UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

CLASS ACTION COMPLAINT

Plaintiff Brenda Linette Griffin, 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, which are commonly used to treat sleep apnea, and ventilators, which treat respiratory failure. In general, all of these devices blow 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. These products contain polyester-based polyurethane ("PE-PUR") foam for

sound abatement. Philips announced that the foam may break down and be inhaled or ingested, and the foam may emit volatile organic compounds ("VOCs") that may be inhaled, result in adverse effects to organs, and cause cancer. Philips explained in an announcement to doctors that these hazards could result in "serious injury which can be life-threatening or cause permanent impairment."

3. In truth, Philips knew about these very serious risks long before the recall. Patients who use the affected devices have complained about black particles in their machines for many years. But Philips did not warn the public about these hazards until late April 2021 and did not recall its machines until June 14, 2021.

4. Nor will Philips actually replace or repair any of the affected devices now or in the near future. Although patients need to use their devices every day, Philips has no concrete timeline for replacing any devices and may not provide replacements or repairs for a year or more.

5. In fact, it appears that Philips timed its recall to coincide with its launch of a next generation of the affected products, which Philips claims does not suffer from the same foam issues. Thus, the only safe option that Philips offers to its customers—many of whom need a CPAP machine to sleep—is to purchase, at full price, Philips's new, next-generation device, thus profiting Philips further.

6. Plaintiff purchased a device that Philips has now recalled. She would not have purchased the device at the price that she paid if she had known that the device had foam that could cause serious health problems. Plaintiff seek to represent a class of similarly situated persons (defined below) who also purchased these defective devices and to obtain relief for their economic injuries.

II. THE PARTIES

A. PLAINTIFF[1]

7. Plaintiff Brenda Linette Griffin resides in North Brunswick, New Jersey. She was diagnosed with obstructive sleep apnea. She has no other history of respiratory problems. She has used CPAP machines since 2015. In December 2020, she purchased a DreamStation. In March, she was diagnosed with a polyp on her vocal cords, a deviated nasal septum, gastroesophageal reflux, and allergic rhinitis. She would not have purchased the DreamStation if she had known it was defective. She wants a refund, replacement with a non-defective device, and costs for ongoing medical monitoring, and all other appropriate damages for all the injuries she has suffered as a result of her 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. At all relevant times, each Defendant acted in all aspects as the agent and alter ego of each other, and reference to "Philips" "Defendant" or "Defendants" herein refers to each and every Defendant individually and collectively.

[1] The Named Plaintiff is a proposed Class Representative for the state law subclass in which she resides.

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 AND 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. These disturbances are called "apneas," and they 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 and Automatic Positive Airway Pressure (APAP). BiPAP machines use two different pressures, one for inhaling and one for exhaling. APAP machines adjust pressure automatically throughout the night to the patient's

pressure needs, for example in response to changed sleeping positions or different sleep stages. Not every therapy is appropriate for every patient. Many patients respond well to one treatment and not others.

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 overdose. 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.

B. PHILIPS RECALLED ITS FOAM-CONTAINING PRODUCTS DUE TO SERIOUS HEALTH HAZARDS THAT THEY CAUSE.

20. Philips manufactures and sells CPAP machines, BiPAP machines, and ventilators, among other products. According to Philips's 2020 Annual Report,[2] Sleep & Respiratory Care constituted 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. Philips has sold millions of CPAP and BiPAP machines and ventilators in the United States.

[2] https://www.results.philips.com/publications/ar20/downloads/pdf/en/PhilipsFullAnnualReport20 20-English.pdf?v=20210531142942

21. Philips's flagship CPAP/BiPAP machine product family is the DreamStation family, including the original DreamStation, launched in October 2015, and the DreamStation Go (a travel version). Philips sells DreamStation products through its subsidiary, Respironics, which 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, a 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, started trying to convince 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 issued a further announcement, stating:

> 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. The recalled products ("Recalled Products") are:

- 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
- A-Series BiPAP A30

28. 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." It adds:

> 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.

29. The announcement detailed two types of hazards from the 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:
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> - Toluene Diamine
>
> - Toluene Diisocyanate
>
> - Diethylene glycol

30. 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.

31. 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)." The PE-PUR foam is black, and when it breaks down, it can release black particles.

32. 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)-

33. Philips admitted that the risks of these VOCs include: "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."

34. As noted herein, Philips has admitted that the Recalled Products are defective and unsafe. The Recalled Products 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.

35. Plaintiff and the Class have all suffered economic injuries as a result of their purchase of the Recalled Products.

C. PHILIPS HAS KNOWN ABOUT THE FOAM PROBLEMS FOR YEARS.

36. Although Philips did not disclose these health risks until June 2021, Philips knew about these health risks well beforehand. As discussed above, when Philips announced the recall, Philips also announced that it had received "several complaints" regarding black particles or debris in the airpath circuit. The DreamStation has been on the market since 2015, and several of the affected models have been on the market even longer.

37. Furthermore, Nick Dunn, who runs the YouTube channel "CPAP Reviews," reported as soon as the recall was announced that he had known about the foam issues for several years because he monitors message boards and social media about CPAP machines. Philips, like most companies, likely did the same monitoring and heard about foam breakdown and black particles in the machines since soon after launch, if not earlier.

38. Message boards still contain many posts about black particles inside or on the filters of the DreamStation and other recalled devices. The following list is provided for illustration.

39. In 2018, the user "trickyneedsleep" reported on apneaboard.com that, using the DreamStation Auto, the filters turned black within three days of use.

40. In 2019, the user "WSHenry" reported on apneaboard.com in a thread entitled "DreamStation Filter Contamination" that "both the pollen and ultra-fine filters in my machine were clogged with black (Carbon?) particles. I also noted that water chamber was completely dry. There were odd odors noted, and the water chamber was undamaged." He explained that he had recently cleaned the filters and that "[t]here was only a small amount of dust on the furniture, and the machine and tubing is clean. I do not burn candles nearby, and the furnace is off. I do have the window slightly opened, as is the case nearly year-round." He asked: "Is it possible the contamination is from the blower?"

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

42. In September 2020, Carol Nickerson posted on Facebook that she found a black mold-like substance in the water reservoir of her Philips DreamStation. She reported that she cleaned the tubing, mask, and reservoir every week and emptied the reservoir daily, and that she lived in a low-humidity environment in Arizona.

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

44. Many of the reports of black particles, dust, or mold in the machines are likely due to foam breakdown.

D. PHILIPS HAS NOT REPLACED ANY DEVICES AND DOES NOT PLAN TO DO SO IN THE NEAR FUTURE.

45. Philips's "recall" does not actually provide patients with new CPAP, BiPAP, or ventilator devices. As Philips's June 14 announcement explains:

> **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.

46. Thus, Philips is not currently replacing the foam in the affected devices and may take a year or more to provide replacements or repairs. Philips did, however, again push its next generation of products on consumers.

47. Due to the design of the devices, it is prohibitively difficult for patients to remove or replace the foam themselves. Nor is replacement foam readily available. Self-service is not a realistic option.

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

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

50. Thus, 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.

V. CLASS ALLEGATIONS

51. 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 Class consists of the following:

> **Nationwide Class:** All persons in the United States who have purchased a Recalled Product for personal use.

Or, in the alternative,

> **New Jersey Class:** All persons in New Jersey who have purchased a Recalled Product for personal use.

52. Together, the Nationwide Class and the New Jersey Class shall be collectively referred to herein as the "Class." Excluded from the Class are Defendants and their employees, officers, and directors; and the Judge(s) assigned to this case.

53. Plaintiff reserves the right to adjust, modify, or narrow the Class prior to class certification.

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

55. 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. Plaintiff is informed and believes that the proposed Class contains at least millions of individuals who purchased a Recalled Product. 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 Recalled Products;

ii. Whether Defendants were negligent in selling the Recalled Products;

iii. Whether Defendants failed to warn consumers regarding the risks of the Recalled Products

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 which 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 Products 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 she intends 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

56. 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 her physicians the true risks associated with the Recalled Products.

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

VII. CAUSES OF ACTION

COUNT 1
STRICT LIABILITY-FAILURE TO WARN

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

59. Defendants had a duty to warn Plaintiff and the Class members regarding the defect and true risks associated with the Recalled Products.

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

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

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

63. Plaintiff and Class members would not have purchased, chosen, and/or paid for all or part of the Recalled Products had they known the defect and risks of purchasing the product.

64. 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.

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

COUNT 2
DESIGN DEFECT STRICT LIABILITY

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

67. The design of the Recalled Products, including but not limited to design and use of the foam and the placement of the foam within the Recalled Product, was defective and unreasonably dangerous, causing degradation and inhalation of the foam, which may cause

headaches, irritation, inflammation, respiratory issues, and exposure to materials with toxic and carcinogenic effects.

68. The design of the Recalled Products and the foam rendered the Recalled Products not reasonably fit, suitable, or safe for their intended purpose.

69. The dangers of the Recalled Products 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, such as Defendants' next-generation Dreamstation machines.

70. Safer, alternative machines from other manufactures were available that did not suffer from the defects as set forth herein and did not have an unreasonable risk of harm as with the Recalled Products and their unsafe foam.

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

72. The Recalled Products did not perform as an ordinary consumer would expect.

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

COUNT 3
NEGLIGENT FAILURE TO WARN

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

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

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

77. Plaintiff and Class members would not have purchased, chosen, and/or paid for all or part of the Recalled Products had they known that the risks associated with purchasing the product.

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

COUNT 4
NEGLIGENT DESIGN DEFECT

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

80. Defendants negligently designed the Recalled Products. Philips owed Plaintiff a duty to design the Recalled Products in a reasonable manner. The design of the Recalled Products, including but not limited to design of the foam and the placement of the foam within the Recalled Product, 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.

81. The design of the Recalled Products and the foam rendered the Recalled Products not reasonably fit, suitable, or safe for their intended purpose.

82. The dangers of the Recalled Products 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, such as Defendants' next-generation Dreamstation machines.

83. Safer, alternative machines from other manufactures were available which did not have an unreasonable risk of harm as with the Recalled Products and their unsafe foam.

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

85. The Recalled Products did not perform as an ordinary consumer would expect.

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

COUNT 5
NEGLIGENT RECALL

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

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

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

90. 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 6
BREACH OF EXPRESS WARRANTY

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

92. Defendants warranted the Recalled Products "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."

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

94. Had Plaintiff and the Class known the Recalled Products were unsafe for use, they would not have purchased them.

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

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

COUNT 7
BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY

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

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

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

100. Had Plaintiff and the Class known the Recalled Products were unsafe for use, they would not have purchased them.

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

102. 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 8
NEW JERSEY CONSUMER FRAUD ACT
(N.J. Stat. Ann. §§ 56:8-1, *et seq*.)
On Behalf of the New Jersey Class

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

104. The New Jersey Consumer Fraud Act ("NJCFA") makes unlawful "[t]he act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing concealment, suppression or omission of any material fact with the intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise or real estate, or with or with the subsequent performance of such person as aforesaid, whether or not any person has in fact been misled, deceived or damaged thereby, is declared to be an unlawful practice." N.J. Stat. Ann. § 56:8-2.

105. Defendants engaged in unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission of any material fact, with respect to the sale and advertisement of the Recalled Products purchased by Plaintiff and New Jersey Class Members, in violation of N.J. Stat. Ann. §§ 56:8-2, including by making statements or representations that were false or misleading regarding the quality of the Recalled Products, and concealing the true risks of the Recalled Products.

106. The above unfair and deceptive practices and acts by Defendants were immoral, unethical, oppressive, and unscrupulous.

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

108. Plaintiff and New Jersey Class members relied on Defendants' representations and omissions in that they would not have purchased, chosen, and/or paid for all or part of Recalled Products had they known of the true risks of purchasing or using the Recalled Products.

109. As a direct and proximate result of Defendants' deceptive acts and practices, Plaintiff and New Jersey Class Members suffered an ascertainable loss of money or property, real or personal, as described above, including the purchase of the Recalled Products and the costs or repairing or replacing the Recalled Products in a timely manner.

110. Plaintiff and New Jersey Class members seek relief under N.J. Stat. Ann. §§ 56:8-2.11 and 56:8-19, including, but not limited to a refund of all moneys acquired by Defendants for the Recalled Product, injunctive relief, damages, treble damages, and attorneys' fees and costs.

COUNT 9
UNJUST ENRICHMENT
(In the Alternative)

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

112. Plaintiff and the Class members conferred a tangible and material economic benefit upon Defendants by purchasing the Recalled Products. Plaintiff and Class members would not have purchased, chosen and/or paid for all or part of Recalled Products had they known that they the true risks of using the Recalled Products while Defendants cannot provide a timely repair or replacement for the Recalled Products. 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.

113. 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 machines safely.

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

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests, 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 Subclass defined above, and designate Plaintiff as the class representative and Plaintiffs' counsel as counsel for the Nationwide Class and New Jersey Class;

B. award equitable and injunctive relief, including but not limited to, requiring Defendants to institute a medical monitoring program for 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.

[Signature pages on next page]

JURY DEMAND

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

Dated: June 29, 2021

Respectfully Submitted,

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