UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA
MIDDLE DIVISION

NICK GREENHAW,	)	
	)	
Plaintiff,	)	
	)	**JURY TRIAL DEMANDED**
vs.	)	
	)	
KONINKLIJKE PHILIPS ELECTRONICS N.V., PHILIPS NORTH AMERICA LLC, PHILIPS HEALTHCARE INFORMATICS, INC., and PHILIPS RS NORTH AMERICA LLC, f/k/a RESPIRONICS, INC.,	)	**CIVIL ACTION FILE NO.:_____**
	)	
Defendants.	)	

COMPLAINT FOR DAMAGES

Plaintiff Nick Greenhaw ("Plaintiff") by and through undersigned counsel, brings this action against Koninklijke Philips N.V. ("Royal Philips"), Philips North America LLC ("Philips NA"), Philips Healthcare Informatics, Inc. ("Philips Health"), and Philips RS North America LLC, f/k/a Respironics, Inc. ("Philips RS") (collectively, "Defendants" or "Philips"), and makes the following allegations based upon information, attorney investigation and belief.

INTRODUCTION

1. Plaintiff brings this action for injuries caused from the use of a defective Continuous Positive Airway Pressure (CPAP) device manufactured by Philips, which contained polyester-based polyurethane sound abatement foam ("PE-PUR Foam").

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

3. On June 14, 2021, Royal Philips issued a recall in the United States of its CPAP, Bi-Level PAP, and mechanical ventilator devices containing PE-PUR Foam, because Philips had determined that: (a) the PE-PUR Foam was at risk for degradation into particles that may enter the devices' pathway and be ingested or inhaled by users and (b) the PE-PUR Foam may off-gas certain chemicals during operation. Philips further disclosed in its Recall Notice that, "these issues can result in serious injury which can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment."

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

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

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

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

8. On June 30, 2021, the U.S. Food and Drug Administration (FDA) issued a public notification alerting customers and health care providers of the Philips' CPAP safety recall. The FDA's announcement reiterated that "[t]he polyester-based polyurethane (PE-PUR) sound abatement foam, which is used to reduce sound and vibration in these affected devices, may break down and potentially enter the device's air pathway" and "black debris from the foam or certain chemicals released into the device's air pathway may be inhaled or swallowed by the person using the device." The FDA also warned that "[b]reathing in chemicals or swallowing small pieces of foam that has broken apart could potentially result in serious injury, which can be life-threatening, cause permanent impairment, and require medical intervention to prevent permanent injury."

9. In July of 2021, the FDA identified the Philips CPAP problem as a Class I recall, the most serious type of recall.

10. On November 9, 2021, the FDA completed an inspection of Philips' Murrysville, Pennsylvania-based manufacturing facility in response to the recall. The purpose of the FDA's inspection was to determine what may have caused the PE-PUR foam issues and to assess Philips' adherence to the FDA's quality standards and requirements.

11. Following the November 9 inspection, the FDA issued an inspection closeout report (FDA Form 483) laying out the FDA's initial observations. The FDA Form 483 pointed out that, dating back to at least 2015, Philips knew about a preventative maintenance servicing procedure implemented by another Philips' entity related to foam degradation issues and complaints. However, despite having this information, Philips did not perform or document any further

investigation, health hazard evaluation, risk analysis, or design review on the issue. The FDA Form 483 noted there were at least 14 instances between April 1, 2016 and January 22, 2021, where Philips was aware of potential foam degradation problems with various sleep and respiratory care devices, but failed to perform an adequate risk analysis within an appropriate time frame.

12. On November 12, 2021, the FDA issued an update of its June 2021 Recall Notice. Among other things, the FDA's updated notice listed several of the potential risks caused by PE-PUR foam and off-gassing of chemicals released by the foam including:

a) Irritation to the skin, eyes, nose, and respiratory tract;

b) Inflammatory response;

c) Hypersensitivity reaction;

d) Headache;

e) Dizziness;

f) Asthma; and

g) Toxic and cancer-causing effects.

13. Since Philips' April 2021 announcement, the FDA has received over 3,000 Medical Device Reports ("MDRs") of adverse events related to foam breakdown (degradation), including cancer, pneumonia, asthma, other respiratory problems, infection, headache, cough, dyspnea (difficulty breathing), dizziness, nodules, and chest pain.

14. In or around 2011, Plaintiff Nick Greenhaw purchased and began using a Philips' "System One" REMstar Auto with A-Flex CPAP machine. He used the Philips' System One CPAP machine on a regular basis for approximately 9 years. In 2020, Plaintiff was diagnosed with bladder cancer and was forced to undergo surgery to remove his bladder.

15. Plaintiff seeks to recover damages based on, *inter alia*, Philips' numerous violations of law associated with its manufacture, marketing and sale of the CPAP device used by Plaintiff (hereafter "Recalled Device(s)").

PARTIES

16. Plaintiff Nick Greenhaw is a resident of Ashville, Alabama.

17. Defendant Philips RS North America LLC (formerly Respironics, Inc.) is a Delaware corporation with its principal place of business located at 1001 Murry Ridge Lane, Murrysville, PA 15668.

18. Defendant Philips North America LLC is a Delaware LLC with its principal place of business at 222 Jacobs Street, Cambridge MA, 02141.

19. Defendant Philips Healthcare Informatics, Inc., a division of Philips North America, LLC, is a Delaware corporation with its principal place of business at 222 Jacobs Street, Cambridge MA, 02141.

20. Defendant Koninklijke Philips N.V is a foreign corporation, with its principal place of business at Philips Center, Amstelplein 2, 1096 BC Amsterdam, The Netherlands. Royal Philips is the parent corporation of Defendants Philips NA, Philips Health and Philips RS.

21. Defendants are collectively in the business of developing, manufacturing, selling, supporting, maintaining, and servicing devices for sleep and respiratory care, including Plaintiff's Recalled Devices.

JURISDICTION AND VENUE

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

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

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

FACTUAL ALLEGATIONS

A. Continuous Positive Airway Pressure Therapy

25. 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 hose and a nasal or facemask device that delivers constant and steady air pressure to an individual's throat to help individuals breathe.

26. Sleep apnea is a common sleep disorder characterized by repeated interruptions in breathing 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.

27. Despite the brevity of the interruptions, the sleep cycle disruption caused by sleep apnea can significantly impact a person's lifestyle, health, and overall well-being. 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.

B. Philips' Sleep and Respiratory Care Devices

28. Philips offers three types of sleep and respiratory care machines: CPAP machines, BiPAP bi-level machines, and mechanical ventilators.

29. Philips developed, marketed, and sold a variety of CPAP, Bi-Level PAP respiratory devices, and mechanical ventilators under the "Sleep & Respiratory Care" segment of its business designed to assist individuals with a number of sleep, breathing, and respiratory conditions, including obstructive sleep apnea, central sleep apnea, complex sleep apnea syndrome, and Chronic Obstructive Pulmonary Disease (COPD), as well as to assist those individuals requiring invasive and non-invasive ventilators for acute and sub-acute hospital environments.

30. Philips advertises itself as a trusted brand and "global leader in the Sleep and Respiratory markets."[1]

[1] https://www.philips.ca/healthcare/solutions/sleep-and-respiratory-care (accessed on January 9, 2022)

31. Philips' branding promises consumers that they will "[b]reathe easier, [and] sleep more naturally[.]"[2]

32. Philips further assures consumers that its "sleep therapy systems are designed with the needs of care practitioners and patients in mind," and that its "quality systems reflect [Philips'] commitment to providing exceptional therapy," among other things.[3]

33. Philips' CPAP, BiPAP and mechanical ventilators can cost several hundred, even thousands, of dollars per machine.

34. Philips has sold millions of these devices in the United States.

C. Philips Sleep & Respiratory Care Devices Endangered Users

35. On April 26, 2021, in its Quarterly Report for Q1 2021, Philips disclosed for the first time, under a section entitled "Regulatory Update," that device user reports had led to a discovery that the type of PE-PUR Foam Philips used to minimize noise in several CPAP and Bi-Level PAP respirators and mechanical ventilators posed Health Risks to its users. 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."

36. Seven weeks later, on June 14, 2021, Philips announced a recall of numerous models of CPAP and Bi-Level PAP devices, as well as a variety of its mechanical ventilators "to address identified potential health risks related to the polyester-based polyurethane (PE-PUR) sound abatement foam component in these devices." Specifically, Philips announced that it had determined that the "PE-PUR foam may degrade into particles which may enter the device's air

[2] https://www.usa.philips.com/healthcare/e/respironics (accessed on January 9, 2022).

[3] *Id.*

pathway and be ingested or inhaled by the user, and the foam may off-gas certain chemicals." In total, Philips announced that "[b]etween 3 million and 4 million" devices are targeted in the recall.

37. The long list of CPAP, BiPAP, and ventilator devices recalled by Philips includes the Recalled Device used by Plaintiff.

38. According to Philips, the PE-PUR Foam used in Recalled Devices puts users at risk of suffering from: "[i]rritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (e.g., kidneys and liver) and toxic carcinogenic affects."

39. Philips reported to physicians that PE-PUR Foam particles "may cause irritation and airway inflammation, and this may be particularly important for patients with underlying lung diseases or reduced cardiopulmonary reserve."

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

41. Philips announced that it has received reports of specific complaints from users of Recalled Devices who suffered from "headache[s], upper airway irritation, cough, chest pressure and sinus infection."

D. The Health Risks Associated with Use of the Recalled Devices Renders Them Worthless

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

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

44. Recognizing this, Philips issued the following advice to patients using any of the Recalled Devices: "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."[4] "For patients using life-sustaining mechanical ventilator devices: DO NOT discontinue or alter prescribed therapy, without consulting physicians to determine appropriate next steps."[5]

45. As a result of the above, Plaintiff will have to undertake considerable expense replacing his Recalled Device.

E. Philips Unreasonably Delayed its Recall

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

[4] https://www.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/philips-recall-faqs-for-dme-hcp.pdf.pdf (accessed January 30, 2022).

[5] *Id.*

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

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

48. According to the FDA's recent Form 483, Philips knew about a preventative maintenance servicing procedure implemented by another Philips entity related to foam degradation issues and complaints dating back to at least 2015. Furthermore, the FDA found at least 14 instances between April 2016 and January 2021 where Philips was aware of potential foam degradation problems with various sleep and respiratory care devices.

49. At a minimum, as a result of user reports, Defendants were aware of the off-gassing and degradation of the PE-PUR Foam used in the Recalled Devices at some point prior to the recall yet continued to manufacture and sell the Recalled Devices with such awareness. During this period, 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 development of serious adverse health effects, including organ failure and cancer.

F. Plaintiff Nick Greenhaw

50. Plaintiff Nick Greenhaw is resident of Ashville, Alabama.

51. Plaintiff purchased his Recalled Device, a Philips' "System One" REMstar Auto with A-Flex CPAP machine, in or around 2011 for treatment of sleep apnea. He used the CPAP machine on a nightly basis for approximately 9 years.

52. In or around February 2020, Plaintiff experienced bleeding while urinating.

53. Several weeks later, he was diagnosed with bladder cancer.

54. Shortly after his bladder cancer diagnosis, Plaintiff had surgery to remove his bladder and prostate.

55. Since his surgery, Plaintiff has been in and out of the hospital on a regular basis.

56. Plaintiff has suffered, and continues to suffer, significant hardship from both the bladder cancer itself and the surgeries that followed.

57. Plaintiff had to quit his job because of these significant health problems.

58. All of the health risks, injuries and damages discussed in Paragraphs 52 through 57 above are collectively referred to as "Health Risks" or "Health Harms" throughout this Complaint.

59. The manuals accompanying Plaintiff's Recalled Device did not contain any language or warnings of the Health Risks associated with use of the device, such as bladder cancer or toxic or cancer-causing effects. Had Defendants informed Plaintiff or his physicians of these Health Risks, he would not have purchased the Recalled Device.

60. Without knowing of the Health Risks associated with use of the Recalled Device, Plaintiff purchased and used the Recalled Device on a regular basis to treat his sleep apnea. After learning of the Recall, Plaintiff began taking steps to secure a replacement device and stopped using the Recalled Device.

TOLLING AND ESTOPPEL

A. Discovery Rule Tolling

61. Plaintiff had no way of knowing about Philips' conduct with respect to the Health Risks associated with the use of the Recalled Device.

62. Plaintiff, through the exercise of reasonable care, could not 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.

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

B. Fraudulent Concealment Tolling

64. By failing to provide immediate notice of the adverse Health Risks associated with continued use of the Recalled Device, Philips concealed its conduct and the existence of the claims asserted herein from Plaintiff.

65. Upon information and belief, Philips intended its acts to conceal the facts and claims 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 discovered Defendants' conduct. For this reason, any statute of limitations that otherwise may apply to the claims of Plaintiff should be tolled.

CLAIMS FOR RELIEF

COUNT I
ALABAMA EXTENDED MANUFACTURER'S LIABILITY DOCTRINE – DESIGN DEFECT

66. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs 1 through 65 as if fully stated herein.

67. Plaintiff alleges that the subject devices made the basis of this action were defective and unreasonably dangerous. As a result thereof, Plaintiff brings this products liability claim against Defendants for defective design pursuant to the Alabama Extended Manufacturer's Liability Doctrine.

68. At all relevant times, Defendants engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing, and promoting the Recalled Devices, including the subject devices, which are defective and unreasonably dangerous to consumers, including Plaintiff, thereby placing the subject devices into the stream of commerce. These actions were under the ultimate control and supervision of Defendants.

69. At all relevant times, Defendants designed, researched, developed, manufactured, produced, tested, advertised, labeled, promoted, marketed, sold, and distributed the Recalled Devices, including the subject devices used by Plaintiff, as described herein.

70. At all relevant times, Defendants' Recalled Devices including the subject devices were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by the public, including Plaintiff.

71. At all relevant times, Defendants' Recalled Devices, including the subject devices reached the intended consumers, handlers, and users or other persons coming into contact with these products within this judicial district and throughout the United States, including Plaintiff, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed and sold the Recalled Devices within this judicial district and aimed at a consumer market within this judicial district. Defendants were at all relevant times involved in the retail and promotion of the Recalled Devices marketed and sold in this judicial district.

72. Defendants' Recalled Devices, including the subject devices as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants, were defective in design and formulation in that, when they left the control of

Defendants' manufacturers and/or suppliers, they were unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would contemplate.

73. Defendants' Recalled Devices, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants, were defective in design and formulation in that, when they left the hands of Defendants' manufacturers and/or suppliers, the foreseeable risks exceeded the alleged benefits associated with their design and formulation.

74. At all relevant times, Defendants knew or had reason to know that the Recalled Devices, including the subject devices were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

75. Therefore, at all relevant times, Defendants' Recalled Devices, including the subject devices as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold and marketed by Defendants were defective in design and formulation, in one or more of the following ways:

a) When placed in the stream of commerce, Defendants' Recalled Devices, including the subject devices were defective in design and formulation, and, consequently, dangerous to an extent beyond that which an ordinary consumer would contemplate;

b) When placed in the stream of commerce, Defendants' Recalled Devices, including the subject devices were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer, respiratory conditions and other serious illnesses when used in a reasonably anticipated manner;

c) When placed in the stream of commerce, Defendants' Recalled Devices, including the subject devices contained unreasonably dangerous design defects and were not reasonably safe when used in a reasonably anticipated or intended manner;

d) Defendants did not sufficiently test, investigate, or study the Recalled Devices, including the subject devices and, specifically, the devices have a PE-PUR foam that may degrade into particles that enter the device's air pathway and be ingested or inhaled by the user and the foam may off-gas certain chemicals.

e) Exposure to Defendants' Recalled Devices, including the subject devices presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the products;

f) Defendants knew or should have known at the time of marketing the Recalled Devices, including the subject devices, that use of the subject devices could result in cancer and other severe illnesses and injuries;

g) Defendants did not conduct adequate post-marketing surveillance of their Recalled Devices; and

h) Defendants could have employed safer alternative designs and formulations making them less prone to causing cancer and other adverse health conditions.

76. Plaintiff was not able to discover, nor could he 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 devices in a way as to make the risk of harm or injury outweigh any benefits.

77. At all times relevant hereto, Plaintiff used and/or was exposed to the use of Defendants' Recalled Devices, including the subject devices, in an intended or reasonably foreseeable manner without knowledge of the devices' dangerous characteristics.

78. The harm caused by Defendants' Recalled Devices, including the subject devices, far outweighed their benefit, rendering Defendants' product dangerous to an extent beyond that which an ordinary consumer would contemplate. Defendants' Recalled Devices, including the subject devices, were and are more dangerous than alternative products, and Defendants could have designed the Recalled Devices, including the subject devices, to make them less dangerous. Indeed, at the time Defendants designed the Recalled Devices, including the subject devices, the state of the industry's scientific knowledge was such that a less risky design or formulation was attainable.

79. At the time the Recalled Devices, including the subject devices left Defendants' control, there was a practical, technically feasible and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' Recalled Devices.

80. Defendants' defective design of the Recalled Devices, including the subject devices was willful, wanton, malicious, and conducted with reckless disregard for the health and safety of users of the Recalled Devices, including Plaintiff.

81. Therefore, as a result of the unreasonably dangerous condition of their Recalled Devices, including the subject devices Defendants are liable to Plaintiff pursuant to the Alabama Extended Manufacturer's Liability Doctrine.

82. The defects in Defendants' Recalled Devices, including the subject devices, were substantial and contributing factors in causing Plaintiff's injuries, and, but for Defendants' misconduct and omissions, Plaintiff would not have sustained these injuries.

83. Defendants' conduct, as described above, was reckless and wanton. Defendants risked the lives of consumers and users of its products, including Plaintiff, with knowledge of the safety problems associated with the Recalled Devices, and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, warn or inform the unsuspecting public. Defendants' reckless and wanton conduct warrants an award of punitive damages.

84. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects that led to his bladder cancer, as well as other severe and 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/or medications, and fear of redeveloping cancer.

85. 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.

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
ALABAMA EXTENDED MANUFACTURER'S LIABILITY DOCTRINE – FAILURE TO WARN

86. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs 1 through 65 as if fully stated herein.

87. Plaintiff alleges that Defendants failed to warn about the dangers of its Recalled Devices, including the subject devices. As a result thereof, Plaintiff brings this products liability claim against Defendants for failure to warn pursuant to the Alabama Extended Manufacturer's Liability Doctrine.

88. At all relevant times, Defendants engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing, and promoting their Recalled Devices, including the subject devices, which are defective and unreasonably dangerous to consumers, including Plaintiff, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of the products. These actions were under the ultimate control and supervision of Defendants.

89. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold the Recalled Devices, including the subject devices within this judicial district and aimed at a consumer market and medical professionals. Defendants were at all relevant times involved in the retail and promotion of the Recalled Devices marketed and sold in in this judicial district.

90. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce its Recalled Devices, including the subject devices, and in the course of same, directly advertised or marketed the products to consumers, physicians and end users, including Plaintiff and his

physician, and therefore had a duty to warn of the risks associated with the use of their Recalled Devices.

91. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure its Recalled Devices, including the subject devices, did not cause users and consumers to suffer from unreasonable and dangerous risks.

92. Defendants had a continuing duty to warn Plaintiff and his physician of dangers associated with Recalled Devices, including the subject devices. Defendants, as manufacturers, sellers, and distributors of medical devices, are held to the knowledge of an expert in the field.

93. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of their Recalled Devices because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products.

94. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety or to minimize the dangers to users and consumers of its Recalled Devices to those who would foreseeably use or be harmed by Defendants' Recalled Devices, including the subject devices, including Plaintiff.

95. Even though Defendants knew or should have known that its Recalled Devices posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure. Defendants omitted and downplayed the significantly increased risks of cancer and other health risks with the Recalled Devices including the subject devices that

Defendants knew or should have known from previous testing and research even prior to the Recalled Devices' FDA clearance.

96. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein, and Defendants failed to adequately warn consumers, i.e., the reasonably foreseeable users, of the risks of exposure to its products.

97. At all relevant times, Defendants' Recalled Devices, including the subject devices, reached the intended consumers, handlers, and users or other persons coming into contact with these products within this judicial district and throughout the United States, including Plaintiff, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

98. Plaintiff was exposed to Defendants' Recalled Devices, including the subject devices, without knowledge of their dangerous characteristics.

99. At all relevant times, Plaintiff used Defendants' Recalled Devices, including the subject devices, while using them for their intended or reasonably foreseeable purposes, without knowledge of their dangerous characteristics.

100. Plaintiff could not have reasonably discovered the defects and risks associated with the Recalled Devices, including the subject devices, prior to use. Plaintiff relied upon the skill, superior knowledge, and judgment of Defendants to know about and disclose serious health risks associated with using Defendants' products.

101. Defendants knew or should have known that the minimal warnings disseminated with their Recalled Devices, including the subject devices, were inadequate, failed to communicate adequate information on the dangers and safe use/exposure, and failed to communicate warnings

and instructions that were appropriate and adequate to render the products safe for their ordinary, intended and reasonably foreseeable uses.

102. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiff to utilize the products safely and with adequate protection. Instead, Defendants disseminated information that was inaccurate, false and misleading, and which failed to communicate accurately or adequately the convey the risk of injuries with use of the Recalled Devices; continued to aggressively promote the safety and efficacy of its products, even after they knew or should have known of the unreasonable risks from use or exposure; and concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of the Recalled Devices, including the subject devices.

103. This alleged failure to warn is not limited to the information contained on the Recalled Devices' labeling. The Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with its Recalled Devices including the subject devices through other non- labeling mediums, i.e., promotion, advertisements, public service announcements, and/or public information sources. But the Defendants did not disclose these known risks through any medium.

104. Pursuant to the Alabama Extended Manufacturer's Liability Doctrine, Defendants are liable to Plaintiff for injuries caused by their negligent or willful failures, as described above, to provide adequate warnings or other clinically relevant information and data regarding the appropriate use of its products and the risks associated with the use of the Recalled Devices.

105. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with the Recalled Devices, including the subject

devices, Plaintiff could have avoided the risk of developing injuries including cancer and could have obtained or used alternative medical equipment.

106. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects that led to his bladder cancer, as well as other severe and 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/or medications, and fear of redeveloping cancer.

107. 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.

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
NEGLIGENCE

108. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs 1 through 65 as if fully stated herein.

109. Defendants had a duty to exercise reasonable care in designing, developing, researching, testing, manufacturing, marketing, supplying, promoting, selling, and distribution of the Recalled Devices, including the subject devices.

110. Defendants knew or should have known that using the subject devices created a significantly increased risk of cancer, among other health harms.

111. 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 without sufficient knowledge as to the significance of cancer risks;

e) Defendants failed to exercise reasonable care in designing the Recalled Devices in a manner which was dangerous to the users;

f) Defendants negligently manufactured the Recalled Devices in a manner which was dangerous to the users;

g) Defendants failed to exercise reasonable care when they collectively decided to conceal information concerning cancer risks.

112. Additionally, Defendants under-reported, underestimated, and downplayed the serious dangers of the Recalled Devices' association with cancer and other health harms.

113. Defendants negligently compared the safety risk and/or dangers of the subject devices with other forms of treatment for sleep apnea and similar conditions.

114. Defendants also failed to warn Plaintiff, prior to actively encouraging the sale of the subject devices, 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.

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

116. Once Defendants gained additional information about the Recalled Devices' association with cancer, it failed to update its warnings and thereafter accompany the Recalled Devices with adequate warnings regarding cancer.

117. 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 to physicians and patients, including the Plaintiff.

118. 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.

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

120. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects that led to his bladder cancer, as well as other severe and 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/or medications, and fear of redeveloping cancer.

121. 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.

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

122. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs 1 through 65 as if fully stated herein.

123. 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 devices that Plaintiff used.

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

125. 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 devices.

126. 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,

hypersensitivity, nausea, vomiting, and toxic 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.

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

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

129. 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.

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

131. Plaintiff was injured as a direct and proximate result of Defendants' failure to warn and instruct because he would not have used or purchased the subject devices 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, hypersensitivity, nausea, vomiting, and cancer.

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

133. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects that led to his bladder cancer, as well as other severe and 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/or medications, and fear of redeveloping cancer.

134. 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.

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
NEGLIGENT MANUFACTURING

135. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs 1 through 65 as if fully stated herein.

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

137. The Defendants had a duty to exercise reasonable care in the manufacturing, assembling, inspecting and packaging of the subject devices.

138. The Defendants knew or, by the exercise of reasonable care, should have known, use of the subject devices carelessly manufactured, assembled, inspected, and packaged was dangerous, harmful and injurious when used by Plaintiff in a reasonably foreseeable manner.

139. 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 devices improperly manufactured assembled, inspected, and packaged.

140. Without limitation, the Defendants breached their duty to exercise reasonable care in manufacturing, assembling, inspecting, and packaging the Recalled Devices, including the subject devices by their:

a) Failure to follow Good Manufacturing Practices ("GMPs");

b) Failure to adequately inspect/test the Recalled Devices during the manufacturing process;

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/test the purity of airflow through the Recalled Devices' airways, especially after the devices have aged.

141. A reasonable manufacturer under the same or similar circumstances would have implemented appropriate manufacturing procedures to better ensure the quality of their devices.

142. Plaintiff was injured as a direct and proximate result of Defendants' failure to use reasonable care in the manufacturing, assembling, inspecting, and packaging of the subject devices as described herein.

143. The Defendants' negligent manufacturing, assembling, inspecting, and packaging of the subject devices was a substantial factor in causing Plaintiff's harms.

144. 1As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects that led to his bladder cancer, as well as other severe and 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/or medications, and fear of redeveloping cancer.

145. 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.

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
NEGLIGENT MISREPRESENTATION

146. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs 1 through 65 as if fully stated herein.

147. Defendants had a duty to exercise reasonable care to those whom they provided information about the Recalled Devices and to all those relying on the information provided, including Plaintiff, his healthcare providers, and the public in general that the devices had been tested and found to be safe and effective for treating sleep apnea.

148. 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.

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

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

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

152. Defendants' false representations that the Recalled Devices were safe for consumers and their failure to disclose material past and existing facts of the Recalled Devices' risk of cancer were made or omitted with the intent to induce Plaintiff to rely upon those facts or omissions.

153. Plaintiff was unaware and did not know that the subject devices were 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.

154. Plaintiff justifiably relied upon the false representations of Defendants.

155. Had Defendants reasonably and purposely 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.

156. As a direct and proximate result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including bladder cancer, as well as other severe and 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/or medications, and fear of redeveloping cancer.

157. 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.

158. 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
BREACH OF EXPRESS WARRANTY

159. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs 1 through 65 as if fully stated herein.

160. Philips marketed and sold the Recalled Devices into the stream of commerce with the intent that the Recalled Devices would be purchased by Plaintiff.

161. Philips expressly warranted, advertised, and represented to Plaintiff that the Recalled Devices were safe and appropriate for human use.

162. Philips made these express warranties regarding the recalled Devices' quality and fitness for use in writing through its website, advertisements, and marketing materials, and on the

Recalled Devices' packaging and labels. These express warranties became part of the basis of the bargain that Plaintiff entered in to upon purchasing the Recalled Devices.

163. Philips' advertisements, warranties, representations, and omissions regarding Health Risks associated with the Recalled Devices, were made in connection with the sale of the Recalled Devices to Plaintiff. Plaintiff relied on Philips' advertisements, warranties, representations, and omissions regarding the Recalled Devices in deciding whether to purchase and use Philips' Recalled Devices.

164. Philips' Recalled Devices do not conform to Philips' advertisements, warranties, representations, and omissions in that they are not safe, healthy, and appropriate for human use, and pose risks of Health Harms and other serious injuries and damages.

165. Philips therefore breached its express warranties by placing Recalled Devices into the stream of commerce and selling them to consumers, when their use posed Health Risks, had dangerous effects and were unsafe, rendering these products unfit for their intended use and purpose, and unsafe and unsuitable for consumer use as marketed by Philips. These associated health effects substantially impair the use, value, safety of the Recalled Devices, and render them worthless.

166. Philips was aware, or should have been aware, of the toxic or dangerous health effects of the use of the Recalled Devices, but nowhere on the package labeling or package inserts or on Philips' websites or other marketing materials did Philips warn Plaintiff that he was at risk of developing adverse health effects as a result of the dangerous PE-PUR Foam used in the Recalled Devices.

167. Instead, Philips concealed the dangerous health effects of the PE-PUR Foam used in the Recalled Devices and deceptively represented that these products were safe, healthy, and

appropriate for use. Philips thus utterly failed to ensure that the material representations they were making to consumers were true.

168. The adverse health effects associated with use of the Recalled Devices existed when they left Philips' possession or control and were sold to Plaintiff. The dangers associated with use of the Recalled Devices were undiscoverable by Plaintiff at the time of purchase of the Recalled Devices.

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

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

171. Philips' affirmations of fact and promises and its omissions were material, and Plaintiff reasonably relied upon such representations and omissions in purchasing and using the Recalled Devices.

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

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

174. As a direct and proximate result of Philips' breaches of express warranty, Plaintiff has been damaged because he did not receive the products as specifically warranted by Philips. Plaintiff did not receive the benefit of the bargain and suffered damages at the point of sale stemming from his overpayment for the Recalled Devices.

175. Plaintiff seeks actual damages, attorneys' fees, costs, and any other just and proper relief available thereunder for Philips' failure to deliver goods conforming to their express warranties and resulting breach.

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 IMPLIED WARRANTY OF MERCHANTABILITY

176. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs 1 through 65 as if fully stated herein.

177. Defendants are merchants engaging in the sale of goods to Plaintiff.

178. There was a sale of goods from Defendants to Plaintiff.

179. At all times mentioned herein, Defendants manufactured or supplied the Recalled Devices, and prior to the time the Recalled Devices were purchased by Plaintiff, Philips impliedly warranted to them that the Recalled Devices were of merchantable quality, fit for their ordinary use, and conformed to the promises and affirmations of fact and omissions made on the Recalled Devices' labels and packaging, including that the Recalled Devices were safe and appropriate for human use. Plaintiff relied on Philips' promises and affirmations of fact and omissions when he purchased and used the Recalled Devices.

180. Contrary to these representations and warranties, the Recalled Devices were not fit for their ordinary use and did not conform to Philips' affirmations of fact and promises and omissions because use of the Recalled Devices is accompanied by the risk of adverse health effects, which does not conform to the labels and packaging of these devices.

181. Defendants breached their implied warranties by selling Recalled Devices that failed to conform to the promises or affirmations of fact made on the packaging or label, as use of each Recalled Devices was accompanied by the risk of developing adverse health effects that do not conform to the packaging or label.

182. Defendants were on notice of this breach, as it was made aware of the adverse health effects accompanying use of the Recalled Devices through user reports submitted to Philips and trough lab testing.

183. Privity exists because Defendants impliedly warranted to Plaintiff through the warranting, packaging, advertising, marketing, and labeling that the Recalled Devices were natural, and suitable for use to treat health conditions, and made no mention of the attendant Health Risks associated with use of the Recalled Devices.

184. As a direct and proximate result of Defendants' conduct, Plaintiff has suffered actual damages in that the Recalled Device he purchased is worth less than the price he paid and which he would not have purchased at all had he known of the attendant Health Risks associated with the use of each Recalled Device.

185. Plaintiff seeks actual damages, attorneys' fees, costs, and any other just and proper relief available thereunder for Defendants' failure to deliver goods conforming to their implied warranties and resulting breach.

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
UNJUST ENRICHMENT

186. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs 1 through 65 as if fully stated herein.

187. Plaintiff conferred substantial benefits on Philips through his purchase of the Recalled Devices. Philips knowingly and willingly accepted and enjoyed these benefits.

188. Philips either knew or should have known that the payments rendered by Plaintiff and was given with the expectation that the Recalled Devices would have the qualities, characteristics, and suitability for use represented and warranted by Philips. As such, it would be inequitable for Philips to retain the benefit of the payments under these circumstances.

189. Philips' acceptance and retention of these benefits under the circumstances alleged herein make it inequitable for Philips to retain the benefits without payment of the value to Plaintiff.

190. Plaintiff is entitled to recover from Philips all amounts wrongfully collected and improperly retained by Defendants, plus interest thereon.

191. Plaintiff seeks actual damages, attorneys' fees, costs, and any other just and proper relief available under the laws.

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
VIOLATION OF THE ALABAMA DECEPTIVE TRADE PRACTICES ACT, Ala. Code §§ 8-19-1, *et seq.*

192. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs 1 through 65 as if fully stated herein.

193. Plaintiff is a "consumer" as defined in the Ala. Code § 8-19-3(2) in that Plaintiff acquired/purchased, other than for purposes of resale, goods from the Defendants for personal use.

194. Defendants' actions in marketing, advertising, and otherwise making public representations about the subject device constitute "trade" as defined by Ala. Code § 8-19-3(8) as they were actions that created, altered, repaired, furnished, made available, provided information about, or, directly or indirectly, solicited or offered for or effectuated a sale, lease, or transfer of consumer goods that affected the people of Alabama.

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

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

197. Defendants mislead consumers regarding the substantial health risks associated with using the Recalled Devices constituting a misrepresentation of unlawful trade practices under Ala. Code §§ 8-19-5(7) and (27).

198. Defendants falsely represented themselves when claiming that the Recalled Devices did not pose unreasonable and substantial risks to their health, and thus violated Ala. Code § 8-19-5(7) by marketing their goods or services to be of a particular standard, quality, grade, style, when they are/were in fact another.

199. Plaintiff acted in reasonable reliance upon Defendants' deceptive trade practices through Defendants' misrepresentations and omissions. Had Defendants not engaged in the deceptive conduct described herein, reasonable consumers and Plaintiff would not have acquired/purchased the Recalled Devices if they had known the devices posed unreasonable and substantial risks to their health. Knowledge of these material factors would have highly impacted the Plaintiff's decision when first acquiring/purchasing and using the subject device.

200. Defendants omitted material facts misleading consumers about the safety and efficacy of the Recalled Devices, thus violating Ala. Code §§ 8-19-5(7) and (27).

201. As a direct and proximate result of the unlawful trade practices of Defendants, in violation of Ala. Code §§ 8-19-1, et seq., Plaintiff suffered and will continue to suffer damages for which he is entitled to recovery, including but not limited to compensatory damages, consequential damages, treble or per-violation damages, interest, costs, attorneys' fees, and all other damages cognizable under § 8-19-1.

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
FRAUD

202. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs 1 through 65 as if fully stated herein.

203. 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 consumers, such as Plaintiff.

204. Defendants knowingly made fraudulent statements regarding the safety of the Recalled Devices and the substantial Health Risks associated with using the Recalled Devices, all the while intending to deceive Plaintiff and the general public.

205. At all reasonable times, Defendants fraudulently misrepresented the Recalled Devices as safe, when in fact the devices posed unreasonable risks of substantial bodily injury.

206. Due to these and other features, the Recalled Devices are not fit for their ordinary, intended use as treatment devices for sleep apnea and similar respiratory conditions.

207. Defendants touted the Recalled Devices as safe, despite a failure to adequately research or test the devices to assess their safety prior to marketing and promoting their use.

208. Defendants further falsely represented the nature and risks associated with the Recalled Devices, and their marketing and strategy regarding the same, in general statements to the media, general public, and federal agencies.

209. Defendants' fraudulent misrepresentations and omissions were material facts that were essential to Plaintiff's decision to purchase the Recalled Device.

210. Plaintiff was unaware that Defendants were knowingly concealing these material facts, which Plaintiff relied on to his detriment.

211. By knowingly misrepresenting this material information, Defendants breached their duty to protect Plaintiff and consumers.

212. Plaintiff justifiably relied to his detriment on Defendants' fraudulent statements. Had Plaintiff been adequately informed of the material facts concealed from him regarding the

safety of the Recalled Device, and not intentionally deceived by Defendants, he would not have acquired/purchased or used the Recalled Device.

213. As a direct and proximate result of Defendants' fraudulent misrepresentations, Plaintiff suffered and continues to suffer from Health Harms and other serious 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 XII
FRAUDULENT MISREPRESENTATION

214. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs 1 through 65 as if fully stated herein.

215. Philips failed to advise Plaintiff that the Recalled Devices posed serious Health Risks to their users and Philips falsely represented to Plaintiff that the Recalled Devices were safe for human use.

216. Philips intentionally, knowingly, and recklessly made these misrepresentations and omissions to induce Plaintiff to purchase the Recalled Devices.

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

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

219. As a direct and proximate result of Philips' conduct, Plaintiff has suffered actual damages in that he purchased the Recalled Devices (a) that were worth less than the price he paid, (b) which he would not have purchased at all had he known of the Recalled Device's risks of hypersensitivity, irritation, inflammation, toxic effects, organ damage, cancer, and other Health Risks, and (c) which did not conform to the Recalled Devices' labels, packaging, advertising, and statements.

220. Plaintiff seeks actual damages, attorneys' fees, costs, and any other just and proper relief available under the laws.

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 XIII
FRAUDULENT CONCEALMENT

221. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs 1 through 65 as if fully stated herein.

222. 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.

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

224. At all reasonable times, Defendants fraudulently misrepresented the Recalled Devices as safe, when in fact the devices posed unreasonable risks of substantial bodily injury. Therefore, the devices are not fit for their ordinary and intended uses.

225. Defendants actually knew about all of the above facts.

226. 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 susceptible users.

227. Defendants further falsely represented the nature and risks associated with the Recalled Devices, and their marketing and strategy regarding the same, in general statements to the media, general public, and federal agencies.

228. Defendants' misrepresentations and omissions were material facts that were essential to Plaintiff's decision making when purchasing and using the Recalled Device.

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

230. 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.

231. 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 Recalled Device.

232. As a direct and proximate result of Defendants' fraudulent concealment, Plaintiff suffered and continues to suffer from the Health Harms and other 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 XIV
FRAUD BY OMISSION

233. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs 1 through 65 as if fully stated herein.

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

235. Philips was under a duty to disclose to Plaintiff the true quality, characteristics, ingredients and suitability of the Recalled Devices because: (a) Philips was in a superior position to know the true state of facts about its products; (b) Philips was in a superior position to know the risks associated with the use of, characteristics of, and suitability of the Recalled Devices for use by individuals; and (c) Philips knew that Plaintiff could not reasonably have been expected to learn or discover prior to purchasing the Recalled Devices that there were misrepresentations and omissions by Philips in the packaging, labels, advertising, and websites regarding the Health Risks associated with use of these devices.

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

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

238. As a direct and proximate result of Philips' conduct, Plaintiff has suffered actual damages in that he purchased the Recalled Devices (a) that were worth less than the price he paid, (b) which he would not have purchased at all had he known of the Health Risks associated with the use of the Recalled Device, and (c) which do not conform to the Recalled Device's labels, packaging, advertising, and statements.

239. Plaintiff seeks actual damages, attorneys' fees, costs, and any other just and proper relief available under the laws.

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 XV
CIVIL CONSPIRACY

240. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs 1 through 65 as if fully stated herein.

241. Defendants knowingly agreed, contrived, confederated, and/or conspired to defraud Plaintiff and consumers of the Recalled Devices regarding the true nature of the devices and their

potential to cause Plaintiff's Health Harms and other serious injuries associated with the PE-PUR foam's particles and chemicals when the devices were used in a reasonably foreseeable manner.

242. Defendants knowingly agreed, contrived, confederated, and/or conspired to defraud Plaintiff and consumers of the Recalled Devices with the purpose of maintaining the popularity and reputation of the devices and therefore maintaining high sales, at the expense of consumer safety.

243. At all relevant times, pursuant to and in furtherance of said conspiracies, Defendants performed the following overt and unlawful acts:

a) Defendants designed and sold the Recalled Devices with full knowledge that the devices were not a safe way to treat sleep apnea; and

b) Upon information and belief, despite available medical and scientific data, literature, and test reports possessed by and available to Defendants, Defendants individually, jointly, and in conspiracy with each other, fraudulently, willfully, and maliciously, to delay reporting to the public the issues and delay the product recall. In the meantime, Defendants continued to represent the Recalled Devices as safe and omitted warnings about serious side effects.

244. Plaintiff and the general public reasonably relied upon the aforementioned fraudulent representations, omissions, and concealments made by Defendants regarding the nature of the Recalled Devices.

245. Were it not for Defendants' unlawful actions to mislead the public and limit the natural dissemination of scientific research and knowledge on the dangers and harms associated with the Recalled Devices, Plaintiff and the general public could have learned of the dangers at an earlier date and potentially prevented their introduction to and use of the devices.

246. As a direct and proximate result of Defendants' overt unlawful acts regarding the nature of the Recalled Devices which were made pursuant to and in furtherance of a common scheme, and Plaintiff's reliance thereon, Plaintiff suffered and continues to suffer from the Health Harms and other 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 XVI
MEDICAL MONITORING

247. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs 1 through 65 as if fully stated herein.

248. At all relevant times, Defendants designed, manufactured, assembled, inspected, tested (or not), 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 them, such as Plaintiff.

249. Defendants have reported that users of the Recalled Devices face risks of serious injury from the degradation of PE-PUR foam contained in the Recalled Devices. Degradation of PE-PUR Foam may be caused by exposure to chemical emissions from the foam material, high heat and high humidity environments in certain regions, and cleaning methods such as ozone may accelerate potential degradation.

250. When PE-PUR Foam degrades into particles that may enter the Recalled Device's pathway and be ingested or inhaled by users of the devices, users face significantly increased risks

of serious injury that can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment. The potential risks of degraded foam exposure include: irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (e.g., kidneys and liver) and toxic carcinogenic effects.

251. The off-gassing of chemicals from the PE-PUR Foam contained in the Recalled Devices poses risks of serious injury that can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment. The potential risks of exposure to off-gassing from PE-PUR Foam include headache/dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, nausea/vomiting, toxic and carcinogenic effects.

252. The absence of visible particles does not mean that PE-PUR Foam breakdown has not already begun. Philips has reported that lab analysis of the degraded foam reveals the presence of harmful chemicals including: TDA, TDI, and DEG.[6] TDI is a powerful irritant to the mucous membranes of the eyes and gastrointestinal and respiratory tracts,[7] and has been reported to cause Occupational Asthma.[8] Exposure to TDA may result in ataxia, tachycardia, nausea, vomiting,

[6] Philips Sleep and Respiratory Care Update; Clinical information for physicians, https://www.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/philips-recall-clinical-information-for-physicians-and-providers.pdf (accessed January 23, 2022).

[7] The National Institute for Occupational Safety and Health (NIOSH) Current Intelligence Bulletin 53, *Toluene Diisocyanate (TDI) and Toluenediamine (TDA): Evidence of Carcinogenicity*, DHHS (NOISH) Publication Number 90-101 (Dec. 1989); *see also* Gunnar Skarping, *et al.*, *Biological monitoring of isocyanates and related amines: Test chamber exposure of humans to toluenediisocyanate*, Dep't of Occupational and Environmental Medicine, University Hospital, S-221 85 Lund, Sweden (1990); https://greenfuture.io/sustainable-living/spray-polyurethane-foam-toxic/.

[8] Bernstein, David I, *Occupational asthma: Definitions, epidemiology, causes, and risk factors*, Wolters Kluwer, UpToDate.com (accessed January 23, 2022).

convulsions, and respiratory depression.[9] TDA can cause chemical cyanosis (i.e., bluish discoloration of the skin) by converting hemoglobin to methemoglobin. This compound can also cause fatty degeneration of the liver.[10] TDA and TDI are potential carcinogens.[11] Repeated exposure to DEG has been associated with damage to the kidneys and renal failure.[12]

253. As a direct and proximate result of Defendants' conduct, Plaintiff has been exposed to substantially increased risks of serious injury from off-gassing and/or degradation of PE-PUR Foam in the Recalled Devices, which is beyond normal background levels of risk.

254. As a direct and proximate result of Defendants' conduct, Plaintiff has a significantly increased risk of suffering serious injury or contracting a serious latent disease and suffering further injury at an unknown date in the future. Such injuries include Plaintiff's Health Harms and/or hypersensitivity reaction, irritation, inflammation, organ damage, cancer, and other serious injuries, among others currently unknown or just being discovered.

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[9]NIOSH, *Toluene Diisocyanate (TDI) and Toluenediamine (TDA): Evidence of Carcinogenicity; see also Skarping, Biological monitoring of isocyanates and related amines: Test chamber exposure of humans to toluenediisocyanate;* https://green future.io/sustainable-living/spray-polyurethane-foam-toxic/.

[10] NIOSH, *Toluene Diisocyanate (TDI) and Toluenediamine (TDA): Evidence of Carcinogenicity.*

[11] *Id.* ("The excess cancer risk for workers exposed to TDI and TDA has not yet been quantified, but the probability of developing cancer should be decreased by minimizing exposure.").

[12] Greg M. Landry, *Diethylene glycol-induced toxicities show marked threshold dose response in rats*, Toxicology and Applied Pharmacology 282 (2015) 244-251 ("DEG has recently been involved in several mass epidemics of renal failure and death world-wide (O'Brien et al., 1998; Schier et al.,2013). DEG poisoning clinically manifests in metabolic acidosis, hepatotoxicity, renal failure, and peripheral neuropathy, with the hallmark being acute renal failure involving proximal tubule cell necrosis and cortical degeneration (Schep et al., 2009)"); Cohen, Jeffrey A., *Demyelinating Diseases of the Peripheral Nerves*, Nerves and Nerve Injuries (2015) ("When consumed DEG causes severe systemic and neurologic complications, including coma, seizures, peripheral neuropathy, and hepatorenal failure.").

255. Monitoring procedures exist that makes the early detection of damage from degraded and/or off-gassed PE-PUR Foam possible. These procedures are different from that normally recommended in the absence of the exposure. These monitoring procedures include non-routine surveillance studies, laboratory testing, and physical examinations, and would be reasonably necessary according to contemporary scientific principles.

256. Existing medical research indicates that exposure to TDI, TDA, and DEG, which Philips has found to exist in off-gassed or degraded PE-PUR Foam, can cause serious, life-threatening and permanent injuries. Philips has received reports from users of the Recalled Devices of headache, upper airway irritation, cough chest pressure and sinus infection. The exposure to the defects inherent in the Recalled Devices has occurred for users, such as Plaintiff, but the full extent of the injuries will not manifest until later in Plaintiff's life. Thus, because of Defendants' conduct, it is reasonably necessary that Plaintiff be placed under period diagnostic testing beyond that normally recommended in the absence of use of the Recalled Devices.

257. Plaintiff demands judgment against Defendants for medical monitoring damages to diagnose injuries caused by the Recalled Devices at an earlier date to allow for timely treatment and prevention of exacerbation of injuries, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems proper.

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 XVII
PUNITIVE DAMAGES

258. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs 1 through 65 as if fully stated herein.

259. Defendants' conduct described herein consisted of oppression, fraud, and/or malice, and was done with advance knowledge, conscious disregard of the safety of others, and/or ratification by Defendants' officers, directors, and/or managing agents.

260. Despite their knowledge of the Recalled Devices' propensity to cause bladder cancer, disease, and other serious injuries, Defendants chose profits over the safety of American citizens suffering with sleep apnea when they sought to create and market a device posing significant health risks.

261. 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.

262. Further, despite having substantial information about the Recalled Devices' serious and unreasonable side effects, Defendants failed to make the decision to pull the devices from the market after receiving indications and after receiving reports from consumers who were experiencing serious injuries associated with the use of the devices.

263. Defendants downplayed and recklessly disregarded their knowledge of the defective nature of the Recalled Devices' potential for causing serious injuries.

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

265. 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.

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against 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:

i. Judgment for Plaintiff and against Defendants;

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

iii. Medical monitoring damages;

iv. Damages pursuant to Ala. Code §§ 8-19-1 *et seq.*

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

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

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

viii. An award of attorneys' fees; and

ix. For any other relief as 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 reliefs 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.

This 17th day of February, 2022.

Counsel for Plaintiff