UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA
PITTSBURGH DIVISION

JACK CLAMPIT and DEBBIE CLAMPIT	)	
Plaintiffs,	)	
v.	)	**Civil Action No. 2:21-cv-1728**
PHILIPS RS NORTH AMERICA LLC, Individually and doing business as Respironics, Inc.; PHILIPS RS NORTH AMERICA HOLDINGS CORPORATION; RESPIRONICS, INC.; KONINKLIJKE PHILIPS N.V.; PHILIPS NORTH AMERICA LLC; and PHILIPS HOLDINGS USA, INC.	)	

COMPLAINT

COME NOW JACK CLAMPIT and DEBBIE CLAIMPIT, Plaintiffs herein, complaining of PHILIPS RS NORTH AMERICA LLC, Individually and doing business as RESPIRONICS, INC.; PHILIPS RS NORTH AMERICA HOLDINGS CORPORATION; RESPIRONICS, INC.; KONINKLIJKE PHILIPS N.V.; PHILIPS NORTH AMERICAL LLC; and PHILIPS HOLDINGS USA, INC., Defendants herein, a for cause of action, jointly and severally, say(s):

Parties

1. Jack Clampit ("Plaintiff") and Debbie Clampit ("Plaintiff Spouse") are, and at all times material hereto were, husband and wife, residents of West Monroe, Louisiana and citizens of the State of Louisiana.

2. Defendant Philips RS North America LLC, Individually and doing business as Respironics, Inc., is, and at all times material hereto was, a corporation organized under the laws

of the State of Delaware, with its principal place of business in Pennsylvania; a citizen of Delaware and Pennsylvania; and may be served by serving its registered agent for service in Delaware: Corporation Service Company, 251 Little Falls Drive, Wilmington, DE 19808.

3. Plaintiffs believe that Defendant Philips RS North America Holdings Corporation is, and at all times material hereto was, a corporation organized under the laws of the State of Delaware, with its principal place of business in Pennsylvania; a citizen of the State of Delaware and the State of Pennsylvania; and may be served by serving its registered agent for service in Delaware: Corporation Service Company, 251 Little Falls Drive, Wilmington, DE 19808.

4. Defendant Respironics, Inc. is, and at all times material hereto was, a corporation organized under the laws of the State of Delaware with its principal place of business in Pennsylvania, a citizen of the State of Delaware and of the State of Pennsylvania; and may be served with process by serving its registered agent for service in Delaware: Corporation Service Company, 251 Little Falls Drive, Wilmington, DE 19808.

5. Defendant Koninklijke Philips N.V. is a public limited liability company established under the laws of The Netherlands, a citizen 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 the Philips Group of healthcare technology businesses, including Connected Care businesses focusing on Sleep & Respiratory Care. 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") by sending duplicate Requests for Service Abroad of Judicial or Extrajudicial Documents and this Complaint to De Officer van Justitie, Postbus 20302, 2500 EH THE HAGUE, Netherlands, Attn: Mrs. Van der Zee or Mrs. Lubbers, serviceconvention@om.nl, for them to forward the process to Frans van Houten, CEO,

Philips Center, Amstelplein 2, 1096 BC Amsterdam, The Netherlands. This Complaint is not required to be translated into Dutch, or any other language, under the Hague Service Convention.

6. Defendant Philips North America LLC is, and at all times material hereto was, a corporation organized under the laws of the State of Delaware, with its principal place of business in Massachusetts, a citizen of Delaware and Massachusetts; and may be served with process by serving its CEO, Vitor Rocha, at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141.

7. Defendant Philips Holdings USA, Inc. is, and at all times material hereto was, a corporation organized under the laws of the State of Delaware, with its principal place of business in Massachusetts, a citizen of Delaware and Massachusetts; and may be service with process by serving its CEO, Brent Shafer, at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141.

8. Defendant Philips RS North America LLC, Defendant Philips RS North America Holdings Corporation, Defendant Respironics, Inc., Defendant Koninklijke Philips N.V., Defendant Philips North America LLC, and Defendant Philips Holdings USA, Inc. shall hereinafter, jointly and severally, be referred to as "Phillips," "Royal Philips," "Defendant," or Defendant Manufacturer.

Relationship Between the Parties

9. Plaintiffs are unaware of the precise relationship between Defendant Philips RS North America LLC, Defendant Philips RS North America Holdings Corporation, Defendant Respironics, Inc., Defendant Koninklijke Philips N.V., Defendant Philips North America LLC, and Defendant Philips Holdings USA, Inc., but believes that their relationship is such that each entity is responsible and liable for the conduct and products of the other parties, including, but not limited to, through alter ego, piercing the corporate veil, joint enterprise, joint venture, successor liability.

10. 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.

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

12. At all times material hereto, 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 devices. 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.

Jurisdiction

13. This Court has original jurisdiction over this matter. The amount in controversy is within the jurisdictional limits of this Court.

14. All Defendants maintained sufficient minimum contacts with the State of Pennsylvania such that the exercise of Jurisdiction over each Defendant in Pennsylvania would not offend traditional notions of fair play and substantial justice. Further, Plaintiffs' claims in this lawsuit arise out of events that occurred in the State of Pennsylvania.

15. This Court has diversity subject matter jurisdiction under 28 U.S.C. §1332, because Plaintiff and Defendants are citizens of different states and the amount in controversy exceeds $75,000.00.

Venue

16. Venue over Plaintiffs' claims lays in this Court because each Defendant regularly conducts business in this county, the cause of action arose in this county, or a transaction or occurrence out of which this cause of action arose occurred in this county.

Statement of Facts Applicable to All Counts

17. Plaintiff has been using the following DreamStation CPAP machine for approximately ten years (the "subject device"):

18. Plaintiff was diagnosed with lung cancer two years ago. Plaintiff has received his treatment for cancer at M D Anderson in Houston, Texas.

19. Philips manufactures, markets, sells, and distributes a variety of products for sleep and home respiratory care, including the DreamStation CPAP machine used by Plaintiff.

20. Phillips manufactures, markets, imports, sells, and distributes a variety of Continuous Positive Airway Pressure (CPAP) and BiLevel Positive Airway Pressure (BiLevel PAP) devices for patients with obstructive sleep apnea ("OSA"), including the DreamStation CPAP machine used by Plaintiff.

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

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

23. 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.[1] Philips further disclosed in its Recall Notice that "these issues can result in serious injury which can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment."[2]

24. Philips has disclosed that the absence of visible particles in the devices does not mean that PE-PUR Foam breakdown has not already begun. Philips reported that lab analysis of the degraded foam reveals the presence of harmful chemicals, including: Toluene Diamine ("TDA"), Toluene Diisocyanate ("TDI"), and Diethylene Glycol ("DEG").[3]

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[1] *See* Philips Recall Notice attached hereto as Exhibit "A."
[2] *See* Philips Recall Notice attached hereto as Exhibit "A."
[3] Philips Sleep and Respiratory Care Update; Clinical information for physicians, https://www.usa.philips.com/healthcare/e/sleep/communications/src-update/information-forphysicians-and-providers.

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

26. In its Recall Notice, Philips disclosed that the potential risks of particulate exposure to users of these devices include: irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (*e.g.*, kidneys and liver) and toxic carcinogenic 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.

27. Philips recommended that patients using the recalled CPAP and Bi-Level PAP devices immediately discontinue using their devices and those patients using the recalled ventilators for life-sustaining therapy consult with their physicians regarding alternative ventilator options. Philips further recommended that patients stop using ozone-related cleaning products.

28. Plaintiff registered his Philips devices' serial numbers on Defendants' website, https://www.philipssrcupdate.expertinquiry.com/registration?ulang=en and confirmed the DreamStation CPAP he had been using was subject to the recall.

29. At all times pertinent to this Complaint, Defendants were and are in the business of designing, manufacturing, marketing, promoting, advertising, and selling devices for the treatment of obstructive sleep apnea, including the subject device.

30. 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.

31. 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 marketed prior to May 28, 1976. No formal review for safety or efficacy is required.

32. 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.

33. 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.

34. 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 therapy is distinguishable from CPAP therapy, however, because Bi-Level PAP 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. Bi-Level PAP 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.

35. Mechanical ventilation is a treatment to help a person breathe when they find it difficult or are unable to breathe on their own. A mechanical ventilator pushes airflow into the patient's lungs to help them breathe. Mechanical ventilation may be invasive ventilation with a tube inserted into the patient's airway, performed in the intensive care unit in the hospital or a long-term institutional setting. Non-invasive ventilation can be used at home by people with respiratory difficulties.

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

several hundred, if not thousands of dollars. Philips has sold millions of these devices in the United States.

37. On April 26, 2021, in its Quarterly Report for Q1 2021, Philips disclosed for the first time, under a section entitled "Regulatory Update," that device user reports had led to a discovery that the type of PE-PUR Foam Philips used to minimize noise in several CPAP and Bi-Level PAP respirators and mechanical ventilators posed health risks to its users. Specifically, Philips disclosed that "the [PE-PUR] foam may degrade under certain circumstances, influenced by factors including use of unapproved cleaning methods, such as ozone [], and certain environmental conditions involving high humidity and temperature."[4]

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

39. Seven weeks later, on June 14, 2021, Philips announced a recall of numerous models of CPAP and Bi-Level PAP devices, as well as a variety of its mechanical ventilators "to address identified potential health risks related to the polyester-based polyurethane (PE-PUR) sound abatement foam component in these devices."[5]

[4] First Quarter Results, PHILIPS (Apr. 26, 2021), https://www.philips.com/aw/about/news/archive/corpcomms/news/press/2021/philips-first-quarter-results-2021.html#:~:text=Philips%20delivers%20Q1%20sales%20of,390%20basis%20points%20to%209.5%25

[5] *Philips issues recall notification* to mitigate potential health risks related to the sound abatement foam component in certain sleep and respiratory care devices*, PHILIPS (June 14, 2021), https://www.usa.philips.com/aw/about/news/archive/standard/news/press/2021/20210614-philips-issues-recall-notificationto-mitigate-potential-health-risks-related-to-the-sound-abatement-foam-component-in-certainsleep-and-respiratory-care-devices.html

40. Specifically, Philips announced that it had determined based on lab testing and evaluations that the "PE-PUR foam may degrade into particles which may enter the device's air pathway and be ingested or inhaled by the user, and the foam may off-gas certain chemicals."[6]

41. According to Philips' Recall Notice, the PE-PUR Foam used in Recalled Devices puts users at risk of suffering from the following health harms: "*Particulate exposure* can cause headache, irritation [skin, eye, and respiratory tract], inflammation, respiratory issues, and possible toxic and carcinogenic effects[;]" whereas the "potential risks of *chemical exposure due to offgassing* include headache, irritation, hypersensitivity, nausea/vomiting, and possible toxic and *carcinogenic* effects."[7]

42. Philips reported to physicians that PE-PUR Foam particles "may cause irritation and airway inflammation, and this may be particularly important for patients with underlying lung diseases or reduced cardiopulmonary reserve."[8]

43. Further, Philips reported that "based on lab testing and evaluations, it may be possible that these potential health risks could result in a wide range of potential patient impact, from transient potential injuries, symptoms and complications, as well as possibly serious injury

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[6] *Philips issues recall notification* to mitigate potential health risks related to the sound abatement foam component in certain sleep and respiratory care devices*, PHILIPS (June 14, 2021), https://www.usa.philips.com/aw/about/news/archive/standard/news/press/2021/20210614-philips-issues-recall-notificationto-mitigate-potential-health-risks-related-to-the-sound-abatement-foam-component-in-certainsleep-and-respiratory-care-devices.html

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

[8] Philips *Sleep and Respiratory Care Update – Clinical information for physicians*, June 14, 2021, https://www.philips.com/c-dam/b2bhc/master/landingpages/src/update/documents/philips-recall-clinical-information-for-physicians-and-providers.pdf (accessed July 20, 2021).

which can be life-threatening or cause permanent impairment, or require medical intervention to preclude permanent impairment."[9]

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

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

45. In its report titled "Clinical Information for Physicians," Philips also disclosed that lab testing performed by and for Philips has also identified the presence of Volatile Organic Compounds (VOCS) which may be emitted from the sound abatement foam component of the affected devices. "VOCs are emitted as gases from the foam included in the [affected devices] and may have short- and long-term adverse health effects. Standard testing identified two compounds of concern which 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)."[13]

46. In total, Philips announced that "[b]etween 3 million and 4 million" devices are targeted in the recall.[11]

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[9] Philips *Sleep and Respiratory Care Update – Clinical information for physicians*, June 14, 2021, https://www.philips.com/c-dam/b2bhc/master/landingpages/src/update/documents/philips-recall-clinical-information-for-physicians-and-providers.pdf

[10] Philips *Sleep and Respiratory Care Update – Clinical information for physicians*, June 14, 2021, https://www.philips.com/c-dam/b2bhc/master/landingpages/src/update/documents/philips-recall-clinical-information-for-physicians-and-providers.pdf

[11] Associated Press, *Philips recalls ventilators, sleep apnea machines due to health risks*, NBC

47. The list of the devices recalled by Philips (the "Recalled Devices") include:[12]

All Devices manufactured before 26 April 2021, 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

All Devices manufactured before 26 April 2021, 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-life Supporting	A-Series BiPAP A40
	A-Series BiPAP A30

48. 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."[13]

- "For patients using life-sustaining mechanical ventilator devices: DO NOT discontinue or alter prescribed therapy, without consulting physicians to determine appropriate next steps."[14]

NEWS, https://www.nbcnews.com/business/consumer/philips-recalls-ventilators-sleep-apneamachines-due-health-risks-%20n1270725

[12] https://www.philipssrcupdate.expertinquiry.com/?ulang=en

[13] Recall Notice (Exhibit "A" hereto); *see also* Medical Device recall notification (U.S. only) / field safety notice (International Markets), PHILIPS RESPIRONICS (June 14, 2021), https://www.usa.philips.com/healthcare/e/sleep/communications/src-update#section_2 (accessed July 20, 2021); Royal Philips Update on the recall notification, https://www.usa.philips.com/aw/about/news/archive/standard/news/press/2021/20210614-philips-issues-recall-notification-tomitigate-potential-health-risks-related-to-the-sound-abatement-foam-component-in-certainsleep-and-respiratory-care-devices.html

[14] Recall Notice (Exhibit "A" hereto); *see also* Medical Device recall notification (U.S. only) / field safety notice (International Markets), PHILIPS RESPIRONICS (June 14, 2021),

49. Defendants have not disclosed when they first received reports from users of its Sleep & Respiratory Care devices "regarding the presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask)."[15] However, given how long ago the first of the Recalled Devices came to market, it is unlikely that Defendants only recently learned of these issues.

50. Thus, as a result 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 Devices, yet continued to manufacture, market, and sell the Recalled Devices 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 Devices and unreasonably put users of the Recalled Devices at risk of developing adverse health effects, including cancer.

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

52. At all times Plaintiff used the subject devices, he used them for a purpose for which the subject devices were marketed, designed, and intended.

53. At all times Plaintiff used the subject devices, he used them in accordance with the directions and instructions issued by his physician who prescribed the use of the subject devices.

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https://www.usa.philips.com/healthcare/e/sleep/communications/src-update#section_2 (accessed July 20, 2021); Royal Philips Update on the recall notification, https://www.usa.philips.com/aw/about/news/archive/standard/news/press/2021/20210614-philips-issues-recall-notification-tomitigate-potential-health-risks-related-to-the-sound-abatement-foam-component-in-certainsleep-and-respiratory-care-devices.html

[15] *Medical Device recall notification (U.S. only) / field safety notice (International Markets)*, PHILIPS RESPIRONICS https://www.usa.philips.com/healthcare/e/sleep/communications/srcupdate#section_2

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

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

56. As a result of the aforesaid conduct and subject devices manufactured, designed, sold, distributed, advertised, and promoted by Defendants, 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.

57. Plaintiffs suffered damages proximately caused by characteristics of the subject device that rendered the subject device unreasonably dangerous and arose from a reasonably anticipated use of the subject device by Plaintiff. LA. REV. STAT. 9:2800.54(A).

58. The characteristics of the subject device that rendered the subject device unreasonably dangerous existed at the time the subject device left the control of Defendants. LA. REV. STAT. 9:2800.54(C).

59. Defendant sold the subject device used by Plaintiff.

60. At the time the subject device in this lawsuit was purchased, and at all times material to this lawsuit, Defendant was in the business of designing, manufacturing and selling such devices.

61. The subject device was in substantially the same condition at the time it was placed into Plaintiff as it was in when it left the control of Defendant Manufacturer.

Count One

For design defect cause of action against Defendants, Plaintiffs say:

62. Plaintiffs adopt by reference each and every Paragraph of the Statement of Facts Applicable to All Counts of this Complaint as if fully copied and set forth at length herein.

63. The subject device was defective in design in one or more of the following particulars, among others:

(a) containing a foam that degraded into harmful particles that were inhaled by the patients;

(b) containing a foam that degraded into carcinogenic particles that were inhaled by the patients;

(c) in containing foam that released harmful gases that were inhaled by patients;

(d) in containing foam that released carcinogenic gases that were inhaled by patients

64. 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 chemicals.

65. Defendants did not conduct adequate post-marketing surveillance of their Recalled Devices.

66. Safer alternative designs to the subject device that were capable of preventing Plaintiff's damages, may include, but may not be limited to, devices:

(a) contained a foam that did not degrade into harmful particles that were inhaled by the patients;

(b) contained a foam that did not degrade into carcinogenic particles that were inhaled by the patients;

(c) contained a foam that did not release harmful gases that were inhaled by patients;

(d) contained a foam that did not release carcinogenic gases that were inhaled by patients.

67. The foam in the subject device degraded and released harmful and/or carcinogenic particles that Plaintiff inhaled, and released harmful and/or carcinogenic gases that Plaintiff inhaled, and which then caused Plaintiff's lung cancer. If the foam in the subject device had not degraded and/or released harmful and/or carcinogenic gases, Plaintiff would not have inhaled the harmful and/or carcinogenic particles and would not have inhaled the harmful and/or carcinogenic gases and would not have suffered lung cancer.

68. The subject device was unreasonably dangerous because:

(a) the utility of the subject device to the user and to the public as a whole was outweighed by the gravity and likelihood of injury from its use. The likelihood the foam in the subject device would degrade and release harmful and/or carcinogenic particles and would release harmful and/or carcinogenic gases that would be inhaled by the patient outweighed any utility of the subject device to the Plaintiff or to the public as a whole.

(b) a substitute product which would meet the same need and not be unsafe or unreasonably expensive was available. CPAP machines that contained foam that did not degrade and release harmful and/or carcinogenic particles and that did not release harmful and/or carcinogenic gases that would be inhaled by the patient were available.

(c) Defendants had the ability to eliminate the unsafe character of the subject device without seriously impairing its usefulness or significantly increasing its costs. CPAP machines that contained foam that did not degrade and release harmful and/or carcinogenic particles and that did not release harmful and/or carcinogenic gases that would be inhaled by the patient were available.

(d) Neither Plaintiff nor his physician were aware (and it could not be anticipated they would be aware) that the foam in the subject device would degrade and release harmful and/or carcinogenic particles and would

release harmful and/or carcinogenic gases that would be inhaled by the patient These dangers in the subject device were not general public knowledge or obvious.

(e) Neither Plaintiff nor his physician expected the foam in the subject device to degrade and release harmful and/or carcinogenic particles and/or harmful and/or carcinogenic gases that would be inhaled by Plaintiff and cause him lung cancer.

69. The above five factors considered holistically, with no single factor needing to be proven on its own, working together show that the subject was unreasonably dangerous.

70. The likelihood that the design of the subject device would cause Plaintiff's damage and the gravity of that damage outweighed the burden on Defendant of adopting such alternative designs, including but not limited to those listed above, and any adverse effect of such an alternative design on the utility of the subject device.

71. The was also unreasonably dangerous because it was dangerous to an extent beyond that which would be contemplated by the ordinary user or handler of such products, with the ordinary knowledge common to the community as to the subject device's characteristics.

72. For the foregoing reasons, among others, Defendant is liable to Plaintiffs in strict liability for defective design.

Count Two

For marketing defect cause of action against Defendants, Plaintiffs say:

73. Plaintiffs adopt by reference each and every Paragraph of the Statement of Facts Applicable to All Counts of this Complaint as if fully copied and set forth at length herein.

74. At the time the subject device left Defendant's control, it possessed characteristics that could cause damage and Defendants failed to use reasonable care to provide an adequate warning of such characteristics and its danger to patients and physicians.

75. The subject device was dangerous to an extent beyond that which would be contemplated by the ordinary user or handler of such products, with the ordinary knowledge common to the community as to the subject device's characteristics.

76. Neither Plaintiff nor his physician knew, and could not have reasonably have been expected to know, that the foam degraded and released harmful and/or carcinogenic particles that would be inhaled by patient and/or released harmful and/or toxic gases that would be inhaled by the patient that could cause cancer and other harm, including lung cancer.

77. Defendant, after the subject device left its control, acquired knowledge that the foam degraded and released harmful and/or carcinogenic particles that would be inhaled by patient and/or released harmful and/or toxic gases that would be inhaled by the patient that could cause cancer, including lung cancer (or would have acquired that knowledge if it had acted as a reasonably prudent manufacturer), and failed to use reasonable care to provide an adequate (including timely) warning of such characteristics of the subject device and its danger to users and handlers of the subject device, including physicians.

78. 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, or to avoid the danger. Instead, Defendants disseminated information that was inaccurate, false and misleading, and which failed to communicate accurately or adequately the convey the risk of injuries with use of the Recalled Devices; continued to aggressively promote the safety and efficacy of its products, even after they knew or should have known of the unreasonable risks from use or exposure; and concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any

information or research about the risks and dangers of the Recalled Devices, including the subject devices.

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

80. If Defendant had adequately and timely notified Plaintiff that the foam in the subject device degraded and released harmful and/or carcinogenic particles, and/or released harmful and/or carcinogenic gases, that would be inhaled by the Plaintiff, Plaintiff could have taken steps to avoid that danger, included ceasing to use the subject device; and, instead using a device whose foam did not degrade and release harmful and/or carcinogenic particles, and/or did not release harmful and/or carcinogenic gases.

81. Because Defendant failed to adequately and timely warn that the foam in the subject device degraded and released harmful and/or carcinogenic particles, and/or released harmful and/or carcinogenic gases, Plaintiff continued to use the subject device without taking any steps to protect himself from that danger, inhaled harmful and/or carcinogenic particles and/or gases that caused his lung cancer. If Defendant had adequately and timely warned Plaintiff and/or his physician that the foam in the subject device degraded and released harmful and/or carcinogenic particles, and/or released harmful and/or carcinogenic gases, Plaintiff would have ceased using the subject device and/or taken steps to protect himself from that danger, would not have inhaled harmful and/or carcinogenic particles and/or gases, and would not have suffered from lung cancer

Count Three

For breach of the implied warranty of merchantability cause of action against Defendants, Plaintiffs say:

82. Plaintiffs adopt by reference each and every Paragraph of the Statement of Facts Applicable to All Counts of this Complaint as if fully copied and set forth at length herein.

83. Defendant sold the subject device.

84. The polyurethane sound abatement foam used in the subject device degraded and produced particulates that entered the product's air pathway and was inhaled by Jack Clampit. Additionally, chemicals were emitted from the foam and inhaled by Jack Clampit. Harmful chemicals that were emitted and inhaled by Jack Clampit include toluene diamine, toluene diisocyanate, diethylene glycol, dimethyl diazine, and phenol 2,6-bis (1,1-dimethylethyl)-4-(1-methylpropyl). These chemicals are toxic and carcinogenic.

85. The danger of serious harm from inhaling toxic substances, as well as the danger of contracting cancer obviously far outweighs any benefit from the use of the product. This danger obviously is beyond the danger that would be contemplated by the ordinary consumer who purchased the subject device, with the ordinary knowledge common to the community as to the products characteristics. This danger is obviously beyond the danger that would be contemplated by the ordinary physician who prescribed the subject device, with the ordinary knowledge common to physicians who prescribe such devices. In other words, the subject device is unreasonably dangerous. Because of this danger, the subject device was unmerchantable and unfit for ordinary purposes. Consequently, the subject device breached the implied warranty of merchantability.

86. Jack Clampit lung cancer two years ago. These injuries were caused by the harmful chemicals that were inhaled by Jack Clampit**.** In other words, these injuries were caused by your breach of the implied warranty of merchantability.

87. Plaintiff notified Defendant of the breach of this warranty prior to filing this suit.

88. The breach of warranty of merchantability proximately caused Plaintiff's injuries and damages more particularly set forth below.

Count Four

For negligence cause of action against Defendant, Plaintiff says:

89. Plaintiff adopts by reference each and every Paragraph of the Statement of Facts Applicable to All Counts of this Complaint as if fully copied and set forth at length herein.

90. Plaintiff adopts by reference each and every Count of this Complaint as if fully copied and set forth at length herein.

91. Defendant owed Plaintiff a duty of reasonable care. Defendant owed Plaintiff a duty to exercise care to discover dangerous propensities of the subject device. Defendant owed Plaintiff a duty to exercise ordinary care in the design, production (manufacture) and sale (marketing) of the subject device

92. Defendant breached the duties it owed to Plaintiff, failed to exercise ordinary care, and was negligent in the following particulars, among others:

(a) manufacturing, marketing and selling a product containing a foam that degraded into harmful particles that were inhaled by the patients;

(b) manufacturing, marketing and selling a product containing a foam that degraded into carcinogenic particles that were inhaled by the patients;

(c) manufacturing, marketing and selling a product containing foam that released harmful gases that were inhaled by patients;

(d) manufacturing, marketing and selling a product containing foam that released carcinogenic gases that were inhaled by patients

93. Each and every one of the foregoing acts or omissions, taken singularly or in any combination, proximately caused Plaintiff's injuries and damages, more particularly set forth below.

Res Ipsa Loquitur

As a basis for application of res ipsa loquitur to this lawsuit, Plaintiff says:

94. Plaintiff adopts by reference each and every Paragraph of the Statement of Facts Applicable to All Counts of this Complaint as if fully copied and set forth at length herein.

95. The character of the incident made the basis of this lawsuit was such that it would not ordinarily occur without negligence; and

96. The subject device was under the management and control of Defendant. Defendant was in control of the subject device at the time that the negligence (inferable from the incident made the basis of this lawsuit) occurred, so that the reasonable probabilities point to the Defendant and support a reasonable inference that Defendant was the negligent party.

97. Defendant has superior knowledge or means of information to determine the cause of the incident made the basis of this lawsuit.

98. By reason of the above and foregoing circumstances, among others, the jury is permitted to infer Defendant's negligence.

Circumstantial Evidence of Defect

99. The malfunction that occurred ordinarily would not occur in the absence of a defect in the subject device.

100. The circumstances provide a reasonable basis for concluding the defective condition did not arise subsequent to Defendant's exercise of control over the subject device.

101. The likelihood of something other than a defect in the subject device is so reduced that the most probable cause of the malfunction was a defect in the subject device. *Shaun T. Mian Corp.,* 237 S.W.3d at 863.

102. Thus, the subject device was defective.

Damages Applicable to All Counts

103. Plaintiff has suffered, and in reasonable medical probability will continue to suffer, the following injuries and damages as a result of Defendants defective product and/or conduct, among others:

(a) physical pain and mental suffering;

(b) physical impairment;

(c) physical disfigurement;

(d) loss of earning capacity;

(e) reasonable and necessary medical expenses.

104. Plaintiff Spouse has suffered, and in reasonable medical probability will continue to suffer, the following injuries and damages as a result of Defendants defective product and/or conduct, among others:

(a) loss of consortium;

(b) loss of household services.

Jury Demand

105. Plaintiffs request trial by jury.

Discovery

106. Plaintiff was unaware of the defects in Defendant's CPAP machines until approximately June 2021, when he saw a story about the recall of Defendant's machines in June 2021. Thus, Plaintiff only learned of the connection between his lung cancer and Defendant's DreamStation CPAP machine he was using until June 2021.

Prayer

WHEREFORE, Plaintiffs pray that Defendants be cited to appear and answer herein, and that upon final trial, Plaintiffs have judgment against Defendants for:

(a) Compensatory damages in an amount in excess of the minimum jurisdictional limits of this Court;

(b) Punitive damages in an amount in excess of the minimum jurisdictional limits of this Court;

(c) Prejudgment interest;

(d) Post-judgment interest;

(e) Costs of court;

(f) Such other and further relief to which Plaintiffs show themselves justly entitled to receive.

Respectfully submitted,

Houssiere, Durant & Houssiere, LLP

By: */s/Charles R. Houssiere, III*

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