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Attorneys for Individual and Representative Plaintiff
LISA MITROVICH

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA, WESTERN DIVISION

LISA MITROVICH, individually and on behalf of herself and all others similarly situated,

Plaintiff,

vs.

KONINKLIJKE PHILIPS N.V., PHILIPS NORTH AMERICA LLC, and PHILIPS RS NORTH AMERICA LLC,

Defendants.

Case No. 2:21-cv-5793

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

CLASS ACTION COMPLAINT

Plaintiff Lisa Mitrovich, individually and on behalf of all others similarly situated, 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 assist people with breathing. 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. These devices are designed to provide medical benefits to those who purchase and use them.

2. On April 26, 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."

[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.

3. The use of a polyester-based polyurethane by Philips for its breathing machines was an unsuitable choice of material for the application.

4. Polyurethane is a polymer composed of organic units joined by carbamate (urethane) links. Polyurethanes are produced by reacting an isocyanate containing two or more isocyanate groups per molecule ($R-(N=C=O)_n$) with a polyol containing on average two or more hydroxyl (O-H) groups per molecule in the presence of a catalyst or by activation with ultraviolet light.

5. The health effects of isocyanate exposure include, among other things, irritation of skin and mucous membranes, chest tightness, and difficult breathing. Isocyanates include compounds classified as potential human carcinogens and known to cause cancer in animals. The additional known hazardous effects of isocyanate exposures are occupational asthma and other lung problems, as well as irritation of the eyes, nose, throat, and skin.

6. Polyurethanes, especially those made using aromatic isocyanates, contain chromophores that interact with light. When polyurethane foam, which is made using aromatic isocyanates, is exposed to visible light, it discolors, turning off-white to yellow to reddish brown, and finally to black.

7. Degradation of polyurethane can result in the material becoming hard and friable, which can cause particles to be propelled by air movement. Degradation of the polyester polyurethane into volatile components (which may include hydrogen cyanide, and other toxic components) which can be ingested into the airways, absorbed on skin and tissue, or into the bloodstream. If depolymerization of the urethane occurs, isocyanate can evolve, which is toxic and potentially carcinogenic. Additionally, amines, glycols, and phosphate may produce additional risks.

8. Philips' ventilators and CPAP/BiPAP machines are used in a high-humidity, elevated-temperature (95-110°F) application complicated by the presence of bacteria and potential fungal growth. Polyester polyurethane is particularly sensitive to degradation from heat, oxygen (ozone), sunlight (ultraviolet) moisture,

microbial and fungal attack. The properties of polyester polyurethanes have been well known and have been well documented and readily available in the scientific literature for many years well before Philips started manufacturing the Recalled Breathing Machines.

9. The selection of polyester polyurethane by Philips for application in its ventilator and CPAP/BiPAP machines was highly inappropriate in that it breached the relevant standard of care because all of health and safety risks set forth in the recall were known before the sale of any of the Recalled Breathing Machines and imminently foreseeable, all the while safe alternatives were available.

10. Furthermore, Philips knew or should have known about these very substantial and material health risks associated with the degradation of polyester polyurethane before any of these machines were sold and nonetheless used the material because it was expedient. In so doing, Defendants knowingly subordinated the health interests of their customers to their own financial gain.

11. Defendants, now report in the recall that "based on testing there are possible risks to users related to this type of foam," and that "Philips has received reports of possible patient impact due to foam degradation."

12. Plaintiff is informed and believes that these "risks" and certainty of degradation were known before any of the Recalled Breathing Machines were sold, because the properties of polyester polyurethane and likelihood of degradation in this application were known to the industry, were common knowledge to polymer experts and were readily available and known to Defendants before the machines went to market.

13. In that context, Defendants defrauded Plaintiff and the Class at the time and place of each sale by failing to disclose the risk of harm – risks which were known or should have been known before the Recalled Breathing Machines were sold. Defendants' awareness of the properties of polyester polyurethane in this application, namely, high temperature, high moisture and susceptibility for fungi and

microbes would lead to degradation and the inevitable and known health risks, required that Defendants disclose these risks before every sale of the products.

14. No one would have purchased these products had the Defendants disclosed the health risks before each sale.

15. The failure to disclose the known risks also constituted an unfair business practice in that it was unfair and fraudulent to consumers and uniformly impacted and damaged Plaintiff and all Class members who would not have otherwise purchased the Recalled Breathing devices.

16. Similarly, the universal warranty promise from Defendants that the Recalled Breathing Machines would be "free from defects of workmanship and materials" was false, misleading and unlawful in that Defendants breached the warranties, express and implied, by so warrantying these products.

17. Consumers 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.

18. Philips has no concrete timeline for replacing or repairing any of the Recalled Breathing Machines.

19. The recall of the Breathing Machines coincides with the launch of its next generation of products, which purportedly do not suffer from the same PE-PUR foam issues. The option that Philips offers to its customers—many of whom need and rely on the Recalled Breathing Machines—is to purchase a newer model, thus further profiting from its own wrongdoing.

20. Plaintiff brings this Class Action Complaint to represent a class of similarly situated persons defined below, who purchased the defective Recalled Breathing Machines, and to obtain damages for the cost of replacement of the machines and/or repair, assuming repair is possible.

II. PARTIES

A. PLAINTIFF

21. Plaintiff Lisa Mitrovich resides in Los Angeles, California. She was diagnosed with sleep apnea and purchased a Dreamstation BiPAP machine in 2019 at a cost of approximately $900. Her use of the Dreamstation was prescribed by her physician. She would not have purchased this product if she had known it was defective, included an unsuitable polyurethane foam which exudes a potentially carcinogenic by product and other material hazardous to her health. To date, Defendants have failed to replace or repair her machine, or to provide any assistance. Because of the recall, Plaintiff has been forced to purchase an expensive replacement machine known as the ResMed Airstation 10 Auto Set at a cost of $937.38. The ResMed Airstation was ordered on July 9, 2021. The machine has been ordered but not yet received. The use of a breathing machine is necessary for her health given her medical condition. Plaintiff demands a refund, replacement with a non-defective device, and all other appropriate economic damages she has or will incur suffered as a result of her defective Dreamstation.

B. DEFENDANTS

22. 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.

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

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

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

III. JURISDICTION AND VENUE

26. 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).

27. This Court has personal jurisdiction over these Defendants because they (i) were authorized to, and have, conducted business in California; (ii) have specifically marketed these devices in California so as to constitute sufficient minimum contacts; and/or (iii) have sufficiently availed itself of California markets through promotion, marketing, and sales of these products in this State to render the exercise of jurisdiction by this Court permissible.

28. Venue is proper in this District because Philips North America LLC does business 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.

29. 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.

30. 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 and/or mouth, which increases air pressure in the throat so that the airway does not collapse during inhalation. CPAP therapy assists breathing during sleep and can successfully treat sleep apnea.

31. 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.

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

33. 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.

34. 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 California, the United States and worldwide.

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

35. 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.

36. 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.

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

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

39. 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.

40. 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.

41. 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.

42. 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.

43. 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

44. 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.

45. 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)."

46. 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)

47. 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."

48. 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. In addition, had Defendants conducted adequate research before selecting PE-PUR for use in its Recalled Breathing Machines, they should have chosen an alternative material for the application.

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

49. Philips's recall does not actually provide patients with new CPAP, BiPAP, or ventilator devices. 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.

50. Philips is not currently replacing the foam in the affected devices. It is unknown when, or if ever, Philips will be able to provide its customers with suitable replacement foam. Thus, instead of replacing or repairing the affected devices, Philips is proposing that its customers purchase its next generation product, the DreamStation 2.

51. 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.

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

53. 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.

54. 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 far less 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.

55. Plaintiff and the Class members have all suffered economic damages as a result of their purchase of the Recalled Breathing Machines in an amount equal to the purchase price of their recalled Breaching Machines and/or the cost of a replacement machine.

V. CLASS ALLEGATIONS

56. 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:

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

57. The California Class is 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.

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

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

60. 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 California 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' and other 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:

1. Whether Defendants are strictly liable for the manufacture and sale of the Recalled Breathing Machines;
2. Whether Defendants were negligent in manufacturing and selling the Recalled Breathing Machines;
3. Whether Defendants breached the express warranties to Plaintiff and the Class;
4. Whether Defendants breached their implied warranties to Plaintiff and the Class;
5. The appropriate measurement of restitution and/or measure of damages to Plaintiff and members of the Class;
6. Whether Defendants breached their implied warranties to Plaintiff and the Class;
7. Whether Defendants violated California's Unfair Competition Law, Bus. & Prof. Code § 17200 *et seq*., by, among other things, engaging in unfair, unlawful, or fraudulent practices;
8. The appropriate nature of class-wide equitable relief;
9. Whether Defendants were unjustly enriched by the sale of the Recalled Breathing Machines;
10. Whether Plaintiff and the Class are entitled to compensatory damages, and the amount of such damages; and
11. Whether Defendants should be declared financially responsible for the costs and expenses of the replacement of all Recalled Breathing Machines.

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 her interests do not conflict with the interests of the Class that she seeks to represent; she 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 her 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

61. The running of any statute of limitations has been equitably tolled by reason of Defendants' fraudulent or negligent 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.

62. 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 the Recalled Breathing Machines were defective and posed dangerous health risks to Plaintiff and the Class.

VII. CAUSES OF ACTION

COUNT I

DESIGN DEFECT STRICT LIABILITY

63. Plaintiff and the Class incorporate by reference all preceding paragraphs, as if fully set forth.

64. 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 exposure to materials with toxic and carcinogenic effects.

65. 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.

66. 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.

67. Safe, 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.

68. The risk benefit profile of the Recalled Breathing Machines was unreasonable, and should not have been sold in the market.

69. The Recalled Breathing Machines failed to perform in a safe manner as an ordinary consumer of the product would expect.

70. Plaintiff and the Class suffered damages equal to the purchase price of the machines, or the cost of replacing the machines and such other economic damages, the amount of which to be determined at trial.

COUNT II

NEGLIGENT DESIGN DEFECT

71. Plaintiff and the Class incorporate by reference all preceding paragraphs, as if fully set forth.

72. 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 exposure to materials with toxic and carcinogenic effects.

73. 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.

74. 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.

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

76. 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.

77. The Recalled Breathing Machines failed to perform in a safe manner as an ordinary consumer would expect.

78. Plaintiff and the Class suffered damages equal to the purchase price of the machines, or the cost of replacing the machines and such other economic damages, the amount of which to be determined at trial.

COUNT III

BREACH OF EXPRESS WARRANTY

79. Plaintiff and the Class incorporate by reference all preceding paragraphs, as if fully set forth herein.

80. 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."

81. Because Defendants were well aware of the defects in materials within two years of purchase of the Recalled Breathing Machines by Plaintiff and all Class members, and failed to disclose to defects, Defendants are barred and estopped from asserting that warranty claims are barred based upon the two year warranty period. Plaintiff and all Class members were unaware of the defects in materials and could not have reasonably learned or discovered of such defects within two years of purchase.

82. Defendants breached this express warranty set forth above, in that the Recalled Breathing Machines did not conform to the express description of the quality, characteristic or performance of the products, which was not reasonably suitable for the ordinary purposes for which it was used; and which did not reasonably conform to the promises made in the warranty. At the point of sale, the Recalled Breathing Machines while appearing normal—contained immediate

defects as set forth herein, rendering them unsuitable, unfit and unsafe for the intended use by all users of the machines.

83. Had Plaintiff and the Class known the Recalled Breathing Machines were unsafe for use, they would not have purchased them. Before the recall, purchasers/consumers did not know of the dangerous condition of the machines but believed them to be safe for its intended use, and used the product in a reasonable manner, appropriate for the purpose for which it was intended. When Plaintiff and the Class used the machines, they had not been altered or modified, and no action by Plaintiff caused or contributed to the defect.

84. 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.

85. As a direct and proximate result of Defendants' breach of express warranty, Plaintiff and the Class suffered damages equal to the purchase price of the machines, or the cost of replacing the machines and such other economic damages, the amount of which to be determined at trial.

COUNT IV

BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY

86. Plaintiff and the Class incorporate by reference all preceding paragraphs, as if fully set forth.

87. 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.

88. 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 consumers and users of the machines. When Plaintiff and the Class used the machines, they had not been altered or modified, an no action by Plaintiff caused or contributed to the defect.

89. Had Plaintiff and the Class known the Recalled Breathing Machines were unsafe for use, they would not have purchased them. Before the recall, purchasers/consumers did not know of the dangerous condition of the machines but believed them to be safe for its intended use, and used the product in a reasonable manner, appropriate for the purpose for which it was intended.

90. 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.

91. Defendants issued the warranty to Plaintiff and the Class. Defendants extended the benefit of the express warranty to Plaintiff and members of the Class. Defendants are therefore in direct privity with each Plaintiff and all members of the Class.

92. Further, the implied warranties incorporated into the transaction between Defendants and its immediate purchasers, which were distributors of the Recalled Breathing Machines, (the "Philips Buyers") were intended solely to benefit Plaintiff and the Class. Plaintiff and the Class are therefore entitled to enforce the implied warranties against Defendants.

93. Further, the implied warranties made by Defendants to the Philips Buyers would be of no economic value to the Philips Buyers unless Plaintiff and Class received the benefit of such warranties. The Philips Buyers are not users of the Recalled Breathing Machines. The economic benefit of implied warranties made by Defendants to the Philips Buyers depends on the ability of end users

who buy their products to obtain redress from Defendants if the warranties are breached.

94. Under *Gilbert Financial Corp. v. Steelform Contracting Co.* (1978) 82 Cal. App. 3d 65, the implied warranties made by Defendants to Plaintiff and the Class are enforceable whether or not Plaintiff or the Class were in privity of contract with Defendants.

95. Defendants breached the implied warranties in that the Recalled Breathing Machines are: (1) not fit for their intended use and (2) not of merchantable quality. The Recalled Breathing Machines are neither merchantable nor fit for their intended use because: (1) the latent defect in the Recalled Breathing Machines insures that they are unsafe and will fail well before the end of their useful life; and (2) purchasers of the Recalled Breathing Machines would not accept the health risks posed by the Recalled Breathing Machines when there are other products for sale which do not present these health risks.

96. Although Plaintiff does not believe that notice to Defendants of their breaches of warranty are required under applicable law, notice to Defendants of their breach of the implied warranties would be futile because Defendants are aware of and have acknowledged and admitted the defects in the Recalled Breathing Machines in the recall and because they cannot provide to Plaintiff and the Class any remedy other than replacement of the Recalled Breathing Machines which they have refused to provide, or cure the defect, or pay the cost to purchase comparable non-defective machines.

97. Because the Recalled Breathing Machines have failed and pose serious health risks within their expected useful life, Defendants are in breach of the warranty. Harm to Plaintiff and the Class is detailed hereinabove.

98. As detailed herein, Defendants have failed to remedy the breach of the warranty for either Plaintiff or the Class.

99. As a direct and proximate result of Defendants' breach of the implied warranty of merchantability, Plaintiff and the Class suffered damages equal to the purchase price of the machines, or the cost of replacing the machines and such other economic damages, the amount of which to be determined at trial.

COUNT V

Breach of Express Warranty - Magnuson-Moss Warranty Act

100. Plaintiff incorporates by reference each allegation set forth in the preceding paragraphs, as if fully set forth.

101. The allegations of this Claim for Relief are based on the breaches of warranty addressed fully in the previous Claims for Relief.

102. The Recalled Breathing Machines are a consumer product as defined in 15 U.S.C. § 2301(1).

103. Plaintiff and the members of the Class are consumers as defined in 15 U.S.C. § 2301(3).

104. Defendants are a supplier and warrantor as defined in 15 U.S.C. § 2301(4) and (5).

105. The warranty contains "written warranties" within the meaning of 15 U.S.C. § 2301(6).

106. As alleged previously, Defendants have breached the warranty.

107. Additionally, pursuant to 15 U.S.C. § 2304(d)(1), Defendants may not assess Plaintiff or the Class any costs the warrantor or his representatives incur in connection with the required remedy of a warranted product... [I]f any incidental expenses are incurred because the remedy is not made within a reasonable time or because the warrantor imposed an unreasonable duty upon the consumer as a condition of securing remedy, then the consumer shall be entitled to recover reasonable incidental expenses which are so incurred in any action against the

warrantor." Defendants have refused to pay all costs associated with the replacement of the Recalled Breathing Machines.

108. Defendants admit the notice of breach of the warranty by virtue of the recall and have had a reasonable opportunity to cure the breach. Defendants have failed to remedy or cure the breach of its obligations to the Class under the warranty.

109. Further notice to Defendants of their breach of the warranty would be futile because Defendants are fully aware of and have acknowledged in their recall the defects in the Recalled Breathing Machines. Defendants cannot provide to Plaintiff and the Class any remedy other than replacement of the Recalled Breathing Machines or the cost to purchase a comparable non-defective machine.

110. As a result of Defendants' breach of the warranty, Plaintiff and the Class have been damaged in an amount to be proven at trial.

COUNT VI

Breach of Express Warranty under Song-Beverly Consumer Warranty Act

111. Plaintiff incorporates by reference each allegation set forth in the preceding paragraphs, as if fully set forth.

112. The allegations of this Claim for Relief are based on the breaches of warranty addressed fully in the previous Claims for Relief.

113. The Recalled Breathing Machines are consumer goods within the meaning of California's Song-Beverly Consumer Warranty Act.

114. The Defendants are a "manufacturer" within the meaning of the statute.

115. Plaintiff and members of the Class purchased the Recalled Breathing Machines within the State of California.

116. As alleged previously, Defendants breached the warranty.

117. Defendants are fully aware of and have admitted their breach of the warranty and have had a reasonable opportunity to cure the breach. Defendants have failed to remedy the breach of its obligations to the Class under the warranty.

118. Further notice to Defendants of their breach of the warranty would be futile because Defendants are aware of and have acknowledged in the recall the defects in the Recalled Breathing Machines and cannot provide Plaintiff and the Class any remedy other than replacement of the Recalled Breathing Machine or the cost to purchase a comparable non-defective machine.

119. As a result of Defendants' breach of the warranty, Plaintiff and the Class have been damaged in an amount to be proven at trial.

COUNT VII

Breach of Implied Warranty - Magnuson-Moss Warranty Act

120. Plaintiff incorporates by reference each allegation set forth in the preceding paragraphs, as if fully set forth.

121. The allegations of this Claim for Relief are based on the breaches of warranty addressed fully above.

122. Plaintiff and members of the Class are consumers as defined in 15 U.S.C. § 2301(3).

123. Defendants are suppliers and warrantors as defined in 15 U.S.C. § 2301(4) and (5).

124. The Recalled Breathing Machines are consumer products as defined in 15 U.S.C. § 2301(1).

125. Under 15 U.S.C. §2301(7), Defendants extended the implied warranties to Plaintiff and the Class.

126. Defendants breached the implied warranties by selling Recalled Breathing Machines that were neither merchantable nor fit for their intended purpose.

127. Under 15 U.S.C. §2310(e), notice of breach of warranty need not be provided until after Plaintiff has been appointed Class Representative.

128. Plaintiff need not provide further notice to Defendants of the breach of the implied warranties because Defendants have recalled the Recalled Breathing Machines and have had a reasonable opportunity to cure the breach. Defendants have failed to remedy the breach of its obligations to the Class under the implied warranties or to cure the defect.

129. As a result of Defendants' breach of the implied warranties, Plaintiff and the Class have been damaged in an amount to be proven at trial.

COUNT VIII

Breach of Implied Warranty under Song-Beverly Consumer Warranty Act

130. Plaintiff incorporates by reference each allegation set forth in the preceding paragraphs, as if fully set forth.

131. The allegations of this Claim for Relief are based on the breaches of warranty addressed fully above.

132. Under the Song-Beverly Consumer Warranty Act, Civ. Code § 1792 *et seq.*, every sale of consumer goods in the State of California is accompanied by both a manufacturer's and retail seller's implied warranty that the goods are merchantable.

133. The Recalled Breathing Machines are consumer goods within the meaning of the statute.

134. Defendants are a "manufacturer" within the meaning of the statute.

135. Plaintiff and members of the Class purchased Recalled Breathing Machines in the State of California.

136. By operation of law, all Defendants made the implied warranties to Plaintiff and the Class concerning the Recalled Breathing Machines.

137. Defendants have breached the implied warranties by selling Recalled Breathing Machines which were not of merchantable quality and

which failed to perform the tasks for which they were intended and expose Plaintiff and Class members to serious risk of harm.

138. Plaintiff and all other Class members do not have to be in privity with any Defendant in order to enforce the implied warranties. Civil Code § 1792, which provides that "[u]nless disclaimed in the manner prescribed by this chapter, every sale of consumer goods that are sold at retail in this state shall be accompanied by the manufacturer's and the retail seller's implied warranty that the goods are merchantable," has no privity requirement.

139. Further, Plaintiff and the Class are intended beneficiaries of the implied warranties between Defendants and its distributors and are therefore entitled to enforce the implied warranties against Defendants.

140. Defendants are fully aware of their breach of the implied warranties in that Defendants recalled the machines and have had a reasonable opportunity to cure the breach. Defendants have failed to remedy the breach of its obligations to the Class under the implied warranties.

141. Further notice to Defendants of their breach of the implied warranties would be futile because Defendants are aware of and have acknowledged the defects in the Recalled Breathing Machines in the recall and, Defendants cannot provide to Plaintiff and the Class any remedy other than replacement of the Recalled Breathing Machines or the cost of purchasing a non-defective comparable machine.

142. As a result of Defendants' breaches of the implied warranties, Plaintiff and Class members have been damaged in an amount to be proven at trial.

COUNT IX
For Violation of Unfair Competition Law

143. Plaintiff incorporates by reference all preceding paragraphs, as if fully set forth herein.

144. Pursuant to Bus. & Prof. Code § 17200, "unfair competition shall mean and include any unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising."

145. Defendants' actions, as alleged herein, constitute deceptive, unfair, fraudulent, and unlawful practices committed in violation of the Bus. & Prof. Code § 17200, *et seq*.

146. All of the conduct and representations alleged herein occurred in the course of the Defendants' business and were part of a pattern or generalized course of conduct.

147. The Defendants' conduct was **unlawful** because it violated the Magnuson-Moss Warranty Act and Song-Beverly Consumer Warranty Act, express warranty of Defendants and implied warranty imposed as a matter of law, as previously alleged

148. The advertising and sale of the Recalled Breathing Machines by use of warranty documents was **fraudulent** because it was likely to and did deceive purchasers into believing that the Recalled Breathing Machines would be free from defects and provide safe and reliable breathing assistance. The Recalled Breathing Machines are not free from defects or safe and pose dangerous and unnecessary health hazards to Plaintiff and Class members. Defendants' omission to disclose the facts it was required to disclose is also **fraudulent** under Bus. & Prof. Code § 17200 in that Defendants have long been aware of all defects that are the basis of the recall and failed to disclose those defects and health hazards to Plaintiff and the Class. The supporting allegations are detailed in paragraphs 2 through 20.

149. Defendants' deceptive, fraudulent, unfair, and unlawful conduct alleged herein was specifically designed to and did induce Plaintiff and members of the Class to purchase the Recalled Breathing Machines.

150. Plaintiff and members of the Class reasonably and justifiably relied on Defendants' deceptive, fraudulent, unfair, and unlawful conduct alleged herein.

But for such conduct, Plaintiff and members of the Class would not have purchased the Recalled Breathing Machines.

151. As a result of Defendants' unfair methods of competition and unfair or deceptive acts or practices, Plaintiff (who paid approximately $900 for her Dreamstation) and members of the Class have suffered injury-in-fact, lost money, and lost property, in that they have incurred out-of-pocket costs and loss associated with the faulty Recalled Breathing Machines, as described more fully herein.

152. Pursuant to Bus. & Prof. Code §§ 17203, 17204, Plaintiff and the Class seek to recover from Defendants restitution of earnings, profits, compensation and benefit obtained as a result of the practices that are unlawful under Bus. & Prof. Code § 17200 et seq., and other appropriate relief, according to proof.

153. Additionally, by failing to provide safe replacement machines and by understating and failing to disclose the health risk resulting from the failure of the Recalled Breathing Machines, Defendants acted unfairly and unlawfully breached all warranties as alleged herein against all members of the Class. Members of the Class have been damaged and will continue to be damaged by the breaches of the warranty and the failure to disclose the risk of harm posed by the Recalled Breathing Machines.

154. The above alleged acts are **unfair** in that they: (1) violate public policy as expressed in the Magnuson-Moss Warranty Act and the Song-Beverly Consumer Warranty action; (2) are immoral, unethical, oppressive, unscrupulous and substantially injurious to consumers for failing to timely disclose to Plaintiff and the Class the known and foreseeable harmful effects of polyester polyurethane when used in the Recalled Breathing Machines, all of which were known to Defendants before and after the machines were purchased. These factors are not offset by the utility of Defendants' conduct since the conduct is intended to and does only provide impediments to the assertion of valid claims for recovery and limit the damages

which Defendants are legally obligated to compensate; and (3) inflict substantial injury on consumers which is not outweighed by any countervailing benefits to consumers or competition and the injury to consumers is one consumers could reasonably have avoided.

COUNT X

Unjust Enrichment

155. Plaintiff incorporates by reference each allegation set forth in the preceding paragraphs, as if fully set forth.

156. Pleading in the alternative to an express warranty, Defendants have been unjustly enriched in that Defendants received the purchase price of the Recalled Breathing Machines, a benefit which Defendants retained at Plaintiff's expense.

157. Plaintiff paid approximately $900 to purchase her Dreamstation breathing machine.

158. The benefit that Plaintiff conferred on Defendants and that Defendants retained at Plaintiff's expense was the purchase price of Plaintiff's Dreamstation breathing machine. The chain of distribution of Plaintiff's Dreamstation machine and the monetary compensation for that machine followed a pattern that is typical to all sales of the Recalled Breathing Machines.

159. Defendants did not typically sell its Recalled Breathing Machines directly to consumers or end users.

160. All Recalled Breathing Machines, including that purchased by Plaintiff, were sold by Defendants through approved distributors.

161. Plaintiff purchased her Dreamstation from Apria Healthcare LLC.

162. Plaintiff is informed and believed that Apria then paid Defendants, using Plaintiff's money, for the cost of the Dreamstation.

163. On information and belief, Apria purchased the Dreamstation it sold to Plaintiff from Defendants.

164. On information and belief, using Plaintiff's money, Apria paid Defendants for Plaintiff's Dreamstation. Plaintiff's money to purchase the Dreamstation was paid initially to one of the Defendants, who then shared such money among themselves, according to proof.

165. In this fashion, the benefit of Plaintiff's money, namely the purchase price of the Dreamstation, was conferred on Defendants and retained by Defendants through the above described distribution channels for Plaintiff's Dreamstation.

166. All of the Recalled Breathing Machines were sold to consumers or end-users in some variation of the above system, namely consumer or end-user pays the distributor who buys the Recalled Breathing Machines from the Defendants.

167. Thus, Defendants were paid with Plaintiff's money indirectly through its distributor Apria. The benefit of the purchase price was conferred on Defendants and retained at Plaintiff's expense.

168. As between Plaintiff and Defendants, it is unjust for Defendants to retain the benefit conferred upon it by Plaintiff based upon the promises from Defendants that the Dreamstation would be free from defects and be safe to use, none of which were delivered or fulfilled.

169. Defendants have been further unjustly enriched in that the price paid by Plaintiff and Class members for the Recalled Breathing Machines did not contemplate that consumers would bear the cost of replacing the defective Recalled Breathing Machines. At this time, Defendants have refused to replace the Recalled Breathing Machines or pay the cost of a new machine. All such expenses conferred an unjust benefit on Defendants by virtue of Defendants improperly shifting the burden of replacement costs to Plaintiff and members of the Class.

170. Defendants have been unjustly enriched in that Plaintiff has expended $937.38 to purchase a ResMed Airstation 10 Auto Set to replace her defective

Dreamstation. As such, a benefit has been conferred upon Defendants and retained at Plaintiff's expense.

171. 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.

172. 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 can no longer use their Recalled Breathing Machines safely.

173. Plaintiff and the Class suffered damages equal to the purchase price of the machines, or the cost of replacing the machines and such other economic damages, the amount of which to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of herself and all others similarly situated, pray the Court to certify the Class as defined hereinabove, to enter judgment against Defendants and in favor of the Class, and to award the following relief:

1. For certification of the proposed Class and each Subclass thereof as may hereafter be alleged;
2. For the cost of replacement of the Recalled Breathing Machines;
3. For compensatory damages as alleged herein, according to proof;
4. For an injunction to compel Defendants to:
   (a) advise consumers affirmatively of their rights to all damages to which they are lawfully entitled;
   (b) make full disclosure to all members of the Class concerning the risk of injury or harm resulting from the failure of the Recalled

Breathing Machines;

(c) establish a protocol, at no charge to Plaintiff and the Class to determine if they are the purchases or users of the Recalled Breathing Machines and the amount of damages suffered by Plaintiff and the Class by virtue of purchasing or using the Recalled Breathing Machines experienced;

5. For costs and attorneys' fees, as allowed by law;

6. For punitive damages;

7. For such other further legal or equitable relief as this Court may deem appropriate under the circumstances; and

8. In the alternative, Plaintiff prays to recover amounts that Defendants were was unjustly enriched, according to proof at trial.

JURY DEMAND

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

Dated: July 16, 2021

Respectfully Submitted,

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