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U.S. DISTRICT COURT
N.D. OF ALABAMA

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

VICKI BAKER	)	
	)	
PLAINTIFF,	)	
	)	
v.	)	Civil Action No. _____
	)	
	)	**JURY DEMAND**
PHILIPS NORTH AMERICA LLC;	)	
PHILIPS HOLDING USA, INC.;	)	
PHILIPS RS NORTH AMERICA LLC; and	)	
KONINKELIJKE PHILIPS N.V.	)	
	)	
DEFENDANTS.	)	

COMPLAINT

Plaintiff Vicki Baker, by and through her undersigned counsel, hereby submits the following Complaint and Demand for Jury Trial against Philips North America LLC, Philips Holding USA, Inc., Philips RS North America LLC and Koninkelijke Philips N.V. and alleges the following upon personal knowledge and belief, and investigation of counsel:

INTRODUCTION

1. This is an action for personal-injury claims centering on recalled medical devices designed, marketed, promoted, manufactured, distributed, and sold by the foreign conglomerate Koninklijke Philips N.V. ("Royal Philips"). Royal Philips designs, markets, sells, operates, and controls its medical-device business through inferior subsidiary and intermediary companies and corporations, including Philips North America LLC ("Philips NA"), Philips Holding USA, Inc. ("Philips Holding"), and Philips RS North America LLC ("Philips RS"). Philips manufactures, markets, sells, and distributes a variety of products for sleep and home respiratory care. All these entities are collectively referred to as "Philips" or "Defendants."

2. This action centers on the design, marketing, manufacture, post-marketing surveillance, sale, advertising, promotion, warning, and distribution of a variety of Continuous Positive Airway Pressure ("CPAP") and Bi-Level Positive Airway Pressure ("BiPAP") devices for patients with sleep apnea. Philips also manufactures, markets, imports, sells, and distributes a variety of ventilator devices subject to the recall.

3. On or about June 14, 2021, Philips voluntarily recalled in the United States many of its CPAP, BiPAP, and mechanical ventilator devices ("Recalled Devices").

4. The Recalled Devices share one common feature that prompted the recall: PE-PUR Foam.

5. Philips made a public *Urgent Medical Device Recall*, having determined that (i) the PE-PUR Foam could degrade into particles that enter the devices' pathway and be ingested or inhaled; and (ii) the PE-PUR Foam may off-gas certain chemicals during operation. "[T]hese issues can result in serious injury which can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment," according to the *Urgent Medical Device Recall.*

6. Plaintiff Vicki Baker was prescribed and purchased one of Philips' Recalled Devices, a DreamStation CPAP machine ("SUBJECT DEVICE"), to treat her sleep apnea. Plaintiff used her SUBJECT DEVICE on a daily basis for a number of years. Plaintiff was ultimately diagnosed with lung cancer.

PARTIES, JURISDICTION, AND VENUE

7. Plaintiff Vicki Baker is a resident and citizen of Jefferson County, Alabama.

8. Following her sleep apnea diagnosis in April of 2018, Plaintiff began using her SUBJECT DEVICE on a nightly basis. Plaintiff used the SUBJECT DEVICE daily prior to being diagnosed with lung cancer.

9. Defendant Koninklijke Philips N.V. ("Royal Philips") is a public limited liability company established under the laws of The Netherlands, having its principal executive offices at Philips Center, Amstelplein 2, 1096 Amsterdam, The Netherlands. Royal Philips is the parent company of the Philips Group of healthcare technology businesses, including Connected Care businesses focusing on Sleep & Respiratory Care. Royal Philips holds directly or indirectly 100% of its subsidiaries Philips NA and Philips RS.[1] Upon information and belief, Royal Philips controls Philips NA and Philips RS in the manufacturing, selling, distributing, and supplying of the recalled CPAP, BiPAP, and mechanical ventilator devices.[2] Royal Philips can be served with process via the *Convention of the Service Abroad of Judicial and Extrajudicial Documents in Civil or Commercial Matters* ("Hague Service Convention").

10. 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

[1] Philips 2020 annual filing with the SEC, fn. 8, https://www.sec.gov/Archives/edgar/data/313216/000031321621000008/phg-exhibit8.htm (accessed November 22, 2021).
[2] Philips 2020 annual filing with the SEC, https://www.sec.gov/Archives/edgar/data/0000313216/000031321621000008/phg-20201231.htm(accessed November 22, 2021).

with its principal place of business located at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141.

11. 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.

12. 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 is a wholly-owned subsidiary of Royal Philips. Philips RS was formerly operated under the business name Respironics, Inc. ("Respironics"). Royal Philips acquired Respironics in 2008.

JURISDICTION AND VENUE

13. At all times pertinent to this Complaint, Defendants were and are in the business of placing medical devices into the stream of commerce by designing, manufacturing, marketing, testing, training, promoting, packaging, labeling, advertising, and selling such devices. The devices at issue, including the SUBJECT DEVICE, are marketed and sold to patients with sleep apnea. All devices at issue are set forth on the notification disseminated by Philips on June 14, 2021, titled *Urgent Medical Device Recall.*

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

15. 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 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.

16. Defendants regularly transact business in Alabama that includes marketing and selling devices for the treatment of sleep apnea, derive substantial revenue from their business transactions in Alabama, and have purposely availed themselves of the privilege of doing business in Alabama.

17. Defendants shipped or participated in shipping the SUBJECT DEVICE and other devices with the reasonable expectation that the devices could or would find their way to Alabama through the stream of commerce.

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

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

20. As detailed below, Plaintiff suffered injuries in Jefferson County, Alabama from the SUBJECT DEVICE that Defendants negligently designed and/or manufactured either in Alabama or outside of Alabama. Thus, Defendants committed a tort either in Alabama or outside of Alabama that caused injuries in Alabama, and the Court has personal jurisdiction over Defendants under Alabama's Long Arm Statute, Ala. R. Civ. P. 42.

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

22. This Court has personal jurisdiction over Royal Philips because of its systematic and continuous contacts with Alabama.

23. 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 $75,000.00.

24. There is complete diversity between Plaintiff and all of the members comprising Philips NA and Philips RS.

25. This Court is a proper venue for this civil action pursuant to 28 U.S.C. § 1391(b)(2) as the events and omissions giving rise to Plaintiff's claims occurred in this District.

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

FACTUAL BACKGROUND

27. At all relevant times, Defendants manufactured, marketed, sold, advertised, promoted, distributed and sold the recalled CPAP and BiPAP medical devices worldwide. Because of the coordinated activities of these Defendants, Plaintiff was prescribed a defective Philips CPAP medical device for her sleep apnea.

28. Defendants sought and obtained Food and Drug Administration ("FDA") clearance 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 marked prior to May 28, 1976. No formal review for safety of efficacy is required.

A. Continuous Positive Airway Pressure Therapy

29. 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.

30. 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. 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.

B. Bi-Level Positive Airway Pressure Therapy

31. 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.

C. Philips' Sleep & Respiratory Care Devices Were Endangering its Users

32. 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 BiLevel PAP respirators and mechanical ventilators posed health risks to its users. 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."[3]

33. Philips uses polyester-based polyurethane (PE-PUR) sound abatement foam to dampen device vibration and sound during routine operation.

34. 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

[3] *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 November 22, 2021).

can result in serious injury which can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment."[4]

35. According to Philips' recall notice, Philips "received several complaints regarding the presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask)."[5]

36. In its Recall Notice, Philips disclosed that "The potential risks of particulate exposure the 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 affects. 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.[6]

37. 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."[7]

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[4] *Id.*
[5] Philips Recall Letter, *available at* https://www.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/philips-recall-letter-2021-05-a-2021-06-a.pdf (accessed November 15, 2021).
[6] *Id.*
[7] *Sleep and Respiratory Care update,* https://www.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/philips-recall-clinical-information-for-physicians-and-providers.pdf (accessed November 15, 2021).

38. In the same report, 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 may be emitted from the foam that are outside of safety thresholds. The compounds identified are the following:

— Dimethyl Diazine

— Phenol, 2, 6-bis (1,1 -dimethylethyl)-4-(1-methylpropyl)-[8]

D. Philips' Recalled Devices

39. In total, Philips estimates that "[b]etween 3 million and 4 million" devices are targeted in the recall.[9]

40. 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."[10]
- "For patients using life-sustaining mechanical ventilator devices: DO NOT discontinue or alter prescribed therapy, without consulting physicians to determine appropriate next steps."[11]

[8] *Id.*
[9] Associated Press, *Philips recalls ventilators, sleep apnea machines due to health risks*, NBC NEWS, https://www.nbcnews.com/business/consumer/philips-recalls-ventilators-sleep-apnea-machines-due-health-risks-%20n1270725 (accessed November 22, 2021).
[10] *Medical Device Recall Notification,* PHILIPS RESPIRONICS (June 14, 2021), https://www.usa.philips.com/healthcare/e/sleep/communications/src-update#section_2 (accessed November 15, 2021).
[11] *Id.*

E. Philips Unreasonably Delayed its Recall

41. The FDA has identified the recall "as a Class I recall, the most serious type of recall" and has advised that the "[u]se of these devices may cause serious injuries or death."[12]

42. Upon information and belief, Defendants knew of the potential risks long before their recall was issued. Philips quietly introduced newer safer versions of the CPAP and BiPAP medical devices, such as the Dreamstation 2, without first making known the dangers about the existing medical devices being used by millions of patients in the United States.

43. Philips, in secretly working on a fix and introducing the safe products before recalling the defective products, continued to make, market, sell, and promote the Recalled Devices as safe, efficacious, and reliable for ordinary, intended use.

44. During this period, Philips unreasonably and unjustly profited from the manufacture and sale of the Recalled Devices and unreasonably exposed users of the Recalled Devices to adverse health effects, including cancer and respiratory failure.

45. Defendants wrongfully withheld from the information sphere the true risk and benefits – the important information about the medical devices at issue. Because of this negative propaganda campaign, Defendants helped convince major medical institutions, providers, and learned intermediaries that in many patients the benefits still outweigh the risks for these Recalled Devices. Defendants used their existing knowledge to influence these institutions, including the Department of Veterans Affairs, that the benefits still outweigh the risks even though there exist

[12] *Philips Respironics Recalls Certain Continuous and Non-Continuous Ventilators, including CPAP and BiPAP, Due to Risk of Exposure to Debris and Chemicals*, U.S. Food & Drug Administration, https://www.fda.gov/medical-devices/medical-device-recalls/philips-respironics-recalls-certain-continuous-and-non-continuous-ventilators-including-cpap-and (accessed November 15, 2021)

many other safer alternative products available to treat sleep apnea and other conditions for which these products are purportedly indicated.

PLAINTIFF VICKI BAKER

46. On or about April 30, 2018, Plaintiff was diagnosed with sleep apnea. Plaintiff was prescribed the use of and purchased a Dreamstation CPAP device ("SUBJECT DEVICE").

47. At the time Plaintiff was prescribed the use of and purchased the SUBJECT DEVICE, she was a resident of Jefferson County, Alabama.

48. Since July of 2018, Plaintiff used the SUBJECT DEVICE daily to treat her sleep apnea.

49. At all times Plaintiff used the SUBJECT DEVICE, she used the SUBJECT DEVICE in accordance with the guidelines, manual and instructions for use set forth by Defendants.

50. At all times Plaintiff used the SUBJECT DEVICE, she used the SUBJECT DEVICE for a purpose for which the SUBJECT DEVICE was marketed, designed, and intended.

51. At all times Plaintiff used the SUBJECT DEVICE, she used the SUBJECT DEVICE in accordance with the directions and instructions issued by her physician who prescribed the use of the SUBJECT DEVICE.

52. As a result of using the SUBJECT DEVICE, Plaintiff suffered personal injuries and damages as alleged herein. These injuries would not have occurred but for the defective nature of the SUBJECT DEVICE and/or Defendants' wrongful conduct.

53. On or about December 10, 2019, Plaintiff was diagnosed with adenocarcinoma lung cancer.

54. 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 continuous medical monitoring and treatment due to the defective nature of the SUBJECT DEVICE and/or Defendants' wrongful conduct.

55. As a result of the aforesaid conduct and the SUBJECT DEVICE designed, manufactured, marketed, sold, and distributed by Philips, Plaintiff was injured, resulting in severe mental and physical pain and suffering. As a result of such injuries, Plaintiff has suffered damages for which compensatory damages and punitive damages should be awarded.

CAUSES OF ACTION

COUNT I

ALABAMA EXTENDED MANUFACTURER'S LIABILITY DOCTRINE – DESIGN DEFECT

56. Plaintiff realleges and incorporates by reference every allegation of this Complaint as though fully set forth herein.

57. The Recalled Devices, including the SUBJECT DEVICE, are defectively designed in that they are unreasonably dangerous and do not meet the reasonable expectations of the ordinary consumer or user as to safety. The warnings, moreover, do not adequately cover the defects set forth in *Urgent Medical Recall* (June 14, 2021) made the basis of this suit, including:

a. When placed in the stream of commerce, Defendants' Recalled Devices, including the SUBJECT DEVICE, 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 DEVICE, 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 DEVICE, 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 DEVICE, 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 harmful chemicals.

e. Exposure to Defendants' Recalled Devices, including the SUBJECT DEVICE, 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 and continued marketing and selling the recalled medical devices, including the SUBJECT DEVICE, that ordinary use could result in cancer and other severe illnesses and injuries;

g. Instead of timely disclosing the dangers – the risks of cancer – Defendants continued to market, sell, and promote the Recalled Devices until they had come up with a fix – enough newer safer devices to quietly and preemptively introduce to the market;

h. Defendants did not conduct adequate post-marketing surveillance of their Recalled Devices; and

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

58. Plaintiff did not discover, nor could she 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 such a way as to make the risk of harm or injury outweigh any benefits.

59. Plaintiff used the SUBJECT DEVICE in an intended or reasonably foreseeable manner without knowledge of the devices' dangerous characteristics.

60. The harm caused by Defendants' Recalled Devices, including the SUBJECT DEVICE, 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 DEVICE, were and are more dangerous than alternative products, and Defendants could have designed the Recalled Devices, including the SUBJECT DEVICE, to make them less dangerous. Indeed, at the time Defendants designed the Recalled Devices, including the SUBJECT DEVICE, the state of the industry's scientific knowledge was such that a less risky design or formulation was attainable.

61. At the time the Recalled Devices, including the SUBJECT DEVICE, 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.

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

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

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

65. 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 Plaintiff, the public, healthcare providers, and the medical community. Defendants' reckless and wanton conduct warrants an award of punitive damages.

66. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects that led to her lung cancer, 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.

67. As a result of the foregoing acts and omissions, Plaintiff has incurred 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.

68. 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

69. Plaintiff realleges and incorporates by reference every allegation of this Complaint as though fully set forth herein.

70. Plaintiff alleges that Defendants failed to warn about the dangers of its Recalled Devices, including the SUBJECT DEVICE. 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.

71. 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 DEVICE, 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.

72. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold the Recalled Devices, including the SUBJECT DEVICE, within this judicial district.

73. 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 DEVICE, and in the course of same, directly advertised or marketed the products to consumers, physicians and end users, including Plaintiff and her physician, and therefore had a duty to warn of the risks associated with the use of their Recalled Devices.

74. 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 DEVICE, did not cause users and consumers to suffer from unreasonable and dangerous risks.

75. Defendants had a continuing duty to warn Plaintiff and her physician of dangers associated with the SUBJECT DEVICE. Defendants, as manufacturers, sellers, and distributors of medical devices, are held to the knowledge of an expert in the field.

76. 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.

77. 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 DEVICE, including Plaintiff.

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

79. 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.

80. At all relevant times, Defendants' Recalled Devices, including the SUBJECT DEVICE, reached the intended consumers, handlers, and users of 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.

81. Plaintiff was exposed to Defendants' Recalled Devices, including the SUBJECT DEVICE, without knowledge of their dangerous characteristics.

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

83. Plaintiff could not have reasonably discovered the defects and risks associated with the Recalled Devices, including the SUBJECT DEVICE, 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.

84. Defendants knew or should have known that the minimal warnings disseminated with their Recalled Devices, including the SUBJECT DEVICE, 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.

85. 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 risks 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 exposures; 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 DEVICE.

86. This alleged failure to warn is not limited to the information contained on the Recalled Devices' labeling. 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 DEVICE, 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.

87. 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.

88. Had Defendants provided adequate warnings and instructions with properly disclosed and disseminated the risks associated with the Recalled Devices, including the SUBJECT DEVICE, Plaintiff could have avoided the risk of developing injuries including cancer and could have obtained or used alternative medical equipment.

89. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects that led to her lung 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.

90. As a result of the foregoing acts and omissions, Plaintiff requires and/or will require more health care and service 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.

91. 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

92. Plaintiff realleges and incorporates by reference every allegation of this Complaint as though fully set forth herein.

93. Defendants negligently designed, manufactured, supplied, distributed, and sold the Recalled Devices, including the SUBJECT DEVICE.

94. Plaintiff was caused substantial harm and suffered both economic and noneconomic damages because of the negligent design, manufacture, and sale of the SUBJECT DEVICE.

95. Defendants knew or should have known that the Recalled Devices, including the SUBJECT DEVICE, were unreasonably dangerous when used ordinary and as intended. Defendants had a duty to avoid causing an unreasonable risk of harm to Plaintiff.

96. 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 DEVICE, to avoid exposing consumers, including Plaintiff to foreseeable and unreasonable risks of harm.

97. Defendants breached their duty of care to Plaintiff by:

a. Designing and developing the Recalled Devices, including the SUBJECT DEVICE, without thoroughly or adequately testing the devices;

b. Selling the Recalled Devices, including the SUBJECT DEVICE, without making proper and sufficient tests to determine the dangers to the users;

c. Failing to adequately or correctly warn Plaintiff, the public, healthcare providers, and the medical community, of the cancer risks associated with the Recalled Devices, including the SUBJECT DEVICE;

d. Advertising and recommending the use of the Recalled Devices, including the SUBJECT DEVICE, for treatment of sleep apnea and other conditions without sufficient knowledge as to the significance of cancer risks;

e. Failing to exercise reasonable care in designing the Recalled Devices, including the SUBJECT DEVICE, in a manner which was dangerous to the users;

f. Negligently manufacturing the Recalled Devices, including the SUBJECT DEVICE, in a manner which was dangerous to the users; and

g. Failing to exercise reasonable care when they collectively decided to conceal information concerning cancer risks.

98. A reasonable manufacturer, distributor, and/or seller under the same or similar circumstances would not have engaged in the acts and omissions complained about here.

99. 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.

100. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects that led to her lung 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.

101. As a result of the foregoing acts and omissions, Plaintiff has incurred 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.

102. 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

103. Plaintiff realleges and incorporates by reference every allegation of this Complaint as though fully set forth herein.

104. 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.

105. 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, including the SUBJECT DEVICE.

106. Defendants owed a duty to all reasonably foreseeable users to disclose the risks associated with the Recalled Devices, including the SUBJECT DEVICE.

107. Defendants breached their duty of care by failing to use reasonable care in providing adequate warnings in the Recalled Devices, including the SUBJECT DEVICE'S, labeling and packaging, and through marketing, promoting, and advertising of the Recalled Devices.

108. 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, including the SUBJECT DEVICES, to physicians, patients, in advertising, and at point of sale, on the Recalled Devices' instructions and inserts, and on the Recalled Devices' labels.

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

110. Plaintiff was injured as a direct and proximate result of Defendants' failure to warn and instruct because she would not have used or purchased the SUBJECT DEVICE had she received adequate warnings and instructions that she 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.

111. 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 Plaintiff's harm.

112. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects that led to her lung 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.

113. As a result of the foregoing acts and omissions, Plaintiff has incurred 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.

114. 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

115. Plaintiff realleges and incorporates by reference every allegation of this Complaint as though fully set forth herein.

116. 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.

117. Defendants had a duty to exercise reasonable care in the manufacturing, assembling, inspecting, and packaging of the Recalled Devices, including the SUBJECT DEVICE.

118. Defendants knew or, by the exercise of reasonable care, should have known, use of the Recalled Devices, including the SUBJECT DEVICE, carelessly manufactured, assembled, inspected, and packaged was dangerous, harmful, and injurious when used by the public, healthcare providers, the medical community, and Plaintiff.

119. 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 improperly manufactured, assembled, inspected, and packaged.

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

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

b. Failure to adequately inspect and/or test the Recalled Devices, including the SUBJECT DEVICE, during the manufacturing process;

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

d. Failure to adequately determine and/or test the purity of airflow through the Recalled Devices', including the SUBJECT DEVICE'S, airways, especially after the devices have aged.

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

122. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects that led to her lung 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.

123. As a result of the foregoing acts and omissions, Plaintiff has incurred 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.

124. 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

125. Plaintiff realleges and incorporates by reference every allegation of this Complaint as though fully set forth herein.

126. Defendants had a duty to the public, healthcare providers, the medical community, and Plaintiff to exercise reasonable and ordinary care in developing, testing, manufacture, marketing, distributing, and sale of the Recalled Devices, including the SUBJECT DEVICE.

127. Defendants breached its duty to the public, healthcare providers, the medical community, and Plaintiff by developing, testing, manufacturing, advertising, marketing, distributing, and selling products to Plaintiff that did not have the qualities, characteristics, and suitability for use as advertised by Defendants and by failing to promptly remove the Recalled Devices, including the SUBJECT DEVICE, from the marketplace or to take other appropriate remedial actions upon becoming aware of the health risks of the Recalled Devices.

128. Defendants knew or should have known that the qualities and characteristics of the Recalled Devices were not as advertised or suitable for their intended use and were otherwise not as warranted and represented by Defendants. Specifically, Defendants knew or should have known that: (a) the use of the Recalled Devices, including the SUBJECT DEVICE, was accompanied by the risk of adverse health effects, including cancer, that do not conform to the packaging and labeling; (b) the Recalled Devices, including the SUBJECT DEVICE, were adulterated, or at risk of being adulterated, by the PE-PUR foam; and (c) the Recalled Devices, including the SUBJECT DEVICE, were otherwise not as warranted and represented by Defendants.

129. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects that led to her lung 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.

130. As a result of the foregoing acts and omissions, Plaintiff has incurred 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.

131. 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

FRAUD

132. Plaintiff realleges and incorporates by reference every allegation of this Complaint as though fully set forth herein.

133. 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, including the SUBJECT DEVICE, into the stream of commerce, and therefore owed a duty of reasonable care to avoid causing harm to consumers, such as Plaintiff.

134. Defendants knowingly made fraudulent statements regarding the safety of the Recalled Devices, including the SUBJECT DEVICE, and the substantial health risks associated with using the devices, all the while intending to deceive Plaintiff, the public, healthcare providers, and the medical community.

135. At all times relevant, Defendants fraudulently misrepresented the Recalled Devices, including the SUBJECT DEVICE, as safe, when in fact the devices posed unreasonable risks of substantial bodily injury. Due to these and other features, the Recalled Devices, including the SUBJECT DEVICE, are not fit for their ordinary and intended use as treatment devices for sleep apnea and similar respiratory conditions.

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

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

138. Defendants' fraudulent misrepresentations and omissions were material facts that were essential to Plaintiff's decision to purchase the SUBJECT DEVICE.

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

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

141. Plaintiff justifiably relied to her detriment on Defendants' fraudulent statements.

142. Had Plaintiff been adequately informed of the material facts concealed from her regarding the safety of the SUBJECT DEVICE, and not intentionally deceived by Defendants, she would not have acquired/purchased or used the SUBJECT DEVICE.

143. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects that led to her lung 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.

144. As a result of the foregoing acts and omissions, Plaintiff has incurred 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.

145. 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

146. Plaintiff realleges and incorporates by reference every allegation of this Complaint as though fully set forth herein.

147. 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, including the SUBJECT DEVICE, 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.

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

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

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

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

152. Defendants further falsely represented the nature and risks associated with the Recalled Devices, including the SUBJECT DEVICE, and their marketing and stretgy regarding the same, in general statements to the media, general public, and federal agencies.

153. Defendants' misrepresentations and omissions were material facts that were essential to Plaintiff's decision making when purchasing the SUBJECT DEVICE.

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

155. Defendants intentionally deceived and concealed material information concerning the safety of the Recalled Devices, including the SUBJECT DEVICE, from Plaintiff, the general public, healthcare providers, and the medical community, which had a direct impact on Plaintiff's and consumers' health and wellbeing.

156. Plaintiff relied to her detriment on Defendants' fraudulent concealment and omissions. Had Plaintiff been adequately informed of the material facts regarding the safety of the Recalled Devices, including the SUBJECT DEVICE, and not intentionally deceived by Defendants, she would not have acquired/purchased, used, or been injured by the SUBJECT DEVICE.

157. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects that led to her lung 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.

158. As a result of the foregoing acts and omissions, Plaintiff has incurred 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.

159. 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

CIVIL CONSPIRACY

160. Plaintiff realleges and incorporates by reference every allegation of this Complaint as though fully set forth herein.

161. Defendants knowingly agreed, contrived, confederated, and/or conspired to defraud Plaintiff, the public, healthcare providers, and the medical community of the Recalled Devices regarding the true nature of the devices and their potential to cause cancer and other serious injuries associated with the PE-PUR foam's particles and chemicals when devise were used in a reasonably foreseeable manner.

162. Defendants knowingly agreed, contrived, confederated, and/or conspired to defraud Plaintiff, the public, healthcare providers, and the medical community 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.

163. 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, including the SUBJECT DEVICE, with 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, including the SUBJECT DEVICE, as safe and omitted warnings about serious side effects.

164. Plaintiff, the general public, healthcare providers, and the medical community relied upon the aforementioned fraudulent representations, omissions, and concealments made by Defendants regarding the nature of the Recalled Devices, including the SUBJECT DEVICE.

165. 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, including the SUBJECT DEVICE, Plaintiff, the public, healthcare providers, and the medical community could have learned of the dangers at an earlier date and potentially prevented their introduction to and use of the devices.

166. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects that led to her lung 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.

167. As a result of the foregoing acts and omissions, Plaintiff has incurred 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.

168. 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

UNJUST ENRICHMENT

169. Plaintiff realleges and incorporates by reference every allegation of this Complaint as though fully set forth herein.

170. 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, including the SUBJECT DEVICE, 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.

171. Defendants were unjustly enriched as a result of their wrongful conduct, including through the false and misleading marketing, promotions, and advertisements that failed to discuss the unreasonable risks of substantial bodily injury resulting from the use of the Recalled Devices, including the SUBJECT DEVICE. Defendants were also unjustly enriched through their developing, manufacturing, promoting, and selling the Recalled Devices, including the SUBJECT DEVICES without adequately testing and investigating their potential side effects and health impacts.

172. Because Defendants' retention of the non-gratuitous benefits conferred on it by Plaintiff is unjust and inequitable, Defendants must pay restitution to Plaintiff for its unjust enrichment, along with all other relief found just and equitable in the premises, including reasonable attorneys' fees and costs.

173. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects that led to her lung 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.

174. As a result of the foregoing acts and omissions, Plaintiff has incurred 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.

175. 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

BREACH OF EXPRESS WARRANTIES

176. Plaintiff realleges and incorporates by reference every allegation of this Complaint as though fully set forth herein.

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

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

179. Defendants made express warranties which extended beyond delivery of the Recalled Devices, including the SUBJECT DEVICE, and expressly warranted for future performance of the devices. Defendants advertised, promoted, and labeled the Recalled Devices, including the SUBJECT DEVICE, as being safe and effective for the treatment of sleep apnea.

180. At all relevant times, Defendants breached said express warranties in that the Recalled Devices, including the SUBJECT DEVICE, were unsafe and caused cancer among other harms. Plaintiff foreseeably used the SUBJECT DEVICE without knowing of the harmful and substantial consequences to her health.

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

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

183. 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.

184. Plaintiff notified Defendants of the breach.

185. 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 she is entitled to recovery, including but not limited to compensatory damages, consequential damages, interest, costs, and attorneys' fees.

COUNT XII

BREACH OF IMPLIED WARRANTY

186. Plaintiff realleges and incorporates by reference every allegation of this Complaint as though fully set forth herein.

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

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

189. Defendants intended to make Plaintiff, the general public, healthcare providers, and the medical community, believe the Recalled Devices, including the SUBJECT DEVICE, were safe.

190. Defendants knowingly mislead Plaintiff, the general public, healthcare providers, and the medical community, to believe the Recalled Devices, including the SUBJECT DEVICE, 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, ordinary consumers such as Plaintiff would be victim to.

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

192. At all relevant times, Defendants willfully failed to disclose the defects and health risks of the Recalled Devices, including the SUBJECT DEVICE, to Plaintiff and the consuming public.

193. Plaintiff relied to her detriment on the information publicized by Defendants.

194. 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.

195. Plaintiff notified Defendants of the breach.

196. As a direct and proximate result of Defendants' warranties concerning the SUBJECT DEVICE, Plaintiff suffered and continues to suffer from the injuries and damages for which she is entitled to recovery, including but not limited to compensatory damages, consequential damages, interest, costs, and attorneys' fees.

COUNT XIII

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

197. Plaintiff realleges and incorporates by reference every allegation of this Complaint as though fully set forth herein.

198. At all relevant times Defendants have been a merchant in regard to the Recalled Devices, including the SUBJECT DEVICE, they created and sold to consumers.

199. Defendants breached their implied warranty of merchantability since the Recalled Devices, including the SUBJECT DEVICE, were defective when created and designed, and do not conform with the promises represented on their labels.

200. Defendants failed to comply with merchantability requirements, as the Recalled devices, including the SUBJECT DEVICE, do not achieve the ordinary purposes they advertise: a healthy treatment for respiratory conditions such as sleep apnea.

201. Beyond Defendants' own direct sales of the Recalled Devices, including the SUBJECT DEVICE, 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. Plaintiffs and consumers are the intended beneficiaries of Defendants' implied warranties since the Recalled devise are manufactured with the express and implied purpose of selling the devices to consumers.

202. As a direct and proximate result of Defendants' breach of their implied warranties of merchantability regarding the SUBJECT DEVICE, Plaintiff was damaged because, had she been aware of the unmerchantable condition of the SUBJECT DEVICE, she would not have acquired/purchase the SUBJECT DEVICE and not suffered injuries and damages from their use, for which she is entitled to recover, including but not limited to compensatory damages, consequential damages, interest, costs, and attorneys' fees.

PUNITIVE DAMAGES

203. Plaintiff realleges and incorporates by reference every allegation of this Complaint as though fully set forth herein.

204. Defendants' conduct describe 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.

205. Despite their knowledge of the Recalled Devices', including the SUBJECT DEVICE'S, propensity to cause cancer and other serious injuries, Defendants chose profits over the safety of America citizens suffering with sleep apnea when they sought to create and market a device posing significant health risks.

206. Despite having substantial information about the Recalled Devices', including the SUBJECT DEVICE'S, serious and unreasonable side effects, Defendants intentionally and

recklessly failed to adequately warn Plaintiff, the public, healthcare providers, and the medical community.

207. Further, despite having substantial information about the Recalled Devices', including the SUBJECT DEVICE'S, 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.

208. Defendants downplayed and recklessly disregarded their knowledge of the defective nature of the Recalled Devices', including the SUBJECT DEVICE'S, potential for causing serious injuries.

209. Defendants chose to do nothing to warn the public about serious and undisclosed side effects with the Recalled Devices, including the SUBJECT DEVICE.

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

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment against Defendants jointly and severally as follows:

a. That the Court enter a judgment against Defendants for all general and compensatory damages allowable to Plaintiff in a sum in excess of the jurisdictional minimum of this Court, including all damages specified above;

b. For all medical, incidental, and hospital expenses according to proof;

c. For pre-judgment and post-judgment interest as provided by law;

d. That the Court enter a judgment against Defendants for all special and consequential damages allowable to Plaintiff in excess of the jurisdictional minimum of this Court, including all damages specified above;

e. For punitive damages in an amount in excess of any jurisdictional minimum of this Court and in an amount sufficient to impress upon Defendants the seriousness of their conduct and to deter similar conduct in the future;

f. That the Court enter a judgment against Defendants for all other relief by Plaintiffs under the present Complaint for Damages;

g. For attorneys' fees, expenses, and costs of this action; and

h. That the Court grant Plaintiffs such further relief which the Court deems appropriate.

DEMAND FOR JURY TRIAL

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

Dated: November 23, 2021

s/ Stephen Hunt Jr.
Stephen Hunt Jr.
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