

1 JEFFREY J. ROONEY, Esq. SBN# 127448  
2 VANTAGE POINT LAW, INC.  
3 A California Professional Corporation  
4 18 Crow Canyon Court, Suite 130  
5 San Ramon, CA 94583  
6 TEL: (925) 934-7400  
7 FAX: (925) 934-7520  
8 jeff@vantagepoint.law

9 Attorney for Plaintiff:  
10 Steven Fisher

11 UNITED STATES DISTRICT COURT  
12 NORTHERN DISTRICT OF CALIFORNIA

13 STEVEN FISHER

14 Plaintiff,

15 vs.

16 KONINKLIJKE PHILIPS N.V.;  
17 PHILIPS NORTH AMERICA LLC; and PHILIPS  
18 RS NORTH AMERICA LLC

19 Defendants

Case No.:

COMPLAINT FOR MONEY DAMAGES  
DEMAND FOR JURY TRIAL

- (1) Negligence
- (2) Product Liability: Design Defect
- (3) Product Liability: Manufacturing Defect
- (4) Product Liability: Failure to Warn
- (5) Breach of Express Warranty
- (6) Breach of Implied Warranty of Merchantability
- (7) Fraudulent Misrepresentation
- (8) Fraud by Omission
- (9) Negligent Misrepresentation

DEMAND FOR JURY TRIAL

22 Plaintiff STEVEN FISHER ("Plaintiff") for his complaint against Defendants Koninklijke  
23 Philips N.V. ("Royal Philips"), Philips North America LLC ("Philips NA"), and Philips RS North  
24 America LLC ("Philips RS") (collectively, Royal Philips, Philips NA, and Philips RS are "Philips" or  
25 the "Defendants"), alleges the following based on (a) personal knowledge, (b) the investigation of  
26 counsel, and (c) information and belief, as follows:

I INTRODUCTION

1  
2 1. Plaintiff brings this action for injuries caused from the use of Continuous Positive  
3 Airway Pressure (CPAP) and Bi-Level Positive Airway Pressure (Bi-Level PAP) devices and  
4 mechanical ventilators manufactured by Philips, which contain polyester-based polyurethane sound  
5 abatement foam (“PE-PUR Foam”).

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

9 3. On June 14, 2021, Royal Philips issued a recall in the United States of its CPAP, Bi-  
10 Level PAP, and mechanical ventilator devices containing PE-PUR Foam, because Philips had  
11 determined that: (a) the PE-PUR Foam was at risk for degradation into particles that may enter the  
12 devices’ pathway and be ingested or inhaled by users, and (b) the PE-PUR Foam may off-gas certain  
13 chemicals during operation. Philips further disclosed in its Recall Notice that, “these issues can result  
14 in serious injury which can be life-threatening, cause permanent impairment, and/or require medical  
15 intervention to preclude permanent impairment.” Despite the recall being issued, Plaintiff Fisher did  
16 not receive any direct notice of the Recall Notice from Defendants.

17 10. Philips has disclosed that the absence of visible particles in the devices does not mean  
18 that PE-PUR Foam breakdown has not already begun. Philips reported that lab analysis of the  
19 degraded foam reveals the presence of harmful chemicals, including Toluene Diamine (“TDA”),  
20 Toluene Diisocyanate (“TDI”), and Diethylene Glycol (“DEG”).

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

25 12. In its Recall Notice, Philips disclosed that the potential risks of particulate exposure to  
26 users of these devices include irritation (skin, eye, and respiratory tract), inflammatory response,  
27 headache, asthma, adverse effects to other organs (e.g., kidneys and liver) and toxic carcinogenic  
28 effects. The potential risks of chemical exposure due to off-gassing of PE-PUR Foam in these devices

1 include headache/dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity,  
2 nausea/vomiting, toxic and carcinogenic effects.

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

6 14. In or around April 2017, Plaintiff STEVEN FISHER was diagnosed with sleep apnea  
7 at the Contra Costa Sleep Center in Walnut Creek, California. He was prescribed a Philips  
8 DreamStation Auto CPAP device, Serial No. J187992102008 (“Plaintiff’s Recalled Devise”) to treat  
9 his sleep apnea and which was purchased by Plaintiff through his insurance. From the date of  
10 prescription, Plaintiff used the Philips DreamStation Auto CPAP device, Serial No. J187992102008  
11 nightly for approximately 8 hours through late 2021 according to the procedures and instructions  
12 which accompanied the CPAP machine and as instructed by the personnel who fitted him for the  
13 mask. Plaintiff took and used Plaintiff’s Recalled Devise with him when he went on trips. Plaintiff  
14 regularly cleaned Plaintiff’s Recalled Devise pursuant to manufacture instructions and never used a  
15 third-party cleaning devise.

16 15. In or around November 2019, Plaintiff began to experience pain in his neck and  
17 headaches. By April 2020 more severe symptoms developed including vision challenges, extreme  
18 neck pain, headaches, nausea, a chronic cough, difficulty swallowing, and shortness of breath.  
19 Plaintiff was admitted to John Muir Hospital in Walnut Creek, California where he was diagnosed  
20 with diagnosed with Glioblastoma, a grade 4 brain cancer tumor which is an extremely aggressive,  
21 terminal form of cancer with no known cure.

22 16. Since April 2020, Plaintiff has been hospitalized numerous times, underwent three  
23 brain cancer surgeries, numerous MRIs, radiation therapies, chemo treatments, and various other  
24 procedures. Plaintiff Fisher brought the Philips DreamStation Auto CPAP device, Serial No.  
25 J187992102008 with him to the hospital and used Plaintiff’s Recalled Devise in the hospital.

26 17. Plaintiff has incurred substantial expenses for medical care and operations. Plaintiff  
27 has been placed on disability with his employer. Since learning of the recall, Plaintiff has  
28

1 experienced anxiety concerning the serious health risks he is facing from possible exposure to off-  
2 gassed or degraded PE-PUR Foam in the Recalled machines, including the machine used by Plaintiff.

3 18. Plaintiff seeks to recover damages based on, inter alia, Philips' negligence, strict  
4 product liability, breach of express warranty, breach of implied warranties, misrepresentations,  
5 omissions, and breaches of state consumer protection laws in connection with its manufacture,  
6 marketing and sales of devices containing PE-PUR Foam.

7 **II PARTIES**

8 19. Plaintiff STEVEN FISHER is a citizen of the State of California.

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

16 21. Defendant Philips NA is a Delaware corporation with its principal place of business  
17 located at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. Philips NA is a wholly  
18 owned subsidiary of Royal Philips.

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

23 **III JURISDICTION AND VENUE**

24 23. Jurisdiction of this Court is based on Diversity of Citizenship and the amount in  
25 controversy is well in excess of the jurisdictional limit of \$75,000.00. 28 U.S.C. Section 1332(a)(1).

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

1           25.     The Court has personal jurisdiction over Defendants because Defendants substantial  
2 business in this District, and the events giving rise to Plaintiff's claims arise out of and relate to  
3 Defendants' contacts with this District. Defendants Philips RS and Philips NA are controlled by their  
4 parent Royal Philips. Defendants' affiliations with this District are so continuous and systematic as to  
5 render them essentially at home in the forum State. Further, Defendants have transacted business,  
6 maintained substantial contacts, purposefully targeted consumers and medical professionals for sales  
7 of its devices and/or committed overt acts in furtherance of the unlawful acts alleged in this  
8 Complaint in this District, as well as throughout the United States. The unlawful acts of Defendants  
9 have been directed at, targeted, and have had the effect of causing injury to persons residing in,  
10 located in, or doing business in this District, as well as throughout the United States.

#### 11                                   **IV    FACTUAL BACKGROUND**

##### 12     **A.    Continuous Positive Airway Pressure Therapy**

13           26.     Continuous Positive Airway Pressure ("CPAP") therapy is a common nonsurgical  
14 treatment primarily used to treat sleep apnea. CPAP therapy typically involves the use of a hose and a  
15 nasal or facemask device that delivers constant and steady air pressure to an individual's throat to  
16 help individuals breathe.

17           27.     Sleep apnea is a common sleep disorder characterized by repeated interruptions in  
18 breathing throughout an individual's sleep cycle. These interruptions, called "apneas," are caused  
19 when the soft tissue in an individual's airway collapses. The airway collapse prevents oxygen from  
20 reaching the individual's lungs which can cause a buildup of carbon dioxide. If the individual's brain  
21 senses the buildup of carbon dioxide, it will briefly rouse the individual from sleep so that the  
22 individual's airway can reopen. Often these interruptions are so brief that the individual will not  
23 remember. Despite the brevity of the interruptions, the sleep cycle disruption caused by sleep apnea  
24 can dramatically impact a person's lifestyle, including negatively impacting energy, mental  
25 performance, and long-term health. CPAP therapy helps treat sleep apnea by preventing the person's  
26 airway from collapsing while breathing during sleep cycles, which can help prevent interruptions in  
27 breathing.

V SUBSTANTIVE ALLEGATIONS

1  
2 30. Philips developed, marketed, and sold a variety of CPAP and Bi-Level PAP  
3 respiratory devices and mechanical ventilators under its “Sleep & Respiratory Care” segment of its  
4 business designed to assist individuals with a number of sleep, breathing, and respiratory conditions,  
5 including obstructive sleep apnea, central sleep apnea, complex sleep apnea syndrome, and Chronic  
6 Obstructive Pulmonary Disease (COPD), as well as to assist those individuals requiring invasive and  
7 non-invasive ventilators for acute and sub-acute hospital environments. Philips’ CPAP and Bi-Level  
8 PAP respirator devices and its mechanical ventilators typically cost several hundred, if not thousands  
9 of dollars. Philips has sold millions of these devices in the United States.

10 **A. Philips Sleep & Respiratory Care Devices Endangered Users**

11 31. On April 26, 2021, in its Quarterly Report for Q1 2021, Philips disclosed for the first  
12 time, under a section entitled “Regulatory Update,” that device user reports had led to a discovery that  
13 the type of PE-PUR Foam Philips used to minimize noise in several CPAP and Bi-Level PAP  
14 respirators and mechanical ventilators posed health risks to its users. Specifically, Philips disclosed  
15 that “the [PE-PUR] foam may degrade under certain circumstances, influenced by factors including  
16 use of unapproved cleaning methods, such as ozone, and certain environmental conditions involving  
17 high humidity and temperature.”

18 32. Seven weeks later, on June 14, 2021, Philips announced a recall of numerous models  
19 of CPAP and Bi-Level PAP devices, as well as a variety of its mechanical ventilators “to address  
20 identified potential health risks related to the polyester-based polyurethane (PE-PUR) sound  
21 abatement foam component in these devices.” Specifically, Philips announced that it had determined  
22 that the “PE-PUR foam may degrade into particles which may enter the device’s air pathway and be  
23 ingested or inhaled by the user, and the foam may off-gas certain chemicals.” In total, Philips  
24 announced that “[b]etween 3 million and 4 million” devices are targeted in the recall.

25 33. The list of the devices recalled by Philips (the “Recalled Devices” or “Recalled  
26 Machines”) include:

27 //

28 //

*Philips CPAP and Bi-Level PAP Devices  
Manufactured Before April 26, 2021 Subject to Recall  
Device Name/Model Type*

- E30 (Emergency Use Authorization) – Continuous Ventilator, Minimum Ventilatory Support, Facility Use
- DreamStation ASV; DreamStation ST, AVAPS; SystemOne ASV4; C Series ASV; C Series S/T and AVAPS; OmniLab Advanced Plus – Continuous Ventilator, Non-life Supporting
- SystemOne (Q Series); DreamStation; DreamStation GO; Dorma 400; Dorma 500; REMStar SE Auto – Non-continuous Ventilator

*Philips Mechanical Respirator Devices  
Manufactured Before April 26, 2021 Subject to Recall  
Device Name/Model Type*

- Trilogy 100 Ventilator; Trilogy 200 Ventilator; Garbin Plus, Aeris, LifeVentVentilator – Continuous Ventilator
- A-Series BiPAP Hybrid A30; Philips A-Series BiPAP V30 Auto – Continuous Ventilator, Minimum Ventilatory Support, Facility Use
- Philips A-Series BiPAP A40; Philips A-Series BiPAP A30 – Continuous Ventilator, Non-life Supporting

34. 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.”

35. 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.”

36. 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.”

1           37. Philips announced that it has received reports of specific complaints from users of  
2 Recalled Devices who suffered from “headache[s], upper airway irritation, cough, chest pressure and  
3 sinus infection.”

4 **B. The Health Risks Associated with Use of the Recalled Devices Renders Them Worthless**

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

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

18           40. Recognizing this, Philips issued the following advice to patients using any of the  
19 Recalled Devices:

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

24           41. As a result of the above, Plaintiff has incurred expense replacing the Recalled Device.

25 **C. Philips Unreasonably Delayed its Recall**

26           42. At no time prior to its Regulatory Update on April 26, 2021, did Philips disclose to  
27 purchasers or users of the Recalled Devices that the PE-PUR Foam contained therein may off-gas or  
28



1 degrade upon use. Similarly, prior to the Update, Philips did not disclose any health risks associated  
2 with use of the Recalled Devices.

3 43. Defendants have not disclosed when they first discovered or received reports from  
4 users of their Sleep & Respiratory Care devices “regarding the presence of black debris/particles  
5 within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask).”

6 44. At a minimum, as a result of user reports, Defendants were aware of the offgassing  
7 and degradation of the PE-PUR Foam used in the Recalled Devices at some point prior to the recall  
8 yet continued to manufacture and sell the Recalled Devices with such awareness. During this period,  
9 Defendants unreasonably and unjustly profited from the manufacture and sale of the Recalled  
10 Devices and unreasonably put users of the Recalled Devices at risk of development of serious adverse  
11 health effects, including organ failure and cancer.

12 **D. Plaintiff STEVE FISHER**

13 45. Plaintiff STEVE FISHER is a resident and citizen of Contra Costa County, California.

14 46. Plaintiff purchased a Recalled Device, the Philips DreamStation Auto CPAP device,  
15 prior to June 14, 2021.

16 47. The manuals accompanying Plaintiff’s device did not contain any language or  
17 warnings of health risks associated with use of the device, including irritation (skin,  
18 eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs  
19 (e.g., kidneys and liver) and toxic carcinogenic effects. Had Defendants informed Plaintiff of these  
20 risks, he would not have purchased or used the Recalled Device.

21 48. Without knowing of the health risks associated with use of the Recalled Device,  
22 Plaintiff used the Recalled Device regularly to treat sleep apnea until learning through news media in  
23 late 2021, that the devices were recalled.

24 49. As a result of the health risks associated with continued use of the Recalled Device,  
25 Plaintiff was diagnosed with Glioblastoma, a grade 4 brain cancer tumor which is an extremely  
26 aggressive, terminal form of cancer with no known cure requiring numerous hospitalizations, three  
27 brain cancer surgeries, numerous MRIs, radiation therapies, chemo treatments, and various other  
28 procedures.

1 **VI TOLLING AND ESTOPPEL**

2 **A. DISCOVERY RULE TOLLING**

3 50. Plaintiff had no way of knowing about Philips' conduct with respect to the health risks  
4 associated with the use of the Recalled Device.

5 51. Plaintiff, through the exercise of reasonable care, could not have discovered the  
6 conduct by Philips alleged herein. Further, Plaintiff did not discover and did not know of facts that  
7 would have caused a reasonable person to suspect that Philips was engaged in the conduct alleged  
8 herein.

9 52. For these, reasons, all applicable statutes of limitation have been tolled by the  
10 discovery rule with respect to claims asserted by Plaintiff.

11 **B. FRAUDULENT CONCEALMENT TOLLING**

12 53. By failing to provide immediate notice of the adverse health effects associated with  
13 continued use of the Recalled Device, Philips concealed its conduct and the existence of the claims  
14 asserted herein from Plaintiff.

15 54. Upon information and belief, Philips intended its acts to conceal the facts and claims  
16 from Plaintiff. Plaintiff was unaware of the facts alleged herein without any fault or lack of diligence  
17 on his part and could not have reasonably discovered Defendants' conduct. For this reason, any  
18 statute of limitations that otherwise may apply to the claims of Plaintiff should be tolled.

19  
20 **VII CLAIMS FOR RELIEF**

21 **FIRST CAUSE OF ACTION**

22 **NEGLIGENCE**

23 55. Defendants had a duty to individuals, including the Plaintiff, to use reasonable care in  
24 designing, manufacturing, marketing, labeling, packaging and selling the recalled machines,  
25 including the Recalled Devices.

26 56. Defendants were negligent in failing to use reasonable care as described  
27 herein in designing and manufacturing, the recalled machines, as well as the machine that  
28 Plaintiff purchased and used. Defendants breached their aforementioned duty by:

- 1 a. Failing to design the recalled machines so as to avoid an unreasonable and
- 2 increased risk of harm of cancer and other injuries in users;
- 3 b. Including in the design of the recalled machines flawed polyurethane PE-PUR
- 4 sound abatement foam that could break down, flake off and/or chemicalize and
- 5 infiltrate the device's air pathway while the user is sleeping, exposing them to
- 6 increased and unnecessary risk of cancer as well as other injuries;
- 7 c. Manufacturing certain Philips machines, including the recalled machines, with
- 8 a specific lot and/or lots of flawed polyurethane PEPUR sound abatement foam
- 9 that could break down, flake off and/or chemicalize and infiltrate the device's
- 10 air pathway while the user is sleeping, exposing them to increased and
- 11 unnecessary risk of cancer as well as other injuries;
- 12 d. Otherwise negligently or carelessly designing, manufacturing, marketing,
- 13 labeling, packaging and/or selling the Recalled Devices.

14 57. Defendants also negligently failed to warn or instruct the Plaintiff in the following  
15 manners:

- 16 a. the recalled machine's flawed polyurethane PE-PUR sound abatement foam
- 17 propensities to break down, flake off and/or chemicalize and infiltrate the
- 18 device's air pathway while the user is sleeping, exposing them to increased and
- 19 unnecessary risk of cancer as well as other injuries;
- 20 b. the recalled machine's polyurethane PE-PUR sound abatement foam
- 21 propensities to degradation, fragmentation and/or chemicalization;
- 22 c. the rate and manner in which the polyurethane PE-PUR sound abatement foam
- 23 would break down, flake off and/or chemicalize and infiltrate the device's air
- 24 pathway while the user is sleeping;
- 25 d. the risk of chronic inflammation resulting from use of the recalled machines;
- 26 e. the risk of chronic infections resulting from the recalled machines;
- 27 f. the risk of cancers from exposure to the PE-PUR sound abatement foam;
- 28

- 1 g. the need for corrective or revision surgery to adjust or remove cancerous
- 2 tumors and/or nodules as a result of usage of the recalled machines;
- 3 h. the severity of complications that could arise as a result of implantation of the
- 4 recalled machines;

5 58. As a direct and proximate result of Defendants' negligence, the Plaintiff has  
6 experienced significant mental and physical pain and suffering, has sustained permanent injury, has  
7 undergone medical treatment and will likely undergo further medical treatment and procedures, has  
8 suffered financial or economic loss, including, but not limited to, obligations for medical services and  
9 expenses, lost income, and other damages.

10 59. WHEREFORE, Plaintiff demands judgment against Defendants, and each of them,  
11 individually, jointly, severally and in the alternative, and requests compensatory damages, punitive  
12 damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court  
13 deems equitable and just.

14 **SECOND CAUSE OF ACTION**

15 **PRODUCT LIABILITY: DESIGN DEFECT**

16 60. The recalled machine used by Plaintiff was not reasonably safe for its intended uses  
17 and was defective as described herein with respect to its design. As previously stated, the machine's  
18 design defects include, but are not limited to:

- 19 a. the use of polyurethane PE-PUR sound abatement foam in the recalled
- 20 machines and the immune reaction that results from such material, causing
- 21 adverse reactions and injuries;
- 22 b. Failing to design the recalled machines so as to avoid an unreasonable and
- 23 increased risk of harm of cancer and other injuries in users;
- 24 c. Including in the design of the recalled machines flawed polyurethane PE-PUR
- 25 sound abatement foam that could break down, flake off and/or chemicalize and
- 26 infiltrate the device's air pathway while the user is sleeping, exposing them to
- 27 increased and unnecessary risk of cancer as well as other injuries;
- 28

- 1 d. Failing to use alternatively available sound abatement materials and/or foams  
2 in the recalled machines, such as plastic, silicone, or rubber, which would not  
3 break down, flake off and/or chemicalize and infiltrate the device's air pathway  
4 while the user is sleeping;
- 5 e. Otherwise negligently or carelessly designing, manufacturing, marketing,  
6 labeling, packaging and/or selling the recalled machines.

7 61. At all times, the use of the recalled machines, as well as Plaintiff's use of the Recalled  
8 Device (and its components, such as the facemask) was at all times foreseeable and foreseen by  
9 Defendants as it was used by Plaintiff in the manner intended by Defendants.

10 62. The recalled machine used by Plaintiff, was defective in its design in that it failed to  
11 perform as safely as a reasonable consumer would expect when used in an intended or reasonably  
12 foreseeable manner.

13 63. The recalled machines, including the Plaintiff's Recalled Device, are further defective  
14 in that the risks of danger inherent in its design outweigh the benefits, in that the gravity of danger  
15 posed by the design was great, the likelihood that such danger would cause injury was substantial,  
16 there were feasible, safer alternative designs known to Defendants at the time of manufacture, the  
17 financial costs of an improved design was minor and there were likely no adverse consequences to  
18 the product, or to the user, that would result from an alternative design.

19 64. Defendants, and each of them, knew that the recalled machines, including Plaintiff's  
20 Recalled Device, and the component parts of these CPAP/BIPAP machines would be purchased and  
21 used without inspection for defects in the design of the machine or its masks/attachments.

22 65. The recalled machines, including the Plaintiff's Recalled Device, and the component  
23 parts of these machines were defective when they left the control of each of these Defendants.

24 66. As a direct and proximate result of the recalled machines, including Plaintiff's  
25 Recalled Device, and the aforementioned defects as described herein, the Plaintiff has experienced  
26 significant mental and physical pain and suffering, has sustained permanent injury, has undergone  
27 medical treatment and will likely undergo future medical treatment and procedures, has suffered  
28

1 financial or economic loss, including, but not limited to, obligations for medical services and  
2 expenses, lost income, and other damages.

3 67. Defendants are strictly liable to the Plaintiff for designing, manufacturing, marketing,  
4 labeling, packaging and selling the recalled machines, including Plaintiff's Recalled Device.

5 68. As a direct and proximate result of one or more of the above-stated negligent acts,  
6 Plaintiff has suffered and will continue to suffer injury of a personal and pecuniary nature, including  
7 pain and suffering, medical expenses, lost income, and disability.

8 69. WHEREFORE, Plaintiff demands judgment against Defendants, and each of them,  
9 individually, jointly, severally and in the alternative, and requests compensatory damages, punitive  
10 damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court  
11 deems equitable and just.

12 **THIRD CAUSE OF ACTION**

13 **PRODUCT LIABILITY: MANUFACTURING DEFECT**

14 70. At all times, the use of the recalled machines, as well as Plaintiff's use of the Recalled  
15 Device (and its components, such as the facemask) was at all times foreseeable and foreseen by  
16 Defendants as it was used by Plaintiff in the manner intended by Defendants.

17 71. The recalled machines were defective at the time of their manufacture, development,  
18 production, testing, inspection, endorsement, sale and distribution, and at the time they left the  
19 possession of the Defendants, in that, and not by way of limitation, the products differed from the  
20 Defendants' intended result and intended design and specifications, and from other ostensibly  
21 identical units of the same product line.

22 72. Defendants, and each of them, knew or should have known of the defective nature of  
23 the recalled machines, including (among other things), that the PE-PUR foam used in the recalled  
24 machine's component parts was prone to flaking, chemicalization, disintegration, that it could enter  
25 the user's airways while they slept, and created an unreasonably high risk while in use, and would  
26 foreseeably result in injury or death to the public, purchasers, and/or consumers.

27 73. The Defendants, and each of them, knew or should have known of the defective nature  
28 of the recalled machines, and the component parts of these CPAP/BIPAP machines, including among

1 other things, that the PE-PUR foam used in the recalled machine's component parts was prone to  
2 flaking, chemicalization, disintegration, that it could enter the user's airways while they slept, and  
3 created an unreasonably high risk while in use, and would foreseeably result in injury or death to the  
4 public, purchasers, and/or consumers.

5 74. Specifically, the Defendants improperly designed the recalled machines by  
6 manufacturing certain Philips machines, including the recalled machines, with a specific lot and/or  
7 lots of flawed polyurethane PE-PUR sound abatement foam that could break down, flake off and/or  
8 chemicalize and infiltrate the device's air pathway while the user is sleeping, exposing them to  
9 increased and unnecessary risk of injury, including cancer, as well as other injuries.

10 75. As a direct and proximate result of one or more of the above-stated negligent acts,  
11 Plaintiff has suffered and will continue to suffer injury of a personal and pecuniary nature, including  
12 pain and suffering, medical expenses, lost income, and disability.

13 76. WHEREFORE, Plaintiff demands judgment against Defendants, and each of them,  
14 individually, jointly, severally and in the alternative, and requests compensatory damages, punitive  
15 damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court  
16 deems equitable and just.

17 **FOURTH CAUSE OF ACTION**

18 **PRODUCT LIABILITY: FAILURE TO WARN**

19 77. The recalled machines, including the Recalled Device used by Plaintiff, were not  
20 reasonably safe for their intended uses and were defective as described herein as a matter of law due  
21 to its lack of appropriate and necessary warnings. Specifically, Defendants did not provide sufficient  
22 or adequate warnings including, but not limited to, the following:

- 23 a. the recalled machine's flawed polyurethane PE-PUR sound abatement foam  
24 propensities to break down, flake off and/or chemicalize and infiltrate the  
25 device's air pathway while the user is sleeping, exposing them to increased and  
26 unnecessary risk of cancer, including cancer, as well as other injuries;
- 27 b. the recalled machine's polyurethane PE-PUR sound abatement foam  
28 propensities to degradation, fragmentation and/or chemicalization;

- c. the rate and manner in which the polyurethane PE-PUR sound abatement foam would break down, flake off and/or chemicalize and infiltrate the device's air pathway while the user is sleeping;
- d. the risk of chronic inflammation resulting from use of the recalled machines;
- e. the risk of chronic infections resulting from the recalled machines;
- f. the risk of cancers from exposure to the PE-PUR sound abatement foam;
- g. the need for corrective or revision surgery to adjust or remove cancerous tumors and/or nodules as a result of usage of the recalled machines;
- h. the severity of complications that could arise as a result of implantation of the recalled machines;

78. As a direct and proximate result of the recalled machine's aforementioned defects as described herein, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

79. Defendants are strictly liable to the Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling a defective device.

80. WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

**FIFTH CAUSE OF ACTION**

**BREACH OF EXPRESS WARRANTY**

81. Philips marketed and sold the Recalled Device into the stream of commerce with the intent that the Recalled Device would be purchased by Plaintiff and other members of the general public.

82. Philips expressly warranted, advertised, and represented to Plaintiff that the Recalled Device was safe and appropriate for human use.



1           83.     Philips made these express warranties regarding the Recalled Device’s quality and  
2 fitness for use in writing through its website, advertisements, and marketing materials, and on the  
3 Recalled Device’s packaging and labels. These express warranties became part of the basis of the  
4 bargain that Plaintiff entered into upon purchasing the Recalled Device.

5           84.     Philips’ advertisements, warranties, representations, and omissions regarding health  
6 risks associated with the Recalled Device, were made in connection with the sale of the Recalled  
7 Device to Plaintiff. Plaintiff relied on Philips’ advertisements, warranties, representations, and  
8 omissions regarding the Recalled Device in deciding whether to purchase and use Philips’ Recalled  
9 Device.

10          85.     The recalled machines, including the Recalled Device used by Plaintiff, did not  
11 conform to Philips’ advertisements, warranties, representations, and omissions in that they are not  
12 safe, healthy, and appropriate for human use, and pose risks of serious injury and disease, including  
13 organ failure and cancer.

14          86.     Philips therefore breached its express warranties by placing the recalled machines,  
15 including the machine used by Plaintiff, into the stream of commerce and selling it to consumers,  
16 when their use posed health risks, had dangerous effects and were unsafe, rendering these products  
17 unfit for their intended use and purpose, and unsafe and unsuitable for consumer use as marketed by  
18 Philips. These associated health effects substantially impair the use, value, and safety of the Recalled  
19 machines, and rendered the machines worthless.

20          87.     Philips was aware, or should have been aware, of the toxic or dangerous health effects  
21 from the use of the recalled machines, including the machine used by Plaintiff, but nowhere on the  
22 package labeling or package inserts or on Philips’ websites or other marketing materials did Philips  
23 warn Plaintiff he was at risk of developing adverse health effects as a result of the dangerous PE-PUR  
24 Foam used in the recalled machines

25          88.     Instead, Philips concealed the dangerous health effects of the PE-PUR Foam  
26 used in the recalled machines, including the machine used by Plaintiff and deceptively represented  
27 that these products were safe, healthy, and appropriate for use. Philips thus utterly failed to ensure  
28 that the material representations they were making to consumers were true.

1           89.     The adverse health effects associated with use of the recalled machines, including the  
2 machine used by Plaintiff existed when they left Philips' possession or control and were sold to  
3 Plaintiff. The dangers associated with use of the recalled machines were undiscoverable by Plaintiff  
4 at the time of purchase of the Recalled Device.

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

8           91.     In addition, or in the alternative, to the formation of an express contract, Philips made  
9 each of the above-described representations and omissions to induce Plaintiff to rely on such  
10 representations and omissions.

11           92.     Philips' affirmations of fact and promises and its omissions were material, and  
12 Plaintiff reasonably relied upon such representations and omissions in purchasing and using  
13 Plaintiff's Recalled Device.

14           93.     All conditions precedent to Philips' liability for its breach of express warranty have  
15 been performed by Plaintiff.

16           94.     Affording Philips an opportunity to cure its breaches of written warranties would be  
17 unnecessary and futile here. Philips was placed on reasonable notice from user reports and its lab  
18 testing that the PE-PUR Foam in the Recalled Devices, including the machine used by Plaintiff was  
19 unsafe. Philips had ample opportunity either to stop using the PE-PUR Foam or to replace the PE-  
20 PUR Foam in the Recalled Devices to make them safe and healthy for use by Plaintiff but failed to do  
21 so until now.

22           95.     As a direct and proximate result of the recalled machines, including the machine's  
23 aforementioned defects as described herein, the Plaintiff has experienced significant mental and  
24 physical pain and suffering, has sustained permanent injury, has undergone medical treatment and  
25 will likely undergo further medical treatment and procedures, has suffered financial or economic loss,  
26 including, but not limited to, obligations for medical services and expenses, and/or lost income, and  
27 other damages.

28

1           96.     WHEREFORE, Plaintiff demands judgment against Defendants, and each of them,  
2 individually, jointly, severally and in the alternative, and requests compensatory damages, punitive  
3 damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court  
4 deems equitable and just.

5   SIXTH CAUSE OF ACTION

6   BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

7           97.     Philips are merchants engaging in the sale of goods to Plaintiff and members of the  
8 general public.

9           98.     There was a direct sale of goods from Philips to Plaintiff, creating privity between  
10 Plaintiff and Defendants.

11           99.     At all times mentioned herein, Philips manufactured or supplied the recalled machines,  
12 including the machine used by Plaintiff, and prior to the time of use, Philips impliedly warranted to  
13 Plaintiff that the Recalled Devices, including the machine used by Plaintiff was of merchantable  
14 quality, fit for their ordinary use, and conformed to the promises and affirmations of fact and  
15 omissions made on the labels and packaging, including that the machines were safe and appropriate  
16 for human use. Plaintiff relied on Philips' promises and affirmations of fact and omissions when he  
17 purchased and used the Recalled Device.

18           100.    Contrary to these representations and warranties, the Recalled Devices, including the  
19 machine used by Plaintiff was not fit for its ordinary use and did not conform to Philips' affirmations  
20 of fact and promises and omissions because use of the Recalled Devices is accompanied by the risk of  
21 adverse health effects, which does not conform to the labels and packaging of these devices.

22           101.    Philips breached its implied warranties by selling a Recalled Device, including the  
23 machine used by Plaintiff that failed to conform to the promises or affirmations of fact made on the  
24 packaging or label, as use of each Recalled Device was accompanied by the risk of developing  
25 adverse health effects that do not conform to the packaging or label.

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

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

5 104. As a direct and proximate result of the Recalled Devices, including the aforementioned  
6 defects as described herein, the Plaintiff has experienced significant mental and physical pain and  
7 suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo  
8 further medical treatment and procedures, has suffered financial or economic loss, including, but not  
9 limited to, obligations for medical services and expenses, and/or lost income, and other damages.

10 105. WHEREFORE, Plaintiff demands judgment against Defendants, and each of them,  
11 individually, jointly, severally and in the alternative, and requests compensatory damages, punitive  
12 damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court  
13 deems equitable and just.

14 **SEVENTH CAUSE OF ACTION**

15 **FRAUDULENT MISREPRESENTATION**

16 106. Philips failed to advise Plaintiff that the Recalled Devices, including the machine used  
17 by Plaintiff posed serious health risks to their users and Philips falsely represented to Plaintiff that the  
18 Recalled Devices were safe for human use.

19 107. Philips intentionally, knowingly, and recklessly made these misrepresentations and  
20 omissions to induce Plaintiff and other members of the general public to purchase the Recalled  
21 Devices, including the machine used by Plaintiff.

22 108. Philips knew that its representations and omissions about the Recalled Devices,  
23 including the machine used by Plaintiff, were false in that the Recalled Devices contained PE-PUR  
24 Foam and thus were at risk of causing adverse health effects to users of the Recalled Devices which  
25 does not conform to the products' labels, packaging, advertising, and statements. Philips knowingly  
26 allowed its packaging, labels, advertisements, promotional materials, and websites to intentionally  
27 mislead consumers, such as Plaintiff.  
28

1           109. Plaintiff did in fact rely on these omissions and misrepresentations and purchased and  
2 used a Recalled Device to his detriment. Given the deceptive manner in which Philips advertised,  
3 represented, and otherwise promoted the Recalled Devices, Plaintiff's reliance on Philips' omissions  
4 and misrepresentations was justifiable.

5           110. As a direct and proximate result of the recalled machines, including the machine's  
6 aforementioned defects as described herein, the Plaintiff has experienced significant mental and  
7 physical pain and suffering, has sustained permanent injury, has undergone medical treatment and  
8 will likely undergo further medical treatment and procedures, has suffered financial or economic loss,  
9 including, but not limited to, obligations for medical services and expenses, and/or lost income, and  
10 other damages.

11           111. WHEREFORE, Plaintiff demands judgment against Defendants, and each of them,  
12 individually, jointly, severally and in the alternative, and requests compensatory damages, punitive  
13 damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court  
14 deems equitable and just.

15   **EIGHTH CAUSE OF ACTION**

16   **FRAUD BY OMISSION**

17           113. Philips concealed from and failed to disclose to Plaintiff that use of Recalled Devices,  
18 including the machine used by Plaintiff is accompanied by a risk of adverse health effects, which  
19 does not conform to the products' labels, packaging, advertising, and statements.

20           114. Philips was under a duty to disclose to Plaintiff the true quality, characteristics,  
21 ingredients and suitability of the Recalled Devices, including the machine used by Plaintiff because:

- 22           a. Philips was in a superior position to know the true state of facts about its  
23 products;
- 24           b. Philips was in a superior position to know the risks associated with the use of,  
25 characteristics of, and suitability of the Recalled Devices; and
- 26           c. Philips knew that Plaintiff could not reasonably have been expected to learn or  
27 discover prior to purchasing the Recalled Device that there were  
28 misrepresentations and omissions by Philips in the packaging, labels,

1 advertising, and websites regarding the health risks associated with use of these  
2 devices.

3 115. The facts concealed or not disclosed by Philips to Plaintiff were material in that a  
4 reasonable consumer would have considered them important when deciding whether to purchase the  
5 Recalled Device.

6 116. Plaintiff justifiably relied on Philips' omissions to his detriment. The detriment is  
7 evident from the true quality, characteristics, and risk associated with the use of the Recalled Devices,  
8 including the machine used by Plaintiff, which is inferior when compared to how the Recalled  
9 Devices are advertised and represented by Philips.

10 117. As a direct and proximate result of the Recalled Devices, including the machine's  
11 aforementioned defects as described herein, the Plaintiff has experienced significant mental and  
12 physical pain and suffering, has sustained permanent injury, has undergone medical treatment and  
13 will likely undergo further medical treatment and procedures, has suffered financial or economic loss,  
14 including, but not limited to, obligations for medical services and expenses, and/or lost income, and  
15 other damages.

16 118. WHEREFORE, Plaintiff demands judgment against Defendants, and each of them,  
17 individually, jointly, severally and in the alternative, and requests compensatory damages, punitive  
18 damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court  
19 deems equitable and just.

20 **NINTH CAUSE OF ACTION**

21 **NEGLIGENT MISREPRESENTATION**

22 119. Philips had a duty to Plaintiff to exercise reasonable and ordinary care in the  
23 developing, testing, manufacture, marketing, distribution, and sale of the Recalled Devices, including  
24 the machine used by Plaintiff.

25 120. Philips breached its duty to Plaintiff by developing, testing, manufacturing,  
26 advertising, marketing, distributing, and selling products to Plaintiff that did not have the qualities,  
27 characteristics, and suitability for use as advertised by Philips and by failing to promptly remove the  
28

1 Recalled Devices, including the machine used by Plaintiff from the marketplace or to take other  
2 appropriate remedial action upon becoming aware of the health risks of the Recalled Devices.

3 121. Philips knew or should have known that the qualities and characteristics of the  
4 Recalled Devices, including the machine used by Plaintiff were not as advertised or suitable for their  
5 intended use and were otherwise not as warranted and represented by Philips. Specifically, Philips  
6 knew or should have known that:

- 7 a. the use of the Recalled Devices was accompanied by risks of adverse health  
8 effects that do not conform to the packaging and labeling;
- 9 b. the Recalled Devices were adulterated, or at risk of being adulterated, by the  
10 PE-PUR Foam; and
- 11 c. the Recalled Devices were otherwise not as warranted and represented by  
12 Philips.

13 122. As a direct and proximate result of Defendants' negligence, the Plaintiff has  
14 experienced significant mental and physical pain and suffering, has sustained permanent  
15 injury, has undergone medical treatment and will likely undergo further medical treatment and  
16 procedures, has suffered financial or economic loss, including, but not limited to, obligations for  
17 medical services and expenses, lost income, and other damages.

18 123. WHEREFORE, Plaintiff demands judgment against Defendants, and each of them,  
19 individually, jointly, severally and in the alternative, and requests compensatory damages, punitive  
20 damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court  
21 deems equitable and just.

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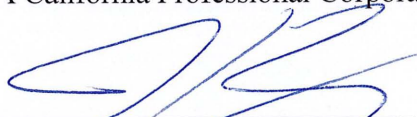
**VIII PRAYER FOR RELIEF**

WHEREFORE, Plaintiff prays for judgment against the Defendants, and each of them, as follows.

- a. For past and future general damages on each cause of action, according to proof;
- b. For past and future pain and suffering, according to proof;
- c. For past and future hospital, medical, nursing care, treatment and incidental expenses, according to proof;
- d. For past and future loss of earnings and earning power, according to proof;
- e. For past and future mental and emotional distress, according to proof;
- f. For restitution, according to proof;
- g. For punitive damages in an amount appropriate to punish and/or set an example of Defendants, or in any other way appropriate;
- h. For past and future costs of suit incurred herein, and attorney's fees as may be allowed by law; and
- i. For such other and further relief as the Court may deem just and proper.

Dated: January 12, 2022

VANTAGE POINT LAW, INC.  
A California Professional Corporation

  
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JEFFREY J. ROONEY, ESQ.