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

IN RE: PHILIPS RECALLED CPAP, BI-LEVEL PAP, AND MECHANICAL VENTILATOR PRODUCTS LITIGATION	Master Docket: Misc. No. 21-1230
This Document Relates to:	MDL No. 3014
LINDA HENDERSON, individually, and as Administrator of the Estate of MICHAEL HENDERSON, deceased,	<b>Case No.</b> 22-142
Plaintiff, v.	COMPLAINT
KONINKLIJKE PHILIPS N.V.; PHILIPS NORTH AMERICA LLC; and PHILIPS RS NORTH AMERICA LLC,	DEMAND FOR JURY TRIAL
Defendants.	

Plaintiff LINDA HENDERSON ("Plaintiff") for her Complaint and Demand for Jury Trial against Defendants Koninklijke Philips N.V. ("Royal Philips"), Philips North America LLC ("Philips NA"), and Philips RS North America LLC ("Philips RS") (collectively, Royal Philips, Philips NA, and Philips RS are "Philips" or the "Defendants"), alleges the following based on personal knowledge, the investigation of counsel, and information and belief, as follows:

# **INTRODUCTION**

1. Plaintiff brings this action for injuries caused on Plaintiff-Decedent MICHAEL HENDERSON ("Decedent") as a user of Continuous Positive Airway Pressure (CPAP) and Bi-Level Positive Airway Pressure (Bi-Level PAP) devices and mechanical ventilators manufactured by Philips, which contain polyester-based polyurethane sound abatement foam ("PE-PUR Foam").

## Case 2205: VACO12025FCD o Dourceme 821 Fifeled 0/2/2/22 PRgg 226855

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

3. Philips 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").

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

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

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

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

8. 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

## Case 2 205: VACO 2025 FCD o Dource meas 1 Fifele d 0/2/2/22 PRage 3 5 8 5 5

the degraded foam reveals the presence of harmful chemicals, including: Toluene Diamine ("TDA"), Toluene Diisocyanate ("TDI"), and Diethylene Glycol ("DEG").<sup>1</sup>

9. 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.

10. 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.

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

12. On or about 2010, Plaintiff's Decedent MICHAEL HENDERSON was prescribed one of Philips recalled devices, a Philips DreamStation CPAP device, to treat his obstructive sleep apnea.

13. In or around January 2019, Plaintiff's Decedent MICHAEL HENDERSON was diagnosed with malignant neoplasm of the lung.

<sup>&</sup>lt;sup>1</sup> Philips Sleep and Respiratory Care Update; Clinical information for physicians, https://www.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/philips-recall-clinicalinformation-for-physicians-and-providers.pdf (accessed June 27, 2021).

## C6.38 2 225: VAQ 02 225 FCD o Dource me 82 1 Fifele d 0/2/2/2/2 2 PR 3 g 4 4 b 8 5 5

14. As a direct and proximate result of Philips' conduct, Plaintiff's Decedent MICHAEL HENDERSON suffered serious and substantial life-altering injuries, including succumbing to lung cancer in March of 2019.

15. As a direct and proximate result of Defendants' negligence, the Plaintiff's Decedent MICHAEL HENDERSON experienced significant mental and physical pain and suffering, sustained permanent injury, including succumbing to lung cancer in March of 2019. As a result, Plaintiff LINDA HENDERSON has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

16. Plaintiff LINDA HENDERSON has now incurred substantial expenses for her Decedent MICHAEL HENDERSON's medical care due to his lung cancer diagnosis and his subsequent passing.

17. Plaintiff LINDA HENDERSON seeks to recover damages based on, *inter alia*, Philips' breach of express warranty, breach of implied warranties, misrepresentations, omissions, and breaches of state consumer protection laws in connection with its manufacture, marketing and sales of devices containing PE-PUR Foam.

#### **PARTIES**

18. Plaintiff LINDA HENDERSON and her decedent, MICHAEL HENDERSON were residents of Arkansas, County of Grant, at all relevant times.

19. Plaintiff LINDA HENDERSON was married to decedent MICHAEL HENDERSON at all relevant times.

20. Defendant Royal Philips is a Dutch multinational corporation with its principal place of business located in Amsterdam, Netherlands. Royal Philips is the parent company of the Philips Group of healthcare technology businesses, including Connected Care businesses focusing on Sleep & Respiratory Care. Royal Philips holds directly or indirectly 100% of its subsidiaries

## C6.38 2 2 2 5: VA 00 1 2 0 2 5 F CD o Dorce me 8 2 1 F Hele & D/2/2/2 2 P R g g & 5 b 8 5 5

Philips NA and Philips RS.<sup>2</sup> Upon information and belief, Royal Philips controls Philips NA and Philips RS in the manufacturing, selling, distributing, and supplying of the recalled CPAP, Bi-Level PAP, and mechanical ventilator devices.<sup>3</sup>

21. Defendant Philips NA is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. Philips NA is a wholly-owned subsidiary of Royal Philips.

22. Defendant Philips RS is a Delaware corporation with its principal place of business located at 6501 Living Place, Pittsburgh, Pennsylvania 15206. Philips RS is a wholly-owned subsidiary of Royal Philips. Philips RS was formerly operated under the business name Respironics, Inc. ("Respironics"). Royal Philips acquired Respironics in 2008.<sup>4</sup>

# JURISDICTION AND VENUE

23. 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 DreamStation CPAP device prescribed for and purchased by Plaintiff's Decedent MICHAEL HENDERSON at issue in this lawsuit (the "subject device").

24. 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

<sup>&</sup>lt;sup>2</sup> Philips 2020 annual filing with the SEC, fn. 8,

https://www.sec.gov/Archives/edgar/data/313216/000031321621000008/phg-exhibit8.htm (accessed June 30, 2021).

<sup>&</sup>lt;sup>3</sup> Philips 2020 annual filing with the SEC,

https://www.sec.gov/ix?doc=/Archives/edgar/data/0000313216/000031321621000008/phg-20201231.htm (accessed June 30, 2021).

<sup>&</sup>lt;sup>4</sup> Philips announces completion of tender offer to acquire Respironics, WEB WIRE, https://www.webwire.com/ViewPressRel.asp?aId=61199 (accessed June 27, 2021).

## C6.38 2 225: VAQ 02 225 FCD o Dource me 82 1 Fifele d 0/2/2/22 PR 3 6 6 6 5 8 5 5

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.

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

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

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

28. This Court has personal jurisdiction over this matter pursuant to 28 U.S.C. § 1391(b)(1) because Defendant PHILIPS RS NORTH AMERICA LLC maintains its principal place of business at 6501 Living Place, Pittsburgh, Pennsylvania 15206, which is located in this district.

29. This Court has personal jurisdiction over Defendants because of their systematic and continuous contacts with Pennsylvania as well as their maintenance of a registered agent for service of process in Pennsylvania.

30. The Court has personal jurisdiction over the Defendants because Defendants conduct substantial business in this District, and the events giving rise to Plaintiff's claims arise out of and relate to Defendants' contacts with this District. Defendants Philips RS and Philips NA

## C6.38 2 2 2 5: VA 00 0 2 0 2 5 F CD o Dource me 8 2 1 F Hele & D/2/2/2 2 P R g g 7 7 5 5 8 5 5

are controlled by their parent Royal Philips. Defendants' affiliations with this District are so continuous and systematic as to render them essentially at home in the forum State. Further, Defendants have transacted business, maintained substantial contacts, purposefully targeted consumers and medical professionals for sales of its devices and/or committed overt acts in furtherance of the unlawful acts alleged in this Complaint in this District, as well as throughout the United States. The unlawful acts of Defendants have been directed at, targeted, and have had the effect of causing injury to persons residing in, located in, or doing business in this District, as well as throughout the United States.

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

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

#### **BACKGROUND**

33. At all relevant times, Defendants developed, manufactured, marketed, distributed 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.

## Case 2 205: VACO 2025 FCD o Dource me 82 1 Fifele d 0/2/2/22 PRgg & & b855

34. Defendants sought and obtained Food and Drug Administration ("FDA") approval to market the Recalled Devices, including the subject device used by Plaintiff's Decedent MICHAEL HENDERSON, 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.

# A. Continuous Positive Airway Pressure Therapy

35. 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.

36. 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**

37. 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 pressurize air (the inspiratory positive level) to assist as a person inhales, and another level (the expiratory level) as a person exhales.

# C. Mechanical Ventilation

38. 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.

# D. Philips' Sleep & Respiratory Care Devices Endangered Users

39. 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

# Case 2205: vr0002225FCD 0 Documente 821 Fifele 0 0/2/2/2/2 PRgg d 0 0 b 855

by factors including use of unapproved cleaning methods, such as ozone[], and certain environmental conditions involving high humidity and temperature."<sup>5</sup>

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

41. 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."<sup>6</sup> Specifically, Philips announced that it had determined 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."<sup>7</sup> In total, Philips announced that "[b]etween 3 million and 4 million" devices are targeted in the recall.<sup>8</sup>

42. The list of the devices recalled by Philips (the "Recalled Devices" or "Recalled Machines") include:

<sup>6</sup> 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.philips.com/a-w/about/news/archive/standard/news/press/2021/20210614-philips-issues-recall-notification-to-mitigate-potential-health-risks-related-to-the-sound-abatement-foam-component-incertain-sleep-and-respiratory-care-devices.html (accessed June 27, 2021).

<sup>7</sup> Id.

<sup>&</sup>lt;sup>5</sup> 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 June 27, 2021).

<sup>&</sup>lt;sup>8</sup> Associated Press, *Philips recalls ventilators, sleep apnea machines due to health risks*, NBC NEWS, https://www.nbcnews.com/business/consumer/philips-recalls-ventilators-sleep-apnea-machines-due-health-risks-n1270725 (accessed June 27, 2021).

Philips CPAP and Bi-Level PAP Devices Manufactured Before April 26, 2021 Subject to Recall <sup>9</sup>	
Device Name/Model Type	Туре
E30 (Emergency Use Authorization)	Continuous Ventilator, Minimum Ventilatory Support, Facility Use
DreamStation ASV	
DreamStation ST, AVAPS	
SystemOne ASV4	Continuous Ventilator, Non-life Supporting
C Series ASV	
C Series S/T and AVAPS	
OmniLab Advanced Plus	
SystemOne (Q Series)	
DreamStation	
DreamStation GO	Non-continuous Ventilator
Dorma 400	
Dorma 500	
REMStar SE Auto	

Philips Mechanical Respirator Devices Manufactured Before April 26, 2021 Subject to Recall <sup>10</sup>	
<b>Device Name/Model Type</b>	Туре
Trilogy 100 Ventilator	
Trilogy 200 Ventilator	Continuous Ventilator
Garbin Plus, Aeris, LifeVentVentilator	
A-Series BiPAP Hybrid A30	Continuous Ventilator, Minimum Ventilatory
Philips A-Series BiPAP V30 Auto	Support, Facility Use
Philips A-Series BiPAP A40	Continuous Ventilator, Non-life Supporting
Philips A-Series BiPAP A30	

<sup>&</sup>lt;sup>9</sup> 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 June 27, 2021); Royal Philips Update on the recall notification, https://www.philips.com/a-

w/about/news/archive/standard/news/press/2021/20210614-philips-issues-recall-notification-to-mitigate-potential-health-risks-related-to-the-sound-abatement-foam-component-in-certain-sleep-and-respiratory-care-devices.html (accessed June 27, 2021).

## Case 2205: vr0002225FCD 0 Domente 821 Fifele 0 0/2/2/22 PRgg 0.2205855

43. According to Philips, the PE-PUR Foam used in Recalled Devices puts users at risk of suffering from: "[i]rritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (e.g. kidneys and liver) and toxic carcinogenic affects."<sup>11</sup>

44. On June 14, 2021, Philips also issued a brief report titled "Clinical Information for Physicians." There, Philips reported 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."<sup>12</sup>

45. In this report, Philips also disclosed that "[1]ab analysis of the degraded foam reveals the presence of potentially harmful chemicals including:

-Toluene Diamine

-Toluene Diisocyanate

-Diethylene glycol."<sup>13</sup>

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

-Dimethyl Diazine

-Phenol, 2,6-bis (1,1-dimethylethyl)-4-(1-methylpropyl)-"14

<sup>11</sup> *Id*.

 <sup>&</sup>lt;sup>12</sup> Philips Sleep and Respiratory Care Update – Clinical information for physicians, June 14, 2021, philips-recall-clinical-information-for-physicians-and-providers.pdf (accessed June 27, 2021).
<sup>13</sup> Id.

<sup>&</sup>lt;sup>14</sup> *Id*.

## Cass@2205;vr0002225FCDoDomenne021FiFele00/2/2/22PRggd.336855

47. Further, Philips reported that "based on lab testing and evaluations, it may be possible that these potential health risks could result in a wide range of potential patient impact, from transient potential injuries, symptoms and complications, as well as possibly serious injury which can be life-threatening or cause permanent impairment, or require medical intervention to preclude permanent impairment."<sup>15</sup>

48. Philips announced that it has received reports of specific complaints from users of Recalled Devices who suffered from "headache[s], upper airway irritation, cough, chest pressure and sinus infection."<sup>16</sup>

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

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

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

<sup>&</sup>lt;sup>15</sup> *Id*.

<sup>&</sup>lt;sup>16</sup> Recall Notice (Exhibit A hereto).

# Case 2205: vr0002225FCD 0 Doctome 821 File d 0/2/2/22 PRgg 0.440 5855

respiratory conditions. Individuals using life-supporting ventilators must seek an alternative treatment before discontinuing use of the Recalled Device.

51. Recognizing this, Philips issued the following advice to patients using any of the

Recalled Devices:

- **"For patients using BiLevel PAP and CPAP devices:** Discontinue use of affected units and consult with physicians to determine the benefits of continuing therapy and potential risks."<sup>17</sup>
- "For patients using life-sustaining mechanical ventilator devices: DO NOT discontinue or alter prescribed therapy, without consulting physicians to determine appropriate next steps."<sup>18</sup>
- F. Philips Unreasonably Delayed its Recall

52. At no time prior to its Regulatory Update on April 26, 2021, did Philips disclose to purchasers or users of the Recalled Devices that the PE-PUR Foam contained therein may off-gas or degrade upon use. Similarly, prior to the Update, Philips did not disclose any health risks associated with use of the Recalled Devices.

53. Defendants have not disclosed when they first discovered or received reports from users of their Sleep & Respiratory Care devices "regarding the presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask)."<sup>19</sup>

54. At a minimum, as a result of user reports, Defendants were aware of the off-gassing and degradation of the PE-PUR Foam used in the Recalled Devices at some point prior to the recall, yet continued to manufacture and sell the Recalled Devices with such awareness. During this period, Defendants unreasonably and unjustly profited from the manufacture and sale of the

<sup>&</sup>lt;sup>17</sup> 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 June 27, 2021) (Questions and answers) (emphasis in original).

<sup>&</sup>lt;sup>18</sup> Id.

<sup>&</sup>lt;sup>19</sup> Recall Notice (Exhibit "A" hereto).

#### Case 2 225 vr 000 2 2 2 5 CD 0 Doctome 8 2 1 File d 0 1/2/2/2 2 PR gg d 5 5 b 8 5 5

Recalled Devices and unreasonably put users of the Recalled Devices at risk of development of serious adverse health effects, including organ failure and cancer.

#### **Decedent MICHAEL HENDERSON**

55. Plaintiff's Decedent MICHAEL HENDERSON ("Decedent") purchased a Recalled Device, a Philips DreamStation CPAP device, prior to June 14, 2021.

56. The manuals accompanying MICHAEL HENDERSON's DreamStation CPAP devices did not contain any language or warnings of health risks associated with use of the device, including irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (*e.g.*, kidneys and liver) and toxic carcinogenic effects. Had Defendants informed MICHAEL HENDERSON of these risks, he would not have purchased or used the Recalled Device.

57. In or around January 2019, Plaintiff's Decedent MICHAEL HENDERSON was diagnosed with malignant neoplasm of the lung.

58. Without knowing of the health risks associated with use of the Recalled Device, Decedent MICHAEL HENDERSON used his Recalled Device regularly to treat sleep apnea until the date of his death.

59. As a direct and proximate result of Philips' conduct, Plaintiff's Decedent MICHAEL HENDERSON suffered serious and substantial life-altering injuries, including succumbing to lung cancer in March of 2019.

# TOLLING AND ESTOPPEL

# I. DISCOVERY RULE TOLLING

60. Plaintiff had no way of knowing about Philips' conduct with respect to the health risks associated with the use of the Recalled Device.

## Cass@2205;vr0002225FCDoDomenne821FHeld00/2/2/22PRggd666b855

61. Plaintiff, through the exercise of reasonable care, could not have discovered the conduct by Philips alleged herein. Further, Plaintiff did not discover and did not know of facts that would have caused a reasonable person to suspect that Philips was engaged in the conduct alleged herein.

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

# II. FRAUDULENT CONCEALMENT TOLLING

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

64. Upon information and belief, Philips intended its acts to conceal the facts and claims from Plaintiff. Plaintiff and Plaintiff's Decedent MICHAEL HENDERSON were unaware of the facts alleged herein without any fault or lack of diligence on their part and could not have reasonably discovered Defendants' conduct. For this reason, any statute of limitations that otherwise may apply to the claims of Plaintiff should be tolled.

#### **CLAIMS FOR RELIEF**

# FIRST CAUSE OF ACTION NEGLIGENCE

65. Defendants had a duty to individuals, including to Plaintiff and to Plaintiff's Decedent MICHAEL HENDERSON, to use reasonable care in designing, manufacturing, marketing, labeling, packaging and selling the recalled machines, including the DreamStation CPAP machine.

66. Defendants were negligent in failing to use reasonable care as described herein in designing and manufacturing, the recalled machines, as well as the DreamStation CPAP machine

# C6ase 2205:vr0002225FCDoDommente 821 Fifee 0 0/2/2/22 PRgg 0.1706855

that Plaintiff's Decedent MICHAEL HENDERSON purchased and used. Defendants breached

their aforementioned duty by:

- a. Failing to design the recalled machines, as well as the DreamStation CPAP machine so as to avoid an unreasonable and increased risk of harm of cancer and other injuries in users;
- b. Including in the design of the recalled machines, as well as the DreamStation CPAP machine, flawed polyurethane PE-PUR sound abatement foam that could break down, flake off and/or chemicalize and infiltrate the device's air pathway while the user is sleeping, exposing them to increased and unnecessary risk of cancer, including lung cancer, as well as other injuries;
- c. Manufacturing certain Philips machines, including the recalled machines and the DreamStation CPAP machine with a specific lot and/or lots of flawed polyurethane PE-PUR sound abatement foam that could break down, flake off and/or chemicalize and infiltrate the device's air pathway while the user is sleeping, exposing them to increased and unnecessary risk of cancer, including lung cancer, as well as other injuries;
- d. Otherwise negligently or carelessly designing, manufacturing, marketing, labeling, packaging and/or selling the DreamStation CPAP machine.
- 67. Defendant also negligently failed to warn or instruct the Plaintiff and Plaintiff's

Decedent in the following manners:

- a. the recalled machines, including the DreamStation CPAP machine's flawed polyurethane PE-PUR sound abatement foam propensities to break down, flake off and/or chemicalize and infiltrate the device's air pathway while the user is sleeping, exposing them to increased and unnecessary risk of cancer, including lung cancer, as well as other injuries;
- b. the recalled machines, including the DreamStation CPAP machine's polyurethane PE-PUR sound abatement foam propensities to degradation, fragmentation and/or chemicalization;
- c. the rate and manner in which the polyurethane PE-PUR sound abatement foam would break down, flake off and/or chemicalize and infiltrate the device's air pathway while the user is sleeping;
- d. The risk of chronic inflammation resulting from use of the recalled machines, including the DreamStation CPAP machine;

- e. the risk of chronic infections resulting from the recalled machines, including the DreamStation CPAP machine;
- f. the risk of lung, kidney, and/or rectal cancers from exposure to the foam;
- g. the need for corrective or revision surgery to adjust or remove cancerous tumors and/or nodules as a result of usage of the recalled machines, including the DreamStation CPAP machine;
- h. the severity of complications that could arise as a result of the use of the recalled machines, including the DreamStation CPAP machine;

68. As a direct and proximate result of Defendants' negligence, the Plaintiff's Decedent MICHAEL HENDERSON experienced significant mental and physical pain and suffering, sustained permanent injury, including succumbing to lung cancer in March of 2019. As a result, Plaintiff LINDA HENDERSON has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

# **SECOND CAUSE OF ACTION**

# PRODUCT LIABILITY DESIGN DEFECT

69. The recalled machines, including the DreamStation CPAP machine used by Decedent MICHAEL HENDERSON was not reasonably safe for its intended uses and was defective as described herein with respect to its design. As previously stated, the DreamStation CPAP machine's design defects include, but are not limited to:

a. the use of polyurethane PE-PUR sound abatement foam in the recalled machines, including the DreamStation CPAP machine and the immune reaction that results from such material, causing adverse reactions and injuries;

- b. Failing to design the recalled machines, as well as the DreamStation CPAP machine so as to avoid an unreasonable and increased risk of harm of cancer and other injuries in users;
- c. Including in the design of the recalled machines, as well as the DreamStation CPAP machine, flawed polyurethane PE-PUR sound abatement foam that could break down, flake off and/or chemicalize and infiltrate the device's air pathway while the user is sleeping, exposing them to increased and unnecessary risk of cancer, including lung cancer, as well as other injuries;
- d. Failing to use alternatively available sound abatement materials and/or foams in the recalled machines, as well as the DreamStation CPAP machine, such as plastic, silicone, or rubber, which would not break down, flake off and/or chemicalize and infiltrate the device's air pathway while the user is sleeping;
- e. Otherwise negligently or carelessly designing, manufacturing, marketing, labeling, packaging and/or selling the recalled machines, including the DreamStation CPAP machine.

70. The use of the recalled machines, as well as Plaintiff's Decedent MICHAEL

HENDERSON's use of the DreamStation CPAP machine (and its components, such as the facemask) was at all times foreseeable and foreseen by Defendants as it was used by MICHAEL

HENDERSON in the manner intended by Defendants.

71. The recalled machines, including the DreamStation CPAP machine used by MICHAEL HENDERSON, was defective in their design in that they failed to perform as safely as a reasonable consumer would expect when used in an intended or reasonably foreseeable manner.

72. The recalled machines, including the DreamStation CPAP machine used by MICHAEL HENDERSON are further defective in that the risks of danger inherent in its design outweigh the benefits, in that the gravity of danger posed by the design was great, the likelihood that such danger would cause injury was substantial, there were feasible, safer alternative designs known to Defendants at the time of manufacture, the financial costs of an improved design was

## Case 2205-vr/0002/025F CD o Domente 821 Fifele 0 0/2/2/22 PRgg 200 b855

minor and there were likely no adverse consequences to the product, or to the user, that would result from an alternative design.

73. Defendants, and each of them, knew that the recalled machines, including MICHAEL HENDERSON's DreamStation machine, and the component parts of these CPAP machines would be purchased and used without inspection for defects in the design of the machine or its masks/attachments.

74. The recalled machines, including the Decedent's MICHAEL HENDERSON's DreamStation machine, and the component parts of these CPAP machines were defective when they left the control of each of these Defendants.

75. As a direct and proximate result of the recalled machines, including MICHAEL HENDERSON's defective DreamStation CPAP machine, and aforementioned defects as described herein, Plaintiff's Decedent MICHAEL HENDERSON experienced significant mental and physical pain and suffering, sustained permanent injury, including succumbing to lung cancer in March of 2019. As a result, Plaintiff LINDA HENDERSON has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

76. Defendants are strictly liable to the Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling the recalled machines, including MICHAEL HENDERSON's defective DreamStation CPAP machines.

77. As a direct and proximate result of one or more of the above-stated negligent acts, Decedent did suffer injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income, and disability and death. As a result, Plaintiff LINDA HENDERSON has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

#### Case 2205 vr 0002025 FCD 0 Domente 021 Fifele 0 0/2/2/22 PRgg 220 b855

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

# THIRD CAUSE OF ACTION

# PRODUCT LIABILITY: MANUFACTURING DEFECT

78. The use of the recalled machines, as well as Decedent MICHAEL HENDERSON's use of the DreamStation CPAP machine (and its components, such as the facemask) was at all times foreseeable and foreseen by Defendants as it was used by MICHAEL HENDERSON in the manner intended by Defendants.

79. The recalled machines, including the DreamStation CPAP machine used by Decedent were defective at the time of their manufacture, development, production, testing, inspection, endorsement, sale and distribution, and at the time they left the possession of the Defendants, in that, and not by way of limitation, the products differed from the Defendants' intended result and intended design and specifications, and from other ostensibly identical units of the same product line.

80. Defendants, and each of them, knew or should have known of the defective nature of the recalled machines, including the DreamStation CPAP machine used by MICHAEL HENDERSON, including (among other things), that the PE-PUR foam used in the recalled machine's component parts was prone to flaking, chemicalization, disintegration, that it could enter the user's airways while they slept, and created an unreasonably high risk while in use, and would foreseeably result in injury or death to the public, purchasers, and/or consumers.

81. Specifically, the Defendants improperly designed the recalled machines, including

## Cass@2205;vr00022025FCDoDorcemet21Fifeled01/2/2/22PRgg@2206855

the Decendent's DreamStation machine, by:

a. Manufacturing certain Philips machines, including the recalled machines and the recalled machines, including the DreamStation CPAP machine with a specific lot and/or lots of flawed polyurethane PE-PUR sound abatement foam that could break down, flake off and/or chemicalize and infiltrate the device's air pathway while the user is sleeping, exposing them to increased and unnecessary risk of cancer, including lung cancer, as well as other injuries;

82. As a direct and proximate result of one or more of the above-stated negligent acts, Decedent did suffer injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income, and disability and death. As a result, Plaintiff LINDA HENDERSON has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

# FOURTH CAUSE OF ACTION

# PRODUCT LIABILITY: FAILURE TO WARN

83. The recalled machines, including the DreamStation CPAP used by Plaintiff's Decedent MICHAEL HENDERSON were not reasonably safe for their intended uses and were defective as described herein as a matter of law due to its lack of appropriate and necessary warnings. Specifically, Defendants did not provide sufficient or adequate warnings including, but not limited to, the following:

a. the recalled machines, including the DreamStation CPAP machine's flawed polyurethane PE-PUR sound abatement foam propensities to break down, flake off and/or chemicalize and infiltrate the device's air pathway while the user is

sleeping, exposing them to increased and unnecessary risk of cancer, including lung cancer, as well as other injuries;

- b. the recalled machines, including the DreamStation CPAP machine's polyurethane PE-PUR sound abatement foam propensities to degradation, fragmentation and/or chemicalization;
- c. the rate and manner in which the polyurethane PE-PUR sound abatement foam would break down, flake off and/or chemicalize and infiltrate the device's air pathway while the user is sleeping;
- d. The risk of chronic inflammation resulting from use of the recalled machines, including the DreamStation CPAP machine;
- e. the risk of chronic infections resulting from the recalled machines, including the DreamStation CPAP machine;
- f. the risk of lung, kidney, and/or rectal cancers from exposure to the foam;
- g. the need for corrective or revision surgery to adjust or remove cancerous tumors and/or nodules as a result of usage of the recalled machines, including the DreamStation CPAP machine;
- h. the severity of complications that could arise as a result of the use of the recalled machines, including the DreamStation CPAP machine;

84. As a direct and proximate result of the recalled machines, including the DreamStation CPAP machine's aforementioned defects as described herein, Plaintiff's Decedent MICHAEL HENDERSON experienced significant mental and physical pain and suffering, sustained permanent injury, including succumbing to lung cancer in March of 2019. As a result, Plaintiff LINDA HENDERSON has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

85. Defendants are strictly liable to the Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling a defective DreamStation CPAP machine.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages,

#### Case 2205 vr 0002025 FCD o Domente 821 Fifele 0 0/2/2/22 PRgg 240 b855

punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

#### FIFTH CAUSE OF ACTION

## **BREACH OF EXPRESS WARRANTY**

86. Philips marketed and sold the Recalled Device into the stream of commerce with the intent that the Recalled Device would be purchased by Decedent and other members of the general public.

87. Philips expressly warranted, advertised, and represented to Plaintiff and to Plaintiff's Decedent that the Recalled Device was safe and appropriate for human use.

88. Philips made these express warranties regarding the Recalled Device's quality and fitness for use in writing through its website, advertisements, and marketing materials, and on the Recalled Device's packaging and labels. These express warranties became part of the basis of the bargain that Plaintiff and Plaintiff's Decedent entered into upon purchasing the Recalled Device.

89. Philips' advertisements, warranties, representations, and omissions regarding health risks associated with the Recalled Device, were made in connection with the sale of the Recalled Device to Plaintiff and Plaintiff's Decedent. Plaintiff and Plaintiff's Decedent relied on Philips' advertisements, warranties, representations, and omissions regarding the Recalled Device in deciding whether to purchase and use Philips' Recalled Device.

90. Philips' recalled machines, including the DreamStation CPAP used by Decedent, do not conform to Philips' advertisements, warranties, representations, and omissions in that they are not safe, healthy, and appropriate for human use, and pose risks of serious injury and disease, including organ failure and cancer.

91. Philips therefore breached its express warranties by placing the recalled machines, including the DreamStation CPAP used by Decedent, into the stream of commerce and selling it

## Case 2205: vr0002225FCD 0 Domented 21 Fifeled 0/2/2/22 PRgg 235 b 855

to consumers, when their use posed health risks, had dangerous effects and were unsafe, rendering these products unfit for their intended use and purpose, and unsafe and unsuitable for consumer use as marketed by Philips. These associated health effects substantially impair the use, value, safety of the Recalled machines, including the DreamStation CPAP used by Decedent.

92. Philips was aware, or should have been aware, of the toxic or dangerous health effects of the use of the Recalled machines, including the DreamStation CPAP used by Decedent, but nowhere on the package labeling or package inserts or on Philips' websites or other marketing materials did Philips warn Plaintiff and MICHAEL HENDERSON that he was at risk of developing adverse health effects as a result of the dangerous PE-PUR Foam used in the Recalled machines, including the DreamStation CPAP used by Decedent.

93. Instead, Philips concealed the dangerous health effects of the PE-PUR Foam used in the Recalled machines, including the DreamStation CPAP used by Decedent and deceptively represented that these products were safe, healthy, and appropriate for use. Philips thus utterly failed to ensure that the material representations they were making to consumers were true.

94. The adverse health effects associated with use of the Recalled machines, including the DreamStation CPAP used by Decedent existed when they left Philips' possession or control and were sold to Plaintiff and Decedent. The dangers associated with use of the Recalled machines, including the DreamStation CPAP used by Decedent were undiscoverable by Plaintiff at the time of purchase of the Recalled machines, including the DreamStation CPAP used by Decedent.

95. As manufacturers, marketers, advertisers, distributors and sellers of the Recalled machines, including the DreamStation CPAP used by Decedent, Philips had exclusive knowledge and notice of the fact that the Recalled machines, including the DreamStation CPAP used by Decedent did not conform to the affirmations of fact and promises.

## Case 2205: vr0002225FCD 0 Domented 21 Fifeled 0 1/2/2/22 PRgg 286 b 855

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

97. Philips' affirmations of fact and promises and its omissions were material, and Decedent reasonably relied upon such representations and omissions in purchasing and using the Recalled machines, including the DreamStation CPAP used by Decedent.

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

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

100. As a direct and proximate result of the recalled machines, including the DreamStation CPAP machine's aforementioned defects as described herein, Plaintiff's Decedent MICHAEL HENDERSON experienced significant mental and physical pain and suffering, sustained permanent injury, including succumbing to lung cancer in March of 2019. As a result, Plaintiff LINDA HENDERSON has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages,

### Case 2205 vr 0002225 FCD 0 Domente 021 Fifele 0 0/2/2/22 PRgg 220 b855

punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

#### SIXTH CAUSE OF ACTION

#### **BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY**

101. Philips are merchants engaging in the sale of goods to Plaintiff, Plaintiff's Decedent and members of the general public.

102. There was a direct sale of goods from Philips to Plaintiff and Decedent, creating privity between Plaintiff and Defendants.

103. At all times mentioned herein, Philips manufactured or supplied the recalled machines, including the DreamStation CPAP used by Decedent, and prior to the time the Recalled machine was purchased by Plaintiff and Decedent, Philips impliedly warranted to them that the Recalled machines, including the DreamStation CPAP used by Decedent was of merchantable quality, fit for its ordinary use, and conformed to the promises and affirmations of fact and omissions made on the Recalled machines, including the DreamStation CPAP used by Decedent labels and packaging, including that the Recalled machines, including the DreamStation CPAP used by Decedent was safe and appropriate for human use. Plaintiff relied on Philips' promises and affirmations of fact and omissions when she purchased and used the Recalled machines, including the DreamStation CPAP used by Decedent.

104. Contrary to these representations and warranties, the Recalled machines, including the DreamStation CPAP used by Decedent was not fit for its ordinary use and did not conform to Philips' affirmations of fact and promises and omissions because use of the Recalled machines, including the DreamStation CPAP used by Decedent is accompanied by the risk of adverse health effects, which does not conform to the labels and packaging of these devices.

## Case 2205: vr0002225FCD 0 Domented 21 Fifeled 0/2/2/22 PRgg 28 & b855

105. Philips breached its implied warranties by selling a Recalled machine, including the DreamStation CPAP used by Decedent that failed to conform to the promises or affirmations of fact made on the packaging or label, as use of each Recalled machines, including the DreamStation CPAP used by Decedent was accompanied by the risk of developing adverse health effects that do not conform to the packaging or label.

106. Philips was on notice of this breach, as it was made aware of the adverse health effects accompanying use of the Recalled machines, including the DreamStation CPAP used by Decedent through user reports submitted to Philips and through lab testing.

107. Privity exists because Philips impliedly warranted to Plaintiff through the warranting, packaging, advertising, marketing, and labeling that the Recalled machines, including the DreamStation CPAP used by Decedent were natural, and suitable for use to treat health conditions, and made no mention of the attendant health risks associated with use of the Recalled machines, including the DreamStation CPAP used by Decedent.

108. As a direct and proximate result of the recalled machines, including the DreamStation CPAP machine's aforementioned defects as described herein, Plaintiff's Decedent MICHAEL HENDERSON experienced significant mental and physical pain and suffering, sustained permanent injury, including succumbing to lung cancer in March of 2019. As a result, Plaintiff LINDA HENDERSON has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

#### SEVENTH CAUSE OF ACTION

# FRAUDULENT MISREPRESENTATION

109. Philips failed to advise Plaintiff that the Recalled machines, including the DreamStation CPAP used by Decedent posed serious health risks to their users and Philips falsely represented to Plaintiff that the Recalled machines, including the DreamStation CPAP used by Decedent was safe for human use.

110. Philips intentionally, knowingly, and recklessly made these misrepresentations and omissions to induce Plaintiff and other members of the general public to purchase the Recalled machines, including the DreamStation CPAP used by Decedent.

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

112. Plaintiff did in fact rely on these omissions and misrepresentations and purchased and used the Recalled machines, including the DreamStation CPAP used by Decedent to his detriment. Given the deceptive manner in which Philips advertised, represented, and otherwise promoted the Recalled machines, including the DreamStation CPAP used by Decedent, Plaintiff's reliance on Philips' omissions and misrepresentations was justifiable.

## Case 2205: vr0002225FCD 0 Domented 21 Fifeled 0/2/2/22 PRgg & G 0 6 8 5 5

113. As a direct and proximate result of the recalled machines, including the DreamStation CPAP machine's aforementioned defects as described herein, Plaintiff's Decedent MICHAEL HENDERSON experienced significant mental and physical pain and suffering, sustained permanent injury, including succumbing to lung cancer in March of 2019. As a result, Plaintiff LINDA HENDERSON has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

# **EIGHTH CAUSE OF ACTION**

## FRAUD BY OMISSION

114. Philips concealed from and failed to disclose to Plaintiff that use of Recalled machines, including the DreamStation CPAP used by Decedent is accompanied by a risk of adverse health effects, which does not conform to the products' labels, packaging, advertising, and statements.

115. Philips was under a duty to disclose to Plaintiff the true quality, characteristics, ingredients and suitability of the Recalled machines, including the DreamStation CPAP used by Decedent because: (a) Philips was in a superior position to know the true state of facts about its products; (b) Philips was in a superior position to know the risks associated with the use of, characteristics of, and suitability of the Recalled machines, including the DreamStation CPAP used by Decedent for use by individuals; and (c) Philips knew that Plaintiff could not reasonably have been expected to learn or discover prior to purchasing the Recalled machines, including the DreamStation the true state of the true state of the true state by Decedent that there were misrepresentations and omissions by

## Case 2205: vr0002225FCD 0 Domented 21 Fifeled 0 1/2/2/22 PRgg & 3 10 10 855

Philips in the packaging, labels, advertising, and websites regarding the health risks associated with use of these devices.

116. The facts concealed or not disclosed by Philips to Plaintiff were material in that a reasonable consumer would have considered them important when deciding whether to purchase the Recalled machines, including the DreamStation CPAP used by Decedent.

117. Decedent justifiably relied on Philips' omissions to his detriment. The detriment is evident from the true quality, characteristics, and risk associated with the use of the Recalled machines, including the DreamStation CPAP used by Decedent, which is inferior when compared to how the Recalled machines, including the DreamStation CPAP used by Decedent are advertised and represented by Philips.

118. As a direct and proximate result of the recalled machines, including the DreamStation CPAP machine's aforementioned defects as described herein, Plaintiff's Decedent MICHAEL HENDERSON experienced significant mental and physical pain and suffering, sustained permanent injury, including succumbing to lung cancer in March of 2019. As a result, Plaintiff LINDA HENDERSON has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

## **NINTH CAUSE OF ACTION**

## **NEGLIGENT MISREPRESENTATION**

## Case 2205; vr 10902/025F CD o Domenne 821 Fifele (0 1)/2/2/22 PRgg & 220 5855

119. Philips had a duty to Plaintiff to exercise reasonable and ordinary care in the developing, testing, manufacture, marketing, distribution, and sale of the Recalled machines, including the DreamStation CPAP used by Decedent.

120. Philips breached its duty to Plaintiff by developing, testing, manufacturing, advertising, marketing, distributing, and selling products to Plaintiff that did not have the qualities, characteristics, and suitability for use as advertised by Philips and by failing to promptly remove the Recalled machines, including the DreamStation CPAP used by Decedent from the marketplace or to take other appropriate remedial action upon becoming aware of the health risks of the Recalled machines, including the DreamStation CPAP used by Decedent.

121. Philips knew or should have known that the qualities and characteristics of the Recalled machines, including the DreamStation CPAP used by Decedent were not as advertised or suitable for their intended use and were otherwise not as warranted and represented by Philips. Specifically, Philips knew or should have known that: (a) the use of the Recalled machines, including the DreamStation CPAP used by Decedent was accompanied by risk of adverse health effects that do not conform to the packaging and labeling; (b) the Recalled machines, including the DreamStation CPAP used by Decedent were adulterated, or at risk of being adulterated, by the PE-PUR Foam; and (c) the Recalled machines, including the DreamStation CPAP used by Decedent were adulterated by Philips.

122. As a direct and proximate result of Defendants' negligence, Plaintiff's Decedent MICHAEL HENDERSON experienced significant mental and physical pain and suffering, sustained permanent injury, including succumbing to lung cancer in March of 2019. As a result, Plaintiff LINDA HENDERSON has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

## Case 2205-vr/0002/025F CD o Domente 021 Fifele 0 0/2/2/22 PRgg & 3 3 5 8 5 5

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

# **TENTH CAUSE OF ACTION**

# LOSS OF CONSORTIUM

123. Plaintiff LINDA HENDERSON is, and at all times herein mentioned was, the lawful spouse of Decedent MICHAEL HENDERSON.

124. As a direct, legal and proximate result of the culpability and fault of the Defendants, be such fault through strict liability of negligence, Plaintiff LINDA HENDERSON suffered the loss of support, service, love, companionship, affection, society, intimate relations, and other elements of consortium, all to her general damage, in an amount in excess of the jurisdictional minimum of this Court.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

## **ELEVENTH CAUSE OF ACTION**

## WRONGFUL DEATH

125. As a result of the foregoing acts and/or omissions of Defendants herein, the decedent, MICHAEL HENDERSON suffered death which was proximately caused in whole or part by the tortious conduct, strict liability and/or negligence, carelessness, recklessness, and gross negligence of Defendants as described herein.

## Case 2205: vr0002225FCD o Domente 821 Fifele 0 0/2/2/22 PRgg 8340 b855

126. Decedent left next of kin and/or distributees surviving who, by reason of the decedent's death, have suffered a pecuniary loss, including but not limited to loss of support and/or income of the decedent, and were all permanently damaged thereby.

127. By reason of the injuries and death of the decedent, certain medical, hospital, funeral, and other bills and expenses were incurred, and said distributees have been and will, in the future, be deprived of the decedent's support, maintenance, guidance, care, and other services as set forth above.

128. By reason of the above, Plaintiff LINDA HENDERSON, as administrator of the Estate of MICHAEL HENDERSON, brings this action for wrongful death and the conscious pain and suffering of Plaintiff's decedent MICHAEL HENDERSON for damages, both general and special, in an amount that exceeds the jurisdictional limits of all lower courts which would otherwise have jurisdiction.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

## PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against the Defendants, and each of them, as follows.

- 1. For past and future general damages on each cause of action, according to proof;
- 2. For past and future pain and suffering, according to proof;
- 3. For past and future hospital, medical, nursing care, treatment and incidental expenses, according to proof;
- 4. For past and future loss of earnings and earning power, according to proof;

- 5. For past and future mental and emotional distress, according to proof;
- 6. For restitution, according to proof;
- 7. For punitive damages in an amount appropriate to punish and/or set an example of Defendants, or is in any other way appropriate.
- 8. For past and future costs of suit incurred herein, and attorney's fees as may be allowed by law; and

For such other and further relief as the Court may deem just and proper.

# DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury for all issues so triable.

DATED: January 21, 2022.

Respectfully submitted,

Millen Derman

W. Steven Berman, Esquire (PA Bar # 45927) Nicholas R. Farnolo (*Pro Hac Vice Anticipated*) NAPOLI SHKOLNIK, PLLC One Greentree Center, Suite 201 10,000 Lincoln Drive Marlton, NJ 08053 (212) 397-1000 WSBerman@Napolilaw.com NFarnolo@Napolilaw.com

Attorneys for Plaintiff