supplied and/or distributed the subject device, in the regular course of business that Plaintiff consumed.

79. The subject device was designed and intended to be used for the treatment of sleep apnea among other health issues.

80. Philips knew or by the exercise of reasonable care should have known, the use of the subject device was danger, harmful and injurious when used by Plaintiff in a reasonably foreseeable manner.

81. Philips knew or by the exercise of reasonable care should have known, ordinary customers such as Plaintiff would not have realized the potential risks and dangers of the subject device.

82. Philips breached their duty by failing to use reasonable care in the design of the subject device by designing the device such that PE-PUR foam inside the device could produce highly harmful particles and gases that enter the device's airway leading the to the user's respiratory system.

83. The subject device contained and produced chemicals and particles which lead to headaches, irritation of the skin and tissue, eyes, and respiratory tract, inflammation of the respiratory system, asthma, adverse effect to vital organs (including the kidneys), hypersensitivity, nausea, vomiting and cancer, all of which Phillips knew or by the exercise of reasonable care should have, ordinary consumers such as Plaintiff would be victim to.

84. Philips breached their duty when they failed to use commercially-feasible alternative designs to minimize the harms, including but not limited to designing products that prevented exposure to particles and off-gasses from PE-PUR foam, using a kind of noise and vibration reducing foam that did not possess these harmful qualities, using

alternative methods of noise and vibration reduction, and/or preventing PE-PUR foam particles and off-gasses from entering the airway of the device, among many other potential alternative designs.

85. Philips breached their duty by failing to use reasonable care by declining to include an expiration date or "best if used by" date, which increased the potential for the subject device's PE-PUR foam to emit harmful particles and off-gasses.

86. As a direct and proximate result of Philips' negligent design, Plaintiff suffered and will continue to suffer for the rest of his life damages for which he is entitled to recover.

COUNT V
NEGLIGENT FAILURE TO WARN

87. Plaintiff and adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further the states as follows.

88. Philips knew or by the exercise of reasonable care should have known, use of the subject device was dangerous, harmful and injurious when used by Plaintiff in a reasonably foreseeable manner.

89. Philips knew or by the exercise of reasonable care should have known, ordinary consumers such as Plaintiff would not have realized the potential risks and dangers of the subject device.

90. Philips knew or by the exercise of reasonable care should have known the subject device posed serious health risks, because such risks were known and knowable in light of scientific and medical knowledge that was generally accepted in the scientific community at the time of design, manufacture and distribution of the subject device.

91. Philips owed a duty to all reasonably foreseeable users to disclose the risks associated with the use of the subject device.

92. Philips breached their duty of care by failing to use reasonable care in providing adequate warnings to Polito and to Plaintiff in the subject device's labelling, packaging, marketing, promoting and advertising of the subject device.

93. At all times relevant to this Complaint, Philips could have provided adequate warnings and instruction to prevent the harms and injuries set forth herein, such as providing full and accurate information about the subject device to Polito and Plaintiff in advertising, at points of sale, on the subject device's instructions and inserts, and on the subject device's labels.

94. A reasonable company under the same or similar circumstances would have warned and instructed Polito and Plaintiff of the dangers inherent in the subject device.

95. As a medical professional specializing in sleep related issues, Polito knew or by the exercise of reasonable care should have known of the recall of the subject device and similar devices issued by Philips.

96. Polito never contacted Plaintiff to inform him that the subject device which Polito had prescribed and order for Plaintiff had been recalled by Philips.

97. Plaintiff was injured as a direct and proximate result of Defendants' failure to warn and instruct because Plaintiff would not have used or purchased the subject device had he received adequate warnings and instructions that he could be exposed to toxic and carcinogenic particles and off-gasses.

98. Philips' lack of adequate and sufficient warnings and instructions and its inadequate and misleading advertising, labeling, and instructions was a substantial contributing factor in causing the harm to Plaintiff.

99. Polito's failure to warn Plaintiff once he became aware of the subject device's recall were a contributing factor in causing harm to Plaintiff.

100. As a direct and proximate result of Defendants' failure to warn Plaintiff, Plaintiff used and continued to use even after the recall the subject device causing him grievous bodily harm.

COUNT VI
NEGLIGENT MANUFACTURING

101. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

102. Philips had a duty to exercise reasonable care in the manufacturing, assembling, inspecting and packaging of the subject device.

103. Philips knew or by the exercise of reasonable care should have known use of the subject device was carelessly manufactured, assembled, inspected and packaged. Thus, use of the subject device in a reasonably foreseeable manner by ordinary customers such as Plaintiff was dangerous, harmful and injurious.

104. Philips knew or by the exercise of reasonable care should have known ordinary customers such as Plaintiff would not have realized the risks and dangers of the improperly manufactured, assembled, inspected and packaged subject device.

105. Without limitation, Philips breached their duty to exercise reasonable care in manufacturing, assembling, inspecting and packaging the subject device by their:

- Failure to follow Good Manufacturing Practices ("GMPs");
- Failure to adequately inspect/test the subject device during the manufacturing process;
- Failure to adequately determine/test the integrity of PE-PUR foam and its qualities, especially after the subject device had aged and been used contiguously for years
- Failure to adequately determine/test the purity of airflow through the subject devices' airway, especially after the subject device had aged and been used contiguously for years

106. A reasonable manufacturer under the same or similar circumstances would have implemented appropriate procedures to better ensure the quality of their devices.

107. Plaintiff was injured as a direct and proximate result of Philips' failure to use reasonable care in the manufacturing, assembling, inspecting and packaging of the subject device as described herein.

108. Philips' negligent manufacturing, assembling, inspecting and packaging of the subject device was a substantial factor in causing Plaintiff's harms.

COUNT VII
NEGLIGENCE/GROSS NEGLIGENCE

109. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

110. Philips had a duty to exercise reasonable care in designing, developing, testing, researching, manufacturing, marketing, supplying, promoting, selling and distributing of the subject device.

111. Philips knew or should have known that using the subject device created a significantly increased risk of cancer, among other health harms.

112. Philips, their agents, servants and/or employees was negligent via the following acts and omissions:

- Philips designed and developed the subject device without thorough adequate testing;
- Philips sold the subject device without making proper and sufficient tests to determine the dangers to the users;
- Philips failed to adequately and correctly warn the Plaintiff, the public, and the medical community, of the health risks associated with use of the subject device;
- Plaintiffs advertised and recommended the use of the subject device for treatment of sleep apnea and other conditions without sufficient knowledge as to the significance of health risks;
- Philips failed to exercise reasonable care in designing the subject device in a manner which was dangerous to its users;
- Philips negligently manufactured the subject device which was dangerous to its users;
- Philips failed to exercise reasonable care when they collectively decided to conceal information concerning health risks associated with use of the subject device.

113. Philips under-reported, underestimated, and downplayed the serious dangers associated with use of the subject device.

114. Philips failed to warn Plaintiff, prior to actively encouraging the sale of the subject device, either directly or indirectly, orally or in writing, about the need for more comprehensive, more regular medical monitoring than usual to ensure early detection of cancer.

115. Philips specifically failed to exercise reasonable care when they failed to accompany the subject device with proper and/or accurate waring regarding all adverse side effects, chiefly cancer, associated with the use of the subject device.

116. Once Philips gained additional information about the subject device's association with cancer, they failed to warn previous purchasers and prescribers of the CPAP machines using the PE-PUR foam including Plaintiff of the dangers of using those devices.

117. Despite the fact that Philips knew or should have known that the subject device caused unreasonably dangerous side effects, like cancer, they made conscious decisions to downplay these risks and continue to market, manufacture, distribute, and/or sell the subject device to physicians and patients, including Plaintiff.

118. Philips knew or should have known that consumers, such as Plaintiff, would foreseeably suffer injury as a result of Philips' failure to failure to exercise ordinary care, as set forth above.

119. Philips' negligence was the proximate cause of Plaintiff's cancer-related injuries, among many other health harms, which Plaintiff suffered and/or will continue to suffer for the rest of his life.

120. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects that led to his kidney cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of redeveloping cancer.

COUNT VIII
NEGLIGENT MISREPRESENTATION

121. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

122. Defendants had a duty to exercise reasonable care to those whom they provided device information about the Recalled Devices and to all those relying on the information provided, including Plaintiff, his healthcare providers, and the public in general that the devices had been tested and found to be safe and effective for treating sleep apnea.

123. Philips, in the course of selling the Recalled Devices, supplied information about the devices through television commercials, advertisements, marketing campaigns, sales representatives, labeling, and warnings.

124. Philips breached their duty by misrepresenting the Recalled Devices' safety to the medical and healthcare community, to the Plaintiff, and the public in general.

125. Philips failed to exercise reasonable care because their goal should have been to put safety before their profits by advising individuals about the realistic risks and expectations that the Recalled Devices could cause cancer and other serious injuries.

126. Philips' representations were made without properly conducting sufficient testing and by providing insufficient warnings about the Recalled Devices' potential risks.

127. Philips' false representations that the Recalled Devices were safe for consumers and their failure to disclose material past and existing facts of the Recalled Devices' risk of cancer were made or omitted with the intent to induce Plaintiff to rely upon those facts or omissions.

128. Plaintiff was unaware and did not know that the subject device was unsafe for the purpose of treating sleep apnea because it caused a significant increased risk of cancer until after he had been exposed to carcinogenic particles and gasses.

129. Plaintiff justifiably relied upon the false representations of Defendants.

130. Had Defendants reasonably and proposed provided adequate warnings of cancer and other serious injuries, such warnings would have been heeded and no healthcare professional, including Plaintiff's physician, Polito, would have prescribed the subject device and no consumer, including Plaintiff, would have purchased and/or used the subject device.

131. As a direct and proximate result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including kidney cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of redeveloping cancer.

132. As a result of the foregoing acts and omissions, Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

COUNT IX
FRAUD

133. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

134. At all relevant times, Defendants designed manufactured, assembled, inspected, tested, packaged, labeled, marketed, advertised, promoted, supplied, distributed, sold and/or otherwise placed the Recalled Devices into the stream of commerce, and therefore owed a duty of reasonable care to avoid causing harm to consumers, such as Plaintiff.

135. Philips knowingly made fraudulent statements regarding the safety of the Recalled Devices and the substantial health risks associated with using the devices, all the while intending to deceive Plaintiff and the general public.

136. At all reasonable times, Philips fraudulently misrepresented the Recalled Devices as safe, when in fact the devices posed unreasonable risks of substantial bodily injury. Due to these and other features, the Recalled Devices are not fit for their ordinary, intended use as treatment devices for sleep apnea and similar respiratory conditions.

137. Philips had a duty to disclose material facts about the Recalled Devices that would substantially affect Plaintiff's and the general public's use when purchasing the devices.

138. At all reasonable times, Philips fraudulently misrepresented the Recalled Devices as safe, when in fact the devices posed unreasonable risks of substantial bodily injury. Therefore, the devices are not fit for their ordinary and intended uses.

139. At all relevant times, Philips touted the Recalled Devices as safe, despite a failure to adequately research or test the devices to assess their safety prior to marketing and promoting their use and fraudulently and deceptively concealed their failure to adequately research or test the Recalled Devices to assess their safety before marketing to susceptible users.

140. Philips further falsely represented the nature and risks associated with the Recalled Devices, and their marketing and strategy regarding the same, in general statements to the media, general public, and federal agencies.

141. Philips' misrepresentations and omissions were material facts that were essential to Plaintiff's decision making when purchasing and using the subject device.

142. Plaintiff was completely unaware that Defendants were concealing these material facts.

143. Philips intentionally deceived and concealed material information concerning the safety of the Recalled Devices from Plaintiff and the general public, which had a direct impact on Plaintiff's and consumers' health and wellbeing.

144. Philips relied to his detriment on Defendants' fraudulent conduct, concealment and omissions. Had Plaintiff been adequately informed of the material facts regarding the safety of the Recalled Devices, and not intentionally deceived by Defendants, he would not have acquired/purchased, used, or been injured by the subject device.

145. Philips touted the Recalled Devices as safe, despite a failure to adequately research or test the devices to assess their safety prior to marketing and promoting their use. Philips further falsely represented the nature and risks associated with the Recalled Devices, and their marketing and strategy regarding the same, in general statements to the media, general public, and federal agencies.

146. Philips' fraudulent misrepresentations and omissions were material facts that were essential to Plaintiff's decision to purchase the subject device.

147. By knowingly misrepresenting this material information, Philips breached their duty to protect Plaintiff and consumers.

148. Plaintiff justifiably relied to his detriment on Philips' fraudulent statements. Had Plaintiff been adequately informed of the material facts concealed from him regarding the safety of the subject device, and not intentionally deceived by Defendants, he would not have acquired/purchased or used the subject device.

WHEREFORE, plaintiff prays for judgement in his favor and against defendants, and each of them, as follows:

- For his actual past and future damages, according to proof,
- For damages by way of punishment and example, according to proof,
- For his costs and
- For such other relief as may be proper

RICHARD J. WIDEMAN, Esq.
Attorneys for Plaintiff

VERIFICATION

I, Robert Murray, do say and declare

1. I am the plaintiff herein.
2. I have read the Complaint herein.
3. I know of my own knowledge that the allegation herein are true and correct or, as to allegations on information and belief, believe them to be true and correct

Executed at Solvang, California on September 21, 2022

ROBERT MURRAY

Exhibit C

IN THE COURT OF COMMON PLEAS OF LEHIGH COUNTY, PENNSYLVANIA

CIVIL DIVISION

SHERRI PAPSUN,	:	**CIVIL ACTION**
Administratrix of the Estate of	:	
DARRELL G. PAPSUN	:	
3350 Airport Road Trailer 70	:	
Allentown, PA 18109	:	
	:	
Plaintiff,	:	
	:	
vs.	:	
	:	
B. BRAUN MEDICAL, INC.	:	**NO.:**
824 12th Avenue	:	
Bethlehem, PA 18018	:	
and	:	
B. BRAUN OF AMERICA, INC.	:	
824 12th Avenue	:	
Bethlehem, PA 18018	:	
and	:	
B. BRAUN CeGaT, LLC	:	
824 12th Avenue	:	
Bethlehem, PA 18018	:	
and	:	
B. BRAUN INTERVENTIONAL	:	
SYSTEMS, INC.	:	
824 12th Avenue	:	
Bethlehem, PA 18018	:	**JURY TRIAL DEMANDED**
and	:	
PHILIPS RS NORTH AMERICA, LLC	:	
6501 Living Place	:	
Pittsburgh, PA 15206	:	
and	:	
PHILIPS NORTH AMERICA, LLC	:	
222 Jacobs Street, Floor 3	:	
Cambridge, MA 02141	:	
and	:	
PHILIPS HOLDING USA, INC.	:	
222 Jacobs Street, Floor 3	:	
Cambridge, MA 02141	:	
and	:	
JOHN DOE,	:	

a fictitious designation pursuant to Pa. R. CiVS. P. 2005 for any company, entity, corporation, LLC, fictitious name, or person whose name, identity and/or action(s) are presently unknown to Plaintiff but whose wrongful, reckless, and/or negligent misconduct, related to emissions of ethylene oxide from the B. Braun plant located at 901 Marcon Boulevard, Allentown, Pennsylvania 18109, caused harm, injuries, and/or damages to the Plaintiff in this action.

Defendants.

COMPLAINT (CIVIL ACTION)

I. NATURE OF ACTION

1. This is an action for damages arising from the death of Plaintiff's Decedent, Darrell G. Papsun. It is brought pursuant to the Wrongful Death and Survival Acts of Pennsylvania, 42 Pa.C.S.A. §§8301; 8302.

II. THE PARTIES

2. Plaintiff Sherri Papsun, who is a citizen of Pennsylvania, residing therein at the above-captioned address in Lehigh County, has been duly appointed the administratrix and personal representative of the estate of her late husband Darrell G. Papsun, who died intestate on October 3, 2022.

3. In addition to plaintiff, the other individual entitled by law to recover damages in this action is his adult daughter:

i) Stephanie Papsun
3350 Airport Road, Trailer 51
Allentown, PA 18109

4. Defendant, B. Braun Medical, Inc., is a corporation organized, existing, and incorporated under the laws of the Commonwealth of Pennsylvania, with its principal place of business located at 824 12th Avenue, Bethlehem, Pennsylvania 18018.

5. Defendant B. Braun of America, Inc., is a corporation organized, existing, and incorporated under the laws of the Commonwealth of Pennsylvania, with its principal place of business located at 824 12th Avenue, Bethlehem, Pennsylvania 18018.

6. Defendant B. Braun CeGaT, LLC, is a limited liability company organized, existing, and incorporated under the laws of the Commonwealth of Pennsylvania, with a principal place of business located at 824 12th Avenue, Bethlehem, Pennsylvania 18018.

7. Defendant, B. Braun Interventional Systems, Inc., is a corporation organized, existing, and incorporated under the laws of the Commonwealth of Pennsylvania, with a principal place of business located at 824 12th Avenue, Bethlehem, Pennsylvania 18018.

8. John Doe is a fictitious designation made pursuant to Pennsylvania Rule of Civil Procedure 2005 for any company, entity, corporation, limited liability company, fictitious name, or person whose name, identity and/or action(s) are presently unknown to Plaintiff but whose wrongful, reckless, and/or negligent conduct, related to emissions of ethylene oxide from the B. Braun plant located at 901 Marcon Boulevard, Allentown, Pennsylvania 18109, caused harm, injuries, and/or damages to the Plaintiff in this action. After conducting a reasonable search with due diligence, John Doe's actual name is unknown to Plaintiff at this time. A reasonable search to determine the actual name of John Doe has been conducted.

9. At all times relevant hereto, Defendants, B. Braun Medical, Inc., B. Braun of America, Inc., B. Braun CeGaT, LLC, B. Braun Interventional Systems, Inc., and John Doe, directly and by and through their agents, were jointly and collectively engaged in the business of

manufacturing, making, emitting, creating, dispensing, using, handling, transporting, storing, transferring, dispensing, and distributing Ethylene Oxide ("EtO"), which is a chemical that is toxic, ultrahazardous, and a known human carcinogen, at the Defendants' plant located at 901 Marcon Boulevard, Allentown, Pennsylvania 18109 (hereinafter referred to as "Defendants' Plant").

10. At all times relevant hereto, Defendants, B. Braun Medical, Inc., B. Braun of America, Inc., B. Braun CeGaT, LLC, B. Braun Interventional Systems, Inc., and John Doe, directly and by and through their agents, were jointly and collectively engaged in the operation, sterilization of products and devices with EtO, management, running, compliance, safety, supervision of EtO emissions, monitoring of EtO emissions, and the sales, profiting, distribution of products sterilized by EtO, manufacture of products sterilized by EtO, marketing of products, shipment of products, and business at the Defendants' Plant.

11. At all times relevant hereto, Defendants B. Braun Medical, Inc., B. Braun of America, Inc., B. Braun CeGaT, LLC, B. Braun Interventional Systems, Inc., and John Doe, directly and by and through their agents, were jointly and collectively engaged in the process of utilizing EtO to sterilize medical devices, medical instruments, and medical equipment that were manufactured, marketed, assembled, sold, and distributed, at Defendants' Plant.

12. At all times relevant hereto, Defendants B. Braun Medical, Inc., B. Braun of American, Inc., B. Braun CeGaT, LLC, B. Braun Interventional Systems, Inc., and John Doe, directly and by and through their agents, transacted business in the Commonwealth of Pennsylvania by: (1) operating, managing, establishing, running, overseeing, monitoring legal compliance within, supervising, and monitoring Defendants' Plan for the purposes of thereby realizing pecuniary benefit; (2) creating, selling manufacturing, distributing, sterilizing, shipping, marketing, delivering, designing, and receiving medical instruments, devices, and products directly or

indirectly into and through the Commonwealth of Pennsylvania for the purpose of thereby realizing pecuniary benefit; and/or (3) engaging in business in the Commonwealth of Pennsylvania.

13. At all times relevant hereto, Defendants, B. Braun Medical, Inc., B. Braun of America, Inc., B. Braun CeGaT, LLC, B. Braun Interventional Systems, Inc., and John Doe, directly and by and through their agents, contracted to supply services or things in the Commonwealth of Pennsylvania, including medical devices, medical instruments, component parts, and products that are and were sterilized with EtO s well as EtO itself.

14. At all times relevant hereto, Defendants B. Braun Medical, Inc., B. Braun of America, Inc., B. Braun CeGaT, LLC, B. Braun Interventional Systems, Inc., and John Doe, directly and by and through their agents, had an interest in, used and/or possessed real property in the Commonwealth of Pennsylvania, including the real property where Defendants' Plant is located and situated, for the purpose of sterilizing medical instruments, devices, and products with EtO.

15. At all times relevant hereto, Defendants, B. Braun Medical, Inc., B. Braun of America, Inc., B. Braun CeGaT, LLC, B. Braun Interventional Systems, Inc., and John Doe, directly and by and through their agents, caused harm and tortious injury, as alleged throughout the entirety of this Complaint, by various acts and/or omissions in the Commonwealth of Pennsylvania.

16. At all times relevant hereto, Defendants B. Braun Medical, Inc., B. Braun of America, Inc., B. Braun CeGaT, LLC, B. Braun Interventional Systems, Inc., and John Doe, directly and by and through their agents, caused harm and tortious injury, as alleged throughout the entirety of this Complaint, by various acts and/or omissions outside the Commonwealth of Pennsylvania.

17. At all times relevant hereto, Defendants B. Braun Medical, Inc., B. Braun of America, Inc., B. Brun CeGaT, LLC, B. Braun Interventional Systems, Inc., and John Doe, directly

and by and through their agents, exploited a market in the Commonwealth of Pennsylvania by purposefully and intentionally creating, selling manufacturing, distributing, sterilizing, shipping, marketing, delivering, designing, and receiving medical instruments, devices, and products sterilized with EtO within the Commonwealth of Pennsylvania for sale, distribution, and receipt within the Commonwealth of Pennsylvania.

18. At all times relevant hereto Defendants, B. Braun Medical, Inc., B. Braun of America, Inc., B. Braun CeGaT, LLC, and B. Braun Interventional Systems, Inc., directly and by and through their agents, have jointly owned and jointly had a proprietary and intellectual property interest in various medical devices and products, with Defendants, and said medical devices and products were at all times manufactured in, assembled in, shipped to, distributed in, sold in, and/or sterilized with EtO at Defendants' Plant in the Commonwealth of Pennsylvania.

19. At all times relevant hereto, Defendants B. Braun Medical, Inc., B. Braun of America, Inc., B. Braun CeGaT, LLC and B. Braun Interventional Systems, Inc., along with B. Braun Melsungen AG, B. Braun SE, and B. Braun Holding GmbH & Co. KG, Defendants' counterpart entities from Germany (sometimes referenced collectively herein, for short, as "German Braun entities") launched, funded, and supported the B. Braun Enterprise Initiatives project which is a partnership between the Defendants and the German Braun entities to provide products, consulting services and education to healthcare providers in the Commonwealth of Pennsylvania who use the Defendants' products that are sterilized with EtO at Defendants' Plant.

20. "B. Braun" is a trade name for a German medical device and pharmaceuticals with large-scale global operations in more than sixty countries.

21. Defendants' conduct substantial business for B. Braun out of Defendants' Plant, including by sterilizing medical devices there.

22. In 2017, the German Braun entities, B. Braun Melsungen AG, B. Braun SE, and/or B. Braun Holding GmbH & Co. KG, stated that they would continue investing into their "major sites," including the major sites in the United States of America.

23. At all times relevant hereto, the German Braun entities have labeled, treated and viewed Defendants' Plant as one of their "major manufacturing" facilities.

24. At all times relevant hereto, the German Braun entities considered Defendants' Plant to be one of their "centers of excellence," meaning the Defendants' Plant is a center within the B. Braun global company responsible for research, development, manufacturing and registration of various products, including the products that were sterilized at Defendants' Plant with the EtO at issue in this action.

25. In 2016, the Chairman of the Management Board of B. Braun Melsungen AG pledged to make investments in the research and development and expansion of product capacity in the United States of America.

26. In 2017, then-CEO of Defendants stated that it was Defendants' priority to invest over $1 billion into the United States branches of the B. Braun company, which includes Defendants and Defendants' Plant.

27. At all times relevant hereto, the German Braun entities shipped merchandise, products, medical devices, medical devices parts, materials, items, things, and/or parts into the Commonwealth of Pennsylvania to Defendants' Plant and/or Defendants' location at 824 12th Avenue, Bethlehem, Pennsylvania to be assembled, used, manufactured, distributed, sold in, and sterilized with EtO at Defendants' Plant, in the Commonwealth of Pennsylvania.

28. At all times relevant hereto, Defendants were jointly and collectively engaged in the process of utilizing EtO to sterilize medical devices, medical instruments, and medical equipment that were manufactured, assembled, sold, and distributed at Defendants' Plant.

29. Defendant Philips RS North America LLC ("Philips RS") is a Delaware corporation with its principal place of business located at 6501 Living Place, Pittsburgh, Pennsylvania 15206. Philips RS was formerly operated under the business name Respironics, Inc. ("Respironics"). Royal Philips acquired Respironics in 2008.

30. Defendant Philips North America LLC ("Philips NA") is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. Philips NA is a wholly-owned subsidiary of Koninklijke Philips ("Royal Philips"), a Dutch corporation. Upon information and belief, Philips NA manages the operation of Royal Philips' various lines of business, including Philips RS, in North America. The sole member of Philips NA is Philips USA.

31. Defendant Philips Holding USA, Inc. ("Philips USA") is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. Philips USA is a holding company that is the sole member of Defendant Philips NA.

III. JURISDICTION AND VENUE

32. This court has jurisdiction over this action pursuant to Pa.C.S.A. §§931 and 5301. All the Defendants associated with the Braun Plant as averred in paragraphs 4 through 28 [collectively referenced as "Braun"] are Pennsylvania corporations regularly conducting business within the Commonwealth.

33. The Defendants identified in paragraphs 29-31 [collectively referenced as "the Philips Defendants"] or "Philips" regularly conduct business within the Commonwealth and have

continuous, systematic contacts with the Commonwealth. Moreover, Defendant Philips RS has its principal place of business in Pennsylvania.

34. The culpable acts and omissions of all Defendants alleged herein occurred within the Commonwealth, and caused harm within the Commonwealth.

35. Venue is proper in Lehigh County inasmuch as the occurrences giving rise to the action occurred therein, plaintiff resides therein, her decedent lived and died therein, and the Braun Defendants are located there.

IV. MATERIAL FACTS

A. The death of Plaintiff's Decedent

36. Beginning in May, 2021, Darrell G. Papsun suffered debilitating pain and fatigue, the cause of which he could not determine. The symptoms progressed to the point that he became disabled from his job as an assembly mechanic, and requiring him to take Family and Medical Leave.

37. By July, 2021, he was completely disabled.

38. As his symptoms persisted, Darrell G. Papsun sought medical advice and underwent a bone marrow test in or around late December, 2021.

39. The results of the test confirmed a diagnosis of leukemia.

40. Upon Darrell G. Papsun's October, 2022 death, his fatal illness was confirmed as acute myeloid leukemia ["AML"].

41. AML is a cancer that originates in the human bone marrow and spreads quickly to the blood. It is a progressive, painful and frequently terminal illness with multiple ill effects, including debilitating weakness, fatigue and disability, all of which Darrell G. Papsun suffered during the course of his illness.

42. By July 21, 2021, Darrell G. Papsun's AML and its ill effects rendered him totally disabled from his longstanding occupation.

43. In an effort to cure his illness, Darrell G. Papsun underwent a long course of prescribed medical treatment, which itself was painful and replete with side effects, at great financial expense.

44. Despite the effort of his physicians and the treatment he received, Mr. Papsun succumbed to his illness and died on October 3, 2022, at the age of fifty-eight (58) years.

45. Well documented causes of AML include exposure to the hazardous chemical which Defendants herein released, and emitted as alleged in greater detail hereinbelow, including but not limited to EtO and volatile organic contaminants such as benzene, toluene and toluene-related compounds and their contaminants, which typically include benzene.

46. As averred in greater detail hereinbelow, Darrell G. Papsun was heavily exposed to these chemicals for years as a result of the acts and omissions of Defendants.

47. Darrell G. Papsun's AML and his resultant death were caused by this exposure.

B. <u>Facts specific to the Braun Defendants</u>

48. All preceding paragraphs are incorporated by reference as fully set forth herein.

49. EtO is a colorless gas that is used to make other chemicals that are sometimes used in manufacturing a range of products, including antifreeze, plastics, detergents and adhesives.

50. EtO is also sometimes used as a means and method of sterilizing certain equipment and medical devices.

51. EtO is not the only means and method of effectively sterilizing equipment and medical devices.

52. The International Agency for Research on Cancer ("IARC") is an agency that studies the risks of cancer associated with various chemicals.

53. IARC employs a stratified system to rank the risk of cancer associated with a given chemical. This system breaks the risk groups into different tiers:

Group 1 (carcinogenic to humans);

Group 2A (probably carcinogenic to humans);

Group 2B (possibly carcinogenic to humans);

Group 3 (not classifiable as to its carcinogenicity to humans); and

Group 4 (probably not carcinogenic to humans).

54. Since as early as 1994, IARC has considered EtO to be in the highest risk category: Group 1 (carcinogenic to humans).

55. Since as early as 2000, the U.S. Department of Health and Human Services has considered EtO to be known to be a human carcinogen.

56. According to the U.S. Environmental Protection Agency ("EPA"), EtO is carcinogenic to humans by the inhalation route of exposure.

57. Human exposure to EtO through inhalation significantly increases the risk of developing various forms of cancer, including leukemia, lymphoma, multiple myeloma, various lymphoid cancers, breast cancer, brain cancer, lung cancer, pancreatic cancer, ovarian cancer, bladder cancer, and uterine cancer.

58. At all times relevant hereto, the Defendants knew or should have known that human exposure to EtO, including environmental exposure, increases the risk of developing cancer in those exposed, including leukemia, lymphoma, multiple myeloma, various lymphoid cancers, breast

cancer, brain cancer, lung cancer, pancreatic cancer, ovarian cancer, bladder cancer, and uterine cancer.

59. At all times relevant hereto, Defendants knew or should have known that EtO was a classified by IARC as a Group 1 carcinogen (carcinogenic to humans).

60. At all times relevant hereto, the Defendants knew or should have known that EtO was not the only means and method of sterilizing the equipment or medical devices the Defendants manufacture and sell.

61. At all times relevant hereto, the Defendants knew or should have known that alternative means and methods of sterilizing the goods they sold existed, including but not limited to, peracetic acid sterilization, nitrogen dioxide sterilization, steam sterilization, autoclave, dry heat sterilization, ozone sterilization, hydrogen peroxide, bleach, plasma gas sterilization, vaporized hydrogen peroxide ("VHP") sterilizers, and radiation sterilization.

62. At all times relevant hereto, the Defendants knew or should have know that there were means and methods of sterilizing their products and devices that were safer than EtO sterilization.

63. At all times relevant hereto, the Defendants knew or should have known that there were means and methods of sterilizing their products and devices that posed a far less risk of cancer to those exposed by the sterilization byproducts than the risk created by EtO sterilization.

64. At all times relevant hereto, the Defendants knew or should have known that the closer a human being was to the plant where the Defendants' EtO sterilization took place, the higher that human's risk of developing cancer was.

65. At all times relevant hereto, the Defendants knew or should have known that the more amount of time a human being spent in the areas in close proximity to the Defendants' plant where EtO sterilization occurred, the higher that human's risk of developing cancer was.

66. At all times relevant hereto, the Defendants knew or should have known that there is a plethora of scientific evidence, data, and literature confirming that environmental EtO exposure through human inhalation directly causes multiple forms of cancer in such human beings.

67. At all times relevant hereto, the Defendants knew or should have known that there were means, methods, equipment, and devices, that could be utilized to minimize or lower the amounts of EtO being emitted and transmitted into the air.

68. In 2016, the EPA classified EtO as a human carcinogen, and considers any exposure to EtO, however, small, to create a risk of cancer since EtO is a powerful mutagen that damages DNA.

69. In addition to cancer, when inhaled, EtO increases the risk of birth defects in the fetuses and children of child-bearing woman.

70. In addition to cancer, when inhaled, EtO increases the risk of miscarriages in child-bearing woman.

C. <u>The Defendants' Emissions of EtO</u>

71. Since at least the late 1980s, the Defendants have knowingly emitted EtO into the air surrounding the Defendants' Plant located at 901 Marcon Boulevard, Allentown, Pennsylvania 18109.

72. The Defendants emit such high amounts of EtO at such a high frequency that citizens who come within certain areas surrounding the Defendants' plant face a risk of developing

cancer that is at least 200 times higher that the average Pennsylvania citizen's risk of developing cancer.

73. After the EtO from Defendants' Plant is emitted, it remains in the air for numerous months as a result of its atmospheric half-life of 211 days, during which time the EtO moves throughout the communities and neighborhoods surrounding Defendants' Plant including the property at 2284 Barness Drive, Allentown, Pennsylvania where Darrell G. Papsun lived for many years and the community where he routinely worked and/or resided at all material times.

74. At all times relevant hereto, the Defendants failed to implement and install adequate controls in the EtO sterilization chamber, which resulted in remarkably dangerous amounts and levels of EtO emissions from the Defendants' Plant.

75. According to EPA data, the Defendants' Plant was recently found to be the 12th largest emitter and polluter of EtO in the entire country.

76. From approximately 2008 to 2015, the Defendants increased the amount of their EtO emissions at the Defendants' Plant four-fold.

77. On or about July 10, 2019, the EPA contacted the Pennsylvania Department of Environmental Protection ("DEP") expressing concerns about the severity and amount of the Defendants' EtO emissions from the Defendants' Plant.

78. As far back as 2014, the Defendants' Plant accounted for 92% of all of Pennsylvania's EtO emissions. This put more than 41,000 residents near this plant at a much higher risk for developing cancer than people who did not live, work, or spend time near the plant.

79. Only after facing close scrutiny and being subject to inspections of their plant, on or around November 26, 2019, the Defendants submitted an air quality plan to the Pennsylvania DEP pledging to reduce their EtO emissions by more than 99%.

80. At all times relevant hereto, the Defendants knew or should have known that here were ways to better reduce or limit their emissions of EtO even if they continued to use EtO sterilization.

81. At all times relevant hereto, the Defendants have emitted extremely dangerous levels and amounts of EtO from the Defendants' plant when Defendants knew or should have known that the levels and amounts of these EtO emissions placed tens of thousands – if not hundreds of thousands – of human beings who came within a certain proximity of their plant at significantly higher risk of developing cancer.

82. Defendants' Plant has released excessive and dangerous amounts of EtO, in both controlled and uncontrolled releases, for multiple decades.

83. Because EtO is odorless and cannot be seen, Plaintiff's Decedent was unknowingly exposed to the carcinogenic EtO for years.

D. Excessive Cancer Risks in Areas Surrounding the Defendants' Plant

84. In August 2018, the EPA released the 2014 National Air Toxics Assessment ("NATA").

85. NATA is a screening tool used by the EPA to calculate cancer risks based upon emissions data in 76,727 census tracts throughout the United States.

86. Out of these 76,727 census tracts, the EPA identified only 109 census tracts in the United States with cancer risk scores higher than what is deemed "acceptable" by the EPA. In other words, only 109 out of the 76,727 (or .14%) of the surveyed census tracts in the entire country had unacceptable cancer risk scores.

87. Seventeen (17) of these one-hundred-and-nine (109) census tracts with unacceptable cancer risk scores are located in the area closely surrounding the Defendants' Plant. In other words,

over 15% of all the census tracts in the entire country that have unacceptable cancer risk scores are in areas surrounding Defendants' Plant.

88. Thirty-eight (38) census tracts surrounding the Defendants' Plant had more than double the average national toxic air cancer risk.

89. According to the EPA, the lifetime risk of developing cancer due to air toxicity in one of the tracts near the Defendants' Plant can be up to 19 times higher than the national average cancer risk.

90. Based on the Defendants' EtO emissions in 2014, the Defendants' Plant ranked as the sixth largest emitter and polluter of EtO in the country.

91. At all times relevant hereto, the Defendants fraudulently concealed from the public and individuals in the communities surrounding Defendants' Plant, including Plaintiff's decedent, the risk of cancer associated with exposure and/or inhalation of EtO.

92. At all times relevant hereto, the Defendants fraudulently concealed from the public and individuals in the communities surrounding Defendants' Plant, including Plaintiff's Decedent, the levels and amounts of EtO being emitted from the Defendants' Plant.

93. At all times relevant hereto, the Defendants fraudulently concealed from the public and individuals in the communities surrounding Defendants' Plant, including Plaintiff's Decedent, that EtO was being emitted from Defendants' Plant.

94. At all times relevant hereto, Defendants fraudulently concealed that Plaintiff's Decedent Darrell G. Papsun's inhalation and exposure to EtO in and from the Defendants' Plant placed him at an increased risk of developing cancer.

95. At all times relevant hereto, Defendants fraudulently concealed that Plaintiff's Decedent Darrell G. Papsun was inhaling a chemical (EtO) which was carcinogenic, toxic, and placed him at an increased risk of developing cancer.

96. At all times relevant hereto, Defendants fraudulently misrepresented directly to Plaintiff's Decedent Darrell G. Papsun that his inhalation and exposure of the air and elements in and around the Defendants' Plant was safe and posed no risk to his health.

97. At all times relevant hereto, Defendants actively misled Plaintiff's Decedent Darrell G. Papsun by representing to him that the air and elements he was inhaling and exposed to in and around Defendants' Plant were safe and posed no risk to his health. As a direct factual and proximate result of being actively misled in this way by Defendants, Plaintiff's Decedent Darrell G. Papsun was precluded from limiting his contact with, exposure to, and inhalation of the hazardous and carcinogenic EtO in and around Defendants' Plant, all of which further exacerbated and aggravated Plaintiff's Decedent Darrell G. Papsun's cancer and the mutagenic damage caused to his cells and DNA by this EtO.

98. At all times relevant hereto, Plaintiff's Decedent Darrell G. Papsun justifiably relied on the Defendants' affirmative misrepresentations that the air and elements in and around Defendants' Plant were safe and posed no risk to his health by continuing to place himself in an environment where he was repeatedly inhaling and being exposed to the EtO in and around Defendants' Plant for multiple years.

99. At all times relevant hereto, the Defendants knew or should have known that the Defendants' Plant from where EtO is emitted was located in an extremely densely populated area nearby dozens of stores and businesses frequented by thousands of people daily, including but not limited to, a Sam's Club, a Target, movie theatre, Cancer Support Center, dozens of popular

restaurants, public parks, grocery stores, multiple hotels, an airport, a UPS store, U.S. Marine Corps Reserve Center, multiple apartment complexes, a Pennsylvania Department of Transportation drivers license center, clothing stores, banks, liquor stores, and schools.

100. At all times material hereto, the Defendants knew or should have known that all the people who frequent this densely populated area where these dozens of stores and businesses are located are at a significantly higher risk of developing cancer than the average Pennsylvanian and average American directly due to the Defendants' excessive and dangerous amounts and levels of EtO emissions coming from the Defendants' Plant.

E. Plaintiff's Decedent's Exposure to the Defendants' Excessive EtO Emissions

101. For multiple years during a time period when the Defendants were emitting dangerous and excessive levels of EtO from the Defendants' Plant, Plaintiff's Decedent Darrell G. Papsun lived in an area in close proximity to the Defendants' Plant where he has been exposed to and inhaled excessive and dangerous amounts of EtO emissions from the Defendants' Plant.

102. For multiple years during a time period when the Defendants were emitting dangerous and excessive levels of EtO from the Defendants' Plant, Plaintiff's Decedent Darrell G. Papsun frequented numerous businesses, stores, and shops in areas nearby the Defendants' Plant, causing him to be exposed to and inhale excessive and dangerous amounts of EtO emissions from the Defendants' Plant.

103. For multiple years during a time period when the Defendants were emitting dangerous and excessive levels of EtO from the Defendants' Plant, Plaintiff's Decedent Darrell G. Papsun has been exposed to and inhaled excessive and dangerous amounts of EtO from within Defendants' Plant.

104. Defendants have been emitting EtO from Defendants' Plant for more than 25 years.

105. At all times relevant hereto, Defendants failed to implement sufficient controls to limit and/or eliminate the emissions of EtO coming from Defendants' Plant and, consequently, thousands of residents in surrounding areas, including Plaintiff's Decedent, were exposed to a known human carcinogen that greatly increases their likelihood of developing cancer.

106. At all times relevant hereto, Defendants knew that Defendants' Plant lacked sufficient controls necessary to limit and/or eliminate or reduce the emissions of EtO from Defendants' Plant to non-harmful levels.

107. At all times relevant hereto, Defendants knew that the EtO being emitted from Defendants' Plant spread beyond the Defendants' property and into the neighboring communities and neighborhoods, where its presence placed individuals in those communities and neighborhoods, including Plaintiff's Decedent, at a greatly increased risk of developing cancer.

108. At all times hereto, Defendants knew that exposure to EtO would increase the risk of developing cancer of those in the communities and neighborhoods of Defendants' Plant, including Plaintiff's Decedent.

109. At all times relevant hereto, Defendants failed to implement sufficient control processes and/or equipment that would have eliminated or reduced EtO emissions to non-harmful levels.

110. At all times relevant hereto, Defendants failed to adopt or implement alternative processes to EtO for sterilizing the medical instruments and devices manufactured, assembled, and distributed in the Defendants' Plant.

111. Plaintiff's Decedent Darrell G. Papsun has consistently inhaled air polluted with the EtO that Defendants emitted from Defendants' Plant in and around his home and place(s) of work for well over a decade.

112. As a direct and proximate result of Plaintiff's Decedent Darrell G. Papsun's repeated exposure and inhalation of excessive amounts of EtO emissions from the Defendants' Plant over a period of multiple years, Plaintiff's Decedent Darrell G. Papsun has been exposed to a risk of developing cancer that was significantly higher than the average Pennsylvanian's or average American risk.

113. At all relevant times, Defendants, by and through their agents, officers, servants, and/or employees, knew the risk that EtO is a Group 1 carcinogen, causes cancer when inhaled, is mutagenic, increases the risk of cancer of those who inhale EtO, and toxic.

114. Despite knowing the risk that EtO is a Group 1 carcinogen, causes cancer when inhaled, is mutagenic, increases the risk of cancer of those who inhale EtO, and toxic, Defendants acted in conscious disregard and with indifference to the safety and wellbeing of individuals inside and/or around Defendants' Plant by repeatedly emitting dangerous and excessive amounts of EtO, concealing this fact from the public and those inhaling the EtO, and consciously deciding to not install or implement available devices and equipment that would substantially lessen or eliminate the Defendants' EtO emissions from Defendants' Plant.

115. As a direct factual and proximate cause and result of Plaintiff's Decedent Darrell G. Papsun's repeated exposure and inhalation of excessive amounts of EtO emissions from the Defendants' Plant over a period of multiple years, Plaintiff's Decedent Darrell G. Papsun developed the AML that caused his death, and all the related harms and damages alleged herein.

F. <u>Facts related to the Philips Defendants</u>

116. The Philips Defendants manufacture, market, sell and distribute a variety of products for sleep and home respiratory care.

117. The Philips Defendants manufacture, market, sell and distribute a variety of Continuous Positive Airway Pressure (CPAP) and BiLevel Positive Airway Pressure (BiPap) devices for patients with sleep apnea.

118. Philips also manufactures, markets, imports, sells, and distributes a variety of ventilator devices for patients with respiratory conditions.

119. On April 26, 2021, as part of its Quarterly Report for Q1 2021, under a section entitled "Regulatory Update," Philips disclosed for the first time that the sound abatement foam in Philip's CPAP, BiPAP, and mechanical ventilator devices posed serious health risks to their users.

120. On June 14, 2021, Philips issued a recall notification for many of its CPAP, BiPAP, and mechanical ventilator devices.

121. In its recall notification, Philips advised of potential health risks related to the sound abatement foam used in the affected devices.

122. Philips' recall advised patients using these affected devices of potential risks from exposure to chemicals released from the sound abatement foam via degradation and/or off-gassing.

123. Specifically, Philips recall notification stated that the risks related to exposure to chemicals given off by the sound abatement foam could include headache, irritation, inflammation, respiratory issues, and possible toxic and carcinogenic effects.

124. Beginning in May, 2017, Plaintiff's Decedent was prescribed the use of at least one of Philips' recalled devices, the DreamStation CPAP machine (hereinafter, the "Device"),

to treat Plaintiff's Decedent's sleep apnea. He used the Device for multiple years before he developed the AML that caused his death, and all the related harms and damages alleged herein.

125. Plaintiff's Decedent used the devices on a daily basis for a number of years.

126. Darrell G. Papsun's AML and resultant death and all related damages were proximately caused as a result of the acts and omissions of the Philips defendants as averred in greater detail hereinbelow.

127. Defendants have long known that the polyester-based polyurethane (PE-PUR) sound-abatement foam in Defendants' CPAP, BiPAP, and mechanical ventilator devices has a tendency to release toxic and carcinogenic microparticles that can be inhaled by users like Plaintiff's Decedent, causing serious injury or death.

128. At all relevant times, Defendants manufactured, sold, and distributed a line of CPAP and BiPap devices as well as mechanical ventilator devices under its "Sleep & Respiratory Care" portfolio. These devices are designed to assist individuals with a number of sleep, breathing, and respiratory conditions, including sleep apnea.

129. Defendants sought and obtained clearance from the Food and Drug Administration ("FDA") to market the recalled devices, including the Device used by Plaintiff's Decedent, under Section 510(k) of the Medical Device Amendment to the Food, Drug, and Cosmetics Act ("FDCA"). Section 510(k) allows marketing of medical devices if the device is deemed substantially equivalent to other legally marketed predicated devices. Obtaining clearance under 510(k) is significantly less rigorous than through the pre-market approval ("PMA") process, as no formal review for safety or efficacy is performed and no clinical data is required.

G. <u>Continuous Positive Airway Pressure (CPAP) Therapy</u>

130. Continuous Positive Airway Pressure ("CPAP") therapy is a common nonsurgical treatment primarily used to treat sleep apnea. CPAP therapy typically involves the use of a nasal or facemask device and a CPAP device, which helps individuals breathe by increasing the air pressure in an individual's throat.

131. Sleep apnea is a common sleep disorder affecting millions of Americans, including Plaintiff's Decedent, and characterized by repeated interruptions in breathing through an individual's sleep cycle. These interruptions, called "apneas," are caused when the soft tissue in an individual's airway collapses. The airway collapse prevents oxygen from reaching the individual's lungs which can cause a buildup of carbon dioxide. If the individual's brain senses the buildup of carbon dioxide, it will briefly rouse the individual from sleep so that the individual's airway can reopen. Often these interruptions are so brief that the individual will not remember. Despite the brevity of the interruption, the sleep cycle disruption caused by sleep apnea can dramatically impact a person's lifestyle, including negative impacts to energy levels, mental performance, and long-term health. CPAP therapy helps treat sleep apnea by forcing pressurized air through the individual's airway, preventing the individual's airway from collapsing while breathing during sleep cycles, which can help prevent interruptions in breathing.

H. <u>Bi-Level Positive Airway Pressure BiPap Therapy</u>

132. Bi-Level Positive Airway Pressure ("BiPap") therapy is a common alternative to CPAP therapy for treating sleep apnea. Similar to CPAP therapy,. BiPAP therapy is nonsurgical and involves the use of a nasal or facemask device to maintain air pressure in an individual's airway. BiPAP is distinguishable from CPAP therapy, however, in that BiPAP devices deliver two alternating levels–inspiratory and expiratory–of pressurized air into a person's airway, rather than the single continuous level of pressurized air delivered by a CPAP device. The

inspiratory positive airway pressure assists a person as a breath is taken in. Conversely, the expiratory positive airway pressure is applied to allow a person to comfortably breathe out. BiPAP devices deliver one level of pressurized air (the inspiratory positive level) to assist as a person inhales, and another level (the expiratory level) as a person exhales.

I. Philips' Sleep & Respiratory Care Devices Were Endangering Users

133. On April 26, 2021, as part of its Quarterly Report for Q1 2021, Philips disclosed for the first time, under a section titled "Regulatory Update," that device user reports had led to a discovery that the type of PE-PUR "sound abatement" foam Philips used to minimize noise in several CPAP, BiPAP, and mechanical ventilator devices posed health risks to its users. Specifically, Philips disclosed that "the [PE-PUR] foam may degrade under certain circumstances, influenced by factors including the use of unapproved cleaning methods, such as ozone[], and certain environmental conditions involving high humidity and temperature."

134. Philips utilized polyester-based polyurethane (PE-PUR) sound abatement foam to dampen device vibration and sound during routine operation.

135. On June 14, 2021, almost two months after Philips notified its stockholders, it finally advised the medical community, medical equipment suppliers and some patients, by issuing a recall notification of specific devices allegedly based upon extensive ongoing review following the announcement on April 26, 2021.

136. In its recall notification, Philips identified examples of potential risks which include exposure to chemicals emitted from the sound abatement foam material via degradation and/or off-gassing.

137. Philips reported that, based on lab testing and evaluations, it may be possible that these potential health risks could result in a wide range of potential patient impact, from

transient potential injuries, symptoms, and complications, as well as possibly serious injury, which can be life-threatening or cause permanent impairment, or require medical intervention to preclude permanent impairment.

138. According to Philips' recall notice, the PE-PUR foam used in recalled devices such as the Device used by Plaintiff's Decedent puts users at risk of suffering from the following health harms: "headache, irritation [skin, eye, and respiratory tract], inflammation, respiratory issues, and possible toxic and carcinogenic effects."

139. On June 14, 2021, Philips also issued a brief report titled "Clinical Information for Physicians." In that report, Philips disclosed that "[l]ab analysis of the degraded foam reveals the presence of potentially harmful chemicals including:

- Toluene Diamine
- Toluene Diisocyanate
- Diethylene glycol."

140. In its report titled "Clinical Information for Physicians," Philips also disclosed that lab testing performed by and for Philips had also identified the presence of Volatile Organic Compounds (VOCs) which may be emitted from the sound abatement foam component of the affected devices, stating "VOCs are emitted as gases from the foam included in the [affected devices] and may have short-and long-term adverse health effects. Standard testing identified two compounds of concern may be emitted from the foam that are outside of safety thresholds. The compounds identified are the following:

- Dimethyl Diazine
- Phenol, 2,6bis (1,1,dimethylethyl)-4-(l-methylpropyl)-

J. <u>Philips' Recalled Devices</u>

141. In total, Philips announced that "[b]etween 3 million and 4 million" devices are targeted in the recall.

142. The list of devices recalled by Philips (the "Recalled Devices") include:

Philips CPAP and BiPAP Devices Subject to Recall	
Device Name/Model	**Type**
Philips E30 (Emergency Use Authorization)	Continuous Ventilator, Minimum Ventilatory Support, Facility Use
Philips DreamStation ASV	Continuous Ventilator, Non-life Supporting
Philips DreamStation ST, AVAPS	Continuous Ventilator, Non-life Supporting
Philips SystemOne ASV4	Continuous Ventilator, Non-life Supporting
Philips C Series ASV, S/T, AVAPS	Continuous Ventilator, Non-life Supporting
Philips OmniLab Advanced Plus, In-Lab Titration Device	Continuous Ventilator, Non-life Supporting
Philips SystemOne (Q Series)	Non-continuous Ventilator
Philips DreamStation, CPAP, Auto CPAP, BiPAP	Non-continuous Ventilator
Philips DreamStation, GO, CPAP, APAP	Non-continuous Ventilator
Philips Dorma 400, 500, CPAP	Non-continuous Ventilator
Philips REMStar SE Auto, CPAP	Non-continuous Ventilator

Philips Device Name/Model	**Type**
Philips Trilogy 100 Ventilator	Continuous Ventilator
Philips Triology 200 Ventilator	Continuous Ventilator
Philips Garbin Plus, Aeris, LifeVent Ventilator	Continuous Ventilator
Philips A-Series BiPAP Hybrid A30	Continuous Ventilator, Minimum Ventilatory Support, Facility Use
Philips A-Series BiPAP V30 Auto Ventilator	Continuous Ventilator, Minimum Ventilatory Support, Facility Use
Philips A-Series BiPAP A40	Continuous Ventilator, Non-life Supporting
Philips A-Series BiPAP A30	Continuous Ventilator, Non-life Supporting

143. Philips issued the following advice to patients using any of the recalled devices:

- "For patients using BiLevel PAP and CPAP devices: Discontinue use of affected units and consult with physicians to determine the benefits of continuing therapy and potential risks."
- "For patients using life-sustaining mechanical ventilator devices: DO NOT discontinue or alter prescribed therapy, without consulting physicians to determine appropriate next steps."

K. Philips Unreasonably Delayed the Recall

144. Defendants have not disclosed when they first received reports from users of its Sleep & Respiratory Care devices "regarding the presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask)." However, given how long ago the first of the recalled devices came to market, it is likely that Defendant learned of these issues for a substantial period of time before the recall. Additionally, Philips released its next-generation CPAP device, the DreamStation 2, which does not have the defective, carcinogenic foam, on April 13, 2016 – not even two full weeks before Philips first publicly disclosed in its Q1 2021 Quarterly Report a potential health issue with its CPAP devices, including Plaintiff's Decedent's defective first-generation DreamStation device. Defendants first sought FDA clearance for the DreamStation 2 in February 2020, and in all likelihood began developing it long before then.

145. Thus, as a result of user reports and other testing performed by and on behalf of Defendants, Defendants were aware of the degradation and off-gassing of the PE-PUR sound abatement foam used in the recalled devices, including Plaintiff's Decedent's Devices, yet continued to manufacture, market, and sell the recalled devices with such cognizance for a significant period of time. During this period, Defendants unreasonably and unjustly profited from the manufacture and sale of the recalled devices and unreasonably put users of the recalled devices at risk of developing adverse health effects, including cancer.

146. In approximately May, 2017, years before he was diagnosed with AML, Darrell G. Papsun was diagnosed with sleep apnea. He was prescribed and purchased one of the medical devices the Philips Defendants eventually recalled, a Philips DreamStation, CPAP, AutoCPAP, BiPAP, a non-continuous ventilator type of CPAP machine. A photograph of the labels identifying the device is attached hereto as Exhibit A [referenced herein as "the subject device" or "the device"].

147. The subject device was designed and manufactured by the Philips Defendants and distributed by Philips RS. It is a subject of the above-referenced FDA Class I recall.

148. In compliance with his prescription, Plaintiff's Decedent used the subject device regularly, until the time he learned of the recall. His use was medically appropriate, and comprised a normal and expected use.

149. At the time the Devices were purchased by Plaintiff's Decedent, they were in the same condition in all relevant respects as when they left Philips' control.

150. Prior to Plaintiff's Decedent's purchase of the Devices, Philips did not warn patients, including Plaintiff's Decedent, physicians, its customers, or it's sales representative/distributors that the Devices were known to emit toxic and/or carcinogenic particles from their PE-PUR sound abatement foam via degradation and/or off-gassing, which could then be directly inhaled by the user, causing severe injury or death.

151. Darrell G. Papsun's use of the Device subjected him to much greater risks of future harm than he had before using the Device.

152. Had Papsun or his physician known that the Device would release carcinogenic particles causing Plaintiff's Decedent's development of AML, then neither he nor his physician would have chosen the Device for treatment of his sleep apnea.

153. Papsun did not know and could not have known that the Devices were defective and causing toxic and carcinogenic compounds to be inhaled, which caused the development of his AML, until Philips issued the recall of the Devices.

154. As a direct and proximate result of use of the subject device, Papsun suffered significant harm, including but not limited to the development of AML and his resultant death, with all the harms and damages alleged herein.

155. Pursuant to federal law, a medical device is deemed to be adulterated if, among other things, it fails to meet established performance standards, or if the methods, facilities or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. 21 U.S.C. §351.

156. Pursuant to federal law, a device is deemed to be misbranded if, among other things, its labeling is false or misleading in any particular, or if it is dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. 21 U.S.C. §352.

157. Pursuant to federal law, manufacturers are required to comply with FDA regulation of medical devices, including FDA requirements for records and reports, in order to prohibit introduction of medical devices that are adulterated or misbranded, and to assure the safety and effectiveness of medical devices. In particular, manufacturers must keep records and make reports if any medical device may have caused or contributed to death or serious injury, or if the device has malfunctioned in a manner likely to cause or contribute to death or serious injury. Federal law also mandates that the FDA establish regulations requiring a manufacturer of a medical device to report promptly to FDA any correction or removal of a device undertaken to reduce a risk to health posed by the device, or to remedy a violation of federal law by which a device may present a risk to health. 21 U.S.C. §360(i).

158. Pursuant to federal law, the Secretary of Health and Human Services may prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, pre-production design validation (including a process to assess the performance of a device, but not including an evaluation of the safety or effectiveness of a device), packaging, storage and installation of a device conform to current good manufacturing practice, as prescribed in such regulations, to assure that the device will be safe and effective and otherwise in compliance with federal law.

159. The regulations requiring conformance to good manufacturing practices are set forth in 21 C.F.R. §820, *et seq.* As explained in the Federal Register, because the Current Good Manufacturing Practice (CGMP) regulations must apply to a variety of medical devices, the regulations do not prescribe the details for how a manufacturer must produce a device. Rather, the quality system regulations provide a framework of basic requirements for each manufacturer to use in establishing a quality system appropriate to the devices designed and manufactured and the manufacturing processes employed. Manufacturers must adopt current and effective methods and procedures for each device they design and manufacture to comply with and implement the basic requirements set forth in the quality system regulations.

160. Pursuant to 21 C.F.R. §820.1(c), the failure to comply with any applicable provision in Part 820 renders a device adulterated under section 501(h) of the Federal Drug & Cosmetic Act ("the Act"). 21 U.S.C. §351.

161. Pursuant to 21 C.F.R. §820.5, each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device designed or manufactured. "Quality system" means the organizational structure, responsibilities, procedures, processes and resources for implementing quality management. 21 C.F.R. §820.3(v).

162. Pursuant to 21 C.F.R. §820.22, each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system.

163. Pursuant to 21 C.F.R. §820.30(a), each manufacturer shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met.

164. Pursuant to 21 C.F.R. §820.30(d), each manufacturer shall establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements.

165. Pursuant to 21 C.F.R. §820.30(e), each manufacturer shall establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device's design development.

166. Pursuant to 21 C.F.R. §820.30(f), each manufacturer shall establish and maintain procedures for verifying the device design to confirm that the device design output meets the design input requirements.

167. Pursuant to 21 C.F.R. §820.30(g), each manufacturer shall establish and maintain procedures for validating the device design. Design validation shall be performed under defined operating conditions on initial production units, lots or batches, or their equivalents. Design validations shall ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions.

168. Pursuant to 21 C.F.R. §820.30(h), each manufacturer shall establish and maintain procedures to ensure that the device design is correctly translated into production specifications.

169. Pursuant to 21 C.F.R. §820.30(i), each manufacturer shall establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review and approval of design changes before their implementation.

170. Pursuant to 21 C.F.R. §820.70(a), each manufacturer shall develop, conduct, control and monitor production processes to ensure that a device conforms to its specifications. Where deviations from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications. Such process controls shall include:

(a) documented instructions, standard operating procedures (SOPs) and methods that define and control the manner of production;

(b) monitoring and control of process parameters and component and device characteristics during production;

(c) compliance with specified reference standards or codes;

(d) the approval of processes and process equipment; and

(e) criteria for workmanship which shall be expressed in documented standards or by means of identified and approved representative samples.

171. Pursuant to 21 C.F.R. §820.70(b), each manufacturer shall establish and maintain procedures for changes to a specification, method, process or procedure.

172. Pursuant to 21 C.F.R. §820.70(c), each manufacturer shall establish and maintain procedures to adequately control environmental conditions that could reasonably be expected to have an adverse effect on product quality, including periodic inspection of environmental control system(s) to verify the system, including necessary equipment, is adequate and functioning properly.

173. Pursuant to 21 C.F.R. §820.70(e) , each manufacturer shall establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on produce quality.

174. Pursuant to 21 C.F.R. §820.70(g), each manufacturer shall ensure that all equipment used in the manufacturing process meets specified requirement and is appropriately designed, constructed, placed and installed to facilitate maintenance, adjustment, cleaning and use.

175. Pursuant to 21 C.F.R. §820.70(h), each manufacturer shall establish and maintain procedures for the use and removal of manufacturing material which could reasonably be expected to have an adverse effect on product quality to ensure that it is removed or limited to an amount that does not adversely affect the device's quality.

176. Pursuant to 21 C.F.R. §820.70(i), when computers or automated data processing systems are used as part of production or the quality system, the manufacturer shall validate computer software for its intended use according to an established protocol.

177. Pursuant to 21 C.F.R. §820.72, each manufacturer shall ensure that all inspection, measuring and test equipment, including mechanical, automated or electronic inspection and test equipment, is suitable for its intended purposes and is capable of producing valid results. Each manufacturer shall establish and maintain procedures to ensure that equipment is routinely calibrated, inspected, checked and maintained.

178. Pursuant to 21 C.F.R. §820.75(a), where the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedures. "Process validation" means establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications. *See* 21 C.F.R. §820.3(z)(1).

179. Pursuant to 21 C.F.R. §820.75(b), each manufacturer shall establish and maintain procedures for monitoring and control of process parameters for validated processes to ensure that the specified requirements continue to be met. Each manufacturer shall ensure that validated processes are performed by qualified individuals.

180. Pursuant to 21 C.F.R. §820.90, each manufacturer shall establish and maintain procedures to control product that does not conform to specified requirements.

181. Pursuant 21 C.F.R. §820.100, each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for:

(a) analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product or other quality problems;

(b) investigating the cause of nonconformities relating to product, processes and the quality system;

(c) identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;

(d) verifying or validating the corrective and preventative action to ensure that such action is effective and does not adversely affect the finished device;

(e) implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;

(f) ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and

(g) submitting relevant information on identified quality problems, as well as corrective and preventative actions, for management review.

182. Upon information and belief, Defendants' Devices are adulterated pursuant to 21 U.S.C. §351 because, among other things, they failed to meet established performance standards and/or the methods, facilities or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. *See*, 21 U.S.C. §351.

183. Upon information and belief, Defendants' Devices are misbranded because, among other things, they are dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. *See*, 21 U.S.C. §352.

184. Upon information and belief, Defendants' Devices are adulterated pursuant to 21 U.S.C. §351 because Philips failed to establish and maintain CGMP for its Devices in accordance with 21 C.F.R. §820, *et seq.*, as set forth above.

185. Upon information and belief, Philips failed to establish and maintain CGMP with respect to the quality audits, quality testing and process validation for the recalled devices, including the Devices at issue.

186. As a result of Philips' failure to establish and maintain CGMP as set forth above, the Devices at issue were defective, resulting in injuries to Plaintiff's Decedent.

187. If Philips had complied with the federal requirements regarding CGMP, Philips' Devices would have been manufactured and/or designed properly such that it would not have resulted in injuries to Plaintiff's Decedent.

V. CAUSES OF ACTION

COUNT ONE – NEGLIGENCE
PLAINTIFF VS. THE BRAUN DEFENDANTS

188. Plaintiff incorporates herein by reference the foregoing paragraphs as though each were set forth in its entirety.

189. The Defendants were negligent in one or more of the following ways:

a. emitting dangerous and/or excessive amounts and levels of EtO from the Defendants' Plant;

b. emitting amounts of EtO from Defendants' Plant that were sufficient to increase the risk of cancer in persons inside Defendants' Plant and in the communities and neighborhoods surrounding Defendants' Plan including Plaintiff's Decedent;

c. failing to warn the individuals in the neighborhood and community where Defendants' Plant was located, including Plaintiff's Decedent, that they were at an increased risk of developing cancer due to inhaling the EtO being emitted from Defendants' Plant;

d. failing to warn the individuals in the neighborhoods and communities surrounding where Defendants' Plant was located, including Plaintiff's Decedent, that they were at an increased risk of developing cancer due to inhaling the EtO being emitted from Defendants' Plant;

e. failing to implement, adopt, and/or enforce proper protocols and methods of reducing or eliminating emissions of EtO from the Defendants' Plant to non-harmful levels;

f. failing to adopt, implement, and/or enforce the appropriate and proper equipment, devices, and/or controls sufficient to eliminate or reduce emissions of EtO from the Defendants' Plant to non-harmful levels;

g. failure to select and utilize safer alternative methods other than EtO for the sterilization of the medical devices, instruments, and equipment, manufactured, assembled, and distributed at Defendants' Plant;

h. failing to study or investigate safer alternative methods other than EtO for the sterilization of the medical devices, instruments, and equipment manufactured, assembled, and distributed at Defendants' Plant;

i. failing to warn or advise those who live or work in the communities and neighborhoods surrounding Defendants' Plant, including Plaintiff's Decedent, that they were being exposed to EtO;

j. engaging in an ultrahazardous activity by emitting dangerous levels and amounts of EtO into the air surrounding Defendants' Plant;

k. failing to adequately record or track the amounts or levels of EtO being emitted from Defendants' Plant;

l. failing to study the effects of EtO, including EtO's effect of increasing the risk of developing cancer in individuals working within the Defendants' Plant;

m. failing to adequately, accurately, and thoroughly report the levels of EtO being emitted from Defendants' Plant;

n. failing to properly and safely store and/or contain the EtO at Defendants' Plant;

o. concealing the elevated risk of cancer associated with exposure to EtO emissions from Defendants' Plant;

p. failing to study the effects of EtO, including EtO's effect of increasing the risk of developing cancer in individuals living, working, and breathing the air in the communities and neighborhoods surrounding Defendants' Plant;

q. failing to test the air surrounding Defendants' Plant to measure or gage the amount or levels of EtO being emitted from Defendants' Plant; and

r. subjecting those who live, work, and breathe the air in the communities and neighborhoods surrounding Defendants' Plant to elevated to risk of developing cancer.

190. In addition to being negligent, all of the Defendants' above acts and omissions were reckless, outrageous, and in conscious disregard of the safety and wellbeing of others including Plaintiff's Decedent Darrell G. Papsun.

191. As a direct and proximate result of the aforementioned negligence, Plaintiff's Decedent suffered the injuries and damages set forth throughout this complaint.

WHEREFORE, Plaintiff demands damages against all Defendants, including punitive damages, in an amount in excess of the prevailing arbitration limits, exclusive of pre-judgment interest, delay damages and costs on all counts.

COUNT TWO – STRICT LIABILITY
PLAINTIFF VS. BRAUN DEFENDANTS

192. Plaintiff incorporates herein by reference the foregoing paragraphs as though each were fully set forth herein.

193. Plaintiff brings this claim pursuant to Restatement (Second) of Torts sections 519 and 520, and Pennsylvania decisional law and common law.

194. The Defendants' use and emissions of EtO from Defendants' Plant constitutes an ultrahazardous activity.

195. The Defendants' use and emissions of EtO from Defendants' Plant constitutes an abnormally dangerous activity.

196. At all times relevant hereto, the Defendants' use and emissions of EtO at Defendants' Plant necessarily involved a high degree of risk of serious harm to persons within Defendants' Plant and in communities surrounding Defendants' Plant, as contemplated by Restatement (Second) of Torts §520(a), including by creating an increased risk of developing various forms of cancer, including leukemia, lymphoma, multiple myeloma, various lymphoid cancers, breast cancer, brain cancer, lung cancer, pancreatic cancer, ovarian cancer, bladder cancer and uterine cancer.

197. At all times relevant hereto, the likelihood that harm would result from the Defendants' use and emissions of EtO was and is great, as contemplated by Restatement (Second) of Torts §520(b), because EtO is toxic, a known human carcinogenic, mutagenic, and hazardous to human beings when inhaled, EtO is easily distributed throughout the body when inhaled, and the Defendants have emitted excessive and dangerous amounts of EtO into the air which thousands of human beings have breathed for multiple years and will continue to breathe in.

198. At all times relevant hereto, the risk of harm posed by EtO is represented by the Defendants to be unable to be completely eliminated by the exercise of reasonable care, as contemplated by Restatement (Second) of Torts §520(c), because EtO is inherently dangerous, toxic, a known human carcinogenic, mutagenic, and hazardous to human beings when inhaled.

199. At all times relevant hereto, the Defendants' use and emissions of EtO was not a mater of common usage, as contemplated by Restatement (Second) of Torts §520(d) because the use and emission of EtO into the air is not an activity that is commonly carried on by the great mass of mankind or by many people in the community.

200. At all times relevant hereto, the Defendants' use and emissions of EtO were inappropriate to the place where EtO was used and emitted, as contemplated by Restatement (Second) of Torts §520(e), because of the high concentration and amount of human beings living, working, congregating, shopping, and breathing in the air in and surrounding Defendants' Plant including Plaintiff's Decedent.

201. At all times relevant hereto, Defendants' use and emissions of EtO at Defendants' Plant produced a high degree of risk of some harm to other persons including Plaintiff's Decedent – namely those individuals within Defendants' Plant and living, working in, and breathing in the air in the areas surrounding Defendants' Plant.

202. At all times relevant hereto, Defendants' emissions of EtO provided no value to the communities and neighborhoods in and surrounding Defendants' Plant, as contemplated by Restatement (Second) of Torts §520(f), because the Defendants' use and emissions of EtO only increased the risk of cancer in individuals in these communities and neighborhoods where the EtO was emitted with no health benefits to inhalation of the EtO.

203. At all times material hereto, EtO was defective and unreasonably dangerous.

204. Defendants knew or should have known of the existence of a high degree of risk of harm to persons in and surrounding Defendants' Plant, including Plaintiff's Decedent, as a result of its activity herein.

205. Defendants knew or should have known that the harm to persons in and surrounding Defendants' Plant, including Plaintiff's Decedent, would be great.

206. Any value to the community of the chemical EtO described herein is greatly outweighed by its dangerous attributes.

207. As a direct and proximate results of the aforementioned strict liability, abnormally dangerous, and ultrahazardous activity of Defendants, Plaintiff's Decedent suffered the injuries and damages set forth throughout this complaint.

WHEREFORE, Plaintiff demands damages against all Defendants, including punitive damages, in an amount in excess of the prevailing arbitration limits, exclusive of pre-judgment interest, delay damages and costs on all counts.

COUNT THREE – PUBLIC NUISANCE
PLAINTIFF VS. BRAUN DEFENDANTS

208. Plaintiff incorporates herein by reference the foregoing paragraphs as though each were fully set forth herein.

209. For decades, the Defendants have known that EtO is hazardous, dangerous, and carcinogenic to humans.

210. At all times relevant hereto, the Defendants' use and emissions of EtO constituted an unreasonable interference with the public's right to breathe in clean air and – more specifically – air that does not contain inhalable carcinogens that place those who inhale them at an increased risk of developing cancers, miscarriages, and birth defects in their children.
The conduct of Defendants, in their use and emissions of EtO, involves a significant interference with the public health and the public safety because the Defendants' use and emissions of EtO places and placed those individuals who inhale the polluted air Defendants put into the environment at a significantly increased risk of developing various forms of cancer, suffering miscarriages, and developing birth defects in their children.

211. The conduct of Defendants, in their use and emissions of EtO, involves and involves a significant interference with the public health and the public safety because the Defendants' use and emissions of EtO places and placed those individuals who inhale the polluted air

Defendants put into the environment at a significantly increased risk of developing various forms of cancer, suffering miscarriages, and developing birth defects in their children.

212. The conduct of Defendants, in their use and emissions of EtO, is of a continuing nature because Defendants are still emitting EtO to this day, Defendants have been emitting EtO for 28 years, and because EtO's half-life causes it to remain in the air and environment for a significant amount of time all the while causing harm to those who inhale that air.

213. The general public has a right to breathe in air that does not place them at an increased risk of developing cancer at the rate their inhalation of the EtO emitted from Defendants' Plant placed them at.

214. The general pubic has a right to breathe clean air that does not contain dangerous and excessive levels of carcinogenic chemicals that increases one's risk of cancer when inhaled.

215. The public's general right to breath clean air is embodied in Article 1 of the Pennsylvania Constitution, Section 27, Natural Resources and the Public Estate, which expressly provides that: "The people have a right to clean air, pure water, and to the preservation of the natural, scenic, historic, and esthetic values of the environment."

216. The Defendants, at all relevant times, knew that the levels of EtO emitted from Defendants' Plant would create a toxic, dangerous, ultrahazardous, and carcinogenic effect upon the health, safety, and wellbeing of persons breathing it including Plaintiff's Decedent.

217. All times relevant hereto, defendants use and emissions of EtO from Defendants' Plant caused those who live and work in the area of the Defendants' Plant, including Plaintiff's Decedent to breathe air containing dangerous and excessive levels of EtO on a regular and routine basis, causing substantially increased and elevated risks of developing cancer.

218. As a direct and proximate result of the Defendants' improper, negligent, wrongful and grossly negligent use and emissions of EtO from Defendants' Plant, Darrell G. Papsun's and the general public's right to breathe clean air without dangerous levels of carcinogens such as EtO was eliminated and/or severely diminished.

219. As a direct and proximate result of Defendants' improper, negligent, wrongful and grossly negligent use and emissions of EtO from Defendants' Plant, Darrell G. Papsun was caused to continually be exposed to EtO through regular and continuous inhalation.

220. As a direct and proximate result of defendants' improper, negligent, wrongful and grossly negligent use and emissions of EtO from Defendants' Plant, Plaintiff's Decedent suffered the injuries and damages set forth throughout this complaint, including Plaintiff's Decedent, Darrell G. Papsun's development of AML.

WHEREFORE, Plaintiff demands damages against all Defendants, including punitive damages, in an amount in excess of the prevailing arbitration limits, exclusive of pre-judgment interest, delay damages and costs on all counts.

COUNT FOUR – PRIVATE NUISANCE
PLAINTIFF VS. THE BRAUN DEFENDANTS

221. Plaintiff incorporates herein by reference the foregoing paragraphs as though each were fully set forth herein.

222. At all times relevant hereto, Plaintiff's Decedent enjoyed an interest in the private use and enjoyment of land upon which Defendants' excessive and wrongful emission of EtO infringed and invaded.

223. The Defendants' use and emissions of EtO invaded the Plaintiff's Decedent's interest in the private use and enjoyment of the land upon which defendants' excessive and wrongful emissions of EtO travelled and infringed.

224. At all relevant times, the Defendants' use and emissions of EtO constituted an infringement and invasion of Plaintiff's Decedent's interest in the private use and enjoyment of land because he had a right to enjoy the land upon which he used and enjoyed without being contaminated by and infiltrated with an inhalable chemical (EtO) that is highly toxic, hazardous, a known human carcinogen, and which greatly increases the risk of developing various forms of cancer, and other serious adverse health effects of those who inhale such contaminated air.

225. At all relevant times, the Defendants' invasion of the Plaintiff's Decedent's interest in the private use and enjoyment of land was intentional because Defendants purposefully and knowingly emitted hundreds and thousands of pounds of EtO into the air surrounding Defendants' Plant, for multiple years, and Defendants knew that their use and emissions of EtO would result in and/or be substantially certain to reach and be inhaled by thousands of people including Plaintiff's Decedent, in the private use and enjoyment of land surrounding Defendants' Plant.

226. At all relevant times, the Defendants' invasion of the Plaintiff's Decedent's interest in the private use and enjoyment of land was intentional because Defendants purposefully and knowingly emitted hundreds and thousands of pounds of EtO into the air surrounding Defendants' Plant, for multiple years, and Defendants knew that EtO is highly toxic, hazardous, and a known human carcinogen which greatly increases the risk of developing various forms of cancer, suffering miscarriages, and developing birth defects in the children of those who inhale such contaminated air.

227. At all relevant times, Defendants' invasion of Plaintiff's Decedent's interest in the private use and enjoyment of land was unreasonable and the gravity of harm attendant in the Defendants' use and emissions of EtO outweighs the utility of the defendants' conduct in the use and emissions of EtO.

228. At all relevant times, Defendants' invasion of Plaintiff's Decedent's interest in the private use and enjoyment of land was unreasonable because the harm caused by Defendants' conduct in their use and emissions of EtO is serious in that the conduct significantly increased the risk of developing various forms of cancer, and other serious adverse health effects in the many people who inhaled this air.

229. At all relevant times, the financial burden to Defendants of compensating others for the harm they did through their use and emissions of EtO would not make the continuation of Defendants' conduct in their use and emissions of EtO not feasible.

230. As a direct factual and proximate result and cause of Defendants' negligent, wrongful, grossly, negligent, and reckless use and emissions of EtO, Plaintiff's Decedent's development of AML.

WHEREFORE, Plaintiff demands damages against all Defendants, including punitive damages, in an amount in excess of the prevailing arbitration limits, exclusive of pre-judgment interest, delay damages and costs on all counts.

COUNT FIVE – VIOLATION OF ARTICLE 1,
SECTION 27 OF THE PENNSYLVANIA CONSTITUTION
PLAINTIFF VS. THE BRAUN DEFENDANTS

231. Plaintiff incorporates herein by reference the foregoing paragraphs as though each were fully set forth herein.

232. At all times relevant hereto, pursuant to Article 1, Section 27 of the Pennsylvania Constitution, Plaintiff's Decedent, Darrell G. Papsun had a right to clean air.

233. For all the reasons outline throughout the entirety of this complaint, the Defendants violated and invaded the right of Plaintiff and her decedent, pursuant to Article 1, Section

27 of the Pennsylvania Constitution, to clean air, by emitting excessive and dangerous amounts of EtO that Plaintiff's Decedent breathed in and consequently acquired AML

234. The Defendants violated and invaded the right of Plaintiff and her decedent, pursuant to Article 1, Section 27 of the Pennsylvania Constitution, to clean air by committing all the various acts and omissions that are specifically outlined and averred in all Counts One through Four of this Complaint, and which also form the basis for Plaintiff's negligence, strict liability, public nuisance, private nuisance, fraud, fraudulent concealment, negligent misrepresentation, and civil conspiracy claims.

235. At all times relevant hereto, Defendants were bound by Article 1, Section 27 of the Pennsylvania Constitution's mandate to ensure that people in Pennsylvania, including Plaintiff's Decedent, Darrell G. Papsun, to have clean air to breathe.

236. As a resident of Pennsylvania, Plaintiff's Decedent, Darrell G. Papsun is one of the class of persons to whom the benefit of Article 1, Section 27 of the Pennsylvania Constitution was specifically conferred.

237. It was the intent of the legislature and citizens and residents of Pennsylvania that a private a right of action and remedy exist pursuant to Article 1, Section 27 of the Pennsylvania Constitution.

238. A private right of action pursuant to Article 1, Section 27 of the Pennsylvania Constitution is consistent with the underlying purpose of the Article 1, Section 27 of the Pennsylvania Constitution to protect people in Pennsylvania from breathing, polluted, unclean or unsafe air.

WHEREFORE, Plaintiff demands damages against all Defendants, including punitive damages, in an amount in excess of the prevailing arbitration limits, exclusive of pre-judgment interest, delay damages and costs on all counts.

CAUSES OF ACTION

COUNT SIX
STRICT LIABILITY - DEFECTIVE DESIGN
PLAINTIFF VS. THE PHILIPS DEFENDANTS

239. Plaintiff incorporates herein by reference the foregoing paragraphs as though each were fully set forth herein.

240. At all times mentioned, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed the Devices as hereinabove described that were prescribed to and used by Plaintiff's Decedent.

241. Defendants each had a duty to place into the stream of commerce, manufacture, distribute, market and promote and sell the Devices so that they were neither defective nor unreasonably dangerous when used for which they were designed, manufactured, distributed, marketed and sold.

242. At all times herein mentioned, the Devices were in an unsafe, defective and inherently dangerous condition for users such as Plaintiff's Decedent.

243. Defendants each had a duty to place into the stream of commerce, manufacture, distribute, market, promote and sell the Devices so that they were neither defective nor unreasonably dangerous when used for which they were designed, manufactured, distributed, marketed and sold.

244. At all times herein mentioned, the Devices were in an unsafe, defective and inherently dangerous condition for uses such as Plaintiff's Decedent.

245. At all times of use of the Devices subject by Plaintiff's Decedent, the Devices were being used for the purposes and in a manner normally intended, namely for use as treatment for sleep apnea.

246. At the time the subject Devices left the possession of Defendants and the time the Devices entered the stream of commerce, they were in an unreasonably dangerous or defective condition. The defects include, but are not limited to, the following:

(a) the Device was not reasonably safe as intended to be used;

(b) the Device had an inadequate design for the purpose of treatment of sleep apnea, in that the sound abatement foam should not release toxic and carcinogenic particles and should not have been placed in the device's airpath where such particles would then travel directly into patients' lungs and bodies;

(c) the Device contained unreasonably dangerous design defects, including an inherently defective design, i.e., placement of a sound abatement foam that releases toxic and carcinogenic particles directly in the airpath of the Device, from where such particles could easily travel to the user;

(d) the Device's defective design resulted in a CPAP device which had risks that far exceeded the benefits of the medical device;

(e) the Device was not appropriately or adequately tested before their distribution; and

(f) the Device has an unreasonably high propensity for the release of toxic and carcinogenic particles under normal and expected use of the Device;

(g) the Device has built-in settings for heat and humidity that are expected to be utilized during normal use, and according to Philips, such environmental factors may exacerbate the release of toxic and carcinogenic particles from the sound abatement foam in the Device.

247. At all times herein mentioned, the Device was expected to and did reach the usual consumers, handlers, and persons coming into contact with the said products without

substantial change in the condition in which it was designed, produced manufactured, sold, distributed, and marketed by Defendants.

248. The Device's unsafe, defective, and inherently dangerous conditions were the cause of injury to Plaintiff's Decedent.

249. The Device failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner.

250. Plaintiff's Decedent's illness and death resulted from use of the Device that was both intended and reasonably foreseeable by Defendants.

251. At the time of Defendants' initial design, manufacture, marketing and sale of the Device, a feasible, alternative safer design for the Device was known and available to Philips.

252. At the time of and subsequent to Defendants' initial design, manufacture, marketing and sale of the Device, including prior to the time of Plaintiff's Decedent's initial purchase and use of the Device, Defendants had the ability to eliminate the unsafe character of the Device without impairing its usefulness, as by either using non-toxic, non-carcinogenic sound abatement foam, or by simply placing the sound abatement foam anywhere else in the Device besides the Device's airpath, among other reasonable alternatives.

253. Had Defendants properly and adequately tested the Devices, Defendants would have discovered that the Device had a high propensity for releasing toxic and carcinogenic particles when used normally by patients.

254. The Device manufactured and supplied by Defendants, was therefore, defective in design or formulation in that, when it left the hands of Defendants, the foreseeable risk of harm from the product exceeded or outweighed the benefit or utility of the Device's particular design

or formulation, and/or it was unreasonably dangerous to the user or consumer, and/or it failed to comply with federal requirements for these medical devices.

255. The foreseeable risks associated with the design or formulation of the Device include, but are not limited to, the fact that the design or formulation of these devices are more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner, and/or it failed to comply with federal requirements.

256. At all times herein mentioned, the Defendants knew, or should have known, that the Device was in a defective condition, and were inherently dangerous and unsafe for use.

257. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed defective products which, when used in their intended or reasonably foreseeable manner, created an unreasonable risk to the health of consumers and to Plaintiff's Decedent, in particular, and Defendants are therefore strictly liable for the injuries sustained by Plaintiff's Decedent.

258. As a direct and proximate result of Plaintiff's Decedent's use of Defendants' Device, as manufactured, designed, sold, supplied, marketed and introduced into the stream of commerce by Defendants and/or their failure to comply with federal requirements, he suffered serious physical injury, harm damages, economic loss and death.

WHEREFORE, Plaintiff demands damages against all Defendants, including punitive damages, in an amount in excess of the prevailing arbitration limits, exclusive of pre-judgment interest, delay damages and costs on all counts.

COUNT SEVEN
STRICT LIABILITY – FAILURE TO WARN
PLAINTIFF VS. THE PHILIPS DEFENDANTS

259. Plaintiff incorporates herein by reference the foregoing paragraphs as though

each were fully set forth herein.

260. At all times relevant herein, Defendants were engaged in the design, development, testing, manufacturing, marketing and sale of the Device.

261. Defendants designed, manufactured, assembled and sold the Philips CPAP device to medical distributors and patients knowing that they would then be used by patients to treat sleep apnea.

262. The Devices placed into the stream of commerce by Defendants were defective due to inadequate warnings, because Defendants knew or should have known that the Device could release toxic and/or carcinogenic particles in patients when used and therefore gives rise to serious physical injury, pain and suffering, debilitation, and death, but failed to give consumers adequate warning of such risks.

263. Defendants had a duty to warn their sales representatives/distributors, prescribing sleep doctors, and patients such as Plaintiff's Decedent, and Defendants breached their duty in that they failed to provide adequate and timely warnings or instructions regarding their Devices, and their known defects and potential risks, including their propensity to release toxic and/or carcinogenic particles when used normally.

264. Adequate efforts to communicate an adequate warning to the ultimate users were not made by Defendants (or Defendants' sales representatives/distributors).

265. Defendants are strictly liable to Plaintiff and the estate and heirs she represents because the warnings to Plaintiff's Decedent, and his prescribing physician about the dangers the Device posed to consumers when used were inadequate. Examples of the lack and/or inadequacy of Defendants' warnings include, but are not limited to, one or more of the following particulars:

(a) the Devices contained warnings insufficient to alert Plaintiff's Decedent, the medical equipment supplier and Plaintiff's Decedent's physicians as to the risk of adverse events, i.e., respiratory issues, development of disease like cancer, and even death, associated with use of the Devices, subjecting Plaintiff's Decedent's to risks which exceeded the benefits of the Devices;

(b) the Devices contained warnings insufficient to alert Plaintiff's Decedent and his physicians as to the release of toxic and carcinogenic particles when used normally;

(c) the Devices contained misleading warnings emphasizing the efficacy of the Device while downplaying the risks associated with it use, thereby making use more dangerous than the ordinary consumer would expect;

(d) the Devices contained insufficient and/or incorrect warnings to alert consumers, including Plaintiff's Decedent, the medical supplier, and the prescribing physicians, regarding the risk, scope, propensity, frequency, duration and severity of the adverse events associated with use of the Devices;

(e) the Devices did not disclose that they were inadequately tested;

(f) the Devices failed to convey adequate post-marketing warnings regarding the risk, severity, propensity, frequency, scope and/or duration of the dangers posed by normal use of the Devices to treat sleep apnea;

(g) the Devices failed to contain instructions sufficient to alert consumers to the dangers they posed and to give them the information necessary to avoid or mitigate those dangers.

266. Further, the Devices are unreasonably dangerous because they were sold to Plaintiff's Decedent without an adequate warning that when used normally, the PE-PUR sound abatement foam will release toxic and carcinogenic particles that can lead to serious injury or death.

267. There are other manufacturers of sleep apnea machines on the market that do not contain this foam design defect and Plaintiff's Decedent could have chosen to acquire a different model and brand had this defect been disclosed.

268. The Devices placed into the stream of commerce by Defendants were used by patients like Plaintiff's Decedent in a manner reasonably anticipated by Defendants.

269. As a direct and proximate result of Defendants' failure to adequately communicate a warning and/or failure to provide an adequate warning and other wrongful conduct as set forth herein, Plaintiff's Decedent has suffered serious physical injury, harm damages and economic loss and will continue to suffer such harm, damages and economic loss in the future, and is entitled to compensatory damages in an amount to be determined by the trier of facts.

WHEREFORE, Plaintiff demands damages against all Defendants, including punitive damages, in an amount in excess of the prevailing arbitration limits, exclusive of pre-judgment interest, delay damages and costs on all counts.

COUNT EIGHT
STRICT PRODUCTS LIABILITY - MANUFACTURING DEFECT AND FAILURE TO ADHERE TO QUALITY CONTROLS
PLAINTIFF VS. THE PHILIPS DEFENDANTS

270. Plaintiff incorporates herein by reference the foregoing paragraphs as though each were fully set forth herein.

271. The recalled devices, including the Subject Device, are defectively manufactured because the foreseeable risks of cancer and other serious injury and illness outweigh the benefits associated with the Devices.

272. The Devices were designed and/or manufactured in a manner violative of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §321 *et. seq.*, and the Medical Devices Amendment thereto (hereafter "FDCA"). The facilities or controls used by defendants in the manufacture, testing, packing, storage, or installation of the Devices were not in conformity with applicable requirements of the FDCA.

273. The Devices were expected to and did reach Plaintiff's Decedent without substantial change or adjustment to its function.

274. Defendants knew or should have known of the manufacturing defects and the risk of serious bodily injury that exceeded the benefits associated with the Devices.

275. Furthermore, the Devices and their defects presented an unreasonably dangerous risk beyond what the ordinary consumer would reasonably expect.

276. The Devices are inherently dangerous for their intended use due to a manufacturing defect or defects and improper functioning. Defendants are therefore strictly liable to Plaintiff for their breach of duty to Plaintiff's Decedent.

277. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff's Decedent developed a fatal form of AML, and suffered all the related harms and damages alleged herein and will continue to suffer severe emotional distress, mental anguish, and other damages for which Plaintiff is entitled to compensatory damages in an amount to be proven at trial.

WHEREFORE, Plaintiff demands damages against all Defendants, including punitive damages, in an amount in excess of the prevailing arbitration limits, exclusive of pre-judgment interest, delay damages and costs on all counts.

COUNT NINE
NEGLIGENCE
PLAINTIFF VS. THE PHILIPS DEFENDANTS

278. Plaintiff incorporates herein by reference the foregoing paragraphs as though each were fully set forth herein.

279. While the focus of Plaintiff's strict liability claims is on the product, the focus of Plaintiff's negligence claim is instead on Defendants' conduct. Defendants had a duty to exercise reasonable care in the design, formulation, manufacture, testing, quality assurance, quality control, labeling, warning, sale and/or distribution of the Devices, including a duty to assure that their products did not pose a significantly increased risk of life-threatening bodily harm and disease.

280. Defendants failed to exercise reasonable care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, warning, marketing, promotions and distribution of the Devices in that Defendants knew or should have known that these products caused significant bodily harm and were not safe for use by consumers.

281. The negligence of Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

(a) negligently designing the recalled devices' PE-PUR sound abatement foam such that it has a high propensity to release toxic and carcinogenic particles during normal use of the device;

(b) negligently designing the recalled devices such that the sound abatement foam is placed in the airpath of the device, where the foam's propensity to release toxic and

carcinogenic particles is most deleterious to a patient's health because they will directly inhale such toxins and carcinogens;

(c) negligently designing the recalled products such that they contain built-in settings for use that allow a user to increase the heat and humidity of the air being convected through the devices' airpaths, despite Defendants knowing that heat and humidity can exacerbate the release of the toxic and carcinogenic particles from the PE-PUR sound abatement foam;

(d) designing, manufacturing, producing, creating, and/or promoting the devices for use in treating sleep apnea without adequately, sufficiently, or thoroughly testing them, including both pre-market testing and post-market surveillance;

(e) not conducting sufficient testing programs to determine whether or not the PE-PUR sound abatement foam was safe for use in the devices;

(f) selling the devices without making proper and sufficient tests to determine the dangers when used in a reasonably foreseeable and normal manner;

(g) negligently failing to adequately and correctly warn Plaintiff's Decedent or Plaintiff's Decedent's physicians, hospitals, healthcare providers, and medical device distributors of the dangers of using the recalled devices, including:

(1) negligently failing to warn of an increased risk of release of toxic and carcinogenic particles;

(2) negligently failing to warn of the risk of development of serious disease such as cancer or even death;

(3) negligently failing to recall their dangerous and defective CPAP devices at the earliest date it became known that the devices were, in fact, dangerous and defective;

(4) negligently advertising and recommending the use of the devices despite the fact Defendants knew or should have known of their dangerous propensities;

(5) negligently representing that the devices were safe for the intended use, when in fact, they were unsafe;

(6) negligently manufacturing the devices in a manner which was dangerous to those individuals who used them;

(h) Defendants under-reported, underestimated, and downplayed the serious dangers associated with the PE-PUR sound abatement foam used in all of the recalled devices;

(i) Defendants failed to use due care in designing and manufacturing the devices so as to ensure good performance and durability and reduce the risk of degradation and off-gassing of toxic and carcinogenic particles that could be directly inhaled by the user;

(j) failed to accompany their products with proper warnings;

(k) failed to accompany their products with proper instructions for use;

(l) failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of the recalled devices when used normally.

282. Despite the fact that Defendants knew or should have known that use of the Devices caused harm to individuals that used them, Defendants continued to market, manufacture, distribute and/or sell the Devices for use in treating sleep apnea.

283. Defendants knew or should have known that consumers such as Plaintiff's Decedent would suffer foreseeable injury, and/or be at increased risk of suffering injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

284. Defendants, furthermore, in advertising, marketing, promoting, packaging and selling the Devices negligently misrepresented material facts regarding their safety, efficacy and fitness for human use by claiming the Devices were fit for their intended purpose of use when, in fact, they were not.

285. Defendants' negligence was the proximate cause of Plaintiff's Decedent's physical, mental and emotional injuries and harm, and economic loss which Plaintiff's Decedent has suffered and/or will continue to suffer.

286. By reason of the foregoing, Plaintiff, her Decedent and the estate she represents experienced and will continue to experience severe harmful effects as a result of Defendants' negligence as set forth above.

287. Defendants' conduct, as described above, including, but not limited to, Defendants' failure to adequately test and warn, as well as their continued marketing and distribution of the Devices when they knew or should have known of the serious health risks these devices created when used normally by patients such as Plaintiff's Decedent.

288. As a direct and proximate result of Defendants' negligence, including negligent testing, failure to warn and misrepresentations, Plaintiff's Decedent incurred his fatal illness, and he and his estate and heirs suffered all the related damages alleged herein.

WHEREFORE, Plaintiff demands damages against all Defendants, including punitive damages, in an amount in excess of the prevailing arbitration limits, exclusive of pre-judgment interest, delay damages and costs on all counts.

COUNT TEN
BREACHOF EXPRESS WARRANTY
13 Pa. CSA §2313
PLAINTIFF VS. THE PHILIPS DEFENDANTS

289. Plaintiff incorporates herein by reference the foregoing paragraphs as though each were fully set forth herein.

290. Defendants expressly warranted that the Devices were safe and effective medical devices to be used for patients suffering from sleep apnea.

291. At the time Defendants marketed, sold and/or distributed the Devices, including the subject Device, they knew that the Devices were intended for human use, and that Plaintiff's Decedent was a foreseeable user of the Devices.

292. The express warranties represented by Defendants were a part of the basis for Plaintiff's Decedent's use of the Devices, and Plaintiff's Decedent and his physicians relied on these warranties in deciding to use the Devices.

293. At the time of the making of the express warranties, Defendants had knowledge of the purpose for which the Devices were to be used, and warrantied the same to be in all respects safe, effective and proper for such purpose.

294. The Devices do not conform to these express representations as shown by the development of AML in Plaintiff's Decedent.

295. At the time Defendants marketed, sold and/or distributed the recalled devices, Defendants expressly warranted that the recalled devices were safe for their intended use.

296. Plaintiff's Decedent and Plaintiff's Decedent's prescribing physicians reasonably relied upon Defendants' express warranties.

297. Plaintiff's Decedent used the Device for its intended purpose, and in a reasonably foreseeable manner.

298. The Devices manufactured and sold by Defendants did not conform to Defendants' express representations because the Devices caused serious injury to Plaintiff's Decedent when used as recommended and directed.

299. As a direct and proximate result of Defendants' breach of express warranty, Plaintiff's Decedent incurred his fatal illness, and he, his estate and heirs suffered and/or continue to suffer the related harms and damages alleged herein.

WHEREFORE, Plaintiff demands damages against all Defendants, including punitive damages, in an amount in excess of the prevailing arbitration limits, exclusive of pre-judgment interest, delay damages and costs on all counts.

COUNT ELEVEN
BREACH OF IMPLIED WARRANTIES OF
MERCHANTABILITY AND FOR A PARTICULAR PURPOSE
13 Pa. CSA §2314
PLAINTIFF VS. THE PHILIPS DEFENDANTS

300. Plaintiff incorporates herein by reference the foregoing paragraphs as though each were fully set forth herein.

301. At the time Defendants designed, manufactured, marketed, sold and distributed the Devices, including the subject Device for use by Plaintiff's Decedent, Defendants knew of the use for which these devices were intended and impliedly warranted these products to be of merchantable quality and safe for such use and that their design, manufacture, labeling and marketing complied with all applicable federal requirements.

302. The Devices manufactured and supplied by Defendants were not of merchantable quality and were not fit for the ordinary and/or particular purpose for which they were intended as, among other defects, the risk included an unreasonably high risk of developing cancer or other serious illness due to the release of toxic and carcinogenic particles from the device's PE-PUR sound abatement foam.

303. Plaintiff's Decedent and/or Plaintiff's Decedent's physician reasonably relied upon the skill and judgment of Defendants as to whether the Devices were of merchantable quality and safe for their intended and particular use and purpose, and upon Defendants' implied warranty as to such matters.

304. Contrary to such implied warranties, the devices were not of merchantable quality or safe for their intended and particular use and purpose, because the products were defective when used normally as described above, and/or failed to comply with federal requirements.

305. As a direct and proximate result of Defendants' breach of implied warranties, Plaintiff's Decedent has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future and is entitled to compensatory damages in an amount to be proven at trial.

306. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the Devices.

307. At the time Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce the Devices, Defendants knew the use for which the Devices were intended, and impliedly warranted Devices to be safe for such use.

308. Plaintiff's Decedent and/or Plaintiff's Decedent's physician reasonably relied upon the skill and judgment of Defendants as to whether the Devices were safe for its intended use.

309. Contrary to Defendants' implied warranties, the Devices were not fit for their intended and particular use and purpose, because the Devices were defective when used as described above, and/or failed to comply with federal requirements.

310. As a direct and proximate result of Defendants' breach of implied warranties, Plaintiff's Decedent has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future and is entitled to compensatory damages in an amount to be proven at trial.

WHEREFORE, Plaintiff demands damages against all Defendants, including punitive damages, in an amount in excess of the prevailing arbitration limits, exclusive of pre-judgment interest, delay damages and costs on all counts.

COUNT THIRTEEN
SURVIVAL ACTION
PLAINTIFF VS. ALL DEFENDANTS.

311. Plaintiff incorporates herein by reference the foregoing paragraphs as though each were fully set forth herein.

312. Plaintiff claims the right to prosecute this action and recover on behalf of the Estate of Darrell G. Papsun all damages allowable under Pennsylvania's Survival Act, 42 Pa. C.S.A. §8302, including but not limited to Darrell G. Papsun's pain, suffering and emotional distress, dread and apprehension of impending death, loss of life's pleasures, loss of earnings and earning capacity, and medical expenses incurred in an effort to treat his AML. All such damages were proximately caused by the culpable acts and omissions of Defendants as alleged herein.

WHEREFORE, Plaintiff asks the Court to enter judgment in her favor and against Defendants, individually, joint and/or severally, in an amount in excess of the jurisdictional limit for mandatory arbitration in this County.

COUNT FOURTEEN
WRONGFUL DEATH
PLAINTIFF VS. ALL DEFENDANTS

313. Plaintiff incorporates herein by reference the foregoing paragraphs as though each were fully set forth herein.

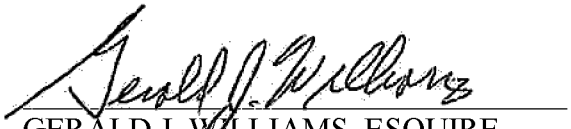
314. Plaintiff claims the right to prosecute this action on behalf of herself and the other beneficiary of Darrell G. Papsun's estate, and to recover all damages allowable under Pennsylvania's Wrongful Death Act, 42 Pa. C.S.A. Sec. 8301, including but not limited to all pecuniary losses resulting from his death, including funeral expenses, and all other damages, including but not limited to current and/or anticipated financial contributions from the Decedent, and the loss of his consortium, companionship and services.

315. All such damages were proximately caused by the culpable acts and/or omissions of defendants alleged herein.

WHEREFORE, Plaintiff asks the Court to enter judgment in her favor and against Defendants, individually, joint and/or severally, in an amount in excess of the jurisdictional limit for mandatory arbitration in this County.

Respectfully submitted,

WILLIAMS CEDAR, LLC

BY: 

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Dated: 05/26/2023

VERIFICATION

SHERRI PAPSUN hereby states that she is the Plaintiff in this action and verifies that the statements made in the foregoing Complaint in Civil Action is true and correct to the best of her knowledge, information and belief. The undersigned understands that the statements therein are made subject to penalties of 18 Pa.C.S.A. Sec. 4904 relating to unsworn falsification to authorities.

SHERRI PAPSUN

Dated: 5/22/23

IN THE COURT OF COMMON PLEAS OF LEHIGH COUNTY, PENNSYLVANIA

CIVIL DIVISION

SHERRI PAPSUN, Administratrix of the Estate of DARRELL G. PAPSUN	:	
Plaintiff	:	
vs.	:	File No.
B. MEDICAL, INC., et al.	:	
Defendant	:	

NOTICE TO DEFEND

You have been sued in court. If you wish to defend against the claims set forth in the following pages, you must take action within twenty (20) days after this complaint and notice are served, by entering a written appearance personally or by attorney and filing in writing with the court your defenses or objections to the claims set forth against you. You are warned that if you fail to do so the case may proceed without you and a judgment may be entered against you by the court without further notice for any money claimed in the complaint or for any other claim or relief requested by the plaintiff. You may lose money or property or other rights important to you.

YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER AT ONCE. IF YOU DO NOT HAVE A LAWYER, GO TO OR TELEPHONE THE OFFICE SET FORTH BELOW. THIS OFFICE CAN PROVIDE YOU WITH INFORMATION ABOUT HIRING A LAWYER.

IF YOU CANNOT AFFORD TO HIRE A LAWYER, THIS OFFICE MAY BE able TO PROVIDE YOU WITH INFORMATION ABOUT AGENCIES THAT MAY OFFER LEGAL SERVICES TO ELIGIBLE PERSONS AT A REDUCED FEE OR NO FEE.

LEHIGH COUNTY BAR ASSOCIATION

LAWYER REFERRAL SERVICE

1114 W. WALNUT STREET

ALLENTOWN, PENNSYLVANIA 18102

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Signature

Gerald J. Williams, Esquire PA I.D> #36418

(Name)

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Exhibit D

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Attorney for Plaintiff

ROGER TRAVERA Plaintiff v. KONINKLIJKE PHILIPS N.V.; PHILIPS NORTH AMERICA, LLC; PHILIPS RS NORTH AMERICA, LLC; ADAPTHEALTH CORP.; and CMMC, INC. Defendants	:	First Judicial District Court of Common Pleas of Philadelphia Civil _____ 2021 Term No. _____ COMPLAINT JURY TRIAL DEMANDED NON-ARBITRATION

COMPLAINT

NOW COMES ROGER TRAVERSA, Plaintiff, by and through Counsel, and who hereby jointly submit the following Complaint, and in support thereof, hereby aver as follows:

1. Roger Traversa, ("Mr. Traversa") for years suffered through health-threatening and debilitating sleep apnea.

2. Sleep apnea is a condition that causes a person to stop breathing for various lengths of time while they sleep; as a result, sleep apnea patients wake repeatedly during the night.

3. The loss of sleep during the night can have numerous deleterious effects, and is associated with an increase in heart disease, liver disease, hypertension, and metabolic syndrome.

4. Sleep apnea can also have serious social and professional consequences, as the lack of sleep during the night often causes excessive daytime sleeping, unintentional nodding off at work, moodiness, and irritability.

5. To treat sleep apnea, sleep medicine specialists prescribe a Continuous Positive Airway Pressure ("CPAP") machine.

6. CPAP works by maintaining a constant flow of filtered, pressurized air through a mask fitted over the mouth and/or nose; the pressurized air works to keeps the airway open.

7. Mr. Traversa relied on a CPAP machine designed, manufactured, and/or sold by the Defendants in order to sleep through the night.

8. Unfortunately, this machine almost killed him.

THE PARTIES

9. At all times relevant hereto, Plaintiff Roger Traversa was (and is) a citizen of the Commonwealth of Pennsylvania, currently residing at 2110 W. Master Street, Unit B, Philadelphia, PA 19121.

10. Defendant Koninklijke Philips N.V. ("Koninklijke") is a Dutch multinational company headquartered in Amsterdam, Netherlands, and is the parent company of Philips North America LLC and Philips RS North America LLC.

11. Defendant Philips North America LLC ("PNA") is a Delaware company with its principal place of business in Cambridge, Massachusetts.

12. Defendant Philips RS North America LLC (formerly Respironics, Inc.) (PRS) is a Delaware company with its headquarters and principal place of business in Murrysville, Pennsylvania.

13. Hereinafter, Koninklijke, PNA, and PRS shall be collectively referenced as "Philips" unless the facts require specifying the Philips entity involved.

14. Defendant AdaptHealth, Inc. ("AdaptHealth") is a Delaware corporation with its principal place of business in Plymouth Meeting, Pennsylvania and is the parent company of CMMC, Inc.

15. Defendant CMMC, Inc. ("CMMC") is a Pennsylvania, non-profit, non-stock company with its principal place of business in Phoenixville, Pennsylvania. CMMC transacts business under the fictitious name of Montgomery Medical Equipment Company.

16. Hereinafter, AdaptHealth and CMMC shall be collectively referenced by its fictitious name "Montgomery" unless the facts require specifying the Montgomery entity involved.

17. At all relevant times, each Philips Defendant acted in all respects as the agent and alter ego of each other.

18. At all relevant times, each Montgomery Defendant acted in all respects as the agent and alter ego of each other.

JURISDICTION AND VENUE

19. Subject matter jurisdiction is proper in this Court pursuant to 42Pa.C.S.A. §931(a), which grants "unlimited original jurisdiction" over "all actions and proceedings..."

20. Personal jurisdiction is established over Defendants PRS and Montgomery by virtue of the presence in the Commonwealth of Pennsylvania.

21. Personal jurisdiction over Defendants Koninklijke and PNA is established pursuant to 42 Pa.C.S.A. §5322(a)(1), because of their regularly conducted business in the Commonwealth of Pennsylvania.

22. Venue is proper in this Court pursuant to Rule 1006(a)(1), because the causes of action arose in Philadelphia County.

FACTUAL ALLEGATIONS

CPAP AND BIPAP MACHINES AND VENTILATORS

23. CPAP and BiPAP ("BiLevel Positive Airway Pressure") machines and ventilators are all used to treat serious respiratory conditions by helping patients to breathe.

24. CPAP and BiPAP machines are used primarily as treatment for sleep apnea.

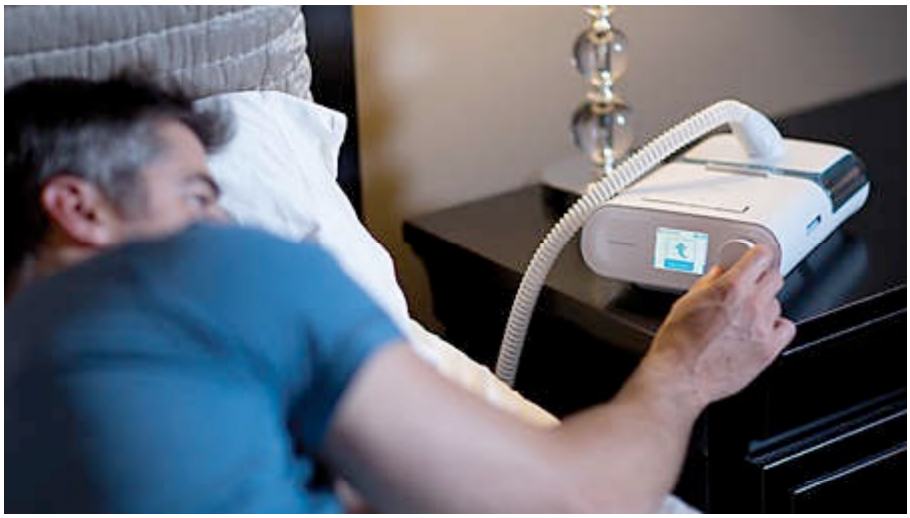
25. Sleep apnea (sometimes called obstructive sleep apnea) is a disorder in which breathing is disturbed temporarily during sleep. Breathing may stop or become very shallow. These periods are called "apneas" or "apnea events" and they may be associated with fatigue, daytime sleepiness, depression, interrupted sleep, or snoring, among other symptoms. Serious cases can lead to hypertension, heart attack, or stroke, among other medical ailments. It is estimated that over 25 million Americans suffer from sleep apnea.

26. CPAP therapy is the most common treatment for sleep apnea. In CPAP therapy, a machine delivers a flow of air through a mask over the nose and/or mouth, which increases air pressure in the throat so that the airway does not collapse during inhalation. CPAP therapy assists breathing during sleep and can successfully treat sleep apnea. According to the Mayo Clinic, "CPAP is the most consistently successful and most commonly used method of treating obstructive sleep apnea."

27. CPAP machines consist of a main unit which connects to a facemask via an air hose. A patient will typically place the main unit on a nightstand and then wear the mask in bed while sleeping.

28. The following images show the general components and typical use of these machines:

29.



30. Sleep apnea patients typically use these machines every night when they sleep. Symptoms may return quickly, often immediately, without continued use.

31. This suit involves the use of the Philips DreamStation machine designed and manufactured by Defendant Philips, and sold by Defendant Montgomery to the Plaintiff.

32. CPAP and BiPAP machines and ventilators are big business. The global sleep apnea devices market size was valued at $3.7 billion in 2020 and is expected to expand considerably in the coming years.

33. Philips is a major manufacturer of CPAP machines, BiPAP machines, and ventilators. Philips has sold millions of CPAP and BiPAP machines and ventilators in the United States.

34. Philips's primary line of CPAP/BiPAP machine products has been the DreamStation line. The original DreamStation launched in October 2015. Philips subsequently launched a more compact version which it advertises as ideal for travel called the DreamStation Go.

35. The DreamStation products have been among the bestselling sleep apnea devices on the market.

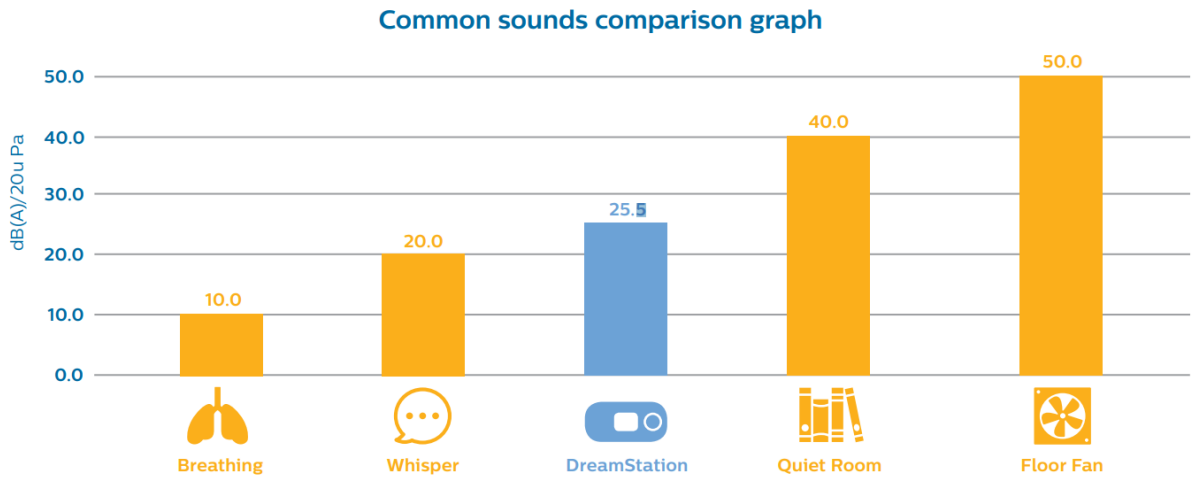
36. Philips designed, manufactured, and/or marketed DreamStation products through its Western Pennsylvania based subsidiary, Respironics (now Philips RS North America LLC), which Philips acquired in 2008.

37. Sales to the ultimate consumer proceeded through medical supply companies; Plaintiff's physician prescribed and ordered the DreamStation and Plaintiff received the DreamStation which was purchased from CMMC on or about November 23, 2015.

38. Many of Philips's CPAP and BiPAP machines and ventilators contain PE-PUR foam in order to reduce sound made by the machines. As designed, air passes through this foam before it is pumped into the patient's airway. Some of the sound generated by the machine is thereby absorbed by the foam.

39. Sound reduction can be an attractive feature since patients operate these devices while they (and their partners) are sleeping. In fact, the relative quiet of DreamStation products factors prominently into Philips's marketing. Philips put out information that it extensively studied and measured the amount of sound produced by DreamStation products. For example, Philips put out the following infographic indicating DreamStation products are barely louder than a whisper:

40. Infographic:



41. On April 13, 2021, Philips announced that it was launching a next-generation model of the DreamStation, called the DreamStation 2.

RECALL AND SERIOUS HEALTH RISKS

42. On April 26, 2021, less than two weeks after it announced the launch of the second-generation, Philips announced the recall of first-generation DreamStation products due to concerns about serious health risks.

43. Philips has determined from user reports and testing that there are possible risks to users related to the sound abatement foam used in certain of Philips' sleep and respiratory care devices currently in use. The risks include that the foam may degrade and/or off-gas under certain circumstances, including being influenced by factors such as use of unapproved cleaning methods, such as ozone, and certain environmental conditions involving high humidity and temperature. The majority of the affected devices are in the first-generation DreamStation product family.

44. On June 14, 2021, Philips issued a further statement about the possible health risks stemming from deterioration of the PE-PUR foam. See https://www.usa.philips.com/a-w/about/news/archive/standard/news/press/2021/20210614-philips-issues-recall-notification-to-mitigate-potential-health-risks-related-to-the-sound-abatement-foam-component-in-certain-sleep-and-respiratory-care-devices.html, a printout of which is attached as Exhibit __.

45. To date, Philips has produced millions of Bi-Level PAP, CPAP and mechanical ventilator devices using the PE-PUR sound abatement foam. Despite a low complaint rate (0.03% in 2020), Philips determined based on testing that there are possible risks to users related to this type of foam. The risks include that the PE-PUR foam may degrade into particles which may enter the device's air pathway

and be ingested or inhaled by the user, and the foam may off-gas certain chemicals. The foam degradation may be exacerbated by use of unapproved cleaning methods, such as ozone, and high heat and high humidity environments may also contribute to foam degradation.

46. Philips further explained that it "has received reports of possible patient impact due to foam degradation. The potential risks of particulate exposure include headache, irritation, inflammation, respiratory issues, and possible toxic and carcinogenic effects. The potential risks of chemical exposure due to off-gassing include headache, irritation, hypersensitivity, nausea/vomiting, and possible toxic and carcinogenic effects."

47. On the same day, Philips also issued "Clinical information for physicians," which explained that the foam breakdown "may lead to patient harm and impact clinical care." Philips warned doctors that the following symptoms and health effects can result:

48. While there have been limited reports of headache, upper airway irritation, cough, chest pressure, and sinus infection that may have been associated with the foam, based on lab testing and evaluations, it may be possible that these potential health risks could result in a wide range of potential patient impact, from transient potential injuries, symptoms and complications, as well as possibly serious injury which can be life-threatening or cause permanent impairment, or require medical intervention to preclude permanent impairment.

49. Deterioration of the foam can release harmful chemicals into the air that the machines are pumping into patients' lungs, including toluene diamine, toluene diisocyanate, and diethylene glycol.

50. The National Institute for Occupational Safety and Health categorizes toluene diisocyanate as "potential carcinogen." The European Union considers toluene diisocyanate "highly toxic" and has concluded that toluene diamine "cannot be considered safe for use."

51. Philips disclosed that it "has received several complaints regarding the presence of black debris or particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask)." The PE-PUR foam is black, and when it breaks down, it can release these particles into the airpath.

52. Harmful gasses can also be released as the foam degrades, including dimethyl diazine and Phenol, 2,6-bis (1,1-dimethylethyl)-4-(1-methylpropyl)-.

53. Philips admitted that these harmful substances can cause: "irritation and airway inflammation, and this may be particularly important for patients with underlying lung diseases or reduced cardiopulmonary reserve" and may lead to the following symptoms: "headache/dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, nausea/vomiting, toxic and carcinogenic effects," as well as "adverse effects to other organs such as kidney and liver."

54. Philips advised patients to stop using affected CPAP and BiPAP machines immediately because of the potential health risks.

55. The statement also acknowledged that it may be too dangerous for patients using affected ventilators to stop using them and more or less advised doctors to decide

whether it was more dangerous to take the patient off the ventilator or to leave the patient on the defective ventilator.

56. At no point has Montgomery informed Plaintiff about the dangers of using the DreamStation CPAP even though Montgomery had a direct relationship with Plaintiff.

57. The products affected by the recall include:

i. E30
ii. DreamStation ASV
iii. DreamStation ST, AVAPS
iv. SystemOne ASV4
v. C Series ASV, S/T, AVAPs
vi. OmniLab Advanced Plus
vii. SystemOne (Q Series)
viii. DreamStation CPAP, Auto CPAP, BiPAP
ix. DreamStation Go CPAP, APAP
x. Dorma 400, 500 CPAP
xi. REMStar SE Auto CPAP
xii. Trilogy 100 and 200
xiii. Garbin Plus, Aeris, LifeVent
xiv. A-Series BiPAP Hybrid A30
xv. A-Series BiPAP V30 Auto
xvi. A-Series BiPAP A40
xvii. A-Series BiPAP A30

58. Philips acknowledged that most of the devices it was recalling are still within the "advised 5-year service life" of the products.

59. Philips has admitted that the recalled products are defective and unsafe and that patients should stop using them immediately. Although still within what was supposed to be their useful life, these products are now effectively useless.

60. Had Plaintiff known about the defect and health risks, he would not have bought the Philips DreamStation CPAP product.

61. Had Plaintiff been informed about the defect and health risks, he could have and would have stopped using the Philips DreamStation CPAP immediately.

PHILIPS KNEW ABOUT THE DEFECT LONG BEFORE ISSUING THE RECALL

62. Although Philips did not disclose these health risks to its consumers or the general public until mid-year 2021, Philips knew about these health risks much earlier.

63. As noted above, when Philips announced the recall, it acknowledged it had already received complaints about black particles in the airways of the machines. The DreamStation line first launched in 2015, and several of the affected models have been on the market even longer.

64. Online message boards, review sites, and social media contain many complaints regarding black particles and foam degradation problems. Philips, like most companies, likely monitors these online forums and would have learned about the problem years ago.

65. The following are just a sampling of the online complaints.

66. In 2019, the user "Skogcat1" reported on apneaboard.com in a thread entitled "Black sticky dust in CPAP machine" that, when using the REMStar Auto, there were "sticky black dust particles" in the humidifier chamber.

67. In September 2020, Carol Nickerson posted on Facebook that she found a black mold-like substance in the water reservoir of her Philips DreamStation.

68. In June 2021, shortly after the recall was announced, on a Reddit thread entitled "Dreamstation Foam, user "BOSSHOG999" posted: "I was wondering what the hell those black particles were in my tube."

69. In addition to consumer complaints, Philip should have known about the foam problems from its prerelease testing. Medical devices go through considerable testing and design prior to release to the public.

70. As noted above, Philips's own marketing dating back to at least 2017, indicates it considered and studied the foam and noise reducing abilities extensively when designing the product.

71. Furthermore, Philips already claims to know that the second-generation DreamStation 2, which it launched just before the recall, is free from the foam degradation defect. This strongly suggests that Philips was aware of and looked at the issue when developing the DreamStation 2.

72. Despite knowing about the foam deterioration defect and related health hazards for years, Philips did nothing to warn consumers, healthcare providers, or the public until very recently.

73. Furthermore, although it has issued a "recall" of the affected products, Philips is not actually repairing or replacing those products. Philips has indicated it may take over a year before it can start repairing or replacing consumers' devices. Instead, Philips is using this as an opportunity to encourage consumers to buy its second-generation products (at full price).

74. Unfortunately for patients who need to use these devices every night to stave off serious health problems, waiting over a year for Philips to offer some sort of repair is not a realistic option.

75. On July 22, 2021, the U.S. Food and Drug Administration ("FDA") upgraded the recall to a Class 1, the most serious type of recall.

76. It was only on December 2, 2021 that Plaintiff received a notice of recall regarding the Philips device, in the form of an SMS text message from the healthcare facility that treats Plaintiff for sleep apnea. See Exhibit __.

EQUITABLE TOLLING OF STATUTES OF LIMITATIONS

77. The running of any statute of limitations, if even applicable, has been equitably tolled by reason of Defendants' fraudulent concealment and omissions of critical safety information. Through its affirmative misrepresentations and omissions, Philips actively concealed from Plaintiff the true risks associated with the recalled product.

78. As a result of Defendants' actions, Plaintiff was unaware, and could not have reasonably known or learned through reasonable diligence, that he had been exposed to the risks and harms set forth herein and that those risks and harms were the direct and proximate result of Defendants' acts and omissions

PLAINTIFF'S INJURIES

79. Mr. Traversa at all times relevant hereto used his Philips DreamStation CPAP as instructed, including performing recommended cleaning and maintenance.

80. Mr. Traversa did not alter or modify the Philips DreamStation CPAP device, and used it in the condition intended by the Defendants.

81. Mr. Traversa, as a long-time sleep apnea patient first used a CPAP device in approximately 2003.

82. Almost immediately, Mr. Traversa's quality of sleep improved; he found himself more refreshed upon waking, more alert during the day, and less irritable.

83. Mr. Traversa experienced no respiratory complications during this period.

84. Mr. Traversa purchased the Philips DreamStation from Defendant CMMC on or about November 23, 2015.

85. In Fall of 2019, Plaintiff developed a persistent cough; shortness of breath; and throat and chest irritation.

86. The quality of Mr. Traversa's sleep did not diminish, even while his breathing was labored and difficult during the day; consequently, Mr. Traversa had no reason to suspect that his Philips CPAP device was defective.

87. Mr. Traversa began to see a series of doctors, hoping to identify the source of his coughing and hacking.

88. For a significant period, Mr. Traversa suffered through what he and his physicians believed to be a mystery illness, even as the coughing worsened.

89. In fact, one coughing fit was so severe that Mr. Traversa suffered a broken rib on his right side.

90. Later coughing fits resulted in additional broken ribs on his right side.

91. In Spring of 2021, while sleeping, Mr. Traversa was awakened by a coughing fit so severe that he took off the CPAP headgear (mask) and got out of bed.

92. On getting out of bed Mr. Traversa passed out and fell striking his head on a wastebasket. When he regained consciousness he climbed back into bed, later calling his health insurer's nursing assistance line.

93. The provider who answered Mr. Traversa's call asked about Mr. Traversa's symptoms, which were: loss of consciousness; shortness of breath; elevated blood pressure, and profuse sweating.

94. The provider recommended Mr. Traversa go the closest hospital emergency department post haste.

95. The combination of broken ribs and constant coughing caused pleural effusion resulted in two trips to the emergency department of Thomas Jefferson University Hospital, ultimately resulting in hospital admission each time for three days on each occasion.

96. Treatment of the pleural effusion consisted of a thoracotomy which is an invasive procedure in which a needle and catheter were inserted between Mr. Traversa's pleura and lung to drain fluid.

97. Mr. Traversa had that procedure performed three times. Twice, once each after admission to the hospital, and once as an outpatient procedure. In each of the two procedures performed while a patient in the hospital approximately two liters of serosanguineous fluid were drained from pleura surrounding his right lung on each occasion. An additional liter-plus of serosanguineous fluid was drained during the outpatient procedure.

98. The pleural effusion resulted in squeezing of Mr. Traversa's lung and thereby resulted in a diminution of available lung capacity.

99. While the thoracotomies drained the fluid, allowing the lung space to reinflate, as of the date of this complaint, Mr. Traversa's lung capacity is still diminished.

100. In April, 2021, shortly after Philips announced the voluntary recall, Mr. Traversa discontinued use of the Philips DreamStation and obtained a different CPAP device.

101. Almost immediately, Mr. Traversa's breathing improved; and within several weeks of discontinuing use of Philips' defective device, Mr. Traversa's persistent cough stopped altogether.

102. As of the date of this pleading, Mr. Traversa has not experienced an aggressive coughing fit since August 2021.

103. These injuries caused substantial pain and suffering.

COUNT I– DESIGN DEFECT STRICT LIABILITY

104. The averments contained in Paragraphs 1 through 103 are reiterated and incorporated by reference, as if more fully set forth at length.

105. Philips designed, manufactured, and/or marketed the DreamStation CPAP device at issue in this complaint.

106. CMMC sold the device to the Plaintiff.

107. The Philips DreamStation CPAP device was in a defective condition as a result of the use of PE-PUR foam, and was unreasonably dangerous to the consumer.

108. All Defendants are in the business of selling CPAP devices.

109. The dangers of PE-PUR in CPAP devices foam are generally unknowable and unacceptable to ordinary CPAP users; Mr. Traversa could not reasonably anticipate and appreciate the dangerous condition of the product and the attendant risk of injury from the PE-PUR foam material used in the Philips DreamStation device.

110. Furthermore, the risk of harm from the defective CPAP device outweighs the burden of precautions, if any, a consumer may take.

111. The use of PE-PUR foam in the Philips DreamStation device directly caused the months of coughing and labored breathing that Mr. Traversa suffered, including the broken ribs that resulted from aggressive coughing fits.

WHEREFORE, Plaintiff Roger Traversa hereby respectfully prays this honorable Court to enter judgment in his favor and against all Defendants; to award compensatory damages in an amount exceeding $50,000; to award punitive damages; and for any other relief the Court may direct.

COUNT II– NEGLIGENT DESIGN AS TO PHILIPS DEFENDANTS

112. The averments contained in Paragraphs 1 through 111 are reiterated and incorporated by reference, as if more fully set forth at length.

113. Philips designed, manufactured, and/or marketed the DreamStation CPAP device at issue in this complaint.

114. Defendant Philips had a duty to design a CPAP machine that operated safely.

115. The use of PE-PUR foam that degraded and flowed directly into Mr. Traversa's airway breached that duty.

116. The negligently designed CPAP machine directly caused Mr. Traversa's injuries.

WHEREFORE, Plaintiff Roger Traversa hereby respectfully prays this honorable Court to enter judgment in his favor and against Defendant Philips; to award compensatory damages in an amount exceeding $50,000; to award punitive damages; and for any other relief the Court may direct.

COUNT III– PERSONAL INJURY

117. The averments contained in Paragraphs 1 through 116 are reiterated and incorporated by reference, as if more fully set forth at length.

118. Defendant Philips, as the designer and manufacturer of the DreamStation 2 CPAP device at issues had a duty to ensure that the device was safe for its intended use.

119. Defendant Montgomery, as the seller of the DreamStation 2 device at issue, had a duty to ensure that the device was safe for its intended use.

120. All Defendants breached their respective duties by:

i. Designing the device to use hazardous PE-PUR foam that degraded and flowed directly into Mr. Traversa's airway;

ii. Manufacturing the device using hazardous PE-PUR foam that degraded and flowed directly into Mr. Traversa's airway;

iii. Selling the device containing the hazardous PE-PUR foam that degraded and flowed directly into Mr. Traversa's airway.

121. The negligently designed CPAP machine directly caused Mr. Traversa's injuries, including broken ribs, multiple pleural effusions, diminished lung capacity, and/or other injuries.

122. As a result of the above injuries, Mr. Traversa suffered damages in the form of lost income; hospital bills; lost quality of life; pain and suffering; emotional distress; and other damages of both an economic and non-economic nature.

WHEREFORE, Plaintiff Roger Traversa hereby respectfully prays this honorable Court to enter judgment in his favor and against all Defendants; to award compensatory

damages in an amount exceeding $50,000; to award punitive damages; and for any other relief the Court may direct.

COUNT IV– BREACH OF WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE AS TO MONTGOMERY DEFENDANTS

123. The averments contained in Paragraphs 1 through 122 are reiterated and incorporated by reference, as if more fully set forth at length.

124. On or about November 23, 2015, Plaintiff purchased a DreamStation CPAP machine from Defendant Montgomery.

125. Plaintiff, Mr. Traversa, purchased the DreamStation for a particular purpose; namely for use in the treatment of sleep apnea.

126. Plaintiff (a) informed Defendant Montgomery of the particular purpose for which he purchased the device, and/or (b) believes Defendant knew of the particular purpose of the device as ascertained by the prescribing physician's instructions.

127. Plaintiff relied on Defendant Montgomery's skill and/or judgment in selecting and/or furnishing suitable goods; and Defendant Montgomery knew or had reason to know Plaintiff was so relying.

128. The DreamStation was not fit for its intended purpose due to the defectively designed inclusion of PE-PUR foam which degraded into Mr. Traversa's airway.

129. Defendant Montgomery had actual, constructive, and equitable notice of the breach due to Philips' recall of the DreamStation.

130. As a result of the breach, Mr. Traversa economic injuries in the form of the total loss of the CPAP device at issue; as well as incidental and consequential damages in the form of out of pocket expenditures to obtain another CPAP device; lost income due to hospitalizations; pain and suffering; and other forms of compensable injury.

WHEREFORE, Plaintiff Roger Traversa hereby respectfully prays this honorable Court to enter judgment in his favor and against Defendant Montgomery; to award compensatory damages in an amount exceeding $50,000; to award punitive damages; and for any other relief the Court may direct.

Charles Thomas, Jr.

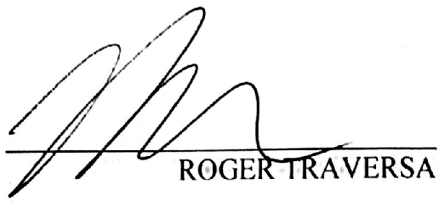
CHARLES THOMAS, JR.

BY: /s/ *Charles Thomas, Jr.*
Attorney for Plaintiff

VERIFICATION

I hereby verify that averments contained in the COMPLAINT are true and correct to the best of my knowledge, information, and belief. I further verify that the averments contained therein are made subject to the penalties set for in 18 Pa.C.S. 4901, relating to unsworn falsification to authorities.

Respectfully submitted,



ROGER TRAVERSA

12/19/21

DATED