IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

JOSEPH MARTIN,	)	
Plaintiff,	)	Case No.: 2:21-cv-1911
	)	
v.	)	COMPLAINT FOR DAMAGES
	)	
PHILIPS NORTH AMERICA LLC;	)	
PHILIPS HOLDING USA, INC.; and	)	DEMAND FOR A JURY TRIAL
PHILIPS RS NORTH AMERICA LLC,	)	
Defendants.	)	
	)	

COMPLAINT

Plaintiff, Joseph Martin, by and through his undersigned counsel, hereby submits the following Complaint and Demand for Jury Trial against Philips North America LLC ("Philips NA"), Philips Holding USA, Inc. ("PHUSA"), and Philips RS North America LLC ("Philips RS") (collectively referred to as "Philips" or the "Defendants") and alleges the following upon personal knowledge and belief, and investigation of counsel:

INTRODUCTION:

1. Philips manufactures, markets, sells, and distributes a variety of respiratory therapy products for sleep and at-home respiratory care.

2. Among these respiratory therapy products are Continuous Positive Airway Pressure (CPAP) and BiLevel Positive Airway Pressure (BiLevel PAP) devices, which are primarily used by individuals suffering from obstructive sleep apnea ("OSA"), as well as mechanical ventilators (“ventilators”).

3. Philips also manufactures, markets, imports, sells, and distributes a variety of mechanical ventilator devices ("ventilators") for individuals suffering from various respiratory conditions.

4. On June 14, 2021, Philips issued a recall notification for many of its CPAP and BiLevel PAP devices as well as a number of its ventilator devices.

5. In its recall notification, Philips advised of potential health risks related to the sound abatement foam used in the affected devices.

6. Philips informed patients using these affected devices of potential risks from exposure to degraded sound abatement foam particles and exposure to chemical emissions from the sound abatement foam material.

7. Specifically, Philips notified patients that the risks related to issues with the sound abatement foam include headache, irritation, inflammation, respiratory issues, and possible toxic and carcinogenic effects.

8. Plaintiff, Joseph Martin, was prescribed the use of and purchased one of Philips' recalled devices, a System One BiPAP device to treat his sleep apnea.

9. Plaintiff used System One BiPAP device on a daily basis for a number of years.

10. In or around November 2017, Plaintiff was diagnosed with kidney cancer.

11. As a direct and proximate result of Philips' misconduct, Plaintiff has suffered serious and substantial life-altering injuries.

12. As a direct and proximate result of the subject device, manufactured, marketed, imported, sold, and distributed by Philips, Plaintiff has suffered physical, emotional, and financial injuries, including kidney cancer.

THE PARTIES AND OTHER RELEVANT ENTITIES

13. Plaintiff, Joseph Martin, is an adult resident and citizen of Staten Island, New York. Staten Island, New York is located in Richmond County.

14. Plaintiff was prescribed the use of the subject device while a resident of New York, he purchased the subject device in New York, and the majority of his use of the subject device occurred in New York.

15. Koninklijke Philips N.V. ("Royal Philips") is a Dutch public limited liability company established under the laws of The Netherlands, having its principal executive offices at Philips Center, Amstelplein 2, 1096 BC Amsterdam, The Netherlands. Royal Philips is the parent company of Philips NA and Philips RS.

16. Defendant Philips North America LLC ("Philips NA") is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. Philips NA is a wholly-owned subsidiary of Royal Philips. Upon information and belief, Philips NA manages the operation of Royal Philips' various lines of business, including Philips RS, in North America. The sole member of Philips NA is PHUSA, which is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. Philips

NA may be served through its registered agent, Corporation Service Company, at 2 Sun Court, Suite 400, Peachtree Corners, Georgia 30092.

17. Defendant Philips Holding USA, Inc. ("PHUSA") is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. PHUSA is a holding company that is the sole member of Defendant Philips NA. PHUSA may be served through its registered agent, Corporation Service Company, at 2 Sun Court, Suite 400, Peachtree Corners, Georgia 30092.

18. Defendant Philips RS North America LLC ("Philips RS") is a Delaware corporation with its principal place of business located at 6501 Living Place, Pittsburgh, Pennsylvania 15206. Philips RS was formerly operated under the business name Respironics, Inc. ("Respironics"). Royal Philips acquired Respironics in 2008.[1] Philips RS may be served through its registered agent, Corporation Service Company, at 2 Sun Court, Suite 400, Peachtree Corners, Georgia 30092.

19. Royal Philips, Philips NA, PHUSA, and Philips RS are hereinafter collectively referred to as "Philips" or the "Defendants."

JURISDICTION AND VENUE

20. At all times pertinent to this Complaint, Defendants were and are in the

[1] *Philips announces completion of tender offer to acquire Respironics*, WEB WIRE, https://www.webwire.com/ViewPressRel.asp?aId=61199 (accessed June 30, 2021).

business of designing, manufacturing, marketing, promoting, advertising, and selling devices for the treatmentof obstructive sleep apnea, including the System One BiPAP device prescribed for and purchased by Joseph Martin (the "subject device").

21. At all times pertinent to this Complaint, Defendants were the mere alter egos or instrumentalities of each other. There is such a unity of interest and ownership between Defendants that the separate personalities of their entities ceased to exist. Defendants operated as a single enterprise, equally controlled each other's business affairs, commingled their assets and funds, disregarded corporate formalities, and used each other as a corporate shield to defeat justice,perpetuate fraud and evade contractual and/or tort liability.

22. At all times pertinent to this Complaint, Defendants acted in all respects as agents or apparent agents of one another.

23. At all times pertinent to this Complaint, Defendants acted in concert in the designing, manufacturing, marketing, promoting, advertising, and selling of devices for the treatment of obstructive sleep apnea, including the subject device. Defendants combined their property and labor in a joint undertaking for profit, with rights of mutual control over each other,rendering them jointly liable to Plaintiff.

24. Defendants regularly transact business in Pennsylvania that includes marketing and selling devices for the treatment of obstructive sleep apnea, derive substantial revenue from their business transactions in Pennsylvania, and have

purposely availed themselves of the privilege of doing business in Pennsylvania.

25. Additionally, Defendant Philips RS has its principal place of business located at 6501 Living Place, Pittsburgh, Pennsylvania 15206.

26. Upon information and belief, many of witnesses and much of the documentary evidence relevant to this litigation likely will be located within the Western District of Pennsylvania.[2]

27. Defendants shipped or participated in shipping the subject devices and other devices with the reasonable expectation that the devices could or would find their way to Pennsylvania through the stream of commerce.

28. Defendants' actions in marketing and selling their devices in Pennsylvania should have led them to reasonably anticipate being hauled into Court in Pennsylvania.

29. Defendants have sufficient "minimum contacts" with Pennsylvania that subjecting them to personal jurisdiction in Pennsylvania does not offend traditional notions of fair play and substantial justice.

30. This Court has personal jurisdiction over Philips NA, PHUSA, and Philips RS because of their systematic and continuous contacts with Pennsylvania as well as their maintenance of a registered agent for service of process in Pennsylvania.

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[2] *See* United States Judicial Panel on Multidistrict Litigation, *In Re: Philips Recalled CPAP, Bi-Level PAP, and Mechanical Ventilator Products Liability Litigation*, Transfer Order, available online at: https://www.jpml.uscourts.gov/sites/jpml/files/MDL-3014-Transfer%20Order-09-21.pdf.

31. This Court has original jurisdiction in this matter pursuant to 28 U.S.C. §1332(a)(1) and §1332(a)(2), as there is complete diversity between Plaintiff and Defendants and the amount in controversy exceeds $75,000.

32. This Court is a proper venue for this civil action pursuant to 28 U.S.C. § 1391(b)(2), because, upon information and belief, many of witnesses and much of the documentary evidence relevant to this litigation likely will be located within the Western District of Pennsylvania.[3] Additionally, upon information and belief, because the recalled products were primarily manufactured by Philips RS, much of Defendants' misconduct and the events giving rise to the claims asserted by Plaintiff, likely occurred in the Western District of Pennsylvania.[4]

33. This Court's exercise of personal jurisdiction over Defendants comports with due process.

BACKGROUND

34. At all relevant times, Defendants manufactured, marketed, sold, and distributed a lineup of CPAP and BiPAP devices as well as ventilator devices under its "Sleep & Respiratory Care" portfolio. These devices are designed to assist individuals with a number of sleep, breathing, and other respiratory conditions, including sleep

[3] *See* United States Judicial Panel on Multidistrict Litigation, *In Re: Philips Recalled CPAP, Bi-Level PAP, and Mechanical Ventilator Products Liability Litigation*, Transfer Order, available online at: https://www.jpml.uscourts.gov/sites/jpml/files/MDL-3014-Transfer%20Order-09-21.pdf.

[4] *Id*.

apnea.

35. Defendants sought and obtained clearance from the Food and Drug Administration ("FDA") to market the Recalled Devices, including the subject device used by Plaintiff, under Section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act. Section 510(k) allows marketing of medical devices if the device is deemed substantially equivalent to other legally marketed predicate devices marketed prior to May 28, 1976. No formal review for safety or efficacy is required. Neither FDA nor any government agency has ever determined the subject devices were safe and effective for the treatment of sleep apnea or any other respiratory condition.

A. PHILIPS MANUFACTURED, MARKETED, SOLD, AND DISTRIBUTED MANY DEFECTIVE AND DANGEROUS SLEEP & RESPIRATORY THERAPY PRODUCTS AND CONTINUES TO DO SO TODAY.

Continuous Positive Airway Pressure Therapy

36. Continuous Positive Airway Pressure ("CPAP") therapy is a common nonsurgical treatment primarily used to treat sleep apnea. CPAP therapy typically involves the use of a nasalor facemask apparatus and a CPAP machine which helps individuals breathe by increasing the air pressure in an individual's throat.

37. Sleep Apnea is a common sleep disorder characterized by repeated interruptions inbreathing throughout an individual's sleep cycle. These interruptions, called "apneas," are caused when the soft tissue in an individual's airway collapses. The airway collapse prevents oxygen from reaching the individual's lungs which can cause a

buildup of carbon dioxide. If the individual's brain senses the buildup of carbon dioxide, it will briefly rouse the individual from sleep so that the individual's airway can reopen. Often these interruptions are so brief that the individual will not remember. Despite the brevity of the interruptions, the sleep cycle disruption caused by sleep apnea can dramatically impact a person's lifestyle, including negatively impacting energy, mental performance, and long-term health. CPAP therapy helps treat sleep apnea by preventing the person's airway from collapsing while breathing during sleep cycles, which can help prevent interruptions in breathing.

Bi-Level Positive Airway Pressure Therapy

38. Bi-Level Positive Airway Pressure ("BiPAP") therapy is a common alternative to CPAP therapy for treating sleep apnea. Similar to CPAP therapy, BiPAP therapy is nonsurgical and involves the use of a nasal or facemask device to maintain air pressure in an individual's airway. BiPAP is distinguishable from CPAP therapy, however, because BiPAP devices deliver two alternating levels—inspiratory and expiratory—of pressurized air into a person's airway, rather than the single continuous level of pressurized air delivered by a CPAP device. The inspiratory positive airway pressure assists a person as a breath is taken in. Conversely, the expiratory positive airway pressure is applied to allow a person to comfortably breathe out. BiPAP devices deliver one level of pressurized air (the inspiratory positive level) to assist as a person inhales, and another level (the expiratory level) as a person exhales.

Mechanical Ventilators

39. Mechanical ventilation works by pushing a mixture of oxygen and air through an endotracheal tube, placed either in a patient's nose or mouth, and into their trachea, then lungs. Similar to CPAP and BiPAP machines, ventilators can also hold a constant amount of low pressure, called positive end-expiratory pressure (PEEP), in order to keep the lungs from collapsing.

B. PHILIPS KNEW ITS RESPIRATORY THERAPY DEVICES WERE ENDANGERING PATIENTS, BUT DID NOTHING TO PREVENT HARM TO PATIENTS.

40. Because Philips' respiratory therapy products are intended to be used while the patient is sleeping, Philips utilized polyester-based polyurethane (PE-PUR) foam to dampen device vibration and sound during routine operation. Using an insulation foam in this fashion is commonly referred to as "sound abatement".

41. On information and belief, at least as early as January 2011, Philips was aware of the propensity of its sound abatement foam to degrade and of preventative measures taken by another Philips entity, which were designed to prevent the degradation of its sound abatement foam and/or to slow the progression of the degradation of its sound abatement foam.

42. On information and belief, in response to this information concerning the safety of its CPAP, BiPAP, and ventilator devices, Philips did nothing. It did not perform or did not document any further investigation; it did not conduct a health hazard evaluation or risk analysis; it did not conduct a design review of the issue. Philips did not

share this information with the public or, more specifically, with healthcare providers and patients, including Joseph Martin.

43. On information and belief, between April 1, 2016, and Jan. 22, 2021, on at least fourteen (14) occasions, Philips was made aware of potential foam degradation problems with various sleep and respiratory care devices.

44. On April 26, 2021, as part of its Quarterly Report for Q1 2021, Philips disclosed for the first time, under a section entitled "Regulatory Update," that device user reports had led toa discovery that the type of PE-PUR "sound abatement" foam Philips used to minimize noise in several CPAP and BiPAP respirators posed health risks to its users.

45. Specifically, Philips disclosed that "the [PE-PUR] foam may degrade under certain circumstances, influenced by factors including use of unapproved cleaning methods, such as ozone[], and certain environmental conditions involving high humidity and temperature."[5]

46. On June 14, 2021, Philips issued a recall notification for specific affected devices.[6]

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[5] *First Quarter Results*, PHILIPS (Apr. 26 2021), https://www.results.philips.com/publications/q121/downloads /pdf/en/philips-first-quarter-results-2021-report.pdf (accessed Dec. 13, 2021).

[6] *Medical Device recall notification (U.S. only) / field safety notice (International Markets)*, PHILIPS RESPIRONICS (June 14, 2021), https://www.usa.philips.com/healthcare/e/sleep/communications/src-update#section_2 (accessed Dec. 13, 2021).

47. In its recall notification, Philips identified examples of potential risks which include exposure to degraded sound abatement foam particles and exposure to chemical emissions from the sound abatement foam material.[7]

48. Philips reported that, based on lab testing and evaluations, it may be possible that these potential health risks could result in a wide range of potential patient impacts, including transient potential injuries, symptoms and complications, as well as possibly serious injuries, which can be life-threatening or cause permanent impairment, or require medical intervention to preclude permanent impairment.[8]

49. According to Philips' recall notice, the PE-PUR Foam used in Recalled Devices puts Recalled Device users at risk of suffering from the following health harms: "*Particulate exposure* can cause headache, irritation [skin, eye, and respiratory tract], inflammation, respiratoryissues, and possible toxic and carcinogenic effects[;]" whereas the "potential risks of *chemical exposure due to off-gassing* include headache, irritation, hypersensitivity, nausea/vomiting, and possible toxic and *carcinogenic* effects."[9]

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[7] *Philips issues recall notification*, PHILIPS RESPIRONICS (June 14, 2021), https://www.usa.philips.com/a-w/about/news/archive/standard/news/press /2021/20210614-philips-issues-recall-notification-to-mitigate-potential- health-risks-related-to-the-sound-abatement-foam-component-in-certain-sleep-and-respiratory-care-devices.html (accessed Dec. 13, 2021) (emphasis added).

[8] *Id*.

[9] *Philips issues recall notification*, PHILIPS RESPIRONICS (June 14, 2021), https://www.usa.philips.com/a-w/about/news/archive/standard/news/press/ 2021/20210614-philips-issues-recall-notification-to-mitigate-potential- health-risks-related-to-the-sound-abatement-foam-component-in-certain-sleep-and-respiratory-care-devices.html (accessed Dec. 13, 2021) (emphasis added).

50. On June 14, 2021, Philips also issued a brief report titled "Clinical Information for Physicians." In this report, Philips disclosed that "[l]ab analysis of the degraded foam reveals the presence of potentially harmful chemicals including:

-Toluene Diamine
-Toluene Diisocyanate
-Diethylene glycol."[10]

51. In its report titled "Clinical Information for Physicians," Philips also disclosed that lab testing performed by and for Philips has also identified the presence of Volatile Organic Compounds (VOCS) which may be emitted from the sound abatement foam component of the affected devices. "VOCs are emitted as gases from the foam included in the [affected devices] and may have short- and long-term adverse health effects. Standard testing identified two compounds of concern that may be emitted from the foam and that are outside of safety thresholds. The compounds identified are the following:

-Dimethyl Diazine

-Phenol, 2,6-bis (1,1-dimethylethyl)-4-(1-methylpropyl)."[11]

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[10] *Sleep and Respiratory Care update, Clinical information for physicians*, PHILIPS (June 14, 2021), https://www.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/philips-recall-clinical- information-for-physicians-and-providers.pdf?_ga=2.43039205.1759564883.1625006706212130326.1624473291&_gl=1*2nhu1w*_ga*MjEyMTMwMzI2LjE2MjQ0NzMyOTE.*_ga_2NMXNNS6LE*MTYyNTE1MTQ3MC4xNi4xLjE2MjUxNTE1OTUuMTg.(accessed December 10, 2021).

[11] *Id*.

C. PHILIPS' RECALLED DEVICES

52. In total, estimates suggest as many as 15 million machines are targeted in the recall.[12]

53. The list of the devices recalled by Phillips (the "Recalled Devices") include:

a) A-Series BiPAP A30;
b) A-Series BiPAP A40;
c) A-Series BiPAP Hybrid A30;
d) A-Series BiPAP V30 Auto;
e) C-Series ASV;
f) C-Series S/T and AVAPS;
g) DreamStation;
h) DreamStation ASV;
i) DreamStation Go;
j) DreamStation ST, AVAPS;
k) Dorma 400;
l) Dorma 500;
m) E30;
n) Garbin Plus, Aeris, LifeVent;
o) OmniLab Advanced+;
p) REMstar SE Auto;
q) SystemOne ASV4;
r) SystemOne (Q-Series);
s) Trilogy 100; and
t) Trilogy 200.[13]

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[12] Parker, L.; Jones, T., *FDA Finds Maker of Recalled Sleep Aid Devices Knew Of Problems For Years, But Didn't Act*, NBC Chicago, available at: https://www.nbcchicago.com/consumer/fda-finds-maker-of-recalled-sleep-aid-devices-knew-of-problems-for-years-but-didnt-act/2698459/ (accessed Dec. 13, 2021).

[13] *Medical Device recall notification (U.S. only) / field safety notice (International Markets)*, PHILIPSRESPIRONICS (June 14, 2021), https://www.usa.philips.com/healthcare/e/sleep/communications/srcupdate#section_2 (accessed June 30, 2021).

54. Philips issued the following advice to patients using any of the Recalled Devices:

a) "For patients using BiLevel PAP and CPAP devices: Discontinue use of affected units and consult with physicians to determine the benefits of continuing therapy and potential risks."[14]

b) "For patients using life-sustaining mechanical ventilator devices: DO NOT discontinue or alter prescribed therapy, without consulting physicians to determine appropriate next steps."[15]

D. PHILIPS UNREASONABLY DELAYED ITS RECALL

55. Defendants have not disclosed when they first received reports from users of its Sleep & Respiratory Care devices "regarding the presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask)."[16] However, based on publicly available information, Defendants knew their Sleep & Respiratory Care devices presented potential health risks to patients by at least 2011. An adverse event report from FDA Manufacturer and User Facility Device Experience ("MAUDE") database shows that, as early as 2011, Respironics learned that a patient reported discovering "black dust" on her nose when she awoke the morning after

[14] *Id*.
[15] *Id*.
[16] *Medical Device recall notification (U.S. only) / field safety notice (International Markets)*, PHILIPS RESPIRONICS https://www.usa.philips.com/healthcare/e/sleep/communications/src-update#section_2 (accessed Dec. 13, 2021).

using a RemStar CPAP device and subsequently underwent treatment for "intoxication" and "chest tightness."[17] Philips investigated this report, and confirmed the device contained evidence of an unk[nown] black substance in the air path and on internal components … present throughout both the intake and exhaust portions of the air path. . . . Philips, however, denied that the presence of the black substance was due to a product defect.[18]

56. Further, there is no reason to believe, based on the length of time that Defendants' Sleep & Respiratory Care devices have been sold, that Defendants did not appreciate the health and safety risks associated with their products earlier than 2011.

57. Based on information and belief, as a result of user reports and other testing performed by and on behalf of Defendants, Defendants were likely aware of the degradation of the PE-PUR sound abatement foam used in the Recalled Devices, yet continued to manufacture, market, and sell the Recalled Devices with such awareness for a significant period of time.

58. From at least 2011 to the present day, Defendants unreasonably and unjustly profited from the manufacture and sale of the Recalled Devices and unreasonably put users of the Recalled Devices at risk of developing adverse health

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[17] *MAUDE Adverse Event Report: RESPIRONICS, INC. REMSTAR PRO INTERNATIONAL, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi__id=2000987&pc=BZD (last visited December 28, 2021).*

[18] *Id.*

effects, including cancer.

PLAINTIFF

59. Plaintiff Joseph Martin is an adult resident and citizen of Staten Island, New York.

60. On or around May 2014, Plaintiff was prescribed the use of and purchased a System One BiPAP device (the "subject device"). The subject device prescribed for and purchased by Plaintiff was one of the Recalled Devices.

61. Since May 2014, Plaintiff used the subject device daily to treat his sleep apnea.

62. At all times Plaintiff used the subject device, he used the subject device in accordance with the guidelines, manual, and instructions for use set forth by Defendants.

63. At all times Plaintiff used the subject device, he used the subject device for a purpose for which the subject device was marketed, designed, and intended.

64. At all times Plaintiff used the subject device, he used the subject device in accordance with the directions and instructions issued by his physician who prescribed the use ofthe subject device.

65. After, and as a result of using the subject device, Plaintiff has suffered personal injuries including harm to his respiratory system, cellular damage, DNA damage, and kidney cancer, among others. These injuries would not have occurred but for the defective nature of the subject device and/or Defendants' wrongful conduct.

66. Plaintiff was diagnosed with kidney cancer in November 2017.

67. Plaintiff's use of the subject device caused or significantly contributed to his development and progression of kidney cancer, which has permanently changed his life.

68. By reason of the foregoing, Plaintiff has had to undergo significant treatment, will be required to undergo significant treatment in the future, and now requires constant and continuous medical monitoring and treatment due to the defective nature of the subject device and/or Defendants' wrongful conduct.

69. As a result of the aforesaid misconduct and subject device manufactured, designed, sold, distributed, advertised, and promoted by Defendants, Plaintiff was injured, resulting in severe mental and physical pain and suffering. Such injuries will result in some permanent disability to his person. As a result of such injuries, Plaintiff has suffered damages for which compensatory damages should be awarded.

EQUITABLE TOLLING OF STATUTE OF LIMITATIONS

70. Neither Plaintiff nor his prescribing physician had any way of knowing about Philips' conduct with respect to the health risks associated with the use of the Recalled Devices.

71. There is no way that Plaintiff or his prescribing physician, through the exercise of reasonable care, could have discovered the conduct by Philips alleged herein. Further, Plaintiff did not discover and did not know of facts that would have caused a

reasonable person to suspect that Philips was engaged in the conduct alleged herein.

72. Additionally, Plaintiff had no way of knowing and, through the exercise of reasonable care, could not have known that Defendants' product was a possible cause of his kidney cancer.

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

74. Additionally, through Defendants' affirmative misrepresentations and omissions of critical safety information, including the failure to provide immediate notice of the adverse health effects associated with continued use of the Recalled Devices, Philips actively and fraudulently concealed from Plaintiff and his physicians the true risks associated with the device.

75. Upon information and belief, Philips intended its acts to conceal the facts and existence of claims asserted herein from Plaintiff. Plaintiff was unaware of the facts alleged herein without any fault or lack of diligence on his part and could not have reasonably known or discovered through reasonable diligence that he had been exposed to the risks and harms set forth and that those risks and harms were the direct and proximate result of Defendants' acts and omissions.

76. For this reason, any statute of limitations that otherwise may apply to the claims of Plaintiff should be tolled.

CAUSES OF ACTION

COUNT I
STRICT PRODUCTS LIABILITY – DESIGN DEFECT

77. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

78. At all times herein mentioned, Defendants were involved in researching, designing, developing, manufacturing, testing, selling and/or distributing the Recalled Devices, including the subject device, which is defective and unreasonably dangerous.

79. The subject device is defective in its design or formulation. It is not reasonably fit, suitable or safe for its intended purpose, and its foreseeable risks exceed the benefits associated with its design. The Recalled Devices, including the subject device, were defectively designed in that the PE-PUR foam comprising part of the devices can degrade into particles that enter the devices' air pathway and can off-gas certain chemicals. These characteristics cause, among other problems, cancer. Plaintiff was unknowingly subjected to breathing toxins, carcinogens, and other deleterious components and contaminants when using the subject device. The subject device is defective in design because it causes headaches, irritation of the skin, eye, and respiratory tract, inflammation respiratory issues, asthma, adverse effect to organs (including the kidneys and liver), hypersensitivity, nausea, vomiting, and toxic and carcinogenic effects. It is more dangerous than other available devices indicated for similar conditions and uses, and the utility of the device does not outweigh its risks.

80. The defective condition of the subject device rendered it unreasonably dangerous and/or not reasonably safe, and the device was in this defective condition at the time it left the hands of Defendants. The subject device was expected to and did reach Plaintiff and his physician without substantial change in the condition in which it was designed, manufactured, labeled, sold,distributed, marketed, promoted, supplied, and otherwise released into the stream of commerce.

81. The subject device was used for its intended purposes by Plaintiff and the subject device was not materially altered or modified prior to its use.

82. The subject device did not perform as an ordinary consumer would expect.

83. The subject device is defective in design because the PE-PUR foam comprising part of the device can degrade into particles that enter the device's air pathway and can off-gas certain chemicals. These characteristics cause, among other problems, cancer.

84. At or before the time the subject device was released on the market and/or sold to Plaintiff, Defendants could have designed the product to make it less prone to causing the above-listed health harms. A technically feasible safer alternative design utilizing either a different foam for sound abatement, like a polyether-urethane or silicone foam, and/or a design which placed the sound abatement foam in a different location would have prevented the harm Plaintiff suffered without substantially impairing the function of the device, and existed at the time Plaintiff purchased and used the subject

devices.

85. As a result of the foregoing design defects, Defendants created risks to the health and safety of its users, including Plaintiff, that were far more significant and devastating than the risks posed by equivalent competitor products with different, safer designs, which treated the same medical conditions.

86. Plaintiff was not able to discover, nor could he or his physicians have discovered through the exercise of reasonable diligence, the defective nature of the subject device. Further, in no way could Plaintiff have known that Defendants had designed, developed, and manufactured the subject device in a way as to make the risk of harm or injury outweigh any benefits.

87. The subject device was used by Joseph Martin in a way which the Defendants intended at the time it was prescribed to Plaintiff.

88. Defendants had a duty to create a device that was not unreasonably dangerous for its normal, intended use and breached this duty.

89. Defendants knew or should have known that the Recalled Devices, including the subject device, would be prescribed to patients and that physicians and patients were relying on them to furnish a suitable device. Further, Defendants knew or should have known that patients for whom the Recalled Devices would be used, such as Plaintiff, could be and would be affected by the defective design and composition of the devices.

90. Defendants researched, designed, manufactured, tested, advertised, promoted, marketed, sold, and distributed a defective device which, when used in its intended or reasonably foreseeable manner, created an unreasonable risk to the health of consumers, such as Plaintiff, and Defendants are therefore strictly liable for the injuries sustained by Plaintiff.

91. Furthermore, Defendants intentionally or recklessly designed the subject device with wanton and willful disregard for the rights and health of Plaintiff and others, and with malice, placing their economic interests above the health and safety of the Plaintiff and others.

92. As a direct and proximate result of Defendants' placement of the subject device into the stream of commerce and Plaintiff's use of the product as designed, manufactured, sold, supplied, and introduced into the stream of commerce by Defendants, Plaintiff suffered serious physical and mental injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, and severally, and requests compensatory and punitive damages, together with costs and interest, and any further relief as the Court deems proper.

COUNT II
STRICT PRODUCTS LIABILITY – FAILURE TO WARN

93. Plaintiff adopts and incorporates by reference all of the foregoing

language of thisComplaint as if fully set forth herein and further states as follows.

94. At all times herein mentioned, Defendants knew or should have known about significant health risks, including cancer, associated with use of the subject device.

95. At all times herein mentioned, Defendants advertised, promoted, marketed, sold, and distributed the subject device that was used by the Plaintiff.

96. The subject device was expected to and did reach the usual consumers, handlers, and persons coming into contact with said device without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendants.

97. As researcher(s), developer(s), designer(s), manufacturer(s), seller(s), distributor(s), and marketer(s) of medical devices, Defendants are held to the knowledge of an expert in the field, and each had an independent and continuing duty to warn the medical community, Plaintiff, and Plaintiff's physicians about the significance of the risks of cancer and other health harms and risks associated with using the subject device.

98. Defendants had a duty to warn Plaintiff and other consumers of the risks of harm resulting from exposure to degraded PE-PUR foam, its particulates and chemical emissions as a result of using the subject devices.

99. These risks are of such a latent nature that health care providers and users could not have recognized the potential harm without proper warnings provided by Defendants.

100. Plaintiff used the subject device in a manner intended and foreseeable by Defendants and without knowledge of its dangerous characteristics.

101. Defendants failed and deliberately refused to investigate, study, test, promote the safety, or minimize the dangers to those would foreseeably use or be harmed by the subject devices, including Plaintiff.

102. The subject device was defective due to inadequate warnings because Defendants knew or should have known that the product created a significantly increased risk of cancer, among other health impacts, could have provided proper warnings or instructions regarding the full and complete risks of the subject device, and yet failed to warn the medical community, Plaintiff, and Plaintiff's physician of the nature of such risks.

103. Defendants omitted, misrepresented, and downplayed the significantly increased risks of cancer and other health risks with the subject device that Defendants knew or should have known from previous testing and research even prior to subject device's FDA clearance.

104. The subject device's labeling was defective because Defendants omitted warnings relative to the device's risk of cancer and other health risks.

105. The subject device's labeling was defective because Defendants inadequately warned of the device's risk of cancer and other health risks.

106. The subject device's labeling was defective because it failed to provide

adequate instructions concerning how to minimize the risks associated with the device, to the extent such minimization of these risks was possible.

107. Although physicians are supposed to weigh the risks and benefits before prescribing a medical device, Defendants knew that their deliberate omissions and misrepresentations would cause physicians, including Plaintiff's physician, to prescribe the subject device without being able to adequately weigh the health risks, including the increased risk of developing cancer.

108. Defendants are able, in accordance with federal law, to disclose the known risks associated with the subject devices through public service announcements, promotions, advertisements, and other public information sources as they did in their April 26, 2021 communication to shareholders, and ultimately have done since announcing the recall on June 14, 2021.

109. If Defendants had properly warned about the subject device's cancer risk and/or other health harms, no reasonable physician, including Plaintiff's physician, would have recommended or prescribed the subject device because the potential benefits of the subject device are significantly outweighed by the risk of cancer and/or other health hazards.

110. Had Defendants provided adequate warnings of cancer and other health risks associated with the subject device, such warnings would have been heeded and no healthcare professional, including Plaintiff's physician, would have prescribed the

subject device and no consumer, including Plaintiff, would have purchased and/or used the subject device.

111. Furthermore, Defendants' failure to provide an adequate warning was done with wanton and willful disregard for the rights and health of Plaintiff and others, and with malice, placing their economic interests above the health and safety of the Plaintiff and others.

112. As a direct and proximate result of the subject device's defects as described herein, Plaintiff developed cancer, and suffered permanent and continuous injuries, pain and suffering,disability and impairment. Plaintiff has further suffered emotional trauma, harm and injuries that will continue into the future. Plaintiff has lost his ability to live a normal life and will continue to be so diminished in the future.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally, and requests compensatory and punitive damages, together with costs and interest, and any further relief as the Court deems proper.

COUNT III
NEGLIGENT DESIGN

113. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

114. At all relevant times, Defendants manufactured, designed, marketed, tested, promoted, supplied, sold and/or distributed the Recalled Devices, including the subject device, in the regular course of business.

115. The subject device was designed and intended to be used for the treatment of sleep apnea and other health issues.

116. Defendants knew or by the exercise of reasonable care, should have known, the use of the subject device was dangerous, harmful and injurious when used by Plaintiff and other consumers in a reasonably foreseeable manner.

117. Defendants knew or, by the exercise of reasonable care, should have known, ordinary consumers such as Plaintiff would not have realized the potential risks and dangers of the subject device.

118. Defendants breached their duty by failing to use reasonable care in the design of the subject device by designing the device such that PE-PUR foam inside the device could produce highly harmful particles and gasses that enter the device's airway leading to the user's respiratory system.

119. The subject device contained and produced chemicals and particles which can lead to headaches, irritation of the skin, eye, and respiratory tract, inflammation respiratory issues, asthma, adverse effect to organs (including the kidneys and liver), hypersensitivity, nausea, vomiting, and cancer, all of which Defendants knew, or by the exercise of reasonable care, should have known, ordinary consumers such as Plaintiff would be victim to.

120. Without limitation, the Defendants breached their duty to exercise reasonable care in designing the Recalled Devices including the subject device by their:

a. Failure to set quality requirements for their raw foam supplier(s), including raw foam components/materials;

b. Failure to adequately inspect/test the Recalled Devices;

c. Failure to adequately determine/test the integrity of PE-PUR foam and its qualities, especially after the devices have aged;

d. Failure to adequately determine or test the purity of airflow through the Recalled Devices' airway, especially after the devices have aged;

e. Failure to perform adequate risk analysis regarding the Recalled Devices;

f. Failure to perform design failure mode effect analysis regarding the Recalled Devices; and

g. Failure to act as a reasonably careful medical device company would under the circumstances.

121. Defendants breached their duty when they failed to use commercially-feasible alternative designs to minimize these harms, including but not limited to utilizing a different foam for sound abatement, like a polyether-urethane or silicone foam, designing a machine whose sound abatement foam was located in a different portion of the machine, designing products that prevented exposure to particles and off-gasses from PE-PUR foam, using a kind of noise and vibration-reducing material that did not possess these harmful qualities, using alternative methods of noise vibration reduction, preventing foam particles and gasses from entering the airway of the product through

use of a filter or by another manner, among many other potential designs.

122. Defendants breached their duty by failing to use reasonable care by declining to include an expiration or best if "used by" date, which left open the potential for the devices' chemical and other properties to change in an even more harmful manner.

123. As a direct and proximate result of Defendants' negligent design, Plaintiff suffered and will continue to suffer damages for which he is entitled to recover, including but not limited to compensatory damages, consequential damages, interest, costs, and attorneys' fees.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally, and requests compensatory and punitive damages, together with costs and interest, and any further relief as the Court deems proper.

COUNT IV
NEGLIGENT FAILURE TO WARN

124. Plaintiff adopts and incorporates by reference all of the foregoing language of thisComplaint as if fully set forth herein and further states as follows.

125. At all relevant times, Defendants designed, manufactured, assembled, inspected, tested (or not), packaged, labeled, marketed, advertised, promoted, supplied, distributed, and/or sold the Recalled Devices, including the subject device that Plaintiff used.

126. The Defendants knew or, by the exercise of reasonable care, should have known, use of the subject device was dangerous, harmful, and injurious when used by

Plaintiff in a reasonably foreseeable manner.

127. The Defendants knew or, by the exercise of reasonable care, should have known,ordinary consumers such as Plaintiff would not have realized the potential risks and dangers of the subject device.

128. The Defendants knew or, by the exercise of reasonable care, should have known,that the Recalled Devices posed risks including headaches, irritation of the skin, eye, and respiratory tract, inflammation respiratory issues, asthma, adverse effect to organs (including the kidneys and liver), hypersensitivity, nausea, vomiting, and cancer, among other harmful effects, as described herein, that were known and knowable in light of scientific and medical knowledge that was generally accepted in the scientific community at the time of design, manufacture, and distribution of the Recalled Devices.

129. The Defendants owed a duty to all reasonably foreseeable users to disclose the risks associated with the use of the Recalled Devices.

130. The Defendants breached their duty of care by failing to use reasonable care in providing adequate warnings to Plaintiff's physician and Plaintiff, in the subject device's labeling and packaging, and through marketing, promoting, and advertising of the subject device.

131. At all relevant times, Defendants could have provided adequate warnings and instructions to prevent the harms and injuries set forth herein, such as providing full and accurate information about the Recalled Devices to physicians, to

patients, in advertising, at point of sale, on the devices' instructions and inserts, and on the devices' labels.

132. A reasonable company under the same or similar circumstances would have warned and instructed of the dangers.

133. Plaintiff was injured as a direct and proximate result of Defendants' failure to warnand instruct because he would not have used or purchased the subject device had he received adequate warnings and instructions that he could be exposed to toxic and carcinogenic particles and gasses that cause headaches, irritation of the skin, eye, and respiratory tract, inflammation respiratory issues, asthma, adverse effect to organs (including the kidneys and liver), hypersensitivity, nausea, vomiting, and cancer.

134. Defendants' lack of adequate and sufficient warnings and instructions and their inadequate and misleading advertising, labeling, and instructions to physicians and patients was a substantial contributing factor in causing the harm to Plaintiff.

135. As a direct and proximate result of Defendants' negligent failure to warn, Plaintiff suffered and will continue to suffer damages for which he is entitled to recover, including but not limited to compensatory damages, consequential damages, interest, costs, and attorneys' fees.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally, and requests compensatory and punitive damages, together with costs and interest, and any further relief as the Court deems proper.

COUNT V
NEGLIGENCE/GROSS NEGLIGENCE

136. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

137. Defendants had a duty to exercise reasonable care in designing, developing, researching, testing, manufacturing, marketing, supplying, promoting, selling, and distributingthe Recalled Devices, including the subject device.

138. Defendants knew or should have known that using the subject device created a significantly increased risk of cancer and other health harms.

139. The negligence of the Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

a. Defendants designed and developed the Recalled Devices without thoroughly or adequately testing the devices;

b. Defendants sold the Recalled Devices without making proper and sufficient tests to determine the dangers to the users;

c. Defendants failed to adequately and correctly warn the Plaintiff, the public, and the medical community, of the cancer risks associated with the Recalled Devices;

d. Defendants advertised and recommended the use of the Recalled Devices for treatment of sleep apnea and other conditions knowing the subject devices posed a risk of cancers and other adverse health effects;

e. Alternatively, knowing they lacked sufficient knowledge as to the efficacy and safety of the subject devices, including the possibility that the subject devices posed a risk of cancer and other adverse health effects, Defendants, nevertheless, advertised and recommended the use of the Recalled Devices for treatment of sleep apnea and other conditions;

f. Defendants failed to exercise reasonable care in designing the Recalled Devices in a manner which was safe to the users;

g. Defendants failed to exercise reasonable care when they failed to disclose information concerning the risk of cancer and other serious adverse health effects associated with the device;

h. Defendants failed to act as a reasonably careful medical device company would under the circumstances.

140. Additionally, Defendants under-reported, underestimated, and downplayed the serious dangers of the Recalled Devices and their association with increasing the risk of developing cancer and other health harms.

141. Defendants failed to act as a reasonable medical device manufacturer would in the same or similar circumstances when they compared the benefits and risks of the subject device with other safer and more efficacious forms of treatment for sleep apnea and similar conditions.

142. Defendants also failed to warn Plaintiff, either directly or indirectly, orally

or in writing, about the need for more comprehensive, more regular medical monitoring than usual to ensure early detection of cancer.

143. Defendants specifically failed to exercise reasonable care when they failed to accompany the subject device with proper and/or accurate warnings regarding *all* adverse side effects—namely cancer—associated with the use of the subject device.

144. Once Defendants gained additional information about the Recalled Devices' association with cancer and other serious health harms, they failed to update their warnings and thereafter accompany the Recalled Devices with adequate warnings regarding cancer and other serious health harms.

145. Despite the fact that Defendants knew or should have known that the Recalled Devices caused unreasonably dangerous side effects, like cancer, they made conscious decisions to downplay these risks and continue to market, manufacture, distribute, and/or sell the devices tophysicians and patients, including the Plaintiff.

146. Defendants knew or should have known that consumers, such as Plaintiff, would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

147. Defendants' negligence was the proximate cause of Plaintiff's cancer-related injuries, among other health harms, which Plaintiff suffered and/or will continue to suffer.

148. As a result of the foregoing acts and omissions, the Plaintiff was caused to

suffer kidney cancer, as well as other personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/ormedications, and fear of recurrent cancer.

149. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

150. Defendants intentionally and recklessly committed the foregoing acts and omissions, doing so with gross negligence, recklessness, and/or wanton and willful disregard for the rights and health of Plaintiff and others, and with malice, placing their economic interests above the health and safety of the Plaintiff and others.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, and severally, and requests compensatory and punitive damages, together with costs and interest, and any further relief as the Court deems proper.

COUNT VI
FRAUDULENT CONCEALMENT AND/OR FRAUD BY OMISSION

151. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

152. At all relevant times, Defendants designed, manufactured, assembled,

inspected, tested, packaged, labeled, marketed, advertised, promoted, supplied, distributed, sold and/or otherwise placed the Recalled Devices into the stream of commerce, and therefore owed a duty of reasonable care to avoid causing harm to those that used the devices, such as Plaintiff.

153. Defendants had a duty to disclose material facts about the Recalled Devices that would substantially affect Plaintiff's and the general public's decisions when purchasing the devices.

154. In connection with selling, promoting, marketing, and labeling their products, including Recalled Devices, Defendants had an opportunity and duty to disclose truthful, complete, and accurate information regarding their products, including Recalled Devices.

155. At all reasonable times, Defendants knowingly made false representations and/or fraudulently misrepresented the Recalled Devices as safe, when in fact the devices posed unreasonable risks of substantial bodily injury.

156. Indeed, the second page of nearly every Philips CPAP and BiPAP machine User Guide provides: "To ensure that you receive the safe, effective therapy prescribed for you, use only Philips Respironics accessories."

157. This statement implies that Philips CPAP and BiPAP therapy is "safe" and "effective," which Philips knew was not true.

158. With respect to the humidifier present in the Recalled Devices, Philips

stated: "For safe operation when using a humidifier, the humidifier must always be positioned below the breathing circuit connection at the mask and the air outlet on the device. The humidifier must be level for proper operation."

159. This statement does not, in any way, warn users that the foam in Recalled Devices may degrade more rapidly in high heat and high humidity environments, as Philips now claims.

160. Likewise, the instructions for "Cleaning the Device," "Cleaning or Replacing the Filter," and "Cleaning the Tubing" advise only that the user should use a "mild detergent" and do not warn—as Philips now claims—that using certain products, such as ozone-based cleaners will accelerate the degradation of the sound abatement foam, causing significant health risks, including an increased risk of cancer.

161. Perhaps, most importantly, Philips did not warn that the subject devices created a significantly increased risk of cancer, among other health impacts.

162. Each and every one of these statements was material.

163. Each and every one of these statements was false and/or misleading.

164. Defendants intended users of the Recalled Devices, including Plaintiff, to rely on these misstatements of fact, knowing they would have no reason to doubt the completeness or veracity of those statements.

165. Even if these statements were technically true, they omitted critical safety and efficacy information such that they were as misleading as outright lies with respect

to Defendants' products, including Recalled Devices.

166. Upon information and belief, at all relevant times, Defendants knew these statements to be false when they were made.

167. Upon information and belief, at all relevant times, Defendants made these statements despite the fact that Defendants did not know them to be true and, therefore, lacked knowledge of their respective truth.

168. At all relevant times, Defendants fraudulently and deceptively concealed their failure to adequately research or test the Recalled Devices to assess their safety before marketing to users.

169. Defendants further falsely represented the nature and risks associated with the Recalled Devices in general statements to the media, general public, and federal agencies.

170. Defendants misrepresented material facts and omitted material facts that were essential to Plaintiff's decision-making when purchasing and using the subject devices.

171. Plaintiff was completely unaware that Defendants were concealing these material facts.

172. Upon information and belief, Defendants intentionally deceived and concealed material information concerning the safety of the Recalled Devices from Plaintiff and the general public, which had a direct impact on Plaintiff's and consumers'

health and wellbeing.

173. Upon information and belief, Defendants intended for their statements and representations with respect to the Recalled Devices to be relied upon by the general public, Plaintiff, and/or healthcare providers, including Plaintiff's healthcare providers.

174. Plaintiff relied to his detriment on Defendants' fraudulent concealment and omissions. Had Plaintiff been adequately informed of the material facts regarding the safety of the Recalled Devices, and not intentionally deceived by Defendants, he would not have acquired, purchased, used, or been injured by the subject device.

175. Upon information and belief, Plaintiff's healthcare providers relied to the detriment of Plaintiff on Defendants' fraudulent concealment and omissions. Had Plaintiff's healthcare providers been adequately informed of the material facts regarding the safety of the Recalled Devices, and not intentionally deceived by Defendants, they would not have prescribed use of the subject devices.

176. As a direct and proximate result of Defendants' fraudulent concealment and omissions, Plaintiff suffered and continues to suffer from the injuries and damages for which he is entitled to recovery, including but not limited to compensatory damages, consequential damages, interest, costs, and attorney fees.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally, and requests compensatory and punitive damages, together with costs and interest, and any further relief as the Court deems proper.

COUNT VII
NEGLIGENT MISREPRESENTATION

177. Plaintiff adopts and incorporates by reference all of the foregoing language of thisComplaint as if fully set forth herein and further states as follows.

178. Defendants had a duty to provide truthful and accurate information regarding whether the devices had been tested and found to be a safe and effective treatment for sleep apnea.

179. Defendants, in the course of selling the Recalled Devices, supplied information about the devices through television commercials, advertisements, marketing campaigns, sales representatives, labeling, and warnings.

180. Defendants breached their duty by misrepresenting the Recalled Devices' safety to the medical and healthcare community, to the Plaintiff, and to the public in general.

181. Defendants failed to exercise reasonable care because their goal should have been to put safety before their profits by providing individuals with information regarding the realistic risks that the Recalled Devices could cause cancer and other serious injuries.

182. Defendants' representations were made without properly conducting sufficient testing and by providing insufficient warnings about the Recalled Devices' potential risks.

183. Defendants' false representations that the Recalled Devices were safe for

consumers and their failure to disclose material facts regarding the Recalled Devices' risk of cancer and other serious injuries were made or omitted with the intent to induce Plaintiff and his health care providers to rely upon those facts or omissions.

184. Plaintiff and his health care providers were unaware and did not know that the subject device was unsafe for the purpose of treating sleep apnea because it caused a significant increased risk of cancer until *after* he had been exposed to carcinogenic particles and gasses.

185. Plaintiff and his health care providers justifiably relied upon the false representations of Defendants.

186. Had Defendants reasonably provided adequate warnings of cancer and other serious injuries, such warnings would have been heeded and no healthcare professional,including Plaintiff's physician, would have prescribed the Recalled Devices and no consumer, including Plaintiff, would have purchased and/or used the Recalled Devices.

187. As a direct and proximate result of the foregoing acts and omissions, Plaintiff wascaused to suffer serious and dangerous side effects, including kidney cancer, which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of recurrent cancer.

188. As a result of the foregoing acts and omissions, Plaintiff requires and/or will

require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, and severally, and requests compensatory and punitive damages, together with costs and interest, and any further relief as the Court deems proper.

COUNT VIII
BREACH OF EXPRESS WARRANTY

189. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

190. The Defendants, through their advertising, promotional materials, and labeling, expressly warranted and affirmed that the Recalled Devices were safe for their intended uses and for uses which were reasonably foreseeable.

191. Defendants' representations became a basis of the bargain.

192. Defendants made express warranties which extended beyond delivery of the Recalled Devices and expressly warranted for future performance of the devices. Defendants warranted the subject devices "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." Defendants breached this express warranty upon the sale and distribution of the subject devices.

193. Furthermore, Defendants advertised, promoted, and labeled the Recalled Devices as being safe and effective for the treatment of sleep apnea. Defendants breached said express warranties in that the Recalled Devices were unsafe and caused cancer among other harms. Plaintiff foreseeably used the subject device without knowing of the harmful and substantial consequences to his health.

194. At all relevant times, Defendants had knowledge of the hazards and health risks posed by the Recalled Devices when used.

195. At all relevant times, Defendants willfully failed to disclose the defects and health risks of the Recalled Devices to Plaintiff and the rest of the public that used the devices.

196. At all relevant times, Philips intended that the subject devices be used in the manner that Plaintiff in fact used them, and expressly warranted that each was safe and fit for use by Plaintiff, that they were of merchantable quality, that their risks were minimal and comparable to other comparable or substantially similar devices, and that they were adequately tested and fit for their intended use.

197. In reliance upon the express warranties made by Defendants, Plaintiff acquired/purchased and used the subject device, believing the subject device was inherently safe and/or a safe treatment for sleep apnea and would perform as specified for at least two years.

198. As a direct and proximate result of Defendants' breach of their express

warranties concerning the subject device, Plaintiff suffered and continues to suffer from the injuries and damages for which he is entitled to recovery, including but not limited to compensatory damages,consequential damages, interest, costs, and attorneys' fees.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally, and requests compensatory and punitive damages, together with costs and interest, and any further relief as the Court deems proper.

COUNT IX
BREACH OF THE IMPLIED WARRANTY OF
FITNESS FOR A PARTICULAR PURPOSE

199. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

200. On or around May 2014, Plaintiff was prescribed the use of and purchased a System One BiPAP device (the "subject device"). The subject device prescribed for and purchased by Plaintiff was one of the Recalled Devices.

201. At all relevant times, Defendants, through their advertising and promotional materials, expressly and impliedly warranted and affirmed that the Recalled Devices' purpose was to offer a reasonably safe treatment for sleep apnea and similar health problems.

202. Defendants touted the Recalled Devices as safe, despite having never adequately researched or tested the devices to assess their safety before placing the devices on the market and promoting them to consumers.

203. Defendants intended to make Plaintiff and the general public believe the Recalled Devices were safe.

204. Defendants knowingly misled Plaintiff and the general public to believe the Recalled Devices were safe for use, despite knowing that the devices could lead to serious injuries, all of which Defendants knew, or by the exercise of reasonable care, should have known, ordinaryconsumers such as Plaintiff would be victim to.

205. At all relevant times, Defendants had knowledge of the hazards and health risks posed by the Recalled Devices when used.

206. At all relevant times, Defendants willfully failed to disclose the defects and healthrisks of the Recalled Devices to Plaintiff and the consuming public.

207. Plaintiff relied to his detriment on the information publicized by Defendants.

208. In reliance upon these implied warranties as to the safety of the subject device by Defendants, Plaintiff acquired/purchased and used the subject device, believing that the subject device was inherently safe.

209. As a direct and proximate result of Defendants' warranties concerning the subject device, as described herein, Plaintiff suffered and continues to suffer from the injuries and damages for which he/she is entitled to recover, including but not limited to compensatory damages, consequential damages, interest, costs, and attorneys' fees.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them,

individually, jointly and severally, and requests compensatory and punitive damages, together with costs and interest, and any further relief as the Court deems proper.

COUNT X
BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY

210. Plaintiff adopts and incorporates by reference all of the foregoing language of thisComplaint as if fully set forth herein and further states as follows.

211. At all relevant times Defendants have been a merchant in regard to the Recalled Devices they created and sold to consumers.

212. Defendants breached their implied warranty of merchantability because the Recalled Devices were defective when designed, and do not conform with the promises represented on their labels.

213. Defendants failed to comply with merchantability requirements, as the Recalled Devices do not achieve the ordinary purposes they advertise: a safe treatment for respiratory conditions such as sleep apnea.

214. Beyond Defendants' own direct sales of the Recalled Devices, Plaintiff and other consumers are third-party beneficiaries of Defendants' agreements with its distributors, dealers, and sellers for the distribution, dealing, and sale of the Recalled Devices to consumers. Plaintiff and consumers are the intended beneficiaries of Defendants' implied warranties since the Recalled Devices are manufactured with the express and intended purpose of selling the devices to consumers.

215. As a direct and proximate result of Defendants' breach of their implied

warranties of merchantability regarding the subject device, Plaintiff was damaged because, had he been aware of the unmerchantable condition of the subject device, he would not have acquired/purchased the subject device and would not have suffered injuries and damages from its use, for which he is entitled to recovery, including but not limited to compensatory damages, consequential damages, interest, costs, and attorneys' fees.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally, and requests compensatory and punitive damages, together with costs and interest, and any further relief as the Court deems proper.

COUNT XI
VIOLATION OF THE NEW YORK DECEPTIVE TRADE PRACTICES ACT

216. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

217. Plaintiff is a "consumer" as defined by the New York Deceptive Trade Practices Act ("DTPA"), N.Y. Gen. Bus. Law § 349, *et. seq.*, and New York common law.

218. At all relevant times, the Defendants knew or should have known of the unreasonably dangerous nature of the subject device.

219. At all relevant times, Defendants, through their labeling, promotion, and marketing of the Recalled Devices, intentionally misrepresented material facts in order to mislead consumers, including Plaintiff and his healthcare providers, that the devices were safe and effective for the treatment of sleep apnea.

220. Defendants misled and deceived consumers, including Plaintiff and his healthcare providers, regarding the substantial health risks associated with using the Recalled Devices, constituting an unlawful trade practice under the DTPA.

221. Defendants falsely represented that the Recalled Devices did not pose unreasonable and substantial risks to patients' health, and thus violated the DTPA by representing that the Recalled Devices had characteristics, uses, benefits, and/or qualities which they did not (and do not) have.

222. Defendants further violated the DTPA by failing to disclose information, relevant to the safety and efficacy of Recalled Devices, which was known at all times relevant to this Complaint.

223. Upon information and belief, Defendants' failure to disclose this information was intended to induce consumers, like Plaintiff, and healthcare professionals, like Plaintiff's healthcare providers, into purchasing Defendants' products, including Recalled Devices.

224. Plaintiff and his healthcare providers acted in reasonable reliance upon Defendants' unlawful trade practices through Defendants' misrepresentations and omissions. Had Defendants not engaged in the deceptive conduct described herein, reasonable consumers, including Plaintiff, would not have acquired/purchased the Recalled Devices, if they had known the devices posed unreasonable and substantial risks to their health.

225. All of these incomplete and inadequate disclosures regarding the safety and efficacy of the Recalled Devices, amounted to deceptive acts and/or business practices as defined by the DTPA.

226. As a direct and proximate result of the deceptive and unlawful trade practices of Defendants, Plaintiff suffered and will continue to suffer damages for which he is entitled to recovery, including but not limited to compensatory damages, treble or per-violation damages, attorneys' fees, and all other damages cognizable under law.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, and severally, and requests compensatory and punitive damages, together with costs and interest, and any further relief as the Court deems proper.

COUNT XII
VIOLATION OF PENNSYLVANIA'S UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION LAW

227. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

228. Plaintiff purchased the subject device from Defendants for personal purposes, as set forth in § 201-9.2 of Pennsylvania's Unfair Trade Practices and Consumer Protection Law ("UTPCPL").

229. At all relevant times, Defendants, through their labeling, promotion, and marketing of the Recalled Devices, intentionally engaged in unfair and deceptive acts or

practices by misrepresenting the characteristics and benefits of the Recalled Devices and misrepresenting their standard, quality, and/or grade.

230. Defendants further violated the UTPCPL by misleading and deceiving consumers, including Plaintiff and his healthcare providers, regarding the substantial health risks associated with using the Recalled Devices, creating a likelihood of confusion and of misunderstanding about the safety of the device at issue.

231. Plaintiff and his healthcare providers acted in reasonable reliance upon Defendants' unlawful trade practices through Defendants' misrepresentations and omissions. Had Defendants not engaged in the deceptive conduct described herein, reasonable consumers, including Plaintiff, would not have acquired/purchased the Recalled Devices, if they had known the devices posed unreasonable and substantial risks to their health.

232. All of these incomplete and inadequate disclosures regarding the safety and efficacy of the Recalled Devices, amounted to deceptive acts and/or business practices as defined by the UTPCPL.

233. As a direct and proximate result of the deceptive and unlawful trade practices of Defendants, Plaintiff suffered and will continue to suffer damages for which he is entitled to recovery, including but not limited to compensatory damages, treble damages, attorneys' fees, and all other damages cognizable under law.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them,

individually, jointly, and severally, and requests compensatory and punitive damages, together with costs and interest, and any further relief as the Court deems proper.

PUNITIVE DAMAGES

234. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

235. Defendants' misconduct described herein consisted of gross negligence, recklessness, oppression, fraud, and/or malice, and was done with advance knowledge, willful and wanton disregard for the safety and health of Plaintiff and others, and/or ratification by Defendants' officers, directors, and/or managing agents.

236. Despite their knowledge of the Recalled Devices' propensity to cause cancer and other serious injuries, Defendants chose profits over the safety of American citizens suffering with sleep apnea and other similar conditions when they created and marketed a device posing significant health risks.

237. Despite having substantial information about the Recalled Devices' serious and unreasonable side effects, Defendants intentionally and recklessly failed to adequately warn the public, physicians, and the medical community.

238. Further, despite having substantial information about the Recalled Devices'serious and unreasonable side effects, including reports from consumers who wereexperiencing serious injuries associated with the use of the devices, Defendants delayed for a period of years in making the decision to pull the devices from the market.

239. Defendants also chose to remain ignorant as to *why* the Recalled Devices had a propensity to cause cancer and other serious injuries. Defendants did not perform or did not document any further investigation or testing. Defendants did not conduct a health hazard evaluation or risk analysis, and Defendants did not conduct a design review of the issue.

240. Defendants' decision to remain ignorant of the risks presented by the Recalled Devices (and how to prevent or reduce the risk) was done deliberately and with a conscious indifference to the health and safety of the millions of patients actually using Recalled Devices.

241. Instead of deciding to better understand this failure mode and to warn the public, Defendants downplayed and recklessly disregarded their knowledge of the defective nature of the Recalled Devices' potential for causing serious injuries.

242. Defendants chose to do nothing to warn the public about serious and undisclosed side effects with the Recalled Devices.

243. Defendants recklessly failed to warn and adequately instruct physicians, including Plaintiff's physician, regarding the increase in reports from consumers who were experiencing serious injuries associated with the use of the Recalled Devices.

244. Consequently, Defendants are liable for punitive damages in an amount to be determined by the jury.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against the Defendants jointly and severally for damages, including punitive damages if applicable, to which he is entitled by law, as well as all costs of this action, interest and attorneys' fees, to the full extent of the law, whether arising under the common law and/or statutory law, including:

a. Judgment for Plaintiff and against Defendants;

b. Damages to compensate Plaintiff for his injuries, economic losses and pain and suffering sustained as a result of the use of Defendants' subject device;

c. Pre and post judgment interest at the lawful rate;

d. Punitive damages, if applicable, on all applicable Counts as permitted by the law;

e. A trial by jury on all issues of the case;

f. An award of attorneys' fees; and

g. For any other relief this Court may deem equitable and just, or that may be available under the law of another forum to the extent the law of another forum is applied, including but not limited to all relief prayed for in this Complaint and in the foregoing Prayer for Relief.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all counts and as to all issues.

Dated: December 29, 2021

Respectfully Submitted,

/s/ Ben C. Martin

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