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IN THE UNITED STATES DISTRICT COURT FOR THE STATE OF UTAH

DOUG SHIFFLER INDIVIDUALLY AND AS PERSONAL REPRESENTATIVE FOR THE ESTATE OF JOLEEN SHIFFLER,

***Plaintiffs*,**

v.

KONINKLIJKE PHILIPS N.V.; PHILIPS NORTH AMERICA, LLC f/k/a RESPIRONICS, INC.; PHILIPS RS NORTH AMERICA HOLDING CORPORATION; WM. T. BURNETT FOAM LLC; WM. T. BURNETT & CO.; WM.T. BURNETT MANAGEMENT, INC.; WM. T. BURNETT HOLDING LLC; WM. T. BURNETT FIBER LLC; and WM. T. BURNETT IP LLC.,

***Defendants*.**

COMPLAINT

Case No.
JURY TRIAL DEMANDED

COMPLAINT

Plaintiff Doug Shiffler, individually and as Personal Representative for the Estate of Joleen Shiffler, by and through undersigned counsel, hereby submits the following Complaint and Demand for Jury Trial against Defendants Koninklijke Philips N.V. ("Royal Philips"), Philips North America LLC ("Philips NA"), Philips Holding USA, Inc.

("PHUSA"), Philips RS North America LLC f/k/a Respironics, Inc. ("Philips RS"), Philips RS North America Holding Corporation ("RS Holding") (collectively referred to as "Philips"), Wm. T. Burnett Foam LLC ("Burnett Foam"), Wm. T. Burnett & Co. ("Burnett & Co."), Wm. T. Burnett Management, Inc. ("Burnett Management"), Wm. T. Burnett & Co., Incorporated ("Burnett & Co., Inc."), Wm. T. Burnett Holding LLC ("Burnett Holding"), Wm. T. Burnett Fiber LLC ("Burnett Fiber"), and Wm. T. Burnett IP LLC ("Burnett IP") (collectively referred to as "Burnett") and alleges the following upon personal knowledge and belief as well as investigation of counsel:

I. INTRODUCTION

1. Philips manufactures, markets, sells, and distributes a variety of products for sleepand home respiratory care.

2. Philips manufactures, markets, imports, sells, and distributes a variety of Continuous Positive Airway Pressure (CPAP) and BiLevel Positive Airway Pressure (BiPAP) devices for patients with obstructive sleep apnea ("OSA").

3. Philips also manufactures, markets, imports, sells, and distributes a variety of ventilator devices for patients with respiratory conditions.

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

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

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

from the sound abatement foam material.

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

8. Plaintiff, at all times relevant to this complaint was the spouse of Joleen Shiffler who was prescribed and purchased one of Philips' Recalled Products, a Philips Dream Wear, to treat her sleep apnea on or about January 24, 2018. The Shifflers had four living children who relied on the constant emotional support of Joleen Shiffler. They are Parker Shiffler, Kyle Shiffler, Trever Shiffler and Nicole Shiffler.

9. Jolene Shiffler used the Philips Noncontinuous Dream Station CPAP Auto device, Serial Number J208856380954 (the "subject device"), one of Philips' Recalled Products, daily from the purchase date of the unit until her death on November 22, 2020.

10. In April 2020, Jolene Shiffler was diagnosed with stage 4 lung cancer which ultimately caused her untimely death. Ms. Shiffler had no other risk factors or lung issues before she began using the subject device in January 2018.

11. As a direct and proximate result of Philips' conduct, Plaintiff has suffered injuries, and an untimely death.

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

II. PARTIES, JURISDICTION, AND VENUE

13. Plaintiffs incorporate by reference all paragraphs of the complaint herein and

further alleges the following:

14. During the time period relevant to this Complaint, Plaintiff Doug Shiffler, and his deceased wife Joleen Shiffler ("Plaintiffs"), were adult residents and citizens of the State of Oregon, residing in Washington County.

15. During the time period relevant to this Complaint, Plaintiffs were also adult residents and citizens of the state of Utah while using the subject device.

16. Joleen Shiffler was prescribed the use of the subject device while a resident of Cumberland County, Oregon in January 2018. She purchased the subject device in Oregon, and much of her use of the use of the subject device occurred over nearly 19 months while living in Oregon until Doug and Joleen moved to Utah to retire, on or about August 12, 2019. She continued to use the device for a little over 15 months after their move before she died from stage 4 lung cancer on November 22, 2020.

17. On March 31st, 2022 Doug Shiffler was appointed as Personal Representative of Joleen Shiffler's estate.

18. 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 BC Amsterdam, The Netherlands. Royal Philips is the parent company of Philips North America LLC, Philips Holding USA, Inc., Philips RS North America LLC f/k/a Respironics, Inc., and Philips RS North America Holding Corporation. Royal Philips can be served with process via the *Convention on the Service Abroad of Judicial and Extrajudicial Documents in Civil or Commercial Matters* ("Hague Service Convention").

19. Defendant Philips North America LLC ("Philips NA") is a Limited Liability Company incorporated in Delaware, with its principal place of business located at 3000

MinutemanRoad, Andover, MA 01810. Philips NA is a wholly owned subsidiary of Royal Philips. 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 Defendant Philips Holding USA, Inc. ("PHUSA"), which is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. Philips NA is 100% owned by PHUSA. Philips NA may be served through its registered agent the Corporation Service Company at 2626 Glenwood Ave., Suite 550, Raleigh, North Carolina 27608.

20. Defendant Philips Holding USA, Inc. ("PHUSA") is a Delaware corporation withits principal place of business located at 222 Jacobs Street, 3rd Floor, Cambridge, Massachusetts02141. PHUSA is a holding company that is the sole member of Defendant Philips NA. PHUSAmay be served through its registered agent, the Corporation Service Company at 2626Glenwood Ave., Suite 550, Raleigh, North Carolina 27608.

21. Defendant Philips RS North America LLC f/k/a Respironics, Inc. ("Philips RS") is a Delaware Limited Liability Company with its principal place of business located in Pittsburgh, Pennsylvania. Philips RS was formerly operated under the business name Respironics, Inc. ("Respironics"). Royal Philips acquired Respironics in 2008.2 Philips RS has a registered agent in Massachusetts, Corporation Service Company, located at 84 State Street, Boston, Massachusetts 02109. Philips RS North America LLC is wholly owned by a single member, Philips RS North America Holding Corporation, which is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Cambridge, Massachusetts 02141. Philips RS North America is wholly owned by Philips Holding USA Inc. Accordingly, Philips RS is a citizen of Massachusetts and Delaware.

22. Philips RS North America Holding Corporation ("RS Holding") is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Cambridge,

Massachusetts 02141, and is wholly owned by PHUSA. Accordingly, Philips North America Holding Corporation is a citizen of Massachusetts and Delaware.

23. Royal Philips acquired Respironics in 2008. Philips RS is wholly owned by a single member, Philips RS North America Holding Corporation, a Delaware corporation with its principal placeof business in Cambridge, Massachusetts.

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

25. Defendant Wm. T. Burnett Foam LLC ("Burnett Foam") is a limited liability company organized and existing under the laws of the State Maryland and has a principal place of business at 1500 Bush Street, Baltimore, Maryland 21230. Burnett Foam may be served through its registered agent at Wm. T. Burnett Management Inc., 1500 Bush Street, Baltimore, Maryland 21230.

26. Defendant Wm. T. Burnett Management, Inc. ("Burnett Management") is a corporation organized and existing under the laws of the State of Maryland and has a principal place of business at 1500 Bush Street, Baltimore, Maryland 21230. Burnett Management may be served through its registered agent at Richard B.C. Tucker, Jr., at 1500 Bush Street, Baltimore, Maryland 21230.

27. Defendant Wm. T. Burnett & Co. ("Burnett & Co.") is a corporation owned and operated by Burnett Management and organized and existing under the laws of the State of Maryland and has a principal place of business at 1500 Bush Street, Baltimore, Maryland 21230.

28. Defendant Wm. T. Burnett & Co., Incorporated ("Burnett & Co., Inc.") is a textiles corporation organized and existing under the laws of the State of Maryland and has a

principal place of business at 1500 Bush Street, Baltimore, Maryland, 21230. Burnett & Co., Inc. may be served through its registered agent Richard B.C. Tucker, Jr., at 1500 Bush Street, Baltimore, Maryland 21230.

29. Defendant Wm. T. Burnett Holding LLC ("Burnett Holding") is a limited liability company organized and existing under the laws of the State of Maryland, has a principal place of business at 1500 Bush Street, Baltimore, Maryland 21230. The Burnett Holding corporate family is comprised of six companies. Burnett Holding may be served through its registered agent at Wm. T. Burnett Management, Inc. at 1500 Bush Street, Baltimore, Maryland 21230.

30. Defendant Wm. T. Burnett Fiber LLC ("Burnett Fiber") is a limited liability company organized and existing under the laws of the State of Maryland and has a principal place of business at 1500 Bush Street, Baltimore, Maryland 21230. Burnett Fiber may be served through its registered agent at Wm. T. Burnett Management, Inc., at 1500 Bush Street, Baltimore, Maryland 21230.

31. Defendants Wm. T. Burnett IP LLC ("Burnett IP") is a limited liability company organized and existing under the laws of the State of Maryland, and has a principal place of business at 1500 Bush Street, Baltimore, Maryland 21230. Burnett IP may be served through its registered agent at Wm. T. Burnett Management, Inc., at 1500 Bush Street, Baltimore, Maryland 21230.

32. Royal Philips, Philips NA, Philips USA, Philips RS, and Philips RS NA Holding are hereinafter collectively referred to as "Philips." Burnett Foam, Burnett Management, Burnett & Co., Burnett Holding, Burnett & Co., Inc., Burnett Fiber, and Burnett IP are hereinafter collectively referred to as "Burnett." Both Philips and Burnett are

collectively referred to as "Defendants."

33. Upon information and belief, Defendants have purposefully availed themselves of the benefits of doing business in Oregon and Utah through manufacturing, designing, labeling, marketing, distributing, supplying and/or selling, the subject device and other products for the treatment of obstructive sleep apnea, including the DreamStation device prescribed for and purchased by Plaintiff at issue in this lawsuit (the "subject device"), and by placing such products into the stream of commerce for those purposes.

34. 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.

35. Defendants operated as a single enterprise, equally controlled each other's business affairs, commingled their assets andfunds, disregarded corporate formalities, and used each other as a corporate shield to defeat justice,perpetuate fraud and evade contractual and/or tort liability.

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

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

38. Defendants regularly transact business in Utah, including the marketing and selling devices for the treatment of obstructive sleep apnea, derive substantial revenue from

their business transactions in Utah, and have purposely availed themselves of the privilege of doing business in Utah.

39. Defendants shipped or participated in shipping the subject device and other deviceswith the reasonable expectation that the devices could or would find their way to Utah through the stream of commerce.

40. Defendants' actions in marketing and selling their devices in Utah should have led them to reasonably anticipate being subject to the jurisdiction of a Utah court.

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

42. As detailed below, Plaintiff and his wife suffered injuries both in Oregon and Utah from the subject device that Defendants negligently designed and/or manufactured either in Utah or outside of Utah. Thus, Defendants committed a tort either in Utah and/or outside of the state that caused injuries in Utah.

43. This Court has subject-matter jurisdiction over this action pursuant to 28 U.S.C. §1332(a) based on complete diversity of citizenship between Plaintiffs and all Defendants. The amount in controversy exceeds $75,000, exclusive of interest and costs.

This Court has personal jurisdiction over Defendants, who at all relevant times were engaged in the manufacturing, designing, labeling, marketing, distributing, supplying and/or selling of their products and introduced such products for the treatment of obstructive sleep apnea into interstate commerce with knowledge and intent that such products be sold in the State of Utah. Each Defendant has sufficient minimum contacts with the state of Utah to be sued and be required to defend here.

44. Venue is proper in this District under 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to the claim occurred in this District. Furthermore, each Defendant purposefully availed itself of the benefits of doing business in Utah through manufacturing, designing, labeling, marketing, distributing, supplying and/or selling of devices for the treatment of obstructive sleep apnea.

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

III. BACKGROUND

46. Plaintiffs incorporate by reference all paragraphs of the complaint herein and further alleges the following:

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

48. Defendants sought and obtained Food and Drug Administration ("FDA") approval to market the Recalled Products, including the subject device used by Plaintiff, under Section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act. Section 510(k)allows marketing of medical devices if the device is deemed substantially equivalent to other legally marketed predicate devices marketed prior to May 28, 1976. No formal review for safetyor efficacy is required.

a) Continuous Positive Airway Pressure Therapy

49. Plaintiffs incorporate by reference all paragraphs of the complaint herein and further alleges the following:

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

51. 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 ("BiPAP")

52. 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 deliverone level of pressurize air (the inspiratory positive level) to assist as a person inhale, and another level (the expiratory level) as a person exhales.

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

53. Plaintiffs incorporate by reference all paragraphs of the complaint herein and further alleges the following:

54. On April 26, 2021, as part of its Quarterly Report for Q1 2021, Philips disclosed for the first time, under a section entitled "Regulatory Update," that device user reports had led toa discovery that the type of polyester-based polyurethane ("PE-PUR Foam") "sound abatement" foam Philips used to minimize noise in several CPAP and BiPAP respirators 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."[1]

55. On June 14, 2021, because of extensive ongoing review following the announcement on April 26, 2021, Philips issued a recall notification for specific affected devices.[2]

[1] *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 August 22, 2021).
[2] *Medical Device Recall Notification*, PHILIPS RESPIRONICS (June 14, 2021),

56. In its recall notification, Philips identified examples of potential risks which includeexposure to degraded sound abatement foam particles and exposure to chemical emissions fromthe sound abatement foam material.

57. Philips reported that, based on lab testing and evaluations, it may be possible that these potential health risks could result in a wide range of potential patient impacts, including transient potential injuries, symptoms, and complications, as well as possibly serious injury which can be life-threatening or cause permanent impairment or require medical intervention to preclude permanent impairment.[3]

58. 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)."[4]

59. According to Philips' recall notice, the PE-PUR Foam used in Recalled Products puts Recalled Device users at risk of suffering from the following health harms: "The potential risks of particulate 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 affects. The potential risks of chemical exposure due to off-gassing include:headache/dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, nausea/vomiting, toxic and carcinogenic effects."[5]

60. 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

https://www.usa.philips.com/healthcare/e/sleep/communications/src-update#section_2 (accessed August 22, 2021).
[3] *Id.*
[4] 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 August 22, 2021).
[5] *Id.*

reveals thepresence of potentially harmful chemicals including:

-Toluene Diamine

-Toluene Diisocyanate

-Diethylene glycol."[6]

61. In the same report, Philips also disclosed that lab testing performed by and for Philips had 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)[7]

D. Philips' Recalled Products

51. Plaintiffs incorporate by reference all paragraphs of the complaint herein and further alleges the following:

52. In total, Philips announced that "[b]etween 3 million and 4 million" devices are targeted in the recall."[8]

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

[6] *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 August 22, 2021).
[7] *Id.*
[8] Reuters.com, June 14, 2021, https://www.reuters.com/business/healthcare-pharmaceuticals/philips-recalls-some-3-4-million-cpap- ventilator-machines-due-foam-part-2021-06-14/ (accessed August 22, 2021).

CPAP AND BIPAP DEVICES	
Device Type	**Model Name and Number (All Serial Numbers)**
Continuous Ventilator, Minimum Ventilatory Support, Facility Use	E30 (Emergency Use Authorization)
Continuous Ventilator, Non-life Supporting	DreamStation ASV
	DreamStation ST, AVAPS
	SystemOne ASV4
	C-Series ASV
	C-Series S/T and AVAPS
	OmniLab Advanced+
Noncontinuous Ventilator	SystemOne (Q-Series)
	DreamStation
	DreamStation Go
	Dorma 400
	Dorma 500
	REMstar SE Auto
VENTILATORS	
Device Type	**Model Name and Number (All Serial Numbers)**
Continuous Ventilator	Trilogy 100
	Trilogy 200
	Garbin Plus, Aeris, LifeVent
Continuous Ventilator, Minimum Ventilatory Support, Facility Use	A-Series BiPAP Hybrid A30 (not marketed in US)
	A-Series BiPAP V30 Auto
Continuous Ventilator, Non-lifeSupporting	A-Series BiPAP A40
	A-Series BiPAP A30

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

- "**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."[9]

- "**For patients using life-sustaining mechanical ventilator devices: DO NOT discontinue or alter prescribed therapy, without consulting physicians to**

[9] *Certain Philips Respironics BiPAP, and CPAP Machines Recalled* https://www.fda.gov/medical-devices/safety-communications/certain-philips-respironics-ventilators-bipap-and-cpap-machines-recalled-due-potential-health-risks (accessed August 22, 2021).

determine appropriate next steps."[10]

55. The United States Food and Drug Administration ("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."[11]

56. The Burnett polyurethane foam was defectively manufactured to allow premature degradation, especially when used in a foreseeably moist environment for hydrolysis and attendant degradation.

57. Upon information and belief, Defendants knew of the potential risks long before their recall was issued.

58. Thus, because of user reports and other testing performed by and on behalf of Defendants, Defendants were aware of the degradation of the PE-PUR sound abatement foam used in the Recalled Products, yet continued to manufacture, market, and sell the Recalled Products with such awareness for a significant period of time. During this period, Defendants unreasonably and unjustly profited from the manufacture and sale of the Recalled Products and unreasonably put users of the Recalled Products at risk of developing adverse health effects.

E. Plaintiff Joleen Shiffler

59. Plaintiffs incorporate by reference all paragraphs of the complaint herein and further alleges the following:

60. In or around January 2018, Plaintiff was prescribed the use of and purchased a Noncontinuous CPAP Auto DreamStation device (the "subject device"). The

[10] *Medical Device Recall Notification*, PHILIPS RESPIRONICS (June 14, 2021), https://www.usa.philips.com/healthcare/e/sleep/communications/src-update#section_2 (accessed August 22, 2021).
[11] *Philips Recalls CPAP and BiPAP*, U.S. FDA, https://www.fda.gov/medical-devices/medical-device-recalls/philips-respironics-recalls-certain-continuous-and-non-continuous-ventilators- including-cpap-and (accessed August 23, 2021).

subject device prescribed for and purchased by Joleen Shiffler was one of the Defendants' Recalled Products.

61. At the time Joleen Shiffler was prescribed the use of and purchased the subject device, she was a resident and citizen of Washington County, Oregon.

62. After the purchase of Defendant's product in 2018, Joleen Shiffler used the subject device daily to treat her sleep apnea.

63. At all times Joleen Shiffler used the subject device, she acted in accordance with the guidelines, manual, and instructions for use set forth by Defendants.

64. At all times she used the subject device, Joleen Shiffler used the subject device for a purpose for which the subject device was marketed, designed, and intended.

65. At all times he used the subject device, Joleen Shiffler used the subject device in accordance with the directions and instructions issued by her physician who prescribed the use of the subject device.

66. As a result of using the subject device, Plaintiff suffered personal injuries damages, and wrongful death as alleged herein. These injuries would not have occurred but for the defective nature o the subject device and/or Defendant's wrongful conduct.

67. Joleen Shiffler was diagnosed with lung cancer in April 2020.

68. Joleen Shiffler underwent significant treatment and suffered an untimely death due to the defective nature of the subject device and/or Defendants' wrongful conduct.

69. As a result of the aforesaid conduct and subject device manufactured, designed, sold, distributed, advertised, and promoted by Defendants, Joleen Shiffler was injured, resulting in severe mental and physical pain, suffering, and an untimely death. As a result of such, she has suffered damages for which compensatory damages should be

awarded.

F. Federal Statutory and Regulatory Requirements

70. Plaintiffs incorporate by reference all paragraphs of the complaint herein and further alleges the following:

71. Pursuant to federal law, a medical device is deemed to be adulterated if, among other things, it fails to meet established performance standards, or if the methods, facilities or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. 21 U.S.C. § 351.

72. Pursuant to federal law, manufacturers are required to comply with FDA regulation of medical devices, including FDA requirements for records and reports, in order to prohibit introduction of medical devices that are adulterated or misbranded, and to assure the safety and effectiveness of medical devices. In particular, manufacturers must keep records and make reports if any medical device may have caused or contributed to death or serious injury, or if the device has malfunctioned in a manner likely to cause or contribute to death or serious injury. Federal law also mandates that the FDA establish regulations requiring a manufacturer of a medical device to report promptly to FDA any correction or removal of a device undertaken to reduce a risk to health posed by the device, or to remedy a violation of federal law by which a device may present a risk to health. 21 U.S.C. § 360(i).

73. Pursuant to federal law, the Secretary of Health and Human Services may prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, pre-production design validation (including a process to assess the performance of a device, but not including an evaluation of the safety or effectiveness of a device), packaging, storage and installation of a device conform to current good manufacturing practice, as prescribed in such regulations, to assure that the device will be safe and effective and otherwise in compliance with federal law.

74. The regulations requiring conformance to good manufacturing practices are set forth in 21 C.F.R. § 820, et seq. As explained in the Federal Register, because the Current Good Manufacturing Practice (CGMP) regulations must apply to a variety of medical devices, the regulations do not prescribe the details for how a manufacturer must produce a

device. Rather, the quality system regulations provide a framework of basic requirements for each manufacturer to use in establishing a quality system appropriate to the devices designed and manufactured and the manufacturing processes employed. Manufacturers must adopt current and effective methods and procedures for each device they design and manufacture to comply with and implement the basic requirements set forth in the quality system regulations.

75. Pursuant to 21 C.F.R. § 820.1(c), the failure to comply with any applicable provision in Part 820 renders a device adulterated under section 501(h) of the Federal Drug & Cosmetic Act ("the Act"). 21 U.S.C. § 351.

76. Pursuant to 21 C.F.R. § 820.5, each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device designed or manufactured. "Quality system" means the organizational structure, responsibilities, procedures, processes and resources for implementing quality management. 21 C.F.R. § 820.3(v).

77. Pursuant to 21 C.F.R. § 820.22, each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system.

78. Pursuant to 21 C.F.R. § 820.30(a), each manufacturer shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met.

79. Pursuant to 21 C.F.R. § 820.30(d), each manufacturer shall establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements.

80. Pursuant to 21 C.F.R. § 820.30(e), each manufacturer shall establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device's design development.

81. Pursuant to 21 C.F.R. § 820.30(f), each manufacturer shall establish and maintain procedures for verifying the device design to confirm that the device design output meets the design input requirements.

82. Pursuant to 21 C.F.R. § 820.30(g), each manufacturer shall establish and maintain procedures for validating the device design. Design validation shall be performed under defined operating conditions on initial production units, lots or batches, or their equivalents. Design validations shall ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions.

83. Pursuant to 21 C.F.R. § 820.30(h), each manufacturer shall establish and maintain procedures to ensure that the device design is correctly translated into production specifications.

84. Pursuant to 21 C.F.R. § 820.30(i), each manufacturer shall establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation.

85. Pursuant to 21 C.F.R. § 820.70(a), each manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications. Where deviations from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications. Such process controls shall include:

a. Documented instructions, standard operating procedures (SOPs) and methods that define and control the manner of production;

b. Monitoring and control of process parameters and component and device characteristics during production;

c. Compliance with specified reference standards or codes;

d. The approval of processes and process equipment; and

e. Criteria for workmanship which shall be expressed in documented standards or by means of identified and approved representative samples.

86. Pursuant to 21 C.F.R. § 820.70(b), each manufacturer shall establish and maintain procedures for changes to a specification, method, process, or procedure.

87. Pursuant to 21 C.F.R. § 820.70(c), each manufacturer shall establish and maintain procedures to adequately control environmental conditions that could reasonably be expected to have an adverse effect on product quality, including periodic inspection of environmental control system(s) to verify that the system, including necessary equipment, is adequate and functioning properly.

88. Pursuant to 21 C.F.R. § 820.70(e), each manufacturer shall establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on produce quality.

89. Pursuant to 21 C.F.R. § 820.70(g), each manufacturer shall ensure that all equipment used in the manufacturing process meets specified requirement and is appropriately designed, constructed, placed and installed to facilitate maintenance, adjustment, cleaning and use.

90. Pursuant to 21 C.F.R. § 820.70(h), each manufacturer shall establish and maintain procedures for the use and removal of manufacturing material which could reasonably be expected to have an adverse effect on product quality to ensure that it is removed or limited to an amount that does not adversely affect the device's quality.

91. Pursuant to 21 C.F.R. § 820.70(i), when computers or automated data processing systems are used as part of production or the quality system, the manufacturer shall validate computer software for its intended use according to an established protocol.

92. Pursuant to 21 C.F.R. § 820.72, each manufacturer shall ensure that all inspection, measuring and test equipment, including mechanical, automated or electronic inspection and test equipment, is suitable for its intended purposes and is capable of producing valid results. Each manufacturer shall establish and maintain procedures to ensure that equipment is routinely calibrated, inspected, checked, and maintained.

93. Pursuant to 21 C.F.R. § 820.75(a), where the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedures. "Process validation" means establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications. See 21 C.F.R. § 820.3(z)(1).

94. Pursuant to 21 C.F.R. § 820.75(b), each manufacturer shall establish and maintain procedures for monitoring and control of process parameters for validated processes to ensure that the specified requirements continue to be met. Each manufacturer shall ensure that validated processes are performed by qualified individuals.

95. Pursuant to 21 C.F.R. § 820.90, each manufacturer shall establish and maintain procedures to control product that does not conform to specified requirements.

96. Pursuant to 21 C.F.R. § 820.100, each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for:

a. analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product or other quality problems;

b. investigating the cause of nonconformities relating to product, processes and the quality system;

c. identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;

d. verifying or validating the corrective and preventative action to ensure that such action is effective and does not adversely affect the finished device;

e. implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;

f. ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and

g. submitting relevant information on identified quality problems, as well as corrective and preventative actions, for management review.

97. Upon information and belief, Defendants' DreamStation CPAP device is adulterated pursuant to 21 U.S.C. § 351 because, among other things, it failed to meet established performance standards and/or the methods, facilities or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. See 21 U.S.C. §351.

98. Upon information and belief, Defendants' DreamStation CPAP device is

misbranded because, among other things, it is dangerous to health when used in the manner prescribed, recommended, or suggested in the labeling thereof. See 21 U.S.C. § 352.

99. Upon information and belief, Defendants' DreamStation CPAP device is adulterated pursuant to 21 U.S.C. § 351 because Philips failed to establish and maintain CGMP for its DreamStation CPAP device in accordance with 21 C.F.R. § 820, et seq., as set forth above.

100. Upon information and belief, Philips failed to establish and maintain CGMP with respect to the quality audits, quality testing and process validation for the recalled devices, including the Philips DreamStation CPAP device.

101. As a result of Philips' failure to establish and maintain CGMP as set forth above, Philips' DreamStation CPAP device was defective, resulting in injuries to Plaintiff.

102. If Philips had complied with the federal requirements regarding CGMP, Philips' DreamStation CPAP device would have been manufactured and/or designed properly such that it would not have resulted in injuries to Plaintiff.

IV. CAUSES OF ACTION

COUNT I
PRODUCTS LIABILITY: DEFECTIVE DESIGN

54. Plaintiffs incorporate by reference all paragraphs of the complaint herein and further alleges the following:

55. Defendants are manufacturers, who designed, developed, manufactured, tested, inspected, packaged, promoted,marketed, distributed, labeled, and/or sold the Recalled

Products.

56. Defendants placed their Recalled Products, into the stream of commerce.

57. Defendants expected their Recalled Products to reach, and did reach consumers, including Plaintiff, without substantial alteration in the condition in which it was sold.

58. The Recalled Products are defective in their design or formulation. They are not reasonably fit, suitable, or safe for their intended purpose and/or their foreseeable risks exceed the benefits associated with their design.

59. The Recalled Products pose a greater likelihood of injury and are more dangerous than other available devices indicated for the same conditions and uses. If the design defects were known at the time of manufacture, a reasonable person would have concluded what the utility of the Recalled Products did not outweigh their risks.

60. The defective condition of the Recalled Products rendered them unreasonably dangerous and/or not reasonably safe in one or more of the following ways:

a) The Recalled Products were more dangerous than would be reasonably contemplated by the ordinary patient or doctor. Plaintiff was unaware of the hazards and defects in Recalled Products including the subject device.

b) The subject device was in this defective condition at the time it left the hands of Defendants. The subject device was expected to and did reach Plaintiff and Plaintiff's doctor without substantial change in the condition in which it was designed, manufactured, labeled, sold,distributed, marketed, promoted, supplied, and otherwise released into the stream of commerce.

c) At the time Plaintiff used the subject device, it was represented to be safe and free from latent defects.

d) During the period that Plaintiff used the subject device, it was being utilized in a manner that was intended by Defendants.

e) The subject device was more dangerous than would be reasonably contemplated by the ordinary patient or doctor.

f) Defendants knew or should have known of the danger associated with the use of their Recalled Products, including the subject device, but continued to design, manufacture, sell, distribute, market, promote and/or supply the Recalled Products to maximize sales and profits at the expense of the public health and safety, in conscious disregard of the foreseeable harm caused by the Recalled Products.

g) The subject device is defective in its design or formulation in that it is not reasonably fit, suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design.

h) The subject device is defective in design because it causes injuries including but not limited to headaches, irritation of the skin, eye, and respiratory tract, inflammatory respiratory issues, asthma, adverse effect to organs (including the kidneys and liver), hypersensitivity, nausea, vomiting, and toxic/carcinogenic effects.

i) It is more dangerous than other available devices indicated for similar conditions and uses, and the utility of the device does not outweigh its risks.

61. The defective condition of the subject device rendered it unreasonably

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

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

63. The subject device is defective in design because the Burnett PE-PUR sound abatement foam comprising part of the device can degrade into particles that enter the device's air pathway and can off-gas certain chemicals.

64. Upon information and belief, Burnett knew about the possibility of PE-PUR foam degradation since it began manufacturing the foam for Philips CPAP and BiPAP devices.

65. Upon information and belief, Burnett continued to manufacture and supply the PE-PUR foam after becoming aware of the problem and risks of foam degradation and knowing it would be used in the CPAP and BiPAP devices.

66. An adverse event report from the FDA Manufacturer and User Facility Device Experience ("MAUDE") database shows that, as early as 2011, Respironics learned that a patient reported discovering "black dust" on her nose when she awoke the morning after using a Philips CPAP device and subsequently underwent treatment for "intoxication" and "chest tightness." Philips investigated this report and confirmed the device contained "evidence of an unknown black substance in the air path and on internal components ... present throughout both the intake and exhaust portions of the airpath." However, Philips

denied that the presence of the black substance was due to product defect.

67. At or before the time the subject device was released on the market and/or sold to Joleen Shiffler, Defendants could have designed the product to make it less prone to causing the above-listed health harms. A technically feasible safer alternative design that would have prevented the harm she suffered without substantially impairing the function of the device.

68. 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 Plaintiff could not have known that Defendants had not designed, developed, and manufactured the subject device in a way as to make the risk of harm or injury outweigh any benefits.

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

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

71. As a direct and proximate result of the foregoing acts and omissions,

Plaintiff was caused to suffer serious and dangerous side effects that contributed to her lung cancer and chronic lung disease, as well as other severe and personal injuries and an untimely death.

COUNT II
PRODUCTS LIABILITY: MANUFACTURING DEFECT

72. Plaintiffs incorporate by reference all paragraphs of the complaint herein and further alleges the following:

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

74. The subject device was expected to and did reach Joleen Shiffler without a substantial change in its condition.

75. The finished subject device deviated, in terms of construction and quality, from the specifications or planned output in a manner that made it unreasonably dangerous.

76. The subject device prescribed to and used by Joleen Shiffler was defective in its manufacture when it left the hands of Defendants in that it deviated from product specifications, posing a clear risk that the device would result in serious complications.

77. At all relevant times, the subject device was defectively manufactured by Defendants in that its design and formulation is more dangerous than what an ordinary consumer would expect when used in an intended and reasonably foreseeable manner.

78. At all relevant times, Defendants actively deceived users that their use of the Recalled Products posed safety risks that far outweighed any benefits.

79. Furthermore, the Recalled Products, including the subject device, were

defectively manufactured in that the PE-PUR foam comprising part of the devices can degrade into particles that enter the devices' air pathway and can off-gas certain chemicals.

80. Joleen Shiffler and other similarly situated consumers were unknowingly subjected to different doses of toxins, carcinogens, and other deleterious components and contaminants when using the Recalled Products.

93. Without limitation, the Defendants breached their duty to exercise reasonable carein manufacturing, assembling, inspecting, and packaging the Recalled Products by their:

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

b) Failure to adequately inspect/test the Recalled Products 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 Products' airway, especially after the devices have aged;

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

95. Joleen Shiffler's death was a direct and proximate result of Defendants' failure to use reasonable care in the manufacturing, assembling, inspecting, and packaging of the subject device as described herein.

COUNT III
PRODUCTS LIABILITY: INADEQUATEWARNINGS OR INSTRUCTION

96. Plaintiffs hereby incorporate by reference each of the allegations set forth

in this Complaint as if fully set forth herein.

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

98. Defendants as the manufacturers, promoters, distributers, suppliers, and sellers ofthe Recalled Products, including the subject device, owed a duty to use reasonable care in the design, development, manufacture, marketing, promotion, distribution, supply, and sale of the Recalled Products, including the subject device.

99. The Defendants knew or, by the exercise of reasonable care, should have known,that use of the subject device was dangerous, harmful, and injurious when used by Joleen Shiffler in a reasonably foreseeable manner.

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

101. The Defendants knew or, by the exercise of reasonable care, should have known, that the Recalled Products 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 Products.

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

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

104. The foreseeable risk of harm from the subject device at issue in this Complaint could have been reduced or avoided by providing adequate instructions or warnings.

105. Defendants failed to provide adequate instructions or warnings regarding the risks of harm from the subject device at issue in this Complaint which were known by Defendants or should reasonably have been known by Defendants.

106. Defendants' failure to provide adequate instructions or warnings regarding the defective condition of the subject device rendered it unreasonably dangerous and/or not reasonably safe.

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

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

109. 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 Products without thoroughly or adequately testing the devices;

b) Defendants sold the Recalled Products without making proper and sufficient

tests to determine the dangers to the users;

c) Defendants failed to adequately and correctly warn the Joleen Shiffler, the public, and medical community of risks associated with the Recalled Products;

d) Defendants advertised and recommended the use of the Recalled Products for treatment of sleep apnea and other conditions without sufficient knowledge as to the significance of risks;

e) Defendants failed to exercise reasonable care in designing the Recalled Products in a manner which was not dangerous to its users;

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

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

110. Additionally, Defendants under-reported, underestimated, and downplayed the serious dangers of the Recalled Products' association with health harms.

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

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

113. Even though Defendants knew or should have known that the Recalled Products caused unreasonably dangerous side effects, they made conscious decisions to downplay these risks and continue to market, manufacture, distribute, and/or sell the devices to physicians and patients, including Joleen Shiffler.

114. Defendants knew or should have known that consumers, including Joleen Shiffler, would foreseeably suffer injury because of Defendants' failure to exercise ordinary care.

115. Defendants' negligence was a proximate cause of Joleen Shiffler's injuries, among many other health harms, which she suffered before her death.

116. Defendants owed Joleen Shiffler a duty to provide reasonably complete and accurate information to herself, her healthcare providers, and the public regarding the products at issue in this Complaint.

117. Defendants breached this duty by failing to adequately warn Joleen Shiffler, her physician and healthcare providers, and the public regarding the Recalled Products.

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

119. Defendants each had an independent duty and continuing duty to warn the medical community and Joleen Shiffler's physicians about the significance of the risks and health harms of the subject device.

120. The subject device was defective due to inadequate warnings because Defendants knew or should have known that the product created a significantly increased risk of health injuries,including those suffered by Joleen Shiffler, and failed to warn the medical community and Joleen Shiffler's physician of the nature of such risks.

121. Defendants omitted and downplayed the significantly increased risks of harm and other health risks with the subject device that Defendants knew or should have known from previous testing and research even prior to subject device's FDA approval.

122. The subject device's labeling and warnings were defective because they omitted and inadequately warned of the device's health risks.

123. Although physicians are supposed to weigh the risks and benefits before prescribinga medical device, Defendants knew that their deliberate omissions would cause physicians, including Joleen Shiffler's physician, to prescribe the subject device without being able to adequately weigh the risk of device's health risks.

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

125. Had Defendants reasonably provided adequate warnings, such warnings would have been heeded and no healthcare professional, including Joleen Shiffler's physician, would have prescribed the subject device and no consumer, including Plaintiff, would have purchasedand/or used the subject device.

126. As a direct and proximate result of the Defendants' failure to provide adequate warnings or instructions, Plaintiffs have suffered harm, damages, economic loss, pain and suffering,and an untimely death.

COUNT IV
PRODUCTS LIABILITY: BREACH OF IMPLIED WARRANTY

127. Plaintiffs incorporate by reference all paragraphs of the complaint herein and further alleges the following:

128. At all relevant times, Defendants, through their advertising and

promotional materials, expressly and impliedly warranted and affirmed that the Recalled Products' purpose was to offer a reasonably safe treatment for sleep apnea and similar health problems.

129. Defendants touted the Recalled Products as safe, despite knowing they had never adequately researched or tested the devices to assess their safety before placing the devices on the market and promoting them to consumers.

130. Defendants intended to make Joleen Shiffler, and the public believe the Recalled Products were safe.

131. Defendants impliedly warranted that the products at issue in this Complaint and its component parts were merchantable and fit for the ordinary and intended purposes for which the Recalled Products are used.

132. Defendants breached their implied warranty of merchantability since the Recalled Products were defective when created and designed, and do not conform with the promises represented on their labels.

133. Defendants failed to comply with merchantability requirements, as the Recalled Products do not achieve the ordinary purposes they advertise: a healthy treatment for respiratoryconditions such as sleep apnea.

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

135. At all relevant times, Defendants willfully failed to disclose the defects and healthrisks of the Recalled Products to Joleen Shiffler and the public.

136. Joleen Shiffler relied to her detriment on the information publicized by Defendants.

137. Joleen Shiffler was a foreseeable user of the products at issue in this

Complaint.

138. At all times relevant to this Complaint, Joleen Shiffler was in privity with Defendants.

139. Joleen Shiffler used the product at issue in this Complaint for its ordinary and intended purpose.

140. The products at issue in this Complaint failed while being used for its ordinary and intended purpose.

141. Defendants sold and Joleen Shiffler was prescribed and purchased the product at issue in this Complaint.

142. As a direct and proximate result of the Defendants' breach of implied warranty, Joleen Shiffler suffered harm, damages, economic loss, pain and suffering, extensive medical treatment and medical expenses, and death.

COUNT V
PRODUCTS LIABILITY: BREACH OF EXPRESS WARRANTY

143. Plaintiffs hereby incorporate by reference each of the allegations set forth in this Complaint as if fully set forth herein.

144. Defendants expressly warranted by affirmation, promise, description, and sample to Joleen Shiffler and Plaintiff's healthcare providers that the products at issue in this Complaint were of a quality and character suitable for implantation and extended safe use to Joleen Shiffler.

145. Such representations by Defendants were meant to and did induce Joleen Shiffler to purchase the products at issue in this Complaint.

146. The products at issue in this Complaint did not conform to the representations made by Defendants.

147. Defendants breached the express warranty it provided with the products at issue in this Complaint.

148. As a result of Defendants' conduct, Joleen Shiffler suffered injuries, damages, and death as alleged herein.

149. As a direct and proximate result of the Defendants' breach of warranty, as set forth above, Plaintiffs have suffered harm, damages, economic loss, pain and suffering, extensive medical treatment, medical expenses, and ultimately death.

COUNT VI
NEGLIGENCE/GROSS NEGLIGENCE

150. Plaintiffs incorporate by reference all paragraphs of the complaint herein and further alleges the following:

151. At all relevant times, Defendants designed, manufactured, assembled, inspected, tested, packaged, labeled, marketed, advertised, promoted, supplied, distributed, sold and/or otherwise placed the Recalled Products into the stream of commerce, and therefore owed a duty of reasonable care to avoid causing harm to consumers, such as Joleen Shiffler.

152. Defendants breached their duty in designing and manufacturing products that utilized PE-PUR foam, which can degrade into particles that enter the devices' air pathway and can result in the off-gas certain chemicals.

153. Through exercising reasonable care, Defendants either knew or should have known of the harms associated with including the PE-PUR foam in its Recalled Products.

154. As a result of Defendants' failure to exercise reasonable care in the design of the Recalled Products, Joleen Shiffler and other similarly situated consumers were unknowingly subjected to receiving different doses of toxins, carcinogens, and other deleterious components and contaminants when using the Recalled Products.

155. Defendants additionally breached their duty in failing to inform their consumers, including Joleen Shiffler, of the harm associated with their Recalled Products.

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

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

158. As a result of Defendants' failure to exercise reasonable care in instructing, or failing to instruct, its consumers of the risks and harms associated with the use of its Recalled Products, Joleen Shiffler and other consumers suffered serious medical harm.

COUNT VII
NEGLIGENT MISREPRESENTATION

159. Plaintiffs incorporate by reference all paragraphs of the complaint herein and further alleges the following:

160. Defendants had a duty to exercise reasonable care to those whom they provided device information about the Recalled Devices and to all those relying on the

information provided, including Plaintiff Etta Gay Fortney, her healthcare providers, and the public in general that the devices had been tested and found to be safe and effective for treating sleep apnea.

161. 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.

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

163. 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 serious injuries.

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

165. 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' health risks were made or omitted with the intent to induce Plaintiffs to rely upon those facts or omissions.

166. Plaintiffs were unaware and did not know that the Subject Devices were unsafe for the purpose of treating sleep apnea because it caused a significant risk of harm until after Plaintiff Joleen Shiffler had been exposed to toxic and carcinogenic particles and gasses.

167. Plaintiff Etta Gay Fortney justifiably relied upon the false representations of Defendants.

168. Had Defendants reasonably and proposed provided adequate warnings of serious injuries, such warnings would have been heeded and no healthcare professional, including Plaintiff Etta Gay Fortney's physician, would have prescribed the Subject Devices and no consumer, including Plaintiff, would have purchased and/or used the Subject Devices

169. As a direct and proximate result of the foregoing acts and omissions, Plaintiff Etta Gay Fortney was caused to suffer serious injuries, physical pain and mental anguish, including diminished enjoyment of life, and her untimely death.

COUNT VIII
NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

170. Plaintiffs incorporate by reference all paragraphs of the complaint herein and further alleges the following:

171. At all times relevant to this Complaint Plaintiff Doug Shiffler slept right next to his spouse, Jolene Shiffler and was every night within the zone of danger of the particulate matter and defects to which Joleen was exposed.

172. Doug Shiffler upon learning of the dangers caused by breathing air processed through Joleen's CPAP machine, feared that he was also exposed to the cancer-causing agents that killed his wife.

173. Being in the zone of danger, Doug Shiffler had to watch his wife suffer from the cancer caused by the Recalled Product and witness her suffering, agony and death.

174. Doug Shiffler also will suffer medical expenses and care monitoring his

own health in the future for the rest of his life to try and prevent the same result that took his best friend and wife, Joleen Shiffler.

175. Both Joleen and Doug Shiffler have suffered, and Doug Shiffler will continue to suffer, emotional distress from witnessing the harm to his wife which was directly and proximately caused by the negligence of Defendants as outlined herein.

COUNT IX
FRAUD

176. Plaintiffs hereby incorporate by reference each of the allegations set forth in this Complaint as if fully set forth herein.

177. At all relevant times, Defendants designed manufactured, assembled, inspected, tested, packaged, labeled, marketed, advertised, promoted, supplied, distributed, sold and/orotherwise placed the Recalled Products into the stream of commerce, and therefore owed a duty of reasonable care to avoid causing harm to consumers, such as Joleen Shiffler.

178. Defendants knowingly made fraudulent statements regarding the safety of the Recalled Products and the substantial health risks associated with using the devices, all the while intending to deceive Joleen Shiffler and the public.

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

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

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

182. Defendants further falsely represented the nature and risks associated with the Recalled Products, and their marketing and strategy regarding the same, in general statementsto the media, the public, and federal agencies.

183. Defendants' fraudulent misrepresentations and omissions were material facts that were essential to Joleen Shiffler's decision to purchase the subject device.

184. Joleen Shiffler was unaware that Defendants were knowingly concealing these material facts, which she relied on to her detriment.

185. By knowingly misrepresenting this material information, Defendants breached their duty to protect Joleen Shiffler and other consumers.

186. Joleen Shiffler justifiably relied to her detriment on Defendants' fraudulent statements. Had she 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.

187. As a direct and proximate result of Defendants' fraudulent misrepresentations, Joleen Shiffler and her husband suffered and continue to suffer from the injuries and damages for which they are entitled to recovery, including but not limited to compensatory damages, general damages, loss of consortium, interest, costs, and attorney fees.

COUNT X
FRAUDULENT CONCEALMENT

188. Plaintiffs hereby incorporate by reference each of the allegations set forth

in this Complaint as if fully set forth herein.

189. At all relevant times, Defendants designed, manufactured, assembled, inspected, tested, packaged, labeled, marketed, advertised, promoted, supplied, distributed, sold and/orotherwise placed the Recalled Products 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 Joleen Shiffler.

190. Defendants had a duty to disclose material facts about the Recalled Products that would substantially affect Joleen Shiffler's and the public's use when purchasing the devices.

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

192. Defendants knew about the facts plead in this Complaint.

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

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

195. Defendants' misrepresentations and omissions were material facts that were essential to Joleen Shiffler's decision making when purchasing and using the subject device.

196. Joleen Shiffler was completely unaware that Defendants were concealing

these material facts.

197. Defendants intentionally deceived and concealed material information concerning the safety of the Recalled Products from Joleen Shiffler and the public, which had a direct impact on her own and other consumers' health and well-being.

198. Joleen Shiffler relied to her detriment on Defendants' fraudulent concealment and omissions. Had she been adequately informed of the material facts regarding the safety of the Recalled Products, and not intentionally deceived by Defendants, she would not have acquired/purchased, used, or been injured by the subject device.

199. As a direct and proximate result of Defendants' fraudulent concealment, Joleen Shiffler and her husband suffered and continue to suffer from the injuries and damages for which they are entitled to recovery,including but not limited to compensatory damages, general damages, loss of consortium, interest, costs, and attorney fees.

COUNT XI
UNJUST ENRICHMENT

200. Plaintiffs hereby incorporate by reference each of the allegations set forth in this Complaint as if fully set forth herein.

201. 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 the devices, such as Plaintiff.

202. 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. Defendants were also unjustly enriched through their developing, manufacturing, promoting, and selling the Recalled Devices without adequately testing and investigating their potential side effects and health impacts.

203. Defendants requested and received a measurable benefit at the expense of Plaintiff in the form of payment for the Subject Devices.

204. Defendants appreciated, recognized, and chose to accept the monetary benefits Plaintiff Joleen Shiffler conferred onto Defendants at Plaintiff's detriment. These benefits were the expected result of Defendants acting in their pecuniary interests at the expense of its customers.

205. There is no justification for Defendants' enrichment. It would be inequitable, unconscionable, and unjust for Defendants to be permitted to retain these benefits because the benefits were procured as a result of their wrongful conduct.

206. Defendants wrongfully obfuscated the harm caused be their conduct. Thus, Plaintiff, who mistakenly enriched Defendants by relying on Defendants' fraudulent representations, could not and did not know the effect that using the Subject Devices would have on Plaintiff's health.

207. Acceptance of the benefit by Defendants under these circumstances would be inequitable.

208. Plaintiff's estate is entitled to restitution of the benefits Defendants unjustly retained and/or any amounts necessary to return Plaintiff to the position she occupied prior to dealing with Defendants. Given the importance of respiratory health and severity of injuries the Subject Devices can cause, Defendants were reasonably notified that Plaintiff

would expect compensation from Defendants' unjust enrichment stemming from their wrongful actions.

COUNT XII
WRONGFUL DEATH

209. Plaintiffs hereby incorporate by reference each of the allegations set forth in this Complaint as if fully set forth herein

210. As a direct and proximate cause of the aforementioned conduct, Defendants caused Plaintiffs' wrongful death, and Plaintiffs are entitled to recover for: A) Sorrow, mental anguish, and solace which may include society, companionship, comfort, guidance, kindly offices and advice of the Plaintiff Joleen Shiffler; (B) compensation for reasonably expected loss and services, protection, care and assistance provided by Plaintiff Joleen Shiffler; (C) expenses for the care, treatment and hospitalization of Joleen Shiffler as a result of her diagnosis of lung cancer resulting in her untimely death; and (D) reasonable funeral expenses.

COUNT XIII

SURVIVAL

211. Plaintiffs hereby incorporate by reference each of the allegations set forth in this Complaint as if fully set forth herein.

212. As a direct and proximate cause of the aforementioned conduct of Defendants, Plaintiff Joleen Shiffler suffered severe injury, including lung cancer, which caused her untimely death.

213. Plaintiff Joleen Shiffler's claims for damages as a result of Defendants' conduct survive her death and may be brought by the Personal Representative of her estate, Plaintiff Doug Shiffler

COUNT XIV
LOSS OF CONSORTIUM

214. Plaintiffs hereby incorporate by reference each of the allegations set forth in this Complaint as if fully set forth herein.

215. At all times mentioned, Plaintiffs Doug Shiffler and Joleen Shiffler were legally married as husband and wife.

216. As a direct and proximate cause of the aforementioned conduct of Defendants and as a result of the injuries and damages to Plaintiff Joleen Shiffler, Plaintiff Doug Shiffler has been deprived of the love, companionship, comfort, affection, society, solace or moral support, protection, loss of enjoyment of sexual relations and loss of physical assistance in the operation and maintenance of the home, of his wife, Plaintiff Joleen Shiffler and has thereby sustained and will continue to sustain damages.

COUNT XV
PUNITIVE DAMAGES

217. Plaintiffs hereby incorporate by reference each of the allegations set forth in this Complaint as if fully set forth herein.

218. 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.

219. Despite their knowledge of the Recalled Products' propensity to cause 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.

220. Despite having substantial information about the Recalled Products'

serious andunreasonable side effects, Defendants intentionally and recklessly failed to adequately warn Joleen Shiffler, the public, physicians, and the medical community.

221. Further, despite having substantial information about the Recalled Products' 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.

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

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

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

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

V. CONCLUSION

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief and judgment against the Defendants jointly and severally as follows:

a) That the Court enter a judgment against the Defendants for all general and compensatory damages and loss of consortium allowable to Plaintiffs 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) For a full refund of all purchase costs paid for the subject device;

e) That the Court enter a judgment against Defendants for all special and general damages allowable to Plaintiffs in excess of the jurisdictional minimum of this Court, including all damages specified above;

f) 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;

g) That the Court enter a judgment against the Defendants for all other relief sought by Plaintiffs under the present Complaint for Damages;

h) For attorneys' fees, expenses, and costs of this action; and

i) That the Court grant Plaintiffs such further relief as the Court deems appropriate.

DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury on all counts and as to all issues.

Dated: April 11th, 2022

Respectfully Submitted,

By:

/s/ Kelly H. Macfarlane

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