UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

THOMAS R. STARNER, on behalf of himself and all others similarly situated, *Plaintiff*, v. KONINKLIJKE PHILIPS N.V.; PHILIPS NORTH AMERICA LLC; and PHILIPS RS NORTH AMERICA LLC, *Defendants*.	**Case No. _____** **CLASS ACTION COMPLAINT** **DEMAND FOR JURY TRIAL**

Plaintiff Thomas R. Starner ("Plaintiff" or "Plaintiff Starner"), on behalf of himself, the class and subclass of all others similarly situated as defined below, for his complaint against Defendants Koninklijke Philips N.V. ("Royal Philips"), Philips North America LLC ("Philips NA"), and Philips RS North America LLC ("Philips RS") (collectively, Royal Philips, Philips NA, and Philips RS are "Philips" or the "Defendants"), alleges the following based on (a) personal knowledge, (b) the investigation of counsel, and (c) information and belief.

INTRODUCTION

1. Plaintiff brings this action on behalf of himself and a proposed class of purchasers and users of Continuous Positive Airway Pressure (CPAP) and Bi-Level Positive Airway Pressure (Bi-Level PAP) devices and mechanical ventilators manufactured by Philips, which contain polyester-based polyurethane sound abatement foam ("PE-PUR Foam").

2. On April 26, 2021, Philips made a public announcement disclosing it had determined there were risks that the PE-PUR Foam used in certain CPAP, Bi-Level PAP, and mechanical ventilator devices it manufactured may degrade or off-gas under certain circumstances.

3. On June 14, 2021, Royal Philips issued a recall in the United States of its CPAP, Bi-Level PAP, and mechanical ventilator devices containing PE-PUR Foam, because Philips had determined that (a) the PE-PUR Foam was at risk for degradation into particles that may enter the devices' pathway and be ingested or inhaled by users, and (b) the PE-PUR Foam may off-gas certain chemicals during operation.[1] Philips further disclosed in its Recall Notice that "these issues can result in serious injury which can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment."[2]

4. Philips has disclosed that the absence of visible particles in the devices does not mean that PE-PUR Foam breakdown has not already begun. Philips reported that lab analysis of the degraded foam reveals the presence of harmful chemicals, including: Toluene Diamine ("TDA"), Toluene Diisocyanate ("TDI"), and Diethylene Glycol ("DEG").[3]

5. Prior to issuing the Recall Notice, Philips received complaints regarding the presence of black debris/particles within the airpath circuit of its devices (extending from the device outlet, humidifier, tubing, and mask). Philips also received reports of headaches, upper airway irritation, cough, chest pressure and sinus infection from users of these devices.

6. In its Recall Notice, Philips disclosed that the potential risks of particulate exposure to users of these devices include: irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (*e.g.*, kidneys and liver) and toxic carcinogenic affects. The potential risks of chemical exposure due to off-gassing

[1] *See* Philips Recall Notice attached hereto as Exhibit "A."

[2] *Id.*

[3] Philips Sleep and Respiratory Care Update; Clinical information for physicians, https://www.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/philips-recall-clinical-information-for-physicians-and-providers.pdf (accessed June 27, 2021).

of PE-PUR Foam in these devices include: headache/dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, nausea/vomiting, toxic and carcinogenic effects.

7. Philips recommended that patients using the recalled CPAP and Bi-Level PAP devices immediately discontinue using their devices and that patients using the recalled ventilators for life-sustaining therapy consult with their physicians regarding alternative ventilator options.

8. In 2013, Plaintiff Starner purchased a Philips Respironics Remstar Pro CPAP device that he used nightly from January 2013 until April 2018.

9. On or about April 26, 2018, Plaintiff Starner purchased a Philips DreamStation Auto CPAP device, which he used nightly from the date of receipt until June 26, 2021.

10. On June 26, 2021, Plaintiff Starner received an email from CPAP.com advising him that his Philips' Respironics Remstar Pro and DreamStation Auto CPAP devices were subject to a recall due to the presence of a dangerous PE-PUR Foam that could cause him to suffer from adverse health effects, including, *inter alia*, cancer and organ failure. Plaintiff Starner was advised to discontinue use of the devices. He was also advised to verify whether his devices were subject to the recall by submitting the serial numbers for his devices to an online database Philips established. Plaintiff Starner received confirmation that both his CPAP devices were subject to recall.

11. Plaintiff Starner has now incurred substantial expenses to replace the devices. In addition, Plaintiff Starner has experienced chest tightness and respiratory irritants during his use of the Philips' CPAP machines. Since being notified of the recall, Plaintiff has experienced anxiety concerning the potential serious health risks he is facing from possible exposure to off-gassed or degraded PE-PUR Foam in the recalled devices.

12. Plaintiff Starner seeks to recover damages based on, *inter alia*, Philips' breach of express warranty, breach of implied warranties, misrepresentations, omissions, and breaches of state consumer protection laws in connection with its manufacture, marketing and sales of devices containing PE-PUR Foam on behalf of himself and the proposed Class and Subclass. In addition, Plaintiff Starner seeks medical monitoring damages for users of Philips' devices identified in the Recall Notice, who are at risk of suffering from serious injury, including irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (*e.g.*, kidneys and liver) and toxic carcinogenic affects.

PARTIES

13. Plaintiff Thomas R. Starner is a citizen of the Commonwealth of Pennsylvania.

14. Defendant Royal Philips is a Dutch multinational corporation with its principal place of business located in Amsterdam, Netherlands. Royal Philips is the parent company of the Philips Group of healthcare technology businesses, including Connected Care businesses focusing on Sleep & Respiratory Care. Royal Philips holds directly or indirectly 100% of its subsidiaries Philips NA and Philips RS.[4] Upon information and belief, Royal Philips controls Philips NA and Philips RS in the manufacturing, selling, distributing, and supplying of the recalled CPAP, Bi-Level PAP, and mechanical ventilator devices.[5]

15. Defendant 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 Royal Philips.

[4] Philips 2020 annual filing with the SEC, fn. 8, https://www.sec.gov/Archives/edgar/data/313216/000031321621000008/phg-exhibit8.htm (accessed June 30, 2021).

[5] Philips 2020 annual filing with the SEC, https://www.sec.gov/ix?doc=/Archives/edgar/data/0000313216/000031321621000008/phg-20201231.htm (accessed June 30, 2021).

16. Defendant Philips RS is a Delaware corporation with its principal place of business located at 6501 Living Place, Pittsburgh, Pennsylvania 15206. Philips RS is a wholly-owned subsidiary of Royal Philips. Philips RS was formerly operated under the business name Respironics, Inc. ("Respironics"). Royal Philips acquired Respironics in 2008.[6]

JURISDICTION AND VENUE

17. This Court has subject-matter jurisdiction pursuant to the Class Action Fairness Act, 28 U.S.C. § 1332(d), because (1) the matter in controversy exceeds the sum or value of $5,000,000, exclusive of interest and costs, (2) the action is a class action, (3) there are members of the Class and Subclass who are diverse from Defendants, and (4) there are more than 100 class members. This Court has supplemental jurisdiction over state law claims pursuant to 28 U.S.C. § 1367, because they form part of the same case or controversy as the claims within the Court's original jurisdiction.

18. Venue is proper in this judicial District pursuant to 28 U.S.C. § 1391(b) and (c) and 18 U.S.C. § 1965, because Defendants transact business in this District, a substantial part of the events or omissions giving rise to Plaintiff's claims occurred in this District; because the Plaintiff resides in this District; and because the Defendants caused harm to class members residing in the District.

19. The Court has personal jurisdiction over the Defendants because Defendants conduct substantial business in this District, and the events giving rise to Plaintiff's claims arise out of and relate to Defendants' contacts with this District. Moreover, Defendant Philips RS has its principal place of business in the forum State. Defendants Philips RS and Philips NA are controlled by their parent Royal Philips. Defendants' affiliations with this District are so

[6] Philips announces completion of tender offer to acquire Respironics, WEB WIRE, https://www.webwire.com/ViewPressRel.asp?aId=61199 (accessed June 27, 2021).

continuous and systematic as to render them essentially at home in the forum State. Further, Defendants have transacted business, maintained substantial contacts, purposefully targeted consumers and medical professionals for sales of its devices and/or committed overt acts in furtherance of the unlawful acts alleged in this Complaint in this District, as well as throughout the United States. The unlawful acts of Defendants have been directed at, targeted, and have had the effect of causing injury to persons residing in, located in, or doing business in this District, as well as throughout the United States.

FACTUAL BACKGROUND

I. Continuous Positive Airway Pressure Therapy

20. 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 hose and a nasal or facemask device that delivers constant and steady air pressure to an individual's throat to help individuals breathe.

21. Sleep apnea 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 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 interruptions, the sleep cycle disruption caused by sleep apnea can dramatically impact a person's lifestyle, including negatively impacting energy, mental performance, and long-term health. CPAP therapy helps treat sleep

apnea by preventing the person's airway from collapsing while breathing during sleep cycles, which can help prevent interruptions in breathing.

II. Bi-Level Positive Airway Pressure Therapy

22. 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 therapy is distinguishable from CPAP therapy, however, because Bi-Level PAP 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. Bi-Level PAP devices deliver one level of pressurize air (the inspiratory positive level) to assist as a person inhales, and another level (the expiratory level) as a person exhales.

III. Mechanical Ventilation

23. Mechanical ventilation is a treatment to help a person breathe when they find it difficult or are unable to breathe on their own. A mechanical ventilator pushes airflow into the patient's lungs to help them breathe. Mechanical ventilation may be invasive ventilation with a tube inserted into the patient's airway, performed in the intensive care unit in the hospital or a long-term institutional setting. Non-invasive ventilation can be used at home by people with respiratory difficulties.

SUBSTANTIVE ALLEGATIONS

24. Philips developed, marketed, and sold a variety of CPAP and Bi-Level PAP respirator devices and mechanical ventilators under its "Sleep & Respiratory Care" segment of

its business designed to assist individuals with a number of sleep, breathing, and respiratory conditions, including obstructive sleep apnea, central sleep apnea, complex sleep apnea syndrome, and Chronic Obstructive Pulmonary Disease (COPD), as well as to assist those individuals requiring invasive and non-invasive ventilators for acute and sub-acute hospital environments. Philips' CPAP and Bi-Level PAP respirator devices and its mechanical ventilators typically cost several hundred, if not thousands of dollars. Philips has sold millions of these devices in the United States.

III. Philips Sleep & Respiratory Care Devices Endangered Users

25. On April 26, 2021, in its Quarterly Report for Q1 2021, 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 Foam Philips used to minimize noise in several CPAP and Bi-Level PAP respirators and mechanical ventilators posed health risks to its users. Specifically, Philips disclosed that "the [PE-PUR] foam may degrade under certain circumstances, influenced by factors including use of unapproved cleaning methods, such as ozone[], and certain environmental conditions involving high humidity and temperature."[7]

26. Seven weeks later, on June 14, 2021, Philips announced a recall of numerous models of CPAP and Bi-Level PAP devices, as well as a variety of its mechanical ventilators "to address identified potential health risks related to the polyester-based polyurethane (PE-PUR) sound abatement foam component in these devices."[8] Specifically, Philip announced that it had

[7] First Quarter Results, PHILIPS (Apr. 26, 2021), https://www.results.philips.com/publications/q121/downloads/pdf/en/philips-first-quarter-results-2021-report.pdf (accessed June 27, 2021).

[8] *Philips issues recall notification* to mitigate potential health risks related to the sound abatement foam component in certain sleep and respiratory care devices*, PHILIPS (June 14, 2021), https://www.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 June 27, 2021).

determined 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."[9] In total, Philips announced that "[b]etween 3 million and 4 million" devices are targeted in the recall.[10]

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

Philips CPAP and Bi-Level PAP Devices Manufactured Before April 26, 2021 Subject to Recall[11]	
Device Name/Model Type	**Type**
E30 (Emergency Use Authorization)	Continuous Ventilator, Minimum Ventilatory Support, Facility Use
DreamStation ASV	Continuous Ventilator, Non-life Supporting
DreamStation ST, AVAPS	
SystemOne ASV4	
C Series ASV	
C Series S/T and AVAPS	
OmniLab Advanced Plus	
SystemOne (Q Series)	Non-continuous Ventilator
DreamStation	
DreamStation GO	
Dorma 400	
Dorma 500	
REMStar SE Auto	

[9] *Id.*

[10] Associated Press, *Philips recalls ventilators, sleep apnea machines due to health risks*, NBC NEWS, https://www.nbcnews.com/business/consumer/philips-recalls-ventilators-sleep-apnea-machines-due-health-risks-n1270725 (accessed June 27, 2021).

[11] Recall Notice (Exhibit "A" hereto); *see also* 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 June 27, 2021); Royal Philips Update on the recall notification, https://www.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 June 27, 2021).

Philips Mechanical Respirator Devices Manufactured Before April 26, 2021 Subject to Recall[12]	
Device Name/Model Type	**Type**
Trilogy 100 Ventilator	Continuous Ventilator
Trilogy 200 Ventilator	
Garbin Plus, Aeris, LifeVentVentilator	
A-Series BiPAP Hybrid A30	Continuous Ventilator, Minimum Ventilatory Support, Facility Use
Philips A-Series BiPAP V30 Auto	
Philips A-Series BiPAP A40	Continuous Ventilator, Non-life Supporting
Philips A-Series BiPAP A30	

28. According to Philips, the PE-PUR Foam used in Recalled Devices puts users at risk of suffering from: "[i]rritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (e.g. kidneys and liver) and toxic carcinogenic affects."[13]

29. Philips reported to physicians that PE-PUR Foam particles "may cause irritation and airway inflammation, and this may be particularly important for patients with underlying lung diseases or reduced cardiopulmonary reserve."[14]

30. Further, 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."[15]

[12] *Id.*

[13] *Id.*

[14] Philips *Sleep and Respiratory Care Update – Clinical information for physicians*, June 14, 2021, philips-recall-clinical-information-for-physicians-and-providers.pdf (accessed June 27, 2021).

[15] *Id.*

31. Philips announced that it has received reports of specific complaints from users of Recalled Devices who suffered from "headache[s], upper airway irritation, cough, chest pressure and sinus infection."[16]

IV. The Health Risks Associated with Use of the Recalled Devices Renders Them Worthless

32. As a result of the health risks associated with the use of the Recalled Devices, together with Defendants' concealment of these risks from the date they were first reported to Defendants or discovered by Defendants through April 26, 2021, the Recalled Devices have been rendered completely worthless or, at the very least, have been substantially diminished in value.

33. The information described above, including the now-known health risks of Philips CPAP devices, Bi-Level PAP devices and mechanical ventilators, the recall, and the medical warnings and advice issued by Philips, have rendered the Recalled Devices worthless to patients with sleep apnea and respiratory conditions. Individuals not using life-supporting ventilators must immediately discontinue their user of the Recalled Devices or face serious health risks as grave as organ failure or cancer. If they choose to discontinue use of the Recalled Devices they must pay for another expensive device in order to receive effective treatment for their sleep apnea and/or respiratory conditions. Individuals using life-supporting ventilators must seek an alternative treatment before discontinuing use of the Recalled Devices.

34. Recognizing this, 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."[17]

[16] Recall Notice (Exhibit A hereto).

- "**For patients using life-sustaining mechanical ventilator devices: DO NOT discontinue or alter prescribed therapy, without consulting physicians to determine appropriate next steps.**"[18]

35. As a result of the above, Plaintiff and the Class and Subclass will have to undertake considerable expense replacing the Recalled Devices.

V. Philips Unreasonably Delayed its Recall

36. At no time prior to its Regulatory Update on April 26, 2021, did Philips disclose to purchasers or users of the Recalled Devices that the PE-PUR Foam contained therein may off-gas or degrade upon use. Similarly, prior to the Update, Philips did not disclose any health risks associated with use of the Recalled Devices.

37. Defendants have not disclosed when they first discovered or received reports from users of their Sleep & Respiratory Care devices "regarding the presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask)."[19]

38. At a minimum, as a result of user reports, Defendants were aware of the off-gassing and degradation of the PE-PUR Foam used in the Recalled Devices at some point prior to the recall, yet continued to manufacture and sell the Recalled Devices with such awareness. 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 development of serious adverse health effects, including organ failure and cancer.

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[17] 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 June 27, 2021) (Questions and answers) (emphasis in original).

[18] *Id.*

[19] Recall Notice (Exhibit "A" hereto).

VI. Plaintiff Thomas R. Starner

39. Plaintiff Thomas R. Starner is a resident and citizen of Philadelphia, Pennsylvania.

40. Plaintiff Starner purchased two of the Recalled Devices, a Philips Respironics Remstar Pro CPAP device and a Philips DreamStation Auto CPAP device, prior to June 14, 2021.

41. The manuals accompanying Plaintiff Starner's Respironics RemStar Pro and DreamStation Auto CPAP devices did not contain any language or warnings of health risks associated with use of the device, including irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (*e.g.*, kidneys and liver) and toxic carcinogenic effects. Had Defendants informed Plaintiff of these risks, he would not have purchased or used the Recalled Devices.

42. Without knowing of the health risks associated with use of the Recalled Devices, Plaintiff Starner used his Recalled Devices regularly to treat sleep apnea until learning on June 26, 2021, that the devices were recalled.

43. As a result of the health risks associated with continued use of these devices and the recall, Plaintiff Starner's Respironics Remstar Pro CPAP and DreamStation Auto CPAP devices are now worthless. Plaintiff Starner was forced to replace the devices at considerable cost.

TOLLING AND ESTOPPEL

I. DISCOVERY RULE TOLLING

44. Plaintiff and the Class and Subclass had no way of knowing about Philips' conduct with respect to the health risks associated with the use of the Recalled Devices.

45. Neither Plaintiff nor any other members of the Class or Subclass, through the exercise of reasonable care, could have discovered the conduct by Philips alleged herein. Further, Plaintiff and members of the Class and Subclass did not discover and did not know of facts that would have caused a reasonable person to suspect that Philips was engaged in the conduct alleged herein.

46. For these, reasons, all applicable statutes of limitation have been tolled by the discovery rule with respect to claims asserted by Plaintiff, the Class, and Subclass.

II. FRAUDULENT CONCEALMENT TOLLING

47. By failing to provide immediate notice of the adverse health effects associated with continued use of the Recalled Devices, Philips concealed its conduct and the existence of the claims asserted herein from Plaintiff and the members of the Class and Subclass.

48. Upon information and belief, Philips intended its acts to conceal the facts and claims from Plaintiff and members of the Class and Subclass. Plaintiff and the members of the Class and Subclass were unaware of the facts alleged herein without any fault or lack of diligence on their part and could not have reasonably discovered Defendants' conduct. For this reason, any statute of limitations that otherwise may apply to the claims of Plaintiff or members of the Class or Subclass should be tolled.

CLASS ACTION ALLEGATIONS

49. Plaintiff brings this action as a class action pursuant to Federal Rules of Civil Procedure 23(a) and 23(b)(3). Plaintiff seeks class certification on behalf of a class defined as follows (the "Class"):

> **NATIONWIDE CLASS**: All persons in the United States who purchased or used a CPAP, Bi-Level PAP, or Mechanical Ventilator device that was manufactured by Philips before April 26, 2021, and recalled by Philips on June 14, 2021.

50. Plaintiff seeks certification on behalf of a subclass defined as follows (the "Subclass"):

> **PENNSYLVANIA SUBCLASS**: All persons who were or are citizens of the Commonwealth of Pennsylvania who purchased or used a CPAP, Bi-Level PAP, or Mechanical Ventilator device that was manufactured by Philips before April 26, 2021, and recalled by Philips on June 14, 2021.

51. Plaintiff reserves the right to modify or refine the definitions of the Class or Subclass based upon discovery of new information and in order to accommodate any of the Court's manageability concerns.

52. Excluded from the Class and Subclass are: (a) any Judge or Magistrate Judge presiding over this action and members of their staff, as well as members of their families; (b) Defendants' and Defendants' predecessors, parents, successors, heirs, assigns, subsidiaries, and any entity in which any Defendants or their parents have a controlling interest, as well as Defendants' current or former employees, agents, officers, and directors; (c) persons who properly execute and file a timely request for exclusion from the Class or Subclass; (d) persons whose claims in this matter have been finally adjudicated on the merits or otherwise released; (e) counsel for Plaintiff and Defendants; and (f) the legal representatives, successors, and assigns of any such excluded persons.

53. **Numerosity (Rule 23(a)(1))**. The Class and Subclass are so numerous that joinder of individual members herein is impracticable. The exact number of members of the Class and Subclass, as herein identified and described, is not known, but sales figures and the Recall Notice indicate that millions of individuals have purchased the Recalled Devices.

54. **Commonality (Rule 23(a)(2))**. Common questions of fact and law exist for each cause of action and predominate over questions affecting only individual Class and Subclass members, including the following:

- whether Defendants owed a duty of care to Plaintiff and the Class and Subclass;
- whether Defendants knew or should have known that the PE-PUR Foam used for sound abatement posed health risks;
- whether Defendants wrongfully represented that the PE-PUR Foam used for sound abatement in the Recalled Devices was safe;
- whether the Recalled Devices retained any value post-recall;
- whether Defendants wrongfully represented that the Recalled Devices were safe to use;
- whether Defendants wrongfully failed to disclose that the PE-PUR Foam used for sound abatement in the Recalled Devices posed health risks to Recalled Device users;
- whether Defendants' representations and omissions in advertising, warranties, packaging, and/or labeling were false, deceptive, and/or misleading;
- whether those representations and omissions were likely to deceive a reasonable consumer;
- whether a reasonable consumer would consider the presence, or risk of, health risks as a material fact in purchasing one of the Recalled Devices;
- whether Defendants had knowledge that those representations and omissions were false, deceptive, and misleading;
- whether Defendants breached their express warranties;
- whether Defendants breached their implied warranties;
- whether Defendants engaged in unfair trade practices;
- whether Defendants engaged in false advertising;

- whether Defendants' conduct was negligent per se;
- whether Defendants made negligent and/or fraudulent misrepresentations and/or omissions; and
- whether Plaintiff and the members of the Class and Subclass are entitled to actual, statutory, and punitive damages.

55. **Typicality (Rule 23(a)(3))**. Plaintiff's claims are typical of the claims of the other members of the proposed Class and Subclass. Plaintiff and members of the Class and Subclass (as applicable) suffered injuries as a result of Defendants' wrongful conduct that is uniform across the Class and Subclass.

56. **Adequacy (Rule 23(a)(4))**. Plaintiff's interests are aligned with the Class and Subclass he seeks to represent. Plaintiff has and will continue to fairly and adequately represent and protect the interests of the Class and Subclass. Plaintiff has retained competent counsel highly experienced in complex litigation and class actions and the types of claims at issue in this litigation, with the necessary resources committed to protecting the interests of the Class and Subclass. Plaintiff has no interest that is antagonistic to those of the Class and Subclass, and Defendants have no defenses unique to Plaintiff. Plaintiff and his counsel are committed to vigorously prosecuting this action on behalf of the members of the Class and Subclass. Neither Plaintiff nor Plaintiff's counsel have any interest adverse to those of the other members of the Class and Subclass.

57. **Superiority**. This class action is appropriate for certification because class proceedings are superior to other available methods for the fair and efficient adjudication of this controversy, and joinder of all members of the Class and Subclass is impracticable. The prosecution of separate actions by individual members of the Class and Subclass would impose

heavy burdens upon the Courts and Defendants, would create a risk of inconsistent or varying adjudications of the questions of law and fact common to members of the Class and Subclass, and would be dispositive of the interests of the other members not parties to the individual adjudications or would substantially impair or impede their ability to protect their interests. Class treatment will create economies of time, effort, and expense and promote uniform decision-making.

58. **Manageability.** This proposed class action presents fewer management difficulties than individual litigation, and provides the benefits of single adjudication, economies of scale, and comprehensive supervision by a single court.

59. Class certification, therefore, is appropriate under Fed. R. Civ. P. 23(b)(3) because the above common questions of law or fact predominate over any questions affecting individual members of the Class, and a class action is superior to other available methods for the fair and efficient adjudication of this controversy.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

BREACH OF EXPRESS WARRANTY
(on behalf of the Class or, alternatively, the Subclass)

60. Plaintiff incorporates the foregoing allegations as if fully set forth herein.

61. Philips marketed and sold the Recalled Devices into the stream of commerce with the intent that the Recalled Devices would be purchased by Plaintiff and the Class and Subclass.

62. Philips expressly warranted, advertised, and represented to Plaintiff and the Class and Subclass that the Recalled Devices were safe and appropriate for human use.

63. Philips made these express warranties regarding the Recalled Devices' quality and fitness for use in writing through its website, advertisements, and marketing materials, and on the

Recalled Devices' packaging and labels. These express warranties became part of the basis of the bargain that Plaintiff and the Class and Subclass entered into upon purchasing the Recalled Devices.

64. Philips' advertisements, warranties, representations, and omissions regarding health risks associated with the Recalled Devices, were made in connection with the sale of the Recalled Devices to Plaintiff and the Class and Subclass. Plaintiff and the Class and Subclass relied on Philips' advertisements, warranties, representations, and omissions regarding the Recalled Devices in deciding whether to purchase and use Philips' Recalled Devices.

65. Philips' Recalled Devices do not conform to Philips' advertisements, warranties, representations, and omissions in that they are not safe, healthy, and appropriate for human use, and pose risks of serious injury and disease, including organ failure and cancer.

66. Philips therefore breached its express warranties by placing Recalled Devices into the stream of commerce and selling them to consumers, when their use posed health risks, had dangerous effects and were unsafe, rendering these products unfit for their intended use and purpose, and unsafe and unsuitable for consumer use as marketed by Philips. These associated health effects substantially impair the use, value, safety of the Recalled Devices, and render them worthless.

67. Philips was aware, or should have been aware, of the toxic or dangerous health effects of the use of the Recalled Devices, but nowhere on the package labeling or package inserts or on Philips' websites or other marketing materials did Philips warn Plaintiff and members of the Class and Subclass that they were at risk of developing adverse health effects as a result of the dangerous PE-PUR Foam used in the Recalled Devices.

68. Instead, Philips concealed the dangerous health effects of the PE-PUR Foam used in the Recalled Devices and deceptively represented that these products were safe, healthy, and appropriate for use. Philips thus utterly failed to ensure that the material representations they were making to consumers were true.

69. The adverse health effects associated with use of the Recalled Devices existed when they left Philips' possession or control and were sold to Plaintiff and members of the Class and Subclass. The dangers associated with use of the Recalled Devices were undiscoverable by Plaintiff and members of the Class and Subclass at the time of purchase of the Recalled Devices.

70. As manufacturers, marketers, advertisers, distributors and sellers of the Recalled Devices, Philips had exclusive knowledge and notice of the fact that the Recalled Devices did not conform to the affirmations of fact and promises.

71. In addition, or in the alternative, to the formation of an express contract, Philips made each of the above-described representations and omissions to induce Plaintiff and members of the Class and Subclass to rely on such representations and omissions.

72. Philips' affirmations of fact and promises and its omissions were material, and Plaintiff and members of the Class and Subclass reasonably relied upon such representations and omissions in purchasing and using the Recalled Devices.

73. All conditions precedent to Philips' liability for its breach of express warranty have been performed by Plaintiff or members of the Class or Subclass.

74. Affording Philips an opportunity to cure its breaches of written warranties would be unnecessary and futile here. Philips was placed on reasonable notice from user reports and its lab testing that the PE-PUR Foam in the Recalled Devices was unsafe. Philips had ample opportunity either to stop using the PE-PUR Foam or to replace the PE-PUR Foam in the

Recalled Devices to make them safe and healthy for use by Plaintiff and members of the Class and Subclass, but failed to do so until now.

75. As a direct and proximate result of Philips' breaches of express warranty, Plaintiff and members of the Class and Subclass have been damaged because they did not receive the products as specifically warranted by Philips. Plaintiff and members of the Class and Subclass did not receive the benefit of the bargain and suffered damages at the point of sale stemming from their overpayment for the Recalled Devices.

76. Plaintiff and the Class and Subclass seek actual damages, attorneys' fees, costs, and any other just and proper relief available thereunder for Philips' failure to deliver goods conforming to their express warranties and resulting breach.

SECOND CLAIM FOR RELIEF

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY (on behalf of the Class or, alternatively, the Subclass)

77. Plaintiff incorporates the foregoing allegations as if fully set forth herein.

78. Philips are merchants engaging in the sale of goods to Plaintiff and the Class and Subclass.

79. There was a sale of goods from Philips to Plaintiff and the Class and Subclass.

80. At all times mentioned herein, Philips manufactured or supplied the Recalled Devices, and prior to the time the Recalled Devices were purchased by Plaintiff and the Class and Subclass, Philips impliedly warranted to them that the Recalled Devices were of merchantable quality, fit for their ordinary use, and conformed to the promises and affirmations of fact and omissions made on the Recalled Devices' labels and packaging, including that the Recalled Devices were safe and appropriate for human use. Plaintiff and the Class and Subclass

relied on Philips' promises and affirmations of fact and omissions when they purchased and used the Recalled Devices.

81. Contrary to these representations and warranties, the Recalled Devices were not fit for their ordinary use and did not conform to Philips' affirmations of fact and promises and omissions because use of the Recalled Devices is accompanied by the risk of adverse health effects, which does not conform to the labels and packaging of these devices.

82. Philips breached its implied warranties by selling Recalled Devices that failed to conform to the promises or affirmations of fact made on the packaging or label, as use of each Recalled Devices was accompanied by the risk of developing adverse health effects that do not conform to the packaging or label.

83. Philips was on notice of this breach, as it was made aware of the adverse health effects accompanying use of the Recalled Devices through user reports submitted to Philips and through lab testing.

84. Privity exists because Philips impliedly warranted to Plaintiff and the Class through the warranting, packaging, advertising, marketing, and labeling that the Recalled Devices were natural, and suitable for use to treat health conditions, and made no mention of the attendant health risks associated with use of the Recalled Devices.

85. As a direct and proximate result of Philips' conduct, Plaintiff and the Class and Subclass have suffered actual damages in that each Recalled Device they purchased is worth less than the price they paid and which they would not have purchased at all had they known of the attendant health risks associated with the use of each Recalled Device.

86. Plaintiff and the Class and Subclass seek actual damages, attorneys' fees, costs, and any other just and proper relief available thereunder for Philips' failure to deliver goods conforming to their implied warranties and resulting breach.

THIRD CLAIM FOR RELIEF

FRAUDULENT MISREPRESENTATION
(on behalf of the Nationwide Class or, alternatively, the Subclass)

87. Plaintiff incorporates the foregoing allegations as if fully set forth herein.

88. Philips failed to advise Plaintiff and the Class and Subclass that the Recalled Devices posed serious health risks to their users and Philips falsely represented to Plaintiff and the Class and Subclass that the Recalled Devices were safe for human use.

89. Philips intentionally, knowingly, and recklessly made these misrepresentations and omissions to induce Plaintiff and the Class and Subclass to purchase the Recalled Devices.

90. Philips knew that its representations and omissions about the Recalled Devices were false in that the Recalled Devices contained PE-PUR Foam and thus were at risk of causing adverse health effects to users of the Recalled Devices, which does not conform to the products' labels, packaging, advertising, and statements. Philips knowingly allowed its packaging, labels, advertisements, promotional materials, and websites to intentionally mislead consumers, such as Plaintiff and the Class and Subclass.

91. Plaintiff and the Class and Subclass did in fact rely on these omissions and misrepresentations and purchased and used the Recalled Devices to their detriment. Given the deceptive manner in which Philips advertised, represented, and otherwise promoted the Recalled Devices, Plaintiff's and the Class' and Subclass' reliance on Philips' omissions and misrepresentations was justifiable.

92. As a direct and proximate result of Philips' conduct, Plaintiff and the Class and Subclass have suffered actual damages in that they purchased the Recalled Devices (a) that were worth less than the price they paid, (b) which they would not have purchased at all had they known of the health risks, including organ failure and cancer, associated with the use of the Recalled Devices, and (c) which did not conform to the Recalled Devices' labels, packaging, advertising, and statements.

93. Plaintiff and the Class and Subclass seek actual damages, attorneys' fees, costs, and any other just and proper relief available under the laws.

FOURTH CLAIM FOR RELIEF

FRAUD BY OMISSION
(on behalf of Nationwide Class or, alternatively, the Subclass)

94. Plaintiff incorporates the foregoing allegations as if fully set forth herein.

95. Philips concealed from and failed to disclose to Plaintiff and the Class and Subclass that use of Recalled Devices is accompanied by a risk of adverse health effects, which does not conform to the products' labels, packaging, advertising, and statements.

96. Philips was under a duty to disclose to Plaintiff and the Class and Subclass the true quality, characteristics, ingredients and suitability of the Recalled Devices because: (a) Philips was in a superior position to know the true state of facts about its products; (b) Philips was in a superior position to know the risks associated with the use of, characteristics of, and suitability of the Recalled Devices for use by individuals; and (c) Philips knew that Plaintiff and the Class and Subclass could not reasonably have been expected to learn or discover prior to purchasing the Recalled Devices that there were misrepresentations and omissions by Philips in the packaging, labels, advertising, and websites regarding the health risks associated with use of these devices.

97. The facts concealed or not disclosed by Philips to Plaintiff and the Class and Subclass were material in that a reasonable consumer would have considered them important when deciding whether to purchase the Recalled Devices.

98. Plaintiff and the Class and Subclass justifiably relied on Philips' omissions to their detriment. The detriment is evident from the true quality, characteristics, and risk associated with the use of the Recalled Devices, which is inferior when compared to how the Recalled Devices are advertised and represented by Philips.

99. As a direct and proximate result of Philips' conduct, Plaintiff and the Class and Subclass have suffered actual damages in that they purchased the Recalled Devices (a) that were worth less than the price they paid, (b) which they would not have purchased at all had they known of the health risks associated with the use of the Recalled Devices, and (c) which do not conform to the Recalled Devices' labels, packaging, advertising, and statements.

100. Plaintiff and the Class and Subclass seek actual damages, attorneys' fees, costs, and any other just and proper relief available under the laws.

FIFTH CLAIM FOR RELIEF

NEGLIGENT MISREPRESENTATION
(on behalf of the Nationwide Class or, alternatively, the Subclass)

101. Plaintiff incorporates the foregoing allegations as if fully set forth herein.

102. Philips had a duty to Plaintiff and the Class and Subclass to exercise reasonable and ordinary care in the developing, testing, manufacture, marketing, distribution, and sale of the Recalled Devices.

103. Philips breached its duty to Plaintiff and the Class by developing, testing, manufacturing, advertising, marketing, distributing, and selling products to Plaintiff and the Class that did not have the qualities, characteristics, and suitability for use as advertised by

Philips and by failing to promptly remove the Recalled Devices from the marketplace or to take other appropriate remedial action upon becoming aware of the health risks of the Recalled Devices.

104. Philips knew or should have known that the qualities and characteristics of the Recalled Devices were not as advertised or suitable for their intended use and were otherwise not as warranted and represented by Philips. Specifically, Philips knew or should have known that: (a) the use of the Recalled Devices was accompanied by risk of adverse health effects that do not conform to the packaging and labeling; (b) the Recalled Devices were adulterated, or at risk of being adulterated, by the PE-PUR Foam; and (c) the Recalled Devices were otherwise not as warranted and represented by Philips.

105. As a direct and proximate result of Philips' conduct, Plaintiff and the Class and Subclass have suffered actual damages in that they purchased the Recalled Devices (a) that were worth less than the price they paid, (b) which they would not have purchased at all had they known they contained PE-PUR Foam that could cause users of the Recalled Devices to suffer adverse health effects, and (c) which do not conform to the products' labels, packaging, advertising, and statements.

106. Plaintiff and the Class and Subclass seek actual damages, attorneys' fees, costs, and any other just and proper relief available.

SIXTH CLAIM FOR RELIEF

UNJUST ENRICHMENT
(on behalf of the Nationwide Class or, alternatively, the Subclass)

107. Plaintiff incorporates the foregoing allegations as if fully set forth herein.

108. Plaintiff and the Class and Subclass conferred substantial benefits on Philips through their purchase of the Recalled Devices. Philips knowingly and willingly accepted and enjoyed these benefits.

109. Philips either knew or should have known that the payments rendered by Plaintiff and the Class and Subclass were given with the expectation that the Recalled Devices would have the qualities, characteristics, and suitability for use represented and warranted by Philips. As such, it would be inequitable for Philips to retain the benefit of the payments under these circumstances.

110. Philips' acceptance and retention of these benefits under the circumstances alleged herein make it inequitable for Philips to retain the benefits without payment of the value to Plaintiff and the Class and Subclass.

111. Plaintiff and the Class and Subclass are entitled to recover from Philips all amounts wrongfully collected and improperly retained by Defendants, plus interest thereon.

112. Plaintiff and the Class and Subclass seek actual damages, attorneys' fees, costs, and any other just and proper relief available under the laws.

SEVENTH CLAIM FOR RELIEF

PENNSYLVANIA UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION LAW, 73 Pa. Cons. Stat. Ann. §§ 201-1, *et seq.* (on behalf of the Nationwide Class, or alternatively, the Subclass, except for Class Members who purchased a Recalled Device for business use only)

113. Plaintiff incorporates the foregoing allegations as if fully set forth herein.

114. At all times mentioned herein, Philips engaged in "trade" or "commerce" in Pennsylvania, as defined by 73 Pa. Cons. Stat. Ann. § 201-2(3), in that they advertised, offered for sale, and sold goods, property, or services primarily for personal, family, or household

purposes, and advertised, solicited, offered for sale, and sold "services," "property," "article[s]," "commodit[ies]," or "thing[s] of value" in Pennsylvania.

115. Pennsylvania's Unfair Trade Practices and Consumer Protection Law ("UTCPL"), 73 Pa. Cons. Stat. Ann. § 201-3 provides that "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce . . . are hereby declared unlawful."

116. For the reasons discussed herein, Philips violated and continues to violate the UTCPL by engaging in the herein described unconscionable, deceptive, unfair acts or practices proscribed by UTCPL §§ 201-1, *et seq*. Philips' acts and practices, including its material omissions, described herein, were likely to, and did in fact, deceive and mislead members of the public, including consumers acting reasonably under the circumstances, to their detriment.

117. Philips repeatedly advertised on the labels and packing for the Recalled Devices, on Philips' websites, and through national advertising campaigns, among other items, that the Recalled Devices were safe and fit for human use. Philips failed to disclose the material information that the PE-PUR Foam used in the Recalled Devices, and therefore the Recalled Devices themselves, were unsafe and unfit for human use.

118. Philips' representations and omissions were material because they were likely to deceive reasonable consumers to induce them to purchase and use the Recalled Devices without being aware that the PE-PUR Foam used in the Recalled Devices, and therefore the Recalled Devices themselves, were unsafe and unfit for human use. As a direct and proximate result of Philips' unfair and deceptive acts or practices, Plaintiff and the Class and Subclass Members suffered damages by purchasing the Recalled Devices because they would not have purchased the Recalled Devices had they known the truth, and they received a product that was worthless

because it contains unsafe PEPUR Foam which can cause a number of adverse health effects, including organ failure and cancer.

119. Philips' deceptive trade practices caused injury in fact and actual damages to Plaintiff and members of the Class and Subclass in the form of the loss or diminishment of value of the Recalled Devices that Plaintiff, Class Members, and Subclass Members purchased, which allowed Defendants to profit at the expense of Plaintiff, Class Members, and Subclass Members. The injuries Plaintiff and Subclass Members sustained were to legally protected interests. The gravity of the harm of Philips' actions is significant and there is no corresponding benefit to consumers of such conduct.

120. Plaintiff, Class Members, and Subclass Members seek relief for the injuries they have suffered as a result of Defendants' unfair and deceptive acts and practices, as provided by 73 Pa. Cons. Stat. Ann. § 201-9.2 and applicable law.

EIGHTH CLAIM FOR RELIEF

MEDICAL MONITORING
(on behalf of the Subclass, except for Class Members who purchased a Recalled Device for business use only)

121. Plaintiff incorporates the foregoing allegations as if fully set forth herein.

122. At all relevant times, the Defendants designed, manufactured, assembled, inspected, tested (or not), 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 those that used them, such as Plaintiff.

123. Defendants have reported that users of the Recalled Devices face risks of serious injury from the degradation of PE-PUR Foam contained in the Recalled Devices. Degradation of

PE-PUR Foam may be caused by exposure to chemical emissions from the foam material, high heat and high humidity environments in certain regions, and cleaning methods such as ozone may accelerate potential degradation.

124. When PE-PUR Foam degrades into particles that may enter the device's pathway and be ingested or inhaled by users of the devices, users face significantly increased risks of serious injury that can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment. The potential risks of degraded foam exposure include: irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (*e.g.*, kidneys and liver) and toxic carcinogenic effects.

125. The off-gassing of chemicals from the PE-PUR Foam contained in the Recalled Devices poses risks of serious injury that can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment. The potential risks of exposure to off-gassing from PE-PUR Foam include: headache/dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, nausea/vomiting, toxic and carcinogenic effects.

126. The absence of visible particles does not mean that PE-PUR Foam breakdown has not already begun. Philips has reported that lab analysis of the degraded foam reveals the presence of harmful chemicals including: TDA, TDI, and DEG.[20] TDI is a powerful irritant to the mucous membranes of the eyes and gastrointestinal and respiratory tracts,[21] and has been

[20] Philips Sleep and Respiratory Care Update; Clinical information for physicians, https://www.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/philips-recall-clinical-information-for-physicians-and-providers.pdf (accessed June 27, 2021).

[21] The National Institute for Occupational Safety and Health (NIOSH) Current Intelligence Bulletin 53, *Toluene Diisocyanate (TDI) and Toluenediamine (TDA): Evidence of Carcinogenicity*, DHHS (NIOSH) Publication Number 90-101 (Dec. 1989); *see also* Gunnar Skarping, *et al.*, *Biological monitoring of isocyanates and related amines: Test chamber exposure of humans to toluene diisocyanate*, Dep't of Occupational and Environmental Medicine, University Hospital, S-221 85 Lund, Sweden (1990); https://greenfuture.io/sustainable-living/spray-polyurethane-foam-toxic/.

reported to cause Occupational Asthma.[22] Exposure to TDA may result in ataxia, tachycardia, nausea, vomiting, convulsions, and respiratory depression.[23] TDA can cause chemical cyanosis (*i.e.*, bluish discoloration of the skin) by converting hemoglobin to methemoglobin. This compound can also cause fatty degeneration of the liver.[24] TDA and TDI are potential carcinogens.[25] Repeated exposure to DEG has been associated with damage to the kidneys and renal failure.[26]

127. As a direct and proximate result of Defendants' conduct, Plaintiff has been exposed to substantially increased risks of serious injury from off-gassing and/or degradation of PE-PUR Foam in the Recalled Devices, which is beyond normal background levels of risk.

128. As a direct and proximate result of Defendants' conduct, Plaintiff has a significantly increased risk of suffering serious injury or contracting a serious latent disease, and suffering further injury at an unknown date in the future. Such injuries include cancer and organ failure, among others currently unknown or just being discovered.

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[22] Bernstein, David I, *Occupational asthma: Definitions, epidemiology, causes, and risk factors*, Wolters Kluwer, UpToDate.com (accessed Jun. 30, 2021).

[23] NIOSH, *Toluene Diisocyanate (TDI) and Toluenediamine (TDA): Evidence of Carcinogenicity*; *see also* Skarping, *Biological monitoring of isocyanates and related amines: Test chamber exposure of humans to toluene diisocyanate*; https://greenfuture.io/sustainable-living/spray-polyurethane-foam-toxic/.

[24] NIOSH, *Toluene Diisocyanate (TDI) and Toluenediamine (TDA): Evidence of Carcinogenicity*.

[25] *Id.* ("The excess cancer risk for workers exposed to TDI and TDA has not yet been quantified, but the probability of developing cancer should be decreased by minimizing exposure.").

[26] Greg M. Landry, *Diethylene glycol-induced toxicities show marked threshold dose response in rats*, Toxicology and Applied Pharmacology 282 (2015) 244-251 ("DEG has recently been involved in several mass epidemics of renal failure and death world-wide (O'Brien et al., 1998; Schier et al., 2013). DEG poisoning clinically manifests in metabolic acidosis, hepatotoxicity, renal failure, and peripheral neuropathy, with the hallmark being acute renal failure involving proximal tubule cell necrosis and cortical degeneration (Schep et al., 2009)"); Cohen, Jeffrey A., *Demyelinating Diseases of the Peripheral Nerves*, Nerves and Nerve Injuries (2015) ("When consumed, DEG causes severe systemic and neurologic complications, including coma, seizures, peripheral neuropathy, and hepatorenal failure.").

129. Monitoring procedures exist that makes the early detection of damage from degraded and/or off-gassed PE-PUR Foam possible. These procedures are different from that normally recommended in the absence of the exposure. These monitoring procedures include non-routine surveillance studies, laboratory testing, and physical examinations, and would be reasonably necessary according to contemporary scientific principles.

130. Existing medical research indicates that exposure to TDI, TDA, and DEG, which Philips has found to exist in off-gassed or degraded PE-PUR Foam, can cause serious, life-threatening and permanent injuries. Philips has received reports from users of the Recalled Devices of headache, upper airway irritation, cough, chest pressure and sinus infection. The exposure to the defects inherent in the Recalled Devices has occurred for users, such as Plaintiff, but the full extent of the injuries will not manifest until later in the Plaintiff's life. Thus, because of Defendants' conduct, it is reasonably necessary that Plaintiff be placed under period diagnostic testing beyond that normally recommended in the absence of use of the Recalled Devices.

131. Plaintiff demands judgment against Defendants for medical monitoring damages to diagnose injuries caused by the Recalled Devices at an earlier date to allow for timely treatment and prevention of exacerbation of injuries, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of all others similarly situated, prays for judgment against Philips as to each and every count, including:

A. An order certifying this action and the Class and Subclass requested herein as a class action, designating Plaintiff as the representative of the Class and Subclass, and appointing Plaintiff's counsel as counsel to the Class and Subclass;

B. An order declaring that Philips' actions constitute: (i) breach of express warranty; (ii) breach of the implied warranty of merchantability; (iii) fraudulent misrepresentation; (iv) fraud by omission; (v) negligent misrepresentation; and (vi) unfair and deceptive business practices in violation of Pennsylvania consumer protection statutes, and that Philips is liable to Plaintiff and the Class and Subclass, as described herein, for damages arising therefrom;

C. A judgment awarding Plaintiff and members of the Class and Subclass all appropriate damages in an amount to be determined at trial;

D. A judgment awarding Plaintiff and the Class and Subclass medical monitoring damages;

E. A judgment awarding Plaintiff and the Class and Subclass prejudgment and post-judgment interest, as permitted by law;

F. A judgment awarding Plaintiff and the Class and Subclass costs and fees, including attorneys' fees, as permitted by law; and

H. Grant such other legal, equitable or further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury for all issues so triable.

DATED: July 1, 2021

Respectfully submitted,

/s/ Sandra L. Duggan
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Arnold Levin (PA Bar #02280)
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Attorneys for Plaintiff

EXHIBIT “A”

URGENT: Medical Device Recall

Philips Respironics
Trilogy 100, Trilogy 200, Garbin Plus, Aeris, LifeVent, BiPAP V30, and BiPAP A30/A40 Series Device Models

Sound Abatement Foam
Susceptibility to Degradation and Volatile Organic Compound Emission

Dear Device Customer,

Philips Respironics is voluntarily recalling the below devices due to two (2) issues related to the polyester-based polyurethane (PE-PUR) sound abatement foam used in Philips Continuous and Non-Continuous Ventilators: 1) PE-PUR foam may degrade into particles which may enter the device's air pathway and be ingested or inhaled by the user, and 2) the PE-PUR foam may off-gas certain chemicals. The foam degradation may be exacerbated by use of unapproved cleaning methods, such as ozone (see FDA safety communication on use of Ozone cleaners), and off-gassing may occur during operation.

These issues can result in serious injury which can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment. To date, Philips Respironics has received several complaints regarding the presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask). Philips also has received reports of headache, upper airway irritation, cough, chest pressure and sinus infection. The potential risks of particulate exposure include: Irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (e.g. kidneys and liver) and toxic carcinogenic affects. The potential risks of chemical exposure due to off-gassing include: headache/dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, nausea/vomiting, toxic and carcinogenic effects. There have been no reports of death as a result of these issues.

All Devices manufactured before 26 April 2021, All serial numbers	
Continuous Ventilator	Trilogy 100
	Trilogy 200
	Garbin Plus, Aeris, LifeVent
Continuous Ventilator, Minimum Ventilatory Support, Facility Use	A-Series BiPAP Hybrid A30 (not marketed in US)
	A-Series BiPAP V30 Auto
Continuous Ventilator, Non-life Supporting	A-Series BiPAP A40
	A-Series BiPAP A30

Immediate Actions to be taken by You, the User:

1. Do not stop or alter your prescribed therapy until you have talked to your physician. Philips recognizes that alternate ventilator options for therapy may not exist or may be severely limited for patients who require a ventilator for life-sustaining therapy, or in cases where therapy disruption is unacceptable. In these situations, and at the discretion of the treating clinical team, the benefit of continued usage of these ventilator devices may outweigh the risks.

2. If your physician determines that you must continue using this device, **use an inline bacterial filter.** Consult your Instructions for Use for guidance on installation.

3. Register your device(s) on the recall website www.philips.com/src-update

    a. The website provides you current information on the status of the recall and how to receive permanent corrective action to address the two (2) issues.
    b. The website also provides you instructions on how to locate your device Serial Number and will guide you through the registration process.
    c. Call 1-877-907-7508 if you cannot visit the website or do not have internet access.

Permanent Corrective Action to be Taken by the Company:
Philips is deploying a permanent corrective action to address the two (2) issues described in this Recall Notice. As part of the registration process above, you will be provided information on the next steps to implement the permanent solution.

Other Information:
If you need any further information or support concerning this recall/issue, please contact the recall support hotline or visit the website:

1-877-907-7508
www.philips.com/src-update

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or fax.

This notice has been reported to the appropriate Regulatory Agencies.

Philips regrets any inconveniences caused by this problem.

Sincerely,

Rodney Mell
Head of Quality and Regulatory
Philips Respironics - Sleep & Respiratory Care

URGENT: Medical Device Recall

Philips Respironics
CPAP and Bi-Level PAP Devices

Sound Abatement Foam
Susceptibility to Degradation and Volatile Organic Compound Emission

Dear Device Customer,

Philips Respironics is voluntarily recalling the below devices due to two (2) issues related to the polyester-based polyurethane (PE-PUR) sound abatement foam used in Philips Continuous and Non-Continuous Ventilators: 1) PE-PUR foam may degrade into particles which may enter the device's the air pathway and be ingested or inhaled by the user, and 2) the PE-PUR foam may off-gas certain chemicals. The foam degradation may be exacerbated by use of unapproved cleaning methods, such as ozone (see FDA safety communication on use of Ozone cleaners), and off-gassing may occur during initial operation and may possibly continue throughout the device's useful life.

These issues can result in serious injury which can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment. To date, Philips Respironics has received several complaints regarding the presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask). Philips also has received reports of headache, upper airway irritation, cough, chest pressure and sinus infection. The potential risks of particulate exposure include: Irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (e.g. kidneys and liver) and toxic carcinogenic affects. The potential risks of chemical exposure due to off-gassing include: headache/dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, nausea/vomiting, toxic and carcinogenic effects. There have been no reports of death as a result of these issues.

All Devices manufactured before 26 April 2021, All serial numbers	
Continuous Ventilator, Minimum Ventilatory Support, Facility Use	E30 (Emergency Use Authorization)
Continuous Ventilator, Non-life Supporting	DreamStation ASV
	DreamStation ST, AVAPS
	SystemOne ASV4
	C-Series ASV
	C-Series S/T and AVAPS
	OmniLab Advanced+
Noncontinuous Ventilator	SystemOne (Q-Series)
	DreamStation
	DreamStation Go
	Dorma 400
	Dorma 500
	REMstar SE Auto

Immediate Actions to be taken by You, the User:

1. Discontinue use of your device and work with your physician or Durable Medical Equipment (DME) provider to determine the most appropriate options for continued treatment. To continue use of your device due to lack of alternatives, consult with your physician to determine if the benefit of continuing therapy with your device outweighs the risks identified in this letter.

2. Register your device on the recall website www.philips.com/src-updates
    d. The website provides you current information on the status of the recall and how to receive permanent corrective action to address the two (2) issues.
    e. The website also provides you instructions on how to locate your device Serial Number and will guide you through the registration process.
    f. Call 1-877-907-7508 if you cannot visit the website or do not have internet access.

Permanent Corrective Action to be Taken by the Company:
Philips is deploying a permanent corrective action to address the two (2) issues described in this Recall Notice. As part of the registration process above, you will be provided information on the next steps to implement the permanent solution.

Other Information:
If you need any further information or support concerning this issue, please contact the recall support hotline or visit the website:

1-877-907-7508
www.philips.com/src-update

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, or by regular mail or fax.

This notice has been reported to the appropriate Regulatory Agencies.

Philips regrets any inconveniences caused by this problem.

Sincerely,

Rodney Mell
Head of Quality and Regulatory
Philips Respironics - Sleep & Respiratory Care