UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

GERRY SHELTON, individually and on behalf of all others similarly situated,	:	Civil Action No.
Plaintiff,	:	**CLASS ACTION COMPLAINT**
v.	:	**JURY TRIAL DEMANDED**
KONINKLIJKE PHILIPS N.V., PHILIPS NORTH AMERICA LLC, and PHILIPS RS NORTH AMERICA LLC,	:	
Defendants.	:	

CLASS ACTION COMPLAINT

Plaintiff Gerry Shelton, individually and on behalf of all others similarly situated, through undersigned counsel, alleges as follows.

I. NATURE OF THE ACTION

1. Defendants Koninklijke Philips N.V., Philips North America LLC, and Philips RS North America LLC (collectively "Philips") manufacture and sell a variety of products that are intended to help people breathe. These include Continuous Positive Airway Pressure ("CPAP") and Bilevel Positive Airway Pressure ("BiPAP") machines, that are commonly used to treat sleep apnea, and ventilators that treat respiratory failure. In general, each of these devices express air into patients' airways. CPAP and BiPAP machines are intended for daily use, and ventilators are used continuously while needed. Without these devices, some patients may experience severe symptoms, including heart attack, stroke, and death by asphyxiation.

2. On June 14, 2021, Philips announced a recall of many of its CPAP/BiPAP machines and its ventilators (the "Recalled Breathing Machines").[1] Specifically, the Recalled Breathing Machines contain polyester-based polyurethane ("PE-PUR") foam for sound abatement. Philips announced that this foam may break down and be inhaled or ingested. Further, the PE-PUR foam may emit volatile organic compounds ("VOCs") that may be inhaled, ingested, adversely affect organs, and are carcinogenic. Philips announced these hazards could result in "serious injury which can be life-threatening or cause permanent impairment."

3. Philips knew about these very substantial and material risks long before the recall. Patients who use the Recalled Breathing Machines have complained about black particles in their machines for several years. Philips, however, did not warn the public or its customers about these hazards until late April 2021 and did not recall the Recalled Breathing Machines until June 14, 2021.

4. Patients use the Recalled Breathing Machines every day but, absent this litigation, Philips had no plan to replace any of the affected devices now or in the future. Philips has no concrete timeline for replacing or repairing any of the Recalled Breathing Machines.

5. In fact, Philips timed its recall of the Recalled Breathing Machines to coincide with the launch of its next generation of products, which purportedly do not suffer from the same PE-PUR foam issues. Thus, the only safe option that Philips offers to its customers—many of whom need and rely on the Recalled Breathing Machines—is to purchase Philips's newer model, thus profiting Philips further.

[1] These include the following models: E30; DreamStation ASV; DreamStation ST, AVAPS; SystemOne ASV4; C Series ASV, S/T, AVAPs; OmniLab Advanced Plus; SystemOne (Q Series); DreamStation CPAP, Auto CPAP, BiPAP; DreamStation Go CPAP, APAP; Dorma 400, 500 CPAP; REMStar SE Auto CPAP; Trilogy 100 and 200; Garbin Plus, Aeris, LifeVent; A-Series BiPAP Hybrid A30; A-Series BiPAP V30 Auto; A-Series BiPAP A40; and A-Series BiPAP A30.

6. Plaintiff brings this Class Action Complaint to represent a class of similarly situated persons defined below, who also purchased the defective Recalled Breathing Machines, and to obtain relief for their injuries.

II. PARTIES

A. PLAINTIFF

7. Plaintiff Gerry Shelton resides in Boring, Oregon. He was diagnosed with sleep apnea and purchased a Dreamstation BiPAP machine in 2020. He would not have purchased this product if he had known it was defective, contained a carcinogenic byproduct, and would be subject to a recall for containing defective materials. Because of the recall, Plaintiff has been forced to cease using his Dreamstation, and he does not have a replacement machine readily available. Plaintiff is a truck driver and had to stop driving because he cannot drive with untreated sleep apnea. Plaintiff also went into atrial fibrillation because he is no longer able to get sufficient sleep without the use of an appropriate device to help him breathe properly. Plaintiff demands a refund, replacement with a non-defective device, costs for ongoing medical monitoring, and all other appropriate damages for all the injuries he has suffered as a result of his defective Dreamstation.

B. DEFENDANTS

8. Koninklijke Philips N.V. is a Dutch multinational company headquartered in Amsterdam, Netherlands, and is the parent company of Philips North America LLC and Philips RS North America LLC.

9. Defendant Philips North America LLC is a Delaware company with its principal place of business in Cambridge, Massachusetts.

10. Defendant Philips RS North America LLC (formerly Respironics, Inc.) is a Delaware company headquartered in Pittsburgh, Pennsylvania.

11. Reference to "Philips," "Defendant," or "Defendants" refers to each and every Defendant individually and collectively.

III. JURISDICTION AND VENUE

12. This Court has subject matter jurisdiction over this class action pursuant to 28 U.S.C. § 1332, as amended by the Class Action Fairness Act of 2005, because the matter in controversy exceeds $5 million, exclusive of interest and costs, and is a class action in which Plaintiff and some members of the Class are citizens of states different than Defendants. *See* 28 U.S.C. § 1332(d)(2)(A).

13. Venue is proper in this District because Philips North America LLC is headquartered in this District and because a substantial part of the events or omissions giving rise to the claim occurred in this District.

IV. FACTUAL ALLEGATIONS

A. CPAP MACHINES, BIPAP MACHINES, AND VENTILATORS TREAT SERIOUS CONDITIONS.

14. Sleep apnea is a sleeping disorder in which breathing is disturbed temporarily during sleep. Breathing may stop or become very shallow. This may be associated with fatigue, daytime sleepiness, interrupted sleep, or snoring, among other symptoms. Serious cases can lead to hypertension, heart attack, or stroke, among other medical ailments.

15. CPAP therapy is a common treatment for sleep apnea. In CPAP therapy, a machine delivers a flow of air through a mask over the nose or mouth, which increases air pressure in the throat so that the airway does not collapse during inhalation. CPAP therapy assists breathing during sleep and can successfully treat sleep apnea.

16. Other therapies to treat sleep apnea include BiPAP therapy and Automatic Positive Airway Pressure ("APAP"). BiPAP machines provide two different pressure settings, one for inhalation and one for exhalation.

17. Patients who use CPAP or BiPAP machines typically use them every day when they sleep. Symptoms may return quickly if therapy is discontinued.

18. Respiratory failure is a condition in which a patient has difficulty breathing or getting enough oxygen into the blood. Many underlying conditions can cause respiratory failure, including physical trauma, sepsis, pneumonia, COVID-19, and drug abuse. Respiratory failure can be fatal.

19. Mechanical ventilators, usually called "ventilators," are often used to treat respiratory failure. Ventilators push air into and out of the patient's lungs like a bellows. Ventilators can also be used in other circumstances, such as during surgery when general anesthesia may interrupt normal breathing. The COVID-19 crisis has led to a significant increase in the demand for ventilators in the United States and worldwide.

B. PHILIPS RECALLED ITS PRODUCTS DUE TO SERIOUS HEALTH HAZARDS FROM THE FOAM THAT IT UTILIZED.

20. Philips manufactures and sells CPAP machines, BiPAP machines, and ventilators, among other products. According to Philips's 2020 Annual Report, Sleep & Respiratory Care constituted approximately 49% of Philips's total sales in its Connected Care line of business, which in turn accounted for 28% of Philips's overall sales of about €19.535 billion.

21. Philips's flagship CPAP/BiPAP machine product family is known as the "DreamStation" family line, which includes the original DreamStation, launched in October 2015, and the DreamStation Go (a travel version). Philips sells DreamStation products through its subsidiary Respironics, that Philips acquired in 2008.

22. Many of Philips's CPAP and BiPAP machines and ventilators contain PE-PUR foam for sound abatement. Owing to the design of the machines, air passes through this foam before it is pumped into the patient's airway.

23. On April 13, 2021, Philips announced that it was launching the DreamStation 2, the next-generation machine in its DreamStation product family.

24. Less than two weeks later, on April 26, 2021, Philips announced the recall and, in the same release, shockingly started pushing consumers to purchase its latest generation device:

> Philips has determined from user reports and testing that there are possible risks to users related to the sound abatement foam used in certain of Philips' sleep and respiratory care devices currently in use. The risks include that the foam may degrade under certain circumstances, influenced by factors including use of unapproved cleaning methods, such as ozone*), and certain environmental conditions involving high humidity and temperature. The majority of the affected devices are in the first-generation DreamStation product family. Philips' recently launched next-generation CPAP platform, DreamStation 2, is not affected. Philips is in the process of engaging with the relevant regulatory agencies regarding this matter and initiating appropriate actions to mitigate these possible risks. Given the estimated scope of the intended precautionary actions on the installed base, Philips has taken a provision of EUR 250 million.

25. On June 14, 2021, Philips then issued a further statement:

> To date, Philips has produced millions of Bi-Level PAP, CPAP and mechanical ventilator devices using the PE-PUR sound abatement foam. Despite a low complaint rate (0.03% in 2020), Philips determined based on testing that there are possible risks to users related to this type of foam. The risks include that the PE-PUR foam may degrade into particles which may enter the device's air pathway and be ingested or inhaled by the user, and the foam may off-gas certain chemicals. The foam degradation may be exacerbated by use of unapproved cleaning methods, such as ozone,** and high heat and high humidity environments may also contribute to foam degradation.
>
> Therefore, Philips has decided to voluntarily issue a recall notification* to inform patients and customers of potential impacts on patient health and clinical use related to this issue, as well as instructions on actions to be taken.

26. Philips stated that "[t]he majority of the affected devices within the advised 5-year service life are in the first-generation DreamStation product family." Philips elaborated:

> Based on the latest analysis of potential health risks and out of an abundance of caution, the recall notification* advises patients and customers to take the following actions:
>
> For patients using affected BiLevel PAP and CPAP devices: 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 the recall notification.*
>
> For patients using affected life-sustaining mechanical ventilator devices: 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 identified in the recall notification.*
>
> **Possible health risks**
>
> The company continues to monitor reports of potential safety issues as required by medical device regulations and laws in the markets in which it operates. To date, there have been no reports of death as a result of these issues. Philips has received reports of possible patient impact due to foam degradation. The potential risks of particulate exposure include headache, irritation, inflammation, respiratory issues, and possible toxic and carcinogenic effects. The potential risks of chemical exposure due to off-gassing include headache, irritation, hypersensitivity, nausea/vomiting, and possible toxic and carcinogenic effects. Philips has received no reports regarding patient impact related to chemical emissions.

27. On the same day, Philips provided additional information in an announcement entitled "Clinical information for physicians," which explained that the foam breakdown "may lead to patient harm and impact clinical care."

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

28. The announcement by Philips detailed two types of hazards from the PE-PUR foam in the devices. First, the announcement described dangers due to foam degradation exposure:

> **Potential Hazard:** Philips has determined from user reports and lab testing that under certain circumstances the foam may degrade into particles which may enter the device's air pathway and be ingested or inhaled by the user of its Continuous Positive Airway Pressure (CPAP), BiLevel Positive Airway Pressure (BiLevel PAP) and Mechanical Ventilator devices. The foam degradation may be exacerbated by environmental conditions of higher temperatures and humidity in certain regions. Unauthorized cleaning methods such as ozone may accelerate potential degradation.
>
> The absence of visible particles does not mean that foam breakdown has not already begun. Lab analysis of the degraded foam reveals the presence of potentially harmful chemicals including:
>
> - Toluene Diamine
>
> - Toluene Diisocyanate
>
> - Diethylene glycol

29. The European Union considers Toluene Diisocyanate "highly toxic" and has concluded that Toluene Diamine "cannot be considered safe for use" even as a hair dye.

30. Philips disclosed that it "has received several complaints regarding the presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask)."

31. The second hazard is the possibility of VOCs, that is, chemical emissions from the PE-PUR foam. Philips explained:

> **Potential Hazard:** Lab testing performed for and by Philips has also identified the presence of VOCs which may be emitted from the sound abatement foam component of affected device(s). VOCs are emitted as gases from the foam included in the CPAP, BiLevel PAP and MV devices and may have short- and long-term adverse health effects.
>
> Standard testing identified two compounds of concern (COC) may be emitted from the foam that are outside of safety thresholds. The compounds identified are the following:

- Dimethyl Diazine

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

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

33. Although Philips did not disclose these health risks until June 2021, Philips has known about these health risks for a long time. For example, customers have complained to Philips about black particles in their machines for several years as evidenced by forum posts and statements from those that follow the industry.

C. PHILIPS HAS NOT REPLACED ANY DEVICES AND HAS NO PLAN TO DO SO.

34. Philips's so-called "recall" does not actually provide patients with new CPAP, BiPAP, or ventilator devices, but again suggests consumers can buy the next generation of its product. As Philips's June 14, 2021 announcement makes clear:

> **Repair and replacement program**
>
> Philips is providing the relevant regulatory agencies with required information related to the launch and implementation of the projected correction. The company will replace the current sound abatement foam with a new material and has already begun the preparations, which include obtaining the relevant regulatory clearances. Philips aims to address all affected devices in scope of this correction as expeditiously as possible.
>
> As part of the program, the first-generation DreamStation product families will be modified with a different sound abatement foam and shipped upon receipt of the required regulatory clearances. Philips' recently launched next-generation CPAP platform, DreamStation 2, is not affected by the issue. To support the program,

> Philips is increasing the production of its DreamStation 2 CPAP devices, that are available in the US and selected countries in Europe.

35. Thus, Philips is not currently replacing the foam in the affected devices and may take a year or more to provide replacement foam.

36. At the same time, Philips intends to profit from the so-called recall by selling more of its next generation product, the DreamStation 2. Philips intentionally timed the recall to coincide with the launch of the DreamStation 2.

37. Due to the design of the Recalled Breathing Machines, it is prohibitively difficult for patients to remove or replace the PE-PUR foam themselves. There is also a general shortage of available replacement machines.

38. But patients need to use their machines every day, or else their symptoms—which can be severe and life-altering—may return.

39. As a result, the recall by Philips leaves patients without safe, free options. Patients may buy Philips's next-generation product or a competitor's product—at full price.

40. Pursuant to the statements issued by Philips that are set forth above, Philips has admitted that the Recalled Breathing Machines are defective and unsafe. The Recalled Breathing Machines are effectively worthless and/or have a far lesser value than what customers paid and would not have been purchased by patients if they were informed of the defect at the time of sale.

41. Plaintiff and the Class members have all suffered economic injuries as a result of their purchase of the Recalled Breathing Machines.

V. CLASS ALLEGATIONS

42. Plaintiff brings this action individually and as a class action pursuant to Fed. R. Civ. P. 23(a), 23(b)(2) and/or 23(b)(3). Specifically, the Classes that Plaintiff seeks to represent consists of the following:

Nationwide Class: All persons in the United States who have purchased a Recalled Breathing Machine for personal use.

Oregon Class: All persons in Oregon who have purchased a Recalled Breathing Machine for personal use.

43. The Nationwide Class and the Oregon Class are collectively referred to herein as the "Class." Excluded from the Class are Defendants and their employees, officers, and directors; and the Judge(s) and any mediator assigned to this case.

44. Plaintiff reserves the right to redefine the Class prior to class certification.

45. The rights of each member of the Class were violated in a similar fashion based upon Defendants' uniform actions.

46. This action has been brought and may be properly maintained as a class action for the following reasons:

a. Numerosity: Members of the Class are so numerous that their individual joinder is impracticable. The proposed Nationwide Class contains at least millions of individuals, and the proposed Oregon Class contains at least thousands of individuals, who purchased a Recalled Breathing Machine. The Class is therefore sufficiently numerous to make joinder impracticable, if not impossible. The precise number of Class members is unknown to Plaintiff at this time but the Class members are readily ascertainable and can be identified by Defendants' records.

b. Existence and Predominance of Commons Questions of Fact and Law: Common questions of law and fact exist as to all members of the Class. These questions predominate over any questions affecting only individual Class members. These common legal and factual questions include, without limitation:

i. Whether Defendants were unjustly enriched by the sale of the Recalled Breathing Machines;

ii. Whether Defendants were negligent in selling the Recalled Breathing Machines;

iii. Whether Defendants failed to warn consumers regarding the risks of the Recalled Breathing Machines;

iv. Whether Defendants' practices constitute unfair or deceptive acts or practices under state consumer protection statutes;

v. The appropriate nature of class-wide equitable relief; and

vi. The appropriate measurement of restitution and/or measure of damages to Plaintiff and members of the Class.

These and other questions of law or fact that are common to the members of the Class predominate over any questions affecting only individual members of the Class.

c. Typicality: Plaintiff's claims are typical of the claims of all members of the Class who purchased the Recalled Breathing Machines for personal use.

d. Adequacy: Plaintiff is an adequate representative of the Class because his interests do not conflict with the interests of the Class that he seeks to represent; he has retained counsel competent and highly experienced in complex class action litigation, and they intend to prosecute this action vigorously. The interests of the Class will be fairly and adequately protected by Plaintiff and his counsel.

e. Superiority: A class action is superior to other available means of fair and efficient adjudication of the claims of Plaintiff and the Class. The injury suffered by each Class member is relatively small in comparison to the burden and expense of individual prosecution of the complex and extensive litigation necessitated by Defendants' conduct. It would be virtually impossible for members of the Class to individually and effectively redress the wrongs done to them. Even if the members of the Class could afford such individual litigation, the court system could not. Individualized litigation presents a potential for inconsistent or contradictory judgments. Individualized litigation also increases the delay and expense to all parties, and to the court system,

presented by the complex legal and factual issues of the case. By contrast, the class action device presents far fewer management difficulties, and provides the benefits of single adjudication, an economy of scale, and comprehensive supervision by a single court.

VI. EQUITABLE TOLLING OF STATUTES OF LIMITATIONS

47. The running of any statute of limitations has been equitably tolled by reason of Defendants' fraudulent concealment and/or omissions of critical safety information. Through its affirmative misrepresentations and omissions, Philips actively concealed from Plaintiff and their physicians the true risks associated with the Recalled Breathing Machines.

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

VII. CAUSES OF ACTION

COUNT I
STRICT LIABILITY-FAILURE TO WARN

49. Plaintiff and the Class incorporate by reference all preceding paragraphs.

50. Defendants had a duty to warn Plaintiff and the Class members regarding the defect and true risks associated with the Recalled Breathing Machines.

51. Defendants failed to provide adequate warnings regarding the risks of the PE-PUR foam.

52. Defendants had information regarding the true risks but failed to warn Plaintiff, Class members, and their physicians to strengthen their warnings.

53. Despite Defendants' obligation to unilaterally strengthen the warnings, Philips instead chose to actively conceal this knowledge.

54. Plaintiff and Class members would not have purchased, chosen, and/or paid for all or part of the Recalled Breathing Machines if they knew of the defect and the risks of purchasing the product.

55. This defect proximately caused Plaintiff's and Class members' injuries which include economic injuries, as well as headache, irritation, inflammation, respiratory issues, and exposure to materials with toxic and carcinogenic effects.

56. Plaintiff and the Class suffered damages in an amount to be determined at trial.

COUNT II
DESIGN DEFECT STRICT LIABILITY

57. Plaintiff and the Class incorporate by reference all preceding paragraphs.

58. The design of the Recalled Breathing Machines, including, but not limited to, design and use of the PE-PUR foam and the placement of the foam within the Recalled Breathing Machines, was defective and unreasonably dangerous, causing degradation and inhalation of the PE-PUR foam, and causing headaches, irritation, inflammation, respiratory issues, and exposure to materials with toxic and carcinogenic effects.

59. The design of the Recalled Breathing Machines and the PE-PUR foam rendered the Recalled Breathing Machines not reasonably fit, suitable, or safe for their intended purpose.

60. The dangers of the Recalled Breathing Machines outweighed the benefits and rendered the products unreasonably dangerous. Indeed, there are other CPAP and other machines that do not use a similarly toxic foam that is subject to degradation, inhalation, and ingestions.

61. Safer, alternative machines from other manufacturers were available that did not suffer from the defect as set forth herein and that did not have an unreasonable risk of harm as with the Recalled Breathing Machines and their unsafe PE-PUR foam.

62. The risk benefit profile of the Recalled Breathing Machines was unreasonable, and

the products should have had stronger and clearer warnings or should not have been sold in the market.

63. The Recalled Breathing Machines did not perform as an ordinary consumer would expect.

64. Plaintiff and the Class suffered damages in an amount to be determined at trial.

COUNT III
NEGLIGENT FAILURE TO WARN

65. Plaintiff and the Class incorporate by reference all preceding paragraphs.

66. Defendants owed Plaintiff and Class members a duty of care and to warn of any risks associated with the Recalled Breathing Machines. Defendants knew or should have known of the true risks but failed to warn Plaintiff, Class members, and their doctors.

67. Defendants' negligent breach of duty caused Plaintiff and Class members economic damages and injuries in the form of headaches, irritation, inflammation, respiratory issues, and exposure to materials with toxic and carcinogenic effects.

68. Plaintiff and Class members would not have purchased, chosen, and/or paid for all or part of the Recalled Breathing Machines if they knew of the defect and the risks associated with purchasing the product.

69. Plaintiff and the Class suffered damages in an amount to be determined at trial.

COUNT IV
NEGLIGENT DESIGN DEFECT

70. Plaintiff and the Class incorporate by reference all preceding paragraphs.

71. Defendants negligently designed the Recalled Breathing Machines. Philips owed Plaintiff and the Class a duty to design the Recalled Breathing Machines in a reasonable manner. The design of the Recalled Breathing Machines, including but not limited to the design of the PE-

PUR foam and the placement of the PE-PUR foam within the Recalled Breathing Machines, was defective and unreasonably dangerous, causing degradation and inhalation of the foam, and causing headaches, irritation, inflammation, respiratory issues, and exposure to materials with toxic and carcinogenic effects.

72. The design of the Recalled Breathing Machines and the PE-PUR foam rendered the Recalled Breathing Machines not reasonably fit, suitable, or safe for their intended purpose.

73. The dangers of the Recalled Breathing Machines outweighed the benefits and rendered the products unreasonably dangerous. Indeed, there are CPAP and other machines that do not use a similarly toxic foam that is subject to degradation, inhalation, and ingestions.

74. Safer, alternative machines from other manufactuers were available that did not have an unreasonable risk of harm as with the Recalled Breathing Machines and their unsafe foam.

75. The risk benefit profile of the Recalled Breathing Machines was unreasonable, and the products should have had stronger and clearer warnings or should not have been sold in the market.

76. The Recalled Breathing Machines did not perform as an ordinary consumer would expect.

77. Plaintiff and the Class suffered damages in an amount to be determined at trial.

COUNT V
NEGLIGENT RECALL

78. Plaintiff and the Class incorporate by reference all preceding paragraphs.

79. In issuing a voluntary recall, Philips assumed duties to Plaintiff and the Class to exercise reasonable care in issuing and implementing the recall.

80. Philips breached its duties by failing to adequately warn Plaintiff and the Class of the dangers associated with the use of the Recalled Breathing Machines by refusing to promptly repair or replace the Recalled Breathing Machines.

81. As a direct result of Defendants' breach of duty, Plaintiff and the Class have suffered harm in an amount to be determined at trial.

COUNT VI
BREACH OF EXPRESS WARRANTY

82. Plaintiff and the Class incorporate by reference all preceding paragraphs.

83. Defendants warranted the Recalled Breathing Machines "shall be free from defects of workmanship and materials and will perform in accordance with the product specifications for a period of two (2) years from the date of sale."

84. Defendants breached this express warranty in connection with the sale and distribution of the Recalled Breathing Machines. At the point of sale, the Recalled Breathing Machines while appearing normal—contained immediate defects as set forth herein, rendering them unsuitable and unsafe for personal use by humans.

85. Had Plaintiff and the Class known the Recalled Breathing Machines were unsafe for use, they would not have purchased them.

86. Defendants have breached their warranty and refused to provide appropriate warranty relief notwithstanding the risks of using the Recalled Breathing Machines. Plaintiff and the Class reasonably expected, at the time of purchase, that the Recalled Breathing Machines were safe for their ordinary and intended use.

87. As a direct and proximate result of Defendants' breach of express warranty, Plaintiff and the Class have sustained damages in an amount to be determined at trial.

COUNT VII
BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY

88. Plaintiff and the Class incorporate by reference all preceding paragraphs.

89. By operation of law, Defendants, as manufacturers of the Recalled Breathing Machines and as the providers of a limited warranty for the Recalled Breathing Machines, impliedly warranted to Plaintiff and the Class that the Recalled Breathing Machines were of merchantable quality and safe for their ordinary and intended use.

90. Defendants breached the implied warranty of merchantability in connection with the sale and distribution of the Recalled Breathing Machines. At the point of sale, the Recalled Breathing Machines while appearing normal—contained defects as set forth herein rendering them unsuitable and unsafe for personal use by humans.

91. Had Plaintiff and the Class known the Recalled Breathing Machines were unsafe for use, they would not have purchased them.

92. Defendants have refused to provide appropriate warranty relief notwithstanding the risks of using the Recalled Breathing Machines. Plaintiff and the Class reasonably expected, at the time of purchase, that the Recalled Breathing Machines were safe for their ordinary and intended use.

93. As a direct and proximate result of Defendants' breach of the implied warranty of merchantability, Plaintiff and the Class have sustained damages in an amount to be determined at trial.

COUNT VIII
OREGON UNLAWFUL TRADE PRACTICES LAW
(Or. Rev. Stat. §§ 646.605, *et seq.*)
On Behalf of the Oregon Class

94. Plaintiff incorporates by reference all preceding paragraphs.

95. Oregon makes it unlawful to for any person to employ "any unconscionable tactic in connection with selling, renting or disposing of real estate, goods or services, or collecting or enforcing an obligation." Or. Rev. Stat. § 646.607(1).

96. Defendants engaged in unfair, unconscionable, or deceptive methods, acts, or practices in the conduct of trade or commerce, with respect to the sale and advertisement of the Recalled Breathing Machines purchased by Plaintiff and Oregon Class Members, in violation of Or. Rev. Stat. §§ 646.605, *et seq*., including by misrepresenting the true quality of the Recalled Breathing Machines, and concealing the true risks of the Recalled Breathing Machines.

97. The above unfair methods of competition and unfair or deceptive acts or practices by Defendants were conducted in "[t]rade" and/or "commerce," as defined by Or. Rev. Stat. § 646.605(8).

98. The above unfair methods of competition and unfair or deceptive acts or practices by Defendants were immoral, unethical, oppressive, and unscrupulous.

99. Defendants' actions were negligent, knowing, and willful, and/or wanton and reckless with respect to the rights of Plaintiff and the Oregon Class members.

100. Plaintiff and Oregon Class members relied on Defendants' representations in that they would not have purchased, chosen, and/or paid for all or part of the Recalled Breathing Machines had they known the true risks of the products.

101. As a direct and proximate result of Defendants' deceptive acts and practices, Plaintiff and Oregon Class Members suffered an ascertainable loss of money or property, real or personal, as described above.

102. Plaintiffs and Oregon Class members seek relief under Or. Rev. Stat. § 646.638, *et seq*., including, but not limited to injunctive relief, restitution, statutory damages, compensatory

damages, punitive damages, civil penalties and attorneys' fees and costs.

COUNT IX
UNJUST ENRICHMENT
(In the Alternative)

103. Plaintiff and the Class incorporate by reference all preceding paragraphs.

104. Plaintiff and the Class members conferred a tangible and material economic benefit upon Defendants by purchasing the Recalled Breathing Machines. Plaintiff and Class members would not have purchased, chosen and/or paid for all or part of Recalled Breathing Machines had they known the true risks of using the Recalled Breathing Machines. Defendants are not providing a timely repair or replacement for the Recalled Breathing Machines. Under these circumstances, it would be unjust and inequitable for Defendants to retain the economic benefits they received at the expense of Plaintiff and the Class.

105. Failing to require Defendants to provide remuneration under these circumstances would result in Defendants being unjustly enriched at the expense of Plaintiff and the Class members who endure being exposed to the risk of developing serious medical conditions and can no longer use their Recalled Breathing Machines safely.

106. Defendants' retention of the benefit conferred upon them by Plaintiff and the Class would be unjust and inequitable.

107. Plaintiff and the Class suffered damages in an amount to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff request, individually and on behalf of the Class, that this Court:

A. determine that the claims alleged herein may be maintained as a class action under Rule 23(a), (b)(2), and/or (b)(3) of the Federal Rules of Civil Procedure on behalf of the

Nationwide Class and Oregon Class defined above, and designate Plaintiff as the class representative, and Plaintiff's counsel as Class Counsel;

B. award equitable and injunctive relief, including but not limited to, requiring Defendants to institute a medical monitoring program for Plaintiff and Class members, restitution, and disgorgement of profits;

C. award all actual, general, special, incidental, punitive, and consequential damages to which Plaintiff and Class members are entitled;

D. award pre-judgment and post-judgment interest on such monetary relief;

E. award reasonable attorneys' fees and costs; and

F. grant such further and other relief that this Court deems appropriate.

JURY DEMAND

Plaintiff and the Class demand a trial by jury on all issues so triable.

Dated: June 29, 2021