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-mc-1230-JFC**
	:	**MDL No. 3014**
This Document Relates to: All Actions	:	**MASTER LONG FORM COMPLAINT FOR PERSONAL INJURIES AND DAMAGES, AND DEMAND FOR JURY TRIAL**

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Plaintiffs file this Master Long Form Complaint for Personal Injuries and Damages, and Demand for Jury Trial ("Master Long Form Complaint" or "Complaint") against Defendants Koninklijke Philips N.V., Philips North America LLC, Philips Holding USA Inc., Philips RS North America LLC, and Philips RS North America Holding Corporation (collectively "Philips" or the "Philips Defendants"), and Defendants Polymer Technologies, Inc., Polymer Molded Products LLC, and Polymer Technologies, Inc. Elastomeric Solutions Division (collectively "PolyTech" or the "PolyTech Defendants"), as an administrative method to set forth common facts and potential claims which individual Plaintiffs, on their own behalf, their spouses, estates, or beneficiaries, may assert against Philips in this litigation. It is anticipated that Plaintiffs alleging personal injury and damages arising from the use of Recalled Device(s) will file a Short Form Complaint,[1] and all allegations pleaded in this Master Long Form Complaint are deemed pleaded in any Short Form Complaint.

The Master Long Form Complaint does not necessarily include all claims or allegations asserted in all of the actions filed in, or transferred to, this Court. Certain Plaintiffs may also add additional Defendant(s), which will be reflected in their respective Short Form Complaints. The Master Long Form Complaint does not constitute a waiver or dismissal of any claims that may be asserted in any individual action, nor do any Plaintiffs relinquish the right to move to amend their respective Short Form Complaint to assert additional claims or allegations as discovery may require, to cure any deficiencies, or for any other reason that circumstances may warrant.

Further, pursuant to Pretrial Order #14 (Doc. 573), entered on May 19, 2022, which sets forth an orderly and efficient process for filing consolidated amended class and master complaints,

[1] The template for the Short Form Complaint is attached hereto as Exhibit "A." All attached Exhibits and referenced materials are incorporated as if fully stated herein.

this is one of three master complaints being filed in this multi-district litigation. The filing of three master complaints is to streamline the pleadings and issues for the parties' mutual convenience only. The three master complaints contemplated in this MDL are divided, for administrative purposes, into one each for Personal Injury, Medical Monitoring, and Economic Loss.

Plaintiffs filing claims for personal injuries using this Master Long Form Complaint and a Short Form Complaint are also members of the putative class in the Consolidated Second Amended Class Action Complaint for Economic Losses (Doc. 637) and the Consolidated Amended Class Action Complaint for Medical Monitoring. Plaintiffs do not waive any of their rights or claims as putative class members in those respective complaints by virtue of filing claims for personal injuries and/or including claims that may be included in either of those two master complaints.

I. NATURE OF THE ACTION

1. Philips designs, manufactures, and sells certain lines of products that are intended to help people breathe. These include Continuous Positive Airway Pressure ("CPAP") and Bilevel Positive Airway Pressure ("BiPAP") machines, which are commonly used to treat sleep apnea, and mechanical ventilators ("ventilators"), which treat respiratory failure. The primary function of these devices is to blow air into patients' airways. CPAP and BiPAP machines are intended for use during sleep, and ventilators are used continuously when needed.

2. On June 14, 2021, Philips announced a recall of millions of its CPAP and BiPAP machines and ventilators (the "Recall") in the United States. Each of these recalled products (referred to herein as a "Recalled Device" or collectively as the "Recalled Devices") contain polyester-based polyurethane ("PE-PUR") foam for sound abatement. Despite knowing for many years that PE-PUR foam would degrade and that this foam should not be used in the Recalled

Devices, Philips waited until June 2021 to issue the Recall and notify the public. In its Recall, Philips announced that the PE-PUR foam may break down into particles and be inhaled or ingested, and may emit volatile organic compounds ("VOCs") that may be inhaled, resulting in "serious injury, which can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment"[2] (referred to herein as the "Defect"). Philips stated that the potential risks of exposure due to such chemicals include "headache/dizziness, irritation (eyes, nose respiratory tract, skin), hypersensitivity, nausea, vomiting, toxic and carcinogenic effects."[3] Philips' announcement to doctors advised that these hazards could result in "serious injury which can be life-threatening or cause permanent impairment."[4]

3. On July 22, 2021, the U.S. Food and Drug Administration ("FDA") confirmed the severity of the problem and classified the Recall as Class I or "the most serious type of recall," meaning use of the Recalled Devices "may cause serious injuries or death."[5]

4. Philips should have known about the risks caused by PE-PUR foam degradation when it was testing the foam pursuant to FDA regulations. And certainly, Philips knew as far back as 2008 that there were serious problems with the foam in the Recalled Devices because Philips received customer complaints about "contaminants, particles, foam, debris, airway, particulate, airpath, and black."[6]

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[2] Philips Recall Notices dated 6/14/2021 (attached hereto as Exhibit "B").

[3] *Id*.

[4] *Id*.

[5] https://www.fda.gov/medical-devices/medical-device-recalls/philips-respironics-recalls-certain-continuous-and-non-continuous-ventilators-including-cpap-and (last accessed Aug 12, 2022).

[6] A redacted version of the FDA's 483 Report issued on November 9, 2021 is available here: https://www.fda.gov/media/154244/download (last accessed Aug. 12, 2022). ("483 Report").

5. Then, according to the FDA, beginning in 2015, Philips received additional data from a variety of sources, including customer complaints, test reports, information from suppliers, and information from another entity owned by the ultimate parent company of Philips, confirming the problem of degradation of the PE-PUR foam contained within the Recalled Devices.

6. Yet, Philips failed to disclose that the Recalled Devices were defective when manufactured and sold until many years later. In fact, it was only after Philips launched its next generation of CPAP/BiPAP machines – the DreamStation 2 devices – which do not contain PE-PUR foam, that Philips announced to their shareholders in a Quarterly Report on April 26, 2021 that its previous generation DreamStation products and other CPAP, BiPAP, and ventilators posed serious health risks to users. Philips then waited an additional seven weeks before it initiated the Recall of the dangerously defective machines in the U.S. Shortly thereafter Philips expanded its recall of defective CPAP, BiPAP, and ventilators worldwide.[7]

7. Philips' flagship line and top seller of its CPAP Recalled Devices are its DreamStation devices. On September 1, 2021, Philips received authorization from the FDA to begin a repair and/or replacement process for affected DreamStation devices in the United States.[8] DreamStation customers, however, were not told when they might receive a replacement device, nor were they given any specifics as to how the replacement program would work. Moreover, the repair and/or replacement process was only for DreamStation Recalled Devices and did not encompass any other Recalled Device.

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[7] *See* https://www.philips.com.au/healthcare/e/sleep/communications/src-update. Other impacted countries include, but are not limited to Australia, Canada, Israel, and Chile.

[8] https://www.usa.philips.com/healthcare/resource-catalog/landing/experience-catalog/sleep/communications/src-update/news/philips-starts-repair-and-replacement-program-of-first-generation-dreamstation-devices-in-the-us-and-other-markets (last accessed Aug. 12, 2022).

8. The Recalled Devices are:

- E30
- DreamStation ASV
- DreamStation ST, AVAPS
- SystemOne ASV4
- C Series ASV, S/T, AVAPs
- OmniLab Advanced Plus
- SystemOne (Q Series)
- DreamStation CPAP, Auto CPAP, BiPAP
- DreamStation Go CPAP, APAP
- Dorma 400, 500 CPAP
- REMStar SE Auto CPAP
- Trilogy 100 and 200
- Garbin Plus, Aeris, LifeVent
- A-Series BiPAP Hybrid A30
- A-Series BiPAP V30 Auto
- A-Series BiPAP A40
- A-Series BiPAP A30

9. All of the Recalled Devices are defective because they contain PE-PUR foam.

10. This action arises from Philips's wrongful conduct, including: (a) designing a defective product that caused serious injuries to users, (b) failing to warn about serious, and reasonably foreseeable health risks caused by the Recalled Devices, (c) engaging in the deliberate concealment, misrepresentation and obstruction of public and regulatory awareness of serious

health risks to users of the Recalled Devices, and (d) failing to utilize reasonable care in, among other things, designing, manufacturing, marketing, selling, distributing, and recalling the Recalled Devices.

II. THE PARTIES

A. PLAINTIFFS

11. Plaintiffs are individuals who used the Recalled Devices and have suffered injuries from the use of the Recalled Devices.

12. As a result of using the Recalled Devices, Plaintiffs have been diagnosed with cancer, COPD, kidney injuries, cardiac injuries, pulmonary injuries, liver damage, inflammation, respiratory issues, asthma, adverse effects to organs; toxic and carcinogenic effects, and other injuries.

13. In addition, in some cases the spouses or minor children of patients are parties with consortium claims, and the estates and survivors of deceased patients are parties with claims arising from the wrongful death of patients who have died due to the use of Recalled Devices.

14. As a proximate result of Philips' wrongful conduct, Plaintiffs have been severely harmed; and have endured pain, suffering, disability, impairment, disfigurement, cancer diagnoses and/or an increased risk of developing cancer, loss of enjoyment of life, aggravation or activation of preexisting conditions, scarring, and/or inconvenience; and incurred costs for a defective device, medical care and treatment, loss of wages and wage-earning capacity, death for certain patients, and other economic and non-economic damages. The losses are permanent and continuing in nature.

15. In addition, each of the Plaintiffs acquired or paid for a Recalled Device. They would not have purchased, leased or otherwise acquired the Recalled Device had they known that the PE-PUR foam in the Recalled Device could expose users to life-threatening injuries or cause

serious health problems, rendering the Recalled Device defective, unsafe, worthless, and not fit for their intended purpose. As a result, they have suffered additional economic harm including, but not limited to: (a) the difference between the values of the Recalled Devices as represented (their prices paid) and their actual values at the time of purchase ($0.00), or (b) the cost to replace the Recalled Devices, and (c) other miscellaneous incidental and consequential damages.

B. DEFENDANTS

16. Defendant Koninklijke Philips N.V. ("Royal Philips") is a Dutch multinational company 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 holds directly or indirectly 100% of its subsidiaries, Philips North America LLC and Philips RS North America LLC.[9] As such, Royal Philips controls Philips North America LLC and Philips RS North America LLC with respect to the manufacturing, selling, distributing, and supplying of the Recalled Devices.[10]

17. Defendant Philips North America LLC ("Philips NA") is a Delaware company with its principal place of business at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. Philips NA is a wholly owned subsidiary of Royal Philips. Philips NA manages the operation of Royal Philips' various lines of business, including Philips RS North America LLC, in North America. The sole member of Philips NA is Philips Holding USA Inc. Philips NA is 100% owned

[9] Philips 2020 annual filing with the SEC, fn. 8, https://www.sec.gov/Archives/edgar/data/313216/000031321621000008/phg-exhibit8.htm (last accessed June 16, 2022).

[10] Philips 2020 annual filing with the SEC, https://www.sec.gov/ix?doc=/Archives/edgar/data/0000313216/000031321621000008/phg-20201231.htm (last accessed Aug. 12, 2022).

by Philips RS North America Holding Corporation which, in turn, is 100% owned by Philips Holding USA Inc.

18. Defendant Philips Holding USA Inc. ("PHUSA") is a Delaware corporation with its principal place of business at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. PHUSA is a holding company that is 100% owned, directly or indirectly, by Royal Philips. PHUSA owns 100% of Philips RS North America LLC and Philips RS North America Holding Corporation, and is the member/manager of Philips NA.

19. Defendant Philips RS North America LLC ("Philips RS") is a Delaware company with its principal place of business at 6501 Living Place, Pittsburgh, Pennsylvania 15206. Philips RS was formerly operated under the business name Respironics, Inc. ("Respironics"). Royal Philips acquired Respironics in 2008.[11] Philips RS is 100% owned by Philips RS North America Holding Corporation, which in turn, is 100% owned by PHUSA.

20. Defendant Philips RS North America Holding Corporation ("Philips RS Holding") is a Delaware corporation with its principal place of business at 222 Jacobs Street, Cambridge, Massachusetts 02141, and is wholly owned by PHUSA. Accordingly, Philips RS Holding is a citizen of Massachusetts and Delaware.

21. At all relevant times, each Philips Defendant acted in all aspects as the agent and alter ego of one another, and reference to "Philips" refers to each Philips Defendant individually and collectively.

22. Defendant Polymer Technologies, Inc. ("Polymer Tech") is a Delaware corporation with its principal place of business at 420 Corporate Blvd, Newark, DE 19702. Polymer Tech

[11] Philips announces completion of tender offer to acquire Respironics, WEB WIRE, https://www.webwire.com/ViewPressRel.asp?aId=61199 (last accessed Aug. 12, 2022).

directly or through another intermediary manufactured, treated, processed, and provided Philips with the PE-PUR foam that was used in the Recalled Devices.

23. Defendant Polymer Molded Products LLC ("PMP") is a Delaware corporation with its principal place of business at 10 Easy Street, Bound Brook, NJ 08805. PMP is a molded polyurethane foam manufacturer. PMP directly or through another intermediary manufactured, treated, processed, and provided Philips with the PE-PUR foam that was used in the Recalled Devices.

24. Defendant Polymer Technologies, Inc. Elastomeric Solutions Division ("ESD") is a Delaware corporation with its principal place of business at 76 Astor Ave #101, Norwood, MA 02062. ESD specializes in shock and vibration isolation materials for products including medical devices. ESD directly or through another intermediary manufactured, treated, processed, and provided Philips with the PE-PUR foam that was used in the Recalled Devices.

25. At all relevant times, Defendants Polymer Tech, PMP, and ESD acted in all respects as the agent and alter ego of one another, and reference hereinafter to "PolyTech" or the "PolyTech Defendants" refers to Defendants Polymer Tech, PMP, and ESD individually and collectively.

26. Other Defendants may be named in the Short Form Complaints.

III. JURISDICTION AND VENUE

27. This Court has subject matter jurisdiction over each individual action pursuant to 28 U.S.C. § 1332, because the amount in controversy in each action exceeds $75,000.00, exclusive of interest and costs, and because there is complete diversity of citizenship between each Plaintiff and each Defendant.

28. Each Defendant has significant contacts with the Western District of Pennsylvania such that they are subject to the personal jurisdiction of the Court.

29. Philips has multiple manufacturing, warehouse, and office facilities in the Western District of Pennsylvania where the Recalled Devices are designed, manufactured, and stored.

30. This Court has personal jurisdiction over each Defendant for the additional reason that they have engaged in substantial, systematic and continuous contacts with Pennsylvania by, *inter alia*, regularly conducting and soliciting business in Pennsylvania and this District, deriving substantial revenue from products and/or services provided to persons in Pennsylvania and this District.

31. The PolyTech Defendants manufactured, treated, and processed the PE-PUR foam by, among other things, applying an adhesive backing and an acoustic lining to the foam, which was provided to Philips for integration in the Recalled Devices within the Western District of Pennsylvania.

32. Each Defendant has significant contacts in each of the States and Territories of the United States, such that personal jurisdiction would be proper in any of them in that they manufactured and supplied materials and Devices that they knew would be sold to and used by consumers throughout the country.

33. Venue is proper in this District under 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to the claims occurred in this District, and additionally, on account of the MDL designation pursuant to 28 U.S.C. § 1407.

IV. FACTUAL ALLEGATIONS

A. CPAP AND BIPAP MACHINES AND VENTILATORS ARE PRESCRIBED TO TREAT BREATHING DISORDERS.

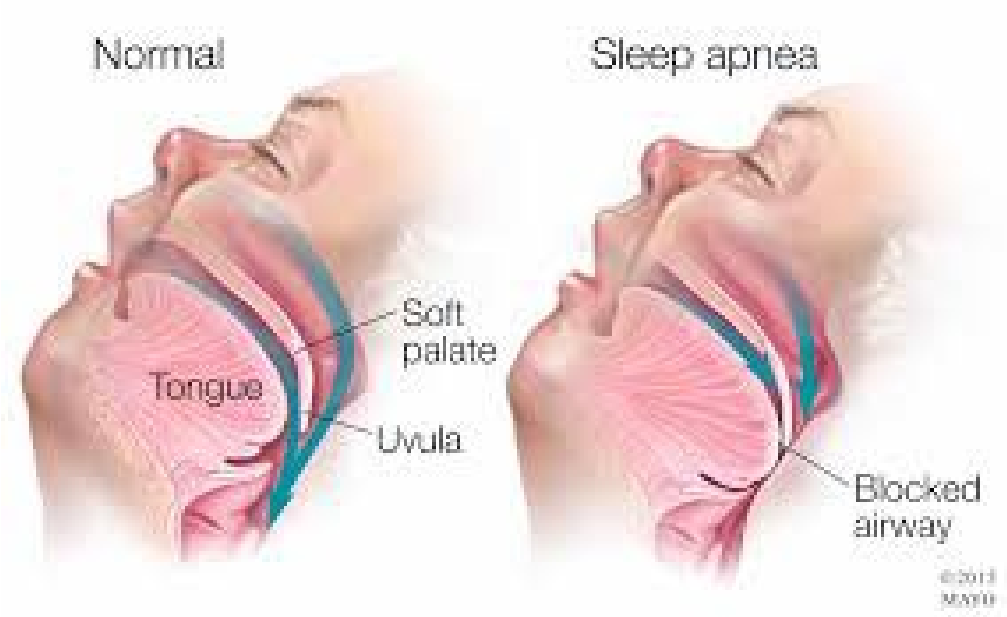
34. Sleep apnea is a sleeping disorder in which breathing is disturbed during sleep. These disturbances are called “apneas.”

35. According to the Mayo Clinic, the main types of sleep apnea are obstructive sleep apnea, central sleep apnea, and complex sleep apnea syndrome (also known as treatment-emergent central sleep apnea).

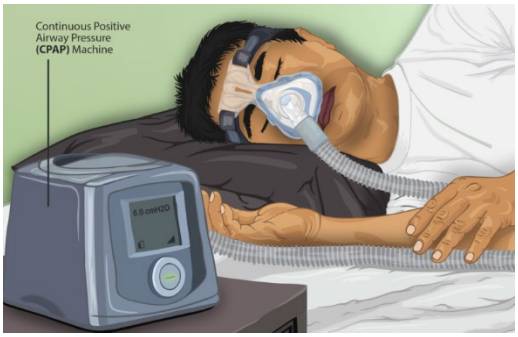
36. Obstructive sleep apnea is the most common type. It occurs when the muscles in the back of the throat relax during inhalation, which causes the airway to narrow or close and prevent sufficient air from passing through. This, in turn, lowers the oxygen level in the blood, which causes the brain to briefly wake the body from sleep to reopen the airway. This reawakening may be so brief that the patient does not remember it, and may be associated with snorting, choking, or gasping. It can happen anywhere from a few times per hour to once every few minutes, and can prevent the patient from reaching the deep, restful phases of sleep.

37. Central sleep apnea occurs when the brain fails to transmit signals to the breathing muscles. As a result, the body stops breathing, which can cause waking with shortness of breath or difficulty getting to sleep or staying asleep.

38. Complex sleep apnea syndrome occurs when a patient has both obstructive sleep apnea and central sleep apnea. An image showing how an airway can be blocked as a result of sleep apnea appears below:

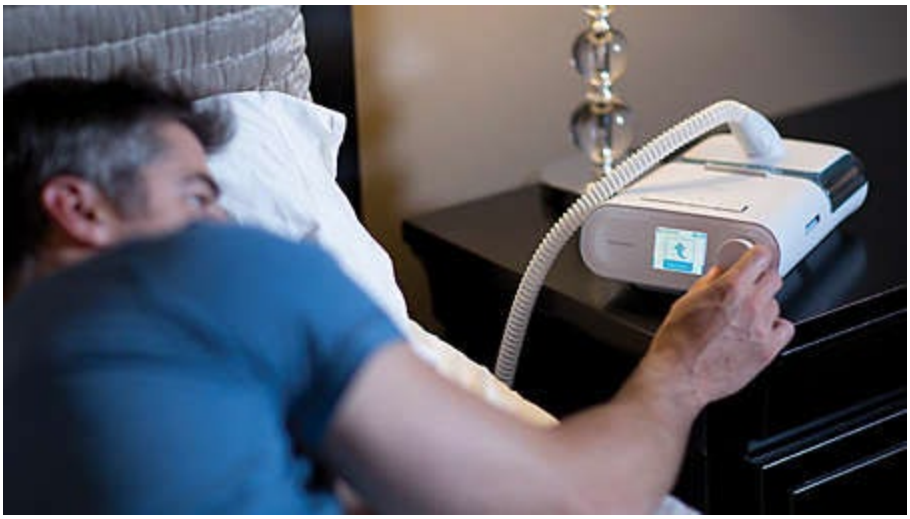


39. CPAP therapy is a common treatment for sleep apnea. In CPAP therapy, a machine delivers a flow of air through a mask over the nose or mouth, which increases air pressure in the throat so that the airway does not collapse during inhalation. CPAP therapy assists breathing during sleep and can successfully treat sleep apnea. The illustration below shows a generic CPAP machine being used by a patient while sleeping.

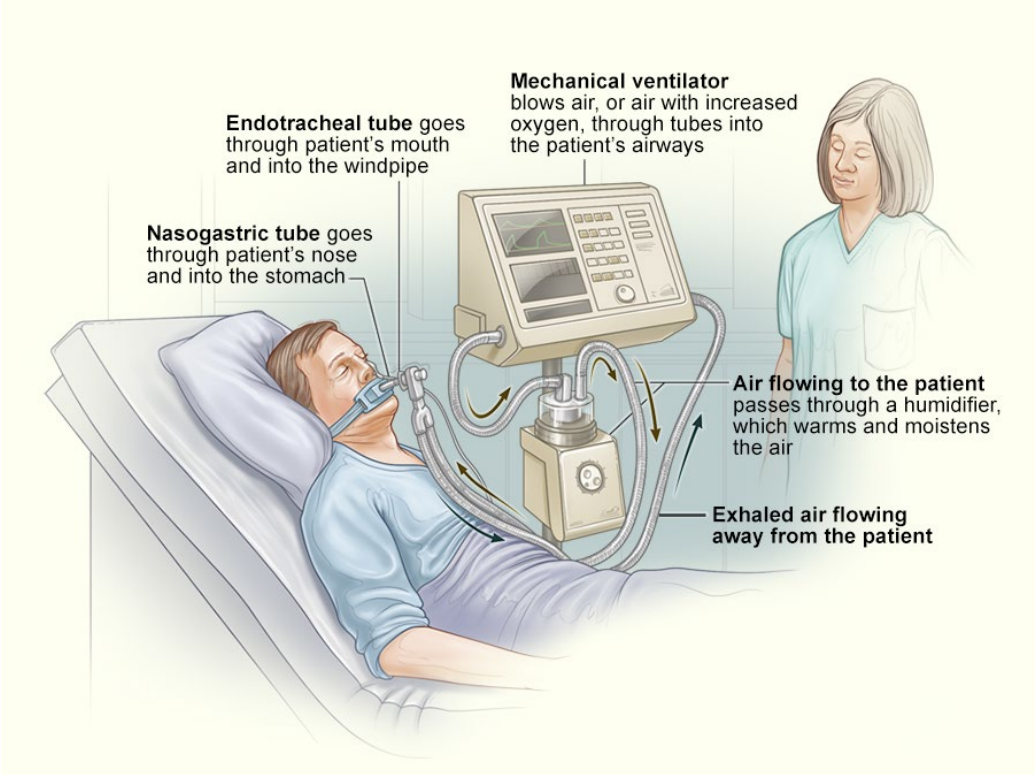


40. Another therapy to treat sleep apnea includes use of BiPAP machines, which use two different pressures – one for inhaling and one for exhaling.

41. Patients customarily place the CPAP or BiPAP machines on a nearby nightstand or shelf. A hose connects the unit to the mask, which is worn over the nose or mouth during sleep. Below is an image of a Philips DreamStation machine on a nightstand.



42. Ventilators are often used to treat respiratory failure. Ventilators push air into and out of the patient's lungs like a bellows, typically through a tube that is connected to the machine on one end and inserted through the patient's nose or mouth into the trachea on the other end. Patients are typically sedated while on ventilation because it can otherwise cause intense pain. Ventilators can also be used in other circumstances, such as during surgery when general anesthesia may interrupt normal breathing. There are also ventilators for home use. The following image from the National Institute of Health ("NIH") shows a typical ventilator and how it works:



B. THE EVOLUTION OF CPAP, BIPAP, AND VENTILATOR DEVICES CONTAINING PE-PUR FOAM.

43. The basic technology used in CPAP and BiPAP devices was developed in 1980 by an Australian pulmonologist, Dr. Colin Sullivan, who used it to treat dogs with respiratory problems, before the technology was adapted for humans.

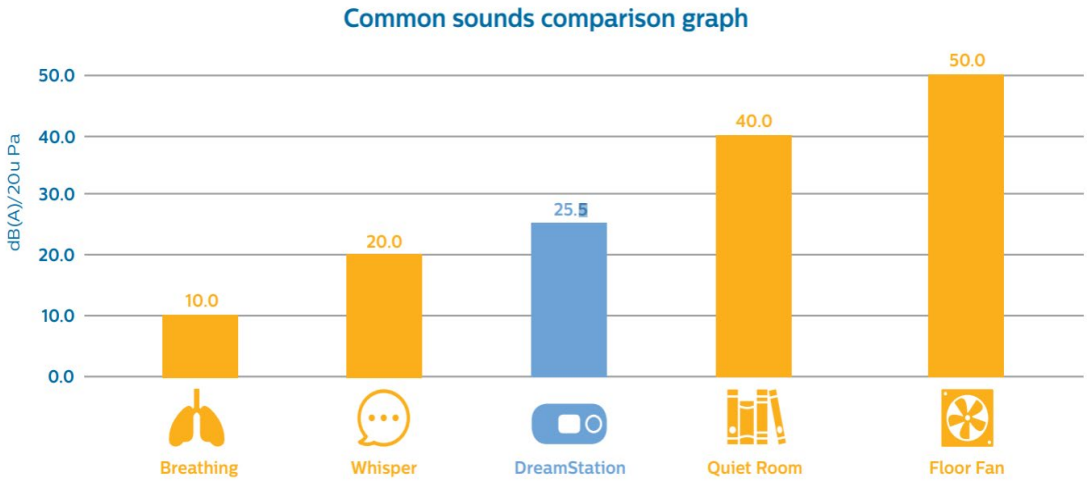
44. Respironics commercialized this technology and sold the first publicly available CPAP device in 1985. ResMed, an industry competitor, followed with the release of its CPAP device in 1989.

45. These first-generation CPAP and BiPAP devices created a new and commercially viable field of respiratory therapy. The devices, however, were large and noisy, resulting in an "arms-race" between manufacturers to develop devices that were smaller, more responsive to patient breathing patterns, and quieter.

46. The noise level of CPAP and BiPAP devices became a driver of adult consumer preference because loud devices interrupt the peaceful sleep of both the patient and their partner.

47. To develop the quietest devices on the market with the lowest decibel ratings, some device manufacturers including Philips swathed the CPAP, BiPAP, and ventilator devices with sound abating foam to reduce the volume of noise emitted from the devices.

48. In fact, the alleged relative quiet nature of the DreamStation products with PE-PUR foam factored prominently into Philips' marketing.[12] Philips represented that it extensively studied and measured the amount of sound produced by DreamStation products. Philips even included an infographic indicating DreamStation products are barely louder than a whisper:[13]



49. Other manufacturers did not utilize foam for sound abatement, instead they utilized silencing technology to abate the sound from the devices.

[12] *See* https://www.documents.philips.com/assets/20170523/62e4f43a1349489ba3cca77c0169c6ef.pdf (last accessed Aug. 15, 2022).

[13] *Id*. at 3.

50. Philips manufactures and sells CPAP and BiPAP machines and ventilators, among other products. According to Royal Philips' 2020 Annual Report,[14] Sleep & Respiratory Care constituted 49% of its total sales in its Connected Care line of business, which, in turn, accounted for 28% of Royal Philips' overall sales of about €19.535 billion. Philips has sold millions of CPAP, BiPAP, and ventilator devices in the United States and elsewhere throughout the globe.

51. Philips provides a User Manual with its CPAP, BiPAP, and ventilator devices. Royal Philips owns the copyright to all, or most, of those User Manuals.[15]

52. Philips made the decision to use PE-PUR foam for sound abatement purposes in its CPAP, BiPAP, and ventilator devices. That decision was made for products distributed by Philips' entities throughout the globe including, but not limited to the United States, Australia, Canada, Israel, and Chile.[16]

53. Polyurethane is an organic polymer in which urethane groups connect the molecular units and is usually formed by reacting a diisocyanate or triisocyanate with a polyol. Under certain circumstances, polyurethane may break down into a diisocyanate or triisocyanate.

54. The two main types of polyurethane are polyester and polyether. Polyester polyurethane has better shock absorption and vibration dampening properties and is commonly used for soundproofing or sound dampening.

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[14] *See* Philips' 2020 Annual Report, available at https://www.results.philips.com/publications/ar20?type=annual-report&origin=2_us_en_5250933_Microsoft+Shopping+%28Bing+Rebates%2C+Coupons%2C+etc.%29_mixedtype_cj&utm_source=5250933&utm_medium=affiliate&utm_campaign=cj&cjevent=ec08e4671a4811ed838f01650a82b821&utm_term=Microsoft+Shopping+%28Bing+Rebates%2C+Coupons%2C+etc.%29&cjdata=MXxOfDB8WXww (last accessed Aug. 15, 2022).

[15] *See, e.g.*, Warranty Exemplars: DreamStation (attached hereto as Exhibit "C-1"); REMstar SE (attached hereto as Exhibit "C-2"); Trilogy 100 (attached hereto as Exhibit "C-3").

[16] *See* Philips Q2 2022 Results, pg. 33, available for download at Philips Q2 2022 Quarterly Results | Philips Results. (last accessed Aug. 15, 2022)

55. It has been known for decades that polyester polyurethane is susceptible to hydrolysis, the chemical breakdown of a compound due to reaction with water, particularly in medical applications. For example, a chapter of a scientific encyclopedia published in 2013 states: "Poly(ester urethanes) were the first generation of PURs used in medical devices but were found unsuitable for long-term implants because of rapid hydrolysis of the polyester soft segment[.]"[17]

56. Polyether polyurethane, on the other hand, is less prone to hydrolysis. The same scientific encyclopedia chapter notes that polyether polyurethanes "with excellent hydrolytic stability replaced poly(ester urethanes) and have been used in medical devices for the past two decades."[18]

57. There were readily available alternative designs available to Philips, other than to use PE-PUR foam in CPAP, BiPAP, and ventilators for sound abatement; including, without limitation, other types of sound abating foam and silencing technologies that do not use foam.

58. For example, Philips' principal competitor, ResMed, uses polyether polyurethane foam or silicone-based foam, not PE-PUR foam, for sound dampening.[19]

C. PHILIPS SOUGHT CLEARANCES FROM THE FDA TO MARKET CPAP, BIPAP, AND VENTILATOR DEVICES THAT IT DESIGNED AND MANUFACTURED.

59. Philips designed and manufactured CPAP and BiPAP devices and ventilators, including the Recalled Devices.

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[17] Pal Singh Chauhan, N., and Kumari Jangid, N., "Polyurethanes and Silicone Polyurethane Copolymers," Chapter in Encyclopedia of Biomedical Polymers and Polymeric Biomaterials, January 2013, *available at* https://www.researchgate.net/publication/236144965_POLYURETHANES_AND_SILICONE_POLYURETHANE_COPOLYMERS (last accessed Aug. 12, 2022).

[18] *Id.*

[19] https://www.resmed.com/en-us/other-manufacturer-recall-2021/ (last accessed Aug. 12, 2022).

60. Defendants obtained 510(k) clearance from the Food and Drug Administration ("FDA") for various CPAP, BIPAP and ventilator devices.

61. 510(k) clearance is distinct from the FDA's pre-market approval ("PMA") process in that clearance does not require clinical confirmation of safety and effectiveness and as such the manufacturer retains all liability for the assertions of safety and effectiveness.

62. 510(k) clearance generally only requires the manufacturer to notify the FDA under section 510(k) of the Medical Device Amendments of 1976 to the Food Device Cosmetic Act (MDA) of its intent to market a device at least 90 days prior to the device's introduction on the market, and to explain the device's substantial equivalence to a pre-MDA predicate device. The FDA may then "clear" the new device for sale in the United States.

63. Philips utilized the 510(k) process to receive clearances for each of its Recalled Devices except the E30 ventilator which was marketed under an Emergency Use Authorization (EUA).

64. With respect to the EUA for the E30 ventilator, on March 24, 2020, in response to "concerns relating to insufficient supply and availability of FDA-cleared ventilators for use in healthcare settings to treat patients during the Coronavirus Disease 2019 (COVID-19) pandemic[,]" the FDA issued an umbrella EUA of ventilators and related equipment. On April 8, 2020, this EUA was extended to the E30 ventilator. A device may be authorized under this umbrella EUA if it "may be effective" in diagnosing, treating, or preventing COVID-19; and according to the FDA, "[t]he 'may be effective' standard for EUAs provides for a lower level of evidence than the 'effectiveness' standard that FDA uses for product approvals."

65. With respect to the 510(k) process for each of the other Recalled Devices, Philips included data, testing, and biocompatibility results along with its applications to claim substantial equivalence to a predicate device.

66. Upon reviewing the submissions, the FDA determined Philips' devices were substantially equivalent to a predicate device.

67. After the devices were sold, Philips had a duty to find, investigate, and report adverse events to the FDA. For example, 21 C.F.R. part 803 requires Philips to conduct a thorough investigation of each event. This duty is triggered when Philips becomes aware of information from any source that reasonably suggests that its device (1) may have caused or contributed to a death or serious injury, or (2) has malfunctioned, and, this device or a similar device it markets, is likely to cause or contribute to a death or serious injury, if the malfunction were to recur. 21 C.F.R. § 803.50.

68. Additionally, as a manufacturer, Philips has unique knowledge concerning the frequency, severity and predictability of the complications and risks associated with its devices. Accordingly, there is a post-market responsibility under the FDA Regulations related to complaint handling, investigation and reporting to the FDA, including but not limited to:

a. 21 C.F.R. § 803.10 (for example, § 803.10(c) requires adverse events to be reported by a manufacturer in set time frames from 5 to 30 days when the event becomes known);

b. 21 C.F.R. § 803.17 ("Medical device manufacturers must develop and implement standardized medical device reporting procedures so that timely evaluation of events and communication of findings can occur.");

c. 21 C.F.R. § 803.18 (§ 803.18(d)(1) requires a device distributor to maintain complaint files and records, including any written, electronic or oral communication, either received or generated by the distributor, that alleges deficiencies related to the identity (e.g., labeling), quality, durability, reliability, safety, effectiveness, or performance of a device.);

d. 21 C.F.R. § 803.20 ("Manufacturers must timely communicate a reportable event. Any information, including professional, scientific, or medical facts, observations, or opinions, may reasonably suggest that a device has caused or may have caused or contributed to an MDR reportable event. An MDR reportable event is a death, a serious injury, or, if you are a manufacturer or importer, a malfunction that would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.");

e. 21 C.F.R. § 803.3 ("If you are a manufacturer, you are considered to have become aware of an event when any of your employees becomes aware of a reportable event that is required to be reported within 30 calendar days or that is required to be reported within 5 work days because we had requested reports in accordance with 803.53(b). You are also considered to have become aware of an event when any of your employees with management or supervisory responsibilities over persons with regulatory, scientific, or technical responsibilities, or whose duties relate to the collection and reporting of adverse events, becomes aware, from any information, including any trend analysis, that a reportable MDR event or events necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health.");

f. 21 C.F.R. § 803.50 ((a) "If you are a manufacturer, you must report to the FDA information required by 803.52 in accordance with the requirements of 803.12(a), no later than 30 calendar days after the day that you receive or otherwise become aware of information, from any source, that reasonably suggests that a device that you market: (1) May have caused or contributed to a death or serious injury or (2) Has malfunctioned and this device or a similar device that you market would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur." Subsection (b) defines information reasonably known to a manufacturer to include: "[a]ny information that you can obtain by contacting a user facility, importer, or other initial reporter; . . . [a]ny information in your possession; or . . . [a]ny information that you can obtain by analysis, testing, or other evaluation of the device." Section 803.50 continues: "(2) You are responsible for obtaining and submitting to us information that is incomplete or missing from reports submitted by user facilities, importers, and other initial reporters. (3) You are also responsible for conducting an investigation of each event and evaluating the cause of the event. If you cannot submit complete information on a report, you must provide a statement explaining why this information was incomplete and the steps you took to obtain the information. If you later obtain any required information that was not available at the time you filed your initial report, you must submit this information in a supplemental report under 803.56 in accordance with the requirements of 803.12(a).");

g. 21 C.F.R. § 803.52 (detailed individual and device information must be submitted for each adverse event);

h. 21 C.F.R. § 803.53 (information regarding detailed individual and device information must be submitted in a timely manner when remedial action may be required);

i. 21 C.F.R. § 803.56 (supplemental reporting must be done if additional information is learned that became known after the initial report was submitted);

j. 21 C.F.R. § 814.82(a)(2) (manufacturer has a duty of "[c]ontinuing evaluation and periodic reporting on the safety, effectiveness, and reliability of the device for its intended use. FDA will state in the PMA approval order the reason or purpose for such requirement and the number of patients to be evaluated and the reports required to be submitted.");

k. 21 C.F.R. § 814.84 (the periodic reports required by law must contain the reports in the scientific literature that pertain to the device which are known or should be known to the manufacturer); and

l. 21 C.F.R. § 820.198 ("Any complaint that represents an event which must be reported to FDA under part 803 of this chapter shall be promptly reviewed, evaluated, and investigated by a designated individual(s) and shall be maintained in a separate portion of the complaint files or otherwise clearly identified. In addition to the information required by 820.198(e), records of investigation under this paragraph shall include a determination of: (1) Whether the device failed to meet specifications; (2) Whether the device was being used for treatment or diagnosis; and (3) The relationship, if any, of the device to the reported incident or adverse event").

69. In addition, there are state law duties to monitor, investigate, evaluate and timely report injuries and other important safety information regarding a medical device, which Philips violated when it failed to: monitor, investigate and report PE-PUR foam degradation risk and incidents; take the necessary steps to continually evaluate the safety, effectiveness and reliability of its Recalled Devices; and take necessary steps to warn, strengthen its warnings, and take other measures to assure compliance with its obligations.

D. PHILIPS' USE OF PE-PUR FOAM POSES SERIOUS HEALTH RISKS TO USERS OF ITS RECALLED DEVICES.

70. Philips has belatedly revealed that the PE-PUR foam in the Recalled Devices degrades and exposes patients to toxic particles and gases. Such exposure has harmed hundreds of thousands of patients across the United States who used the Recalled Devices.

71. On the same day as the Recall, Philips released an announcement entitled "Clinical information for physicians." In this announcement, Philips disclosed that it "has received several

complaints regarding the presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask)."[20] The PE-PUR foam is black, and when it breaks down, it can release black particles.[21] The announcement stated that the foam breakdown "may lead to patient harm and impact clinical care,"[22] explaining:

> While there have been limited reports of headache, upper airway irritation, cough, chest pressure and sinus infection that may have been associated with the foam, 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.***[23]

72. The announcement mentioned two types of hazards from the foam in the devices: dangers from foam degradation and dangers from release of VOCs.

73. First, the announcement described dangers arising from foam degradation exposure:

> **Potential Hazard:** Philips has determined from user reports and lab testing that under certain circumstances the foam may degrade into particles which may enter the device's air pathway and be ingested or inhaled by the user of its Continuous Positive Airway Pressure (CPAP), BiLevel Positive Airway Pressure (BiLevel PAP) and Mechanical Ventilator devices. The foam degradation may be exacerbated by environmental conditions of higher temperatures and humidity in certain regions. Unauthorized cleaning methods such as ozone may accelerate potential degradation.
>
> The absence of visible particles does not mean that foam breakdown has not already begun. Lab analysis of the degraded foam reveals the presence of potentially harmful chemicals including:
>
> - Toluene Diamine

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[20] Sleep and respiratory care update: Clinical information for physicians: philips-recall-clinical-information-for-physicians-and-providers.pdf (last accessed Aug. 15, 2022).

[21] *Id.*

[22] *Id.*

[23] *Id.*

- Toluene Diisocyanate

- Diethylene glycol.[24]

74. This particulate matter can harm a patient using a Recalled Device in multiple ways including, but not limited to damaging the respiratory system and by transmitting toxic compounds into the respiratory and gastrointestinal systems.

75. The inhalation of extremely fine particulates, even non-toxic particulates, can lead to adverse health outcomes. The Environmental Protection Agency ("EPA") notes that exposure to particles less than 10 micrometers can be linked to a variety of health problems including: aggravated asthma, decreased lung function, increased respiratory symptoms, and cardiac related diseases."[25]

76. On July 8, 2021, Philips released a global supplemental clinical information document that was based on their own testing of the affected devices, stating that, "According to analysis performed by Philips, the majority of particulates are of a size (>8 µm) . . . Smaller particulates (<1-3 µm) are capable of diffusing into deep lung tissue and deposit into the alveoli. During testing performed by an outside laboratory on lab degraded foam, the smallest particulate size identified was 2.69 µm."[26]

77. The purity of the air coming from a breathing device to a patient is highly important and material. Philips advertises the filtration systems in its devices, for example, noting them on a

[24] *Id*.

[25] *See* Health and Environmental Effects of Particulate Matter (PM) | US EPA. (last accessed Aug. 15, 2022).

[26] *See* philips-global-supplemental-clinical-information-document.pdf.

diagram in its DreamStation Family Brochure.[27] Philips' filtration system, however, does not filter out the particles described above.

78. In addition to the hazards created by the inhalation of extremely fine particulates, Philips has stated that the particulates created via PE-PUR foam degradation contain toxic compounds such as toluene diamine, toluene diisocyanate, and diethylene glycol.[28] As discussed in more detail below, these compounds are toxic and/or carcinogenic when inhaled or ingested.

79. Philips concluded in its Health Hazard Evaluations ("HHEs") regarding the PE-PUR foam degradation risk that "[b]ased on the cytotoxicity and genotoxicity results and toxicological risk assessment, combined with [the] conclusion that particles are likely to reach the upper airway and potentially the lower respiratory track [*sic*], a reasonable worst-case estimate for the general and higher risk (e.g., patient populations with preexisting conditions or comorbidities) patient populations is a severity level 3 (Crucial) for both short/intermediate and long term exposure."[29]

80. Philips' HHEs note that the harm due to foam degradation "'may not be immediately recognizable and may not be something that the customer would/could report,' adding that certain harms 'may not be easily linked to the hazardous situation or device use in general'—and that in the case of genetic mutations in particular, 'a presumed lag time from exposure to harm development may make it difficult for patients to attribute their individual harm to the device

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27 https://www.documents.philips.com/assets/20180205/15ef65ad106d4ddc88fca87e0134dc60.pdf?_gl=1*1l6jo9f*_ga*MTM1OTI5NDM5Ny4xNjIzODE3MzMz*_ga_2NMXNNS6LE*MTYyNjkxMDEyNC4yMi4xLjE2MjY5MTQyNTkuMjc.&_ga=2.220564312.1106063144.1626914226-1359294397.1623817333 (last accessed Aug. 15, 2022).

28 *See* philips-global-supplemental-clinical-information-document.pdf.

29 518(b) Notice at 3-4.

usage.'"[30]

81. The second hazard is the release of VOCs, that is, toxic and carcinogenic chemical emissions from the PE-PUR foam. Philips explained:

> **Potential Hazard:** Lab testing performed for and by Philips has also identified the presence of VOCs which may be emitted from the sound abatement foam component of affected device(s). VOCs are emitted as gases from the foam included in the CPAP, BiLevel PAP and MV devices and may have short- and long-term adverse health effects.
>
> Standard testing identified two compounds of concern (COC) 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).[31]

82. In addition to these two compounds, Philips has also found high levels of formaldehyde, a known carcinogen, in analyses of the Recalled Devices. Collectively, these compounds released by PE-PUR foam—formaldehyde, toluene diamine, toluene diisocyanate, diethylene glycol, dimethyl diazine, and phenol, 2,6-bis (1,1-dimethylethyl)-4-(1-methylpropyl)—are referred to herein as the "Foam Toxins."

83. Philips admitted that the risks of these VOCs include: "irritation and airway inflammation, and this may be particularly important for patients with underlying lung diseases or reduced cardiopulmonary reserve" and may lead to the following symptoms: "headache/dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, nausea/vomiting, toxic and carcinogenic effects," as well as "adverse effects to other organs such as kidney and liver."[32]

84. It is beyond reasonable dispute that patients using the Recalled Devices were

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[30] *Id.* at 5.

[31] *See* philips-recall-clinical-information-for-physicians-and-providers.pdf.

[32] *Id.*

exposed to harmful particulates and the toxic Foam Toxins. As detailed below, each of the Foam Toxins poses a serious health hazard to users of the Recalled Devices.

1. Formaldehyde Is A Known Carcinogen.

85. Although Philips has not publicly acknowledged that formaldehyde is used in the manufacturing process for PE-PUR foam or is a byproduct of PE-PUR foam degradation, Philips' internal testing (dated May 22, 2019) reported the presence of formaldehyde in analyses of DreamStation 1 devices, finding "tolerable limits of the Formaldehyde compound were exceeded during initial operation, as well as at the [redacted]."[33]

86. Formaldehyde has been classified as carcinogenic to humans (Group 1)[34] by the International Agency for Research on Cancer ("IARC") since 2006.[35] Governmental authorities in the United States have reached similar conclusions: the National Toxicology Program in the United State Department of Health and Human Services ("NTP") has classified formaldehyde as a known human carcinogen since 2011[36]; and the EPA has considered formaldehyde to be a probable human

[33] *See* 483 Report at 6.

[34] The IARC, an agency of the World Health Organization, groups carcinogenic and potentially carcinogenic substances into five categories: Group 1, carcinogenic to humans; Group 2A, probably carcinogenic to humans; Group 2B, possibly carcinogenic to humans; Group 3, not classifiable as to its carcinogeneity to humans; and Group 4, probably not carcinogenic to humans. International Agency for Research on Cancer, *Agents Classified by the IARC Monographs, Volumes 1–129*, IARC (last updated Jul. 1, 2022), *available at* http://monographs.iarc.fr/ENG/Classification/index.php. The EPA uses an equivalent grouping system of five categories (Groups A-E). *See Risk Assessment for Carcinogenic Effects*, EPA.com, *available at* https://www.epa.gov/fera/risk-assessment-carcinogenic-effects.

[35] *Formaldehyde*, IARC Monograph – 100F, IARC, *available at* https://monographs.iarc.who.int/wp-content/uploads/2018/06/mono100F-29.pdf .

[36] *Formaldehyde*, Report on Carcinogens, NTP, *available at* https://ntp.niehs.nih.gov/ntp/roc/content/profiles/formaldehyde.pdf.

carcinogen (Group B1) since 1989.[37]

87. There is extensive research, including dozens of human epidemiological studies, showing an association between formaldehyde exposure and numerous forms of cancer, including: nasopharyngeal cancer; sinonasal cancer; leukemia; lung cancer; lymphohematopoietic cancers (other than leukemia); nasal, oral, and throat cancers (other than nasopharyngeal and sinonasal cancers); brain cancer; hepatic cancer; esophageal cancer; thyroid cancer; and pancreatic cancer.[38] Additionally, exposure to formaldehyde appears to have a strong causal relationship to asthma.[39]

2. Toluene Diisocyanate Is A Likely Carcinogen.

88. Toluene diisocyanates ("TDIs") are used primarily to manufacture flexible polyurethane foams such as PE-PUR foam. Philips has recognized that PE-PUR foam releases TDIs as it degrades.[40]

89. TDI is classified as possibly carcinogenic to humans (Group 2B) by IARC.[41] The United States Center for Disease Control ("CDC"), Occupational Safety and Health

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[37] *See* https://www.cancer.gov/about-cancer/causes-prevention/risk/substances/formaldehyde/formaldehyde-fact-sheet#r1 (last accessed Aug. 15, 2022).

[38] *See, e.g.*, *Formaldehyde*, Report on Carcinogens, NTP, *available at* https://ntp.niehs.nih.gov/ntp/roc/content/profiles/formaldehyde.pdf; *1910.1048 App C - Medical surveillance – Formaldehyde*, OSHA.com, *available at* https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1048AppC. (last accessed Aug. 15, 2022).

[39] *See, e.g.*, *1910.1048 App C - Medical surveillance – Formaldehyde*, OSHA.com, *available at* https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1048AppC.

[40] *See* https://www.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/global-supplemental-clinical-information-document-070821-r6.pdf ("[T]he degradative by-products of a PE-PUR foam after a humid ageing experiment were found to include … toluene diisocyanate isomers (TDI)").

[41] *Toluene diisocyanates*, IARC Monographs Vol. 71, IARC, *available at*, https://publications.iarc.fr/_publications/media/download/2317/fb198ec8e8f32d0a60294331930c5a04f82cac60.pdf. (last accessed Aug. 15, 2022).

Administration ("OSHA"), and National Institute for Occupational Safety and Health ("NIOSH") also regard TDI as a potential human carcinogen based on tumorigenic responses in TDI treated rats and mice.[42] The EPA has taken action under the Toxic Substances Control Act to allow oversight of the use of TDI in consumer products.[43] NTP classifies TDI as "reasonably anticipated to be a human carcinogen" based on sufficient evidence of carcinogenicity from studies in experimental animals.[44] The European Union warns that TDI "is fatal if inhaled."[45]

90. Administration of TDI by stomach tube caused liver tumors (hepatocellular adenoma) in female rats and mice, benign tumors of the mammary gland (fibroadenoma) and pancreas (islet-cell adenoma) in female rats, and benign tumors of the pancreas (acinar-cell adenoma) in male rats. It also increased the combined incidences of benign and malignant tumors of subcutaneous tissue (fibroma and fibrosarcoma) in rats of both sexes and of the blood vessels (hemangioma and hemangiosarcoma) in female mice.[46] Exposure to TDI also has been documented to cause respiratory irritation, asthma, and lung damage.[47]

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[42] *See, e.g.*, *Toluene diisocyanates*, Report on Carcinogens, NTP, *available at* https://ntp.niehs.nih.gov/ntp/roc/content/profiles/toluenediisocyanates.pdf; *Current Intelligence Bulletin 53, Toluene Diisocyanate (TDI) and Toluenediamine (TDA): Evidence of Carcinogenicity*, NIOSH Pub. No. 90-101 (Dec. 1989), *available at* https://www.cdc.gov/niosh/docs/90-101/default.html. (last accessed Aug. 15, 2022).

[43] https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/fact-sheet-toluene-diisocyanate-tdi-and-related#action.

[44] *See* https://ntp.niehs.nih.gov/ntp/roc/content/profiles/toluenediisocyanates.pdf (last accessed Aug. 17, 2022).

[45] https://echa.europa.eu/substance-information/-/substanceinfo/100.043.369 (last accessed Aug. 15, 2022, 2022).

[46] *See* https://ntp.niehs.nih.gov/ntp/roc/content/profiles/toluenediisocyanates.pdf. (last accessed Aug. 15, 2022).

[47] *See, e.g.*, *Toluene diisocyanates*, IARC Monographs Vol. 71, IARC, *available at*, https://publications.iarc.fr/_publications/media/download/2317/fb198ec8e8f32d0a60294331930c5a04f82cac60.pdf.

3. Toluene Diamine Is A Likely Carcinogen.

91. Philips has recognized that PE-PUR foam releases toluene diamine ("TDA") as it degrades.[48] Additionally, TDA is a hydrolysis product of TDI.

92. IARC has classified TDA as possibly carcinogenic to humans (Group 2B),[49] and the EPA classifies it as a probable human carcinogen.[50] The European Union has concluded that TDA "cannot be considered safe for use" even as a hair dye, let alone breathed into the lungs for many hours each night.[51] The NTP classifies TDA as reasonably anticipated to be a human carcinogen based on animal studies.[52]

93. Available data on TDA primarily comes from animal studies. These studies strongly support an association between TDA and hepatic cancer.[53] There is evidence of a link between TDA exposure and pulmonary fibrosis based on in vitro studies in which human lung fibroblasts were exposed to TDI and TDA.[54] The EPA has determined that acute exposure to TDA

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[48] *See* https://www.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/global-supplemental-clinical-information-document-070821-r6.pdf ("[T]he degradative by-products of a PE-PUR foam after a humid ageing experiment were found to include … toluene diamine isomers (TDA)").

[49] *See Toluene diisocyanates*, IARC Monographs Vol. 71, IARC, *available for download at*, https://publications.iarc.fr/_publications/media/download/2317/fb198ec8e8f32d0a60294331930c5a04f82cac60.pdf.

[50] *See Toluene 2,4 diamine*, EPA (Jan. 2000), *available at* https://www.epa.gov/sites/default/files/2016-09/documents/toluene-2-4-diamine.pdf.

[51] https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_093.pdf (last accessed Aug. 15, 2022), at 5.

[52] *2,4-Diaminotoluene*, Report on Carcinogens, NTP, *available at* https://ntp.niehs.nih.gov/ntp/roc/content/profiles/diaminotoluene.pdf.

[53] *Id.*

[54] It is well established that TDI is converted to TDA through hydrolysis (a reaction caused by exposure to water). *See Current Intelligence Bulletin 53, Toluene Diisocyanate (TDI) and Toluenediamine (TDA): Evidence of Carcinogenicity*, NIOSH Pub. No. 90-101 (Dec. 1989), *available at* https://www.cdc.gov/niosh/docs/90-101/default.html. Thus, ingested TDI may react

can produce severe skin and eye irritation, sometimes leading to permanent blindness, respiratory problems (*e.g.*, asthma), rise in blood pressure, dizziness, convulsions, fainting, and coma.[55] Exposure to TDA can also cause irritation of the skin, nose, and throat, damage to reproductive and neurological systems, eye irritation, dermatitis, ataxia, tachycardia, respiratory depression, stomach gas, hypertension, nausea, vomiting, methemoglobinemia, cyanosis, headache, weakness, exhaustion, dizziness, convulsions, fainting, and coma.[56]

4. Diethylene Glycol Is Toxic To Humans.

94. Diethylene glycol ("DEG") is a widely used solvent. It is a colorless and odorless liquid with a sweetish taste and has often been a contaminant in consumer products, resulting in numerous epidemics of poisoning. DEG is used in the production of polyester polyurethane foam, and Philips has advised that DEG is a byproduct of PE-PUR foam degradation.[57]

95. DEG has an historical involvement in mass poisonings around the world. Famously, DEG caused the death of 100 people across 15 states in the 1937 Elixir Sulfanilamide Incident, which served as a catalyst for the enactment of the Federal Food, Drug, and Cosmetic Act ("FDCA") in 1938.[58]

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with saliva and/or gastrointestinal fluids and convert to TDA. Additionally, there is evidence that inhaled TDI is converted into TDA by reaction with a substance (gluthathione) present in the lungs. As a result, observed effects ascribed to TDI may be due to unmeasured conversion to TDA after exposure.

[55] *Id.*

[56] *See Toluene 2,4 diamine*, EPA (Jan. 2000), *available at* https://www.epa.gov/sites/default/files/2016-09/documents/toluene-2-4-diamine.pdf.

[57] *See* https://www.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/global-supplemental-clinical-information-document-070821-r6.pdf ("[T]he degradative by-products of a PE-PUR foam after a humid ageing experiment were found to include diethylene glycol (DEG) … .").

[58] https://www.fda.gov/files/about%20fda/published/The-Sulfanilamide-Disaster.pdf (last accessed Aug. 15, 2022).

96. DEG is a toxic substance with a mean fatal dose of 1 mL/kg of pure DEG.[59] Ingesting only a small amount may result in gastrointestinal distress and stupor.[60] Exposure may cause irritation of the eyes, skin, and mucous membranes.[61] DEG has also been shown to have damaging toxic, irritating, and inflammatory properties when inhaled.[62]

5. Dimethyl Diazine Is A Precursor To A Known Carcinogen.

97. Dimethyl diazene ("DD"), also known as azomethane, is "associated with the production process of the [PE-PUR] foam."[63] Philips has admitted that DD is emitted from PE-PUR foam under normal conditions and possibly also as the result of degradation.[64]

98. IARC has not yet evaluated the potential carcinogenicity of DD to humans, as there is scant data concerning the effects of DD on humans and animals. However, DD is a member of a family of carcinogenic substances: 1,2-dimethylhydrazine (a Group 2A probable human carcinogen that exhibits hepatotoxic effects along with injuries to other organs in animal experiments[65]) dehydrogenates into DD, which then oxidizes into azoxymethane (a known

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[59] L.J. Schep, *et al*., *Diethylene glycol poisoning*, Clin. Toxicol. 47(6):525-35 (Jul.2009).

[60] *See Ethylene Glycol: Systemic Agent*, NIOSH, *available at* https://www.cdc.gov/niosh/ershdb/emergencyresponsecard_29750031.html#:~:text=Agent%20Characteristics&text=DESCRIPTION%3A%20Ethylene%20glycol%20is%20a,also%20be%20a%20pharmaceutical%20vehicle. (last accessed Aug. 15, 2022).

[61] *Id.*

[62] *See*, *e.g.*, C.J. Hardy, *et al.*, *Twenty-eight-day repeated-dose inhalation exposure of rats to diethylene glycol monoethyl ether*, Fundam. Appl. Toxicol. 38(2):143-7 (Aug. 1997).

[63] *See* https://www.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/global-supplemental-clinical-information-document-070821-r6.pdf. (finding that during "testing which ran a device at 35°C ± 2°C for 168 hours, two compounds of concern were emitted from the device: dimethyl diazene and phenol 2,6-bis (1,1-dimethylethyl)-4-(1-methylpropyl)").

[64] *Id.*

[65] G. Choudary, *Toxicological Profile for Hydrazines*, Agency for Toxic Substances and Disease Registry (1997); R.B. Wilson, *Species variation in response to dimethylhydrazine, Toxicology and Applied Pharmacology*, 38:3 (1976); M.A. Bedell, *et al*., *Cell Specificity in Hepatocarcinogenesis:*

carcinogen that has not yet been classified by the EPA or IARC). Azoxymethane further oxidizes into methylazoxymethanol, a Group 2B possible human carcinogen.[66] Both methylazoxymethanol and 1,2-dimethylhydrazine have been found to metabolize into formaldehyde, a Group 1 known carcinogen.[67] Thus, an individual regularly exposed to DD may also have been exposed to 1,2-dimethylhydrazine, azoxymethane, methylazoxymethanol, and/or formaldehyde—each of which is recognized as a known or probable carcinogen—as these compounds are oxidized and metabolized.

99. DD is clearly linked to colorectal cancer in mice. Azoxymethane, the product of oxidized DD, is used to induce colorectal cancer in animals and has been shown to cause hepatic lesions, intestinal tumors, and renal tumors.[68] Oxidized azoxymethane produces methylazoxymethanol, which is known to cause DNA damage and has been associated with amyotropic lateral sclerosis, parkinsonism, dementia, colon cancer, liver cancer, and prostate

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Preferential Accumulation of O6 Methylguanine in Target Cell DNA during Continuous Exposure of Rats to 1,2-Dimethylhydrazine, Cancer Res 42:3079-3083 (1982); W.J. Visek, *et al*., *Dietary protein and chronic toxicity of 1,2-dimethylhydrazine fed to mice*, Journal of Toxicology and Environmental Health, 32:4, 383-413 (1991).

[66] E. Fiala, *Investigations into the metabolism and mode of action of the colon carcinogen 1, 2-dimethylhydrazine*, Cancer, 36:2407-12 (Dec. 1975); S. Wolter, N. Frank, *Metabolism of 1,2-dimethylhydrazine in isolated perfused rat liver*, Chemico-Biological Interactions, 42:3, 335-344 (1982); IARC Monograph – 71-42, IARC (1987); IARC Monograph Supplement 7, IARC (1987); H. Druckrey, *Production of colonic carcinomas by 1,2-dialkylhydrazines and azoxyalkanes*, Carcinoma of the Colon and Antecedent Epithelium 267-279 (1970).

[67] P. Harbach, *et al*., *Effects of selenium on 1,2-dimethylshydrazine metabolism and DNA alkylation* (1981); S.N. Newaz, *et al*., *Metabolism of the Carcinogen 1,2Dimethylhydrazine by Isolated Human Colon Microsomes and Human Colon Tumor Cells in Culture* (1983); J. Erikson, *et al*., *Oxidative Metabolism of Some Hydrazine Derivatives by Rat Liver and Lung Tissue Fractions* (1986).

[68] M. Kobaek-Larsen, *et al*., *Secondary effects induced by the colon carcinogen azoxymethane in BDIX rats*, APMIS 112(6):319-29 (2004 Jun.).

cancer.[69] Exposure to DD—as the precursor to these carcinogenic compounds—means exposure to these other compounds and the health risks they pose.

6. Phenol, 2,6-bis (1,1-dimethylethyl)-4-(1-methylpropyl) Is A Toxic Compound.

100. The substance Phenol, 2,6-bis(1,1-dimethylethyl)-4-(1-methylpropyl) ("DTBSBP") is "associated with the production process of the foam." [70] According to Philips, DTBSBP is emitted from PE-PUR foam under normal conditions and possibly also as the result of degradation.[71]

101. In 2010, the Canadian government determined that DTBSBP was a Schedule 1 toxic substance under the Canadian Environmental Protection Act "based on available information regarding possible persistence, accumulation in organisms and potential to cause harm to organisms."[72] These findings prompted Canadian regulators to propose "virtual elimination" of DTBSBP.[73]

E. PHILIPS KNEW OF THE DANGERS OF PE-PUR FOAM FOR MANY YEARS PRIOR TO THE RECALL.

102. At the time it installed PE-PUR foam into the Recalled Devices, Philips was required to test the devices in accordance with ISO 18562-2:2017 and ISO 18562-3:2017.

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[69] P. Spencer, *et al*., *Unraveling 50-Year-Old Clues Linking Neurodegeneration and Cancer to Cycad Toxins: Are microRNAs Common Mediators?*, Frontiers in Genetics 3 (2012).

[70] *See* https://www.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/global-supplemental-clinical-information-document-070821-r6.pdf (finding that during "testing which ran a device at 35°C ± 2°C for 168 hours, two compounds of concern were emitted from the device: dimethyl diazene and phenol 2,6-bis (1,1-dimethylethyl)-4-(1-methylpropyl)").

[71] *Id.*

[72] *Phenol, 2,6-bis(1,1-dimethylethyl)-4-(1-methylpropyl)- (DTBSBP)*, Government of Canada, Canada.ca, *available at* https://www.canada.ca/en/health-canada/services/chemical-substances/challenge/batch-8/1-methylpropyl.html. (last accessed Aug. 15, 2022).

[73] *Id.*

103. At that time, Philips should have known the PE-PUR foam posed a safety risk to users.

104. The FDA concluded after an investigation of Philips' Recalled Devices that beginning in at least 2008, and over time, Philips received hundreds of thousands of customer complaints regarding foam degradation in the Recalled Devices and, years later, received data from a variety of sources confirming foam degradation.

105. The FDA's findings were based, in part, on twenty-one (21) site inspections of Philips' Murrysville, Pennsylvania facility between August 26, 2021 and November 9, 2021. The lead FDA investigator, Katelyn A. Staub-Zamperini, memorialized the agency's findings in a 28-page FDA-483 Report issued on November 9, 2021.[74] The FDA delivered the 483 Report to Rodney Mell, Head of Quality and Regulatory at Philips Respironics, on or around November 9, 2021.[75]

106. A 483 Report "is issued to firm management at the conclusion of an inspection when an investigator(s) has observed any conditions that in their judgment may constitute violations of the Food Drug and Cosmetic (FD&C) Act and related Acts."[76] These observations are made in a 483 Report "when in the investigator's judgment, conditions or practices observed would indicate that any food, drug, device or cosmetic has been . . . or is being prepared, packed, or held under conditions whereby it may become adulterated or rendered injurious to health."[77]

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[74] FDA 483 Report, *available at*: https://www.fda.gov/media/154244/download.

[75] *Id.* at 1, 28.

[76] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/fda-form-483-frequently-asked-questions (last accessed Aug. 15, 2022).

[77] *Id.*

107. In connection with its investigation for its 483 Report, the FDA learned that Philips received hundreds of thousands of complaints from customers about degradation of the foam in its Recalled Devices beginning at least as early as 2008:

> [A] query of your firm's consumer complaints from 01/01/2008 to current, for the keywords contaminants, particles, foam, debris, airway, particulate, airpath, and black, **resulted in over 222,000 complaints, and over 20,000 of which occurred between 2008 to 2017 and involved Trilogy devices**. Additionally, your firm performed a foam related complaint data analysis in April 2021 on complaints confirmed to be related to or involve foam degradation issues. The raw complaint data documents that **30 Trilogy related complaints were received from 2014 to 2017, and 1,254 related complaints were received across all products containing the affected foam, from 2014 to 2021**.[78]

108. Yet, "[n]o formal investigation, risk analysis, or CAPA were initiated, performed, or documented [by or on behalf of Philips], in response to the at least 222,000 complaints that could potentially be related to foam degradation and received from 2008 to 2017 . . . ."[79]

109. A Corrective and Preventative Action ("CAPA") refers to procedures that medical device manufactures must follow to identify and attempt to correct a quality problem after one is detected. *See* 21 C.F.R. § 820.100. A CAPA is designed "to collect information, analyze information, identify and investigate product and quality problems, and take appropriate and effective corrective and/or preventive action to prevent their recurrence."[80]

110. The FDA also found that Philips "was made aware of polyester polyurethane [PE-PUR] foam degradation issues in/around October 2015 . . . ."[81]

111. In fact, an adverse event report from the FDA Manufacturer and User Facility Device Experience ("MAUDE") database shows that, as early as 2011, Philips knew that a patient

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[78] 483 Report at 12 (emphasis added).

[79] *Id.* at 16.

[80] https://www.fda.gov/corrective-and-preventive-actions-capa (last accessed Aug. 15, 2022).

[81] 483 Report at 18.

discovered "black dust" on her nose when she awoke after using a Philips RemStar CPAP device and subsequently underwent treatment for "intoxication" and "chest tightness."[82]

112. Philips investigated this report and confirmed that the device contained "evidence of an unk[nown] black substance in the air path and on internal components . . . present throughout both the intake and exhaust portions of the air path . . . ."[83]

113. The FDA found that Philips' analysis of consumer complaints was itself defective in that it "was not adequately performed to identify or detect quality problems."[84] The FDA concluded that "potential foam degradation in Trilogy ventilator devices is not an isolated incident, and you [Philips] also have not documented a detailed rationale for why harm is not likely to occur again, as required by your Health Hazard Evaluation's instructions."[85] In light of this, the FDA concluded that Philips' "risk analysis is inadequate or was not performed when appropriate or within an appropriate time frame of your firm becoming aware" of these issues.[86]

114. The FDA has concluded that:

> Beginning in 2015, Philips received data from a variety of sources regarding degradation of the PE-PUR foam contained within the recalled devices, including complaints, test reports, information from suppliers, and information from another entity owned by Philips' parent company. Philips failed to adequately evaluate this data and incorporate it into its CAPA [Corrective and Preventive Actions] system for further investigation and potential mitigation, as required by current good manufacturing practice requirements codified in 21 C.F.R. § 820.100.[87]

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[82] MAUDE Adverse Event Report: RESPIRONICS, INC. REMSTAR PRO INTERNATIONAL, http://www.fdable.com/advanced_maude_query/324fd08a137ce36c2d5faf453ee26f2f (last accessed Aug. 15, 2022).

[83] *Id*.

[84] 483 Report at 16.

[85] *Id.* at 13.

[86] *Id.* at 3.

[87] https://www.fda.gov/media/158129/download (last accessed Aug. 15, 2022) ("518(b) Notice"), at 6.

115. The FDA 483 Report also noted, that "an incorrect and non-specified polyester polyurethane, raw foam product, sourced from your [Philips'] raw foam supplier resulted in non-conforming Trilogy Evo ventilatory finished devices being approved, released, and distributed which further resulted in the ongoing correction and removal."[88] The correction and removal "were established as part of [Philips'] response to failed VOC and ISO 18562 testing of related Trilogy EVO ventilatory medical devices, which resulted from the presence of the non-specified polyester polyurethane foam component, incorrectly supplied by [Philips'] raw foam supplier."[89]

116. On May 2, 2022, the FDA issued a formal notice to Philips pursuant to Section 518(b) of the FDCA, 21 U.S.C. § 360h(b) (the "518(b) Notice").[90] The 518(b) Notice stated that the FDA's "Center for Devices and Radiological Health (CDRH) is proposing that an order should be issued pursuant to section 518(b)" of the FDCA "to require Philips to submit a plan for the repair, replacement, and/or refund of the purchase price of devices subject to the recall that were manufactured after November 2015, sufficient to assure that the unreasonable risk of substantial harm to the public health presented by those devices will be eliminated."[91] This notice was directed to Thomas J. Fallon, Head of Quality, Sleep and Respiratory Care, for Philips Respironics, Inc.

117. The 518(b) Notice stated that "there is sufficient evidence for FDA to determine that the devices subject to the recall present an unreasonable risk of substantial harm to the public health" and "that there are reasonable grounds to believe that the recalled devices that Philips

[88] 483 Report at 25.

[89] *Id.*

[90] 518(b) Notice, available at https://www.fda.gov/media/158129/download.

[91] 518(b) Notice at 1.

manufactured after November 2015 were not properly manufactured with reference to the state of the art as it existed at the time of the devices' manufacture."[92]

118. The FDA concluded that "patients and providers cannot readily mitigate the unreasonable risk associated with the recalled devices[.]"[93]

119. The FDA also concluded that "[t]his risk is not the unavoidable byproduct of current ventilator, CPAP machine, and BiPAP machine technologies. Indeed, Philips and its competitors market ventilators, CPAP machines, and BiPAP machines that do not use PE-PUR foam."[94]

1. In 2015, Philips Communicated With Its Foam Suppliers About The Problem Of PE-PUR Foam Degradation.

120. The PE-PUR foam that Philips used in its Recalled Devices was manufactured by William T. Burnett & Co. ("Burnett"), a bulk foam manufacturer. Burnett produces foam in sheets that are between approximately four feet to more than six feet wide and may be as long as one hundred or two hundred feet.

121. Burnett sells its bulk foam to intermediaries, including PolyTech and The SoundCoat Company ("SoundCoat"). PolyTech and SoundCoat then sell the foam to Philips, either directly or through another intermediary, such as Paramount Die Corporation, which may modify the foam.

122. According to the FDA, "email correspondence between [Philips] and its raw foam supplier [PolyTech] beginning 10/30/2015 and forward, document that [Philips] was made aware

[92] *Id.* at 2.

[93] *Id.*

[94] *Id.* at 6.

of polyester polyurethane [PE-PUR] foam degradation issues in/around October 2015, which was later confirmed by [Philips'] foam supplier on 08/05/2016, via email."[95]

123. On August 5, 2016, Bob Marsh, a PolyTech employee, wrote to Lee Lawler,[96] an employee of Burnett, referencing a concern expressed by one of its customers [Philips] in the Fall of 2015 regarding foam degradation in its medical devices.[97] Mr. Marsh stated: "They [Philips] are asking again, and wondered if we could give them any estimate on lifespan of the foam when exposed to 40 C and high humidity."[98] Mr. Lawler responded that, under those conditions, he "would not be surprised if ester foam . . . would exhibit signs of hydrolysis in as short a time as a year."[99] He added that "that is not a good environment for polyester foam. Polyether foam could last years in that environment."[100] Presumably referring to Philips, Mr. Marsh responded that he would "let them know they'd be better off with the ether."[101]

124. Knowing about these issues with the PE-PUR foam, Philips tested the foam material used in its Recalled Devices. According to the FDA, "this testing spoke only to the limited finding that in the case of the [redacted] foam samples 'returned from service in a Pacific rim location,' spectroscopy results were 'consistent with an environmental/chemical exposure causing

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[95] 483 Report at 18.

[96] The Affidavit of Lee Lawler, Technical and R&D Manager at Burnett, is filed in MDL 3014, Case 2:21-mc-01230-JFC, at Doc. 589-7 and attached hereto, without exhibits, as Exhibit "D" ("Lawler Aff.").

[97] *See* Email exchange between Bob Marsh at PolyTech and Lee Lawler at Burnett (Lawler Aff. Exh. E) (attached hereto as Exhibit "E"), at WTB 000056.

[98] *Id.*

[99] *Id.*

[100] *Id.*

[101] *Id.*

base polymer cleavage and embrittlement of the material.'"[102] Nonetheless, based on the results of this limited testing, Philips concluded that no escalation to a CAPA process was required.[103]

125. According to the FDA, "no further investigation, health hazard evaluation, risk analysis, or design review was performed or documented by Philips at that time . . . and no preventative maintenance procedures were implemented[,]" other than a limited "preventative maintenance procedure" instituted by a Philips "entity owned by the parent company of Philips Respironics . . . to replace the air intake assembly of Trilogy ventilator products, due to complaints that had been received regarding degradation of the PE-PUR foam contained in the products."[104] And even then, "Philips did not verify the effectiveness of this measure."[105]

126. As Philips continued to ask its supplier about the properties of the PE-PUR foam and encountered more warning signs, it continued to put that foam in medical devices that millions of its customers were breathing through daily.

127. Testing conducted for Philips in 2016 confirmed that Mr. Lawler from Burnett was correct. According to the FDA, this testing "determined that the PE-PUR foam was susceptible to degradation, resulting in the conclusion at that time that 'polyester urethanes show bad resistance against high humidity in combination with high temperature.'"[106] Additional testing "determined that, compared to PE-PUR foam, another type of foam, polyether urethane, 'show[s] a far better resistance against high humidity at high temperature.'"[107]

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[102] 518(b) Notice at 7.

[103] *Id.*

[104] *Id.* at 6-7.

[105] *Id.* at 8.

[106] *Id.* at 7-8.

[107] *Id.* at 8.

128. The 483 Report identified "at least fourteen instances, assessments, and/or test reports, dated from 04/01/2016 to 01/22/2021, where [Philips] was aware of issues and concerns related to potential foam degradation and/or Volatile Organic Compound (VOC) emissions, with various Sleep and Respiratory care devices."[108] It listed the specific analyses and tests, including one which concluded that "contrary to polyester urethane foams, [redacted] foams shows a far better resistance against high humidity at high temperature."[109]

129. Philips received at least 110 complaints confirmed to be related to foam degradation between 2014 and 2017.[110] Approximately 80 of these complaints concerned CPAP and BiPAP devices.[111]

130. Nonetheless, Philips continued manufacturing and selling the now Recalled Devices containing PE-PUR foam and failed to warn prescribing physicians, durable medical equipment companies and the patient consumers of this problem.

2. Philips Opened An Internal Investigation Into Foam Degradation In Mid-2018 That Confirmed PE-PUR Foam Is Prone To Degradation.

131. In April 2018, Philips opened a precursor to a formal CAPA, referred to by Philips as a CAPA INV 0988, "to investigate complaints related to potential foam degradation for the Trilogy devices in Australia and to determine what actions should be taken."[112] Philips reported that "[u]nits were returned from the field where the Trilogy Removable Air Path Foam [redacted]

[108] 483 Report at 3.

[109] *Id.* at 4.

[110] 518(b) Notice at 7.

[111] *Id.* at 8.

[112] *Id.*

and the foam in the Inlet Air Path Assembly [redacted] was degrading, and getting into the motor/air path, causing at least 1 Trilogy unit to fail."[113]

132. On April 20, 2018, Vincent Testa, a Project Mechanical Engineer at Philips, emailed Bonnie Peterson, a Project Manager at PolyTech. Mr. Testa stated, "We use the PAFS foam in the air path of our Trilogy family of ventilators as a means for noise reduction . . . ."[114] PAFS foam is PolyTech's open cell, flexible acoustical grade PE-PUR foam.[115] Mr. Testa at Philips continued: "Recently weve [*sic*] received a few complaints from our customers that the foam is disintegrating . . . . The material sheds and is pulled into the ventilator air path. As you can imagine, this is not a good situation for our users."[116] Mr. Testa asked, "what could cause this material to break down."[117]

133. On April 23, 2018, Mr. Marsh from PolyTech forwarded Philips' April 20, 2018 email to Mr. Lawler from Burnett, reporting that "[t]he customer [Philips] is finding degradation of the ester foam and the urethane film in their device, such that particles are breaking off and flowing in the airstream."[118]

134. On May 2, 2018, Mr. Marsh added in an email to Mr. Lawler that "Philips gave us another bit of information. They tested ether vs ester in high heat and humidity and found ether to

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[113] 483 Report at 14.

[114] *See* Email from Vincent Testa at Philips to Bonnie Peterson at PolyTech (Lawler Aff. Exh. H) (attached hereto as Exhibit "F"), at WTB 000070.

[115] https://www.polytechinc.com/products/acoustic-foam (last accessed Aug. 15, 2022).

[116] *See* Email from Vincent Testa at Philips to Bonnie Peterson at PolyTech (Lawler Aff. Exh. H) (Exhibit "F" hereto), at WTB 000070.

[117] *Id.*

[118] *See* Email from Bob Marsh to Lee Lawler dated 4/23/2018 (Lawler Aff. Exh. H) (Exhibit "F" hereto), at WTB 000069-000070.

be the better performer. It validated what we (you) had conveyed."[119] Mr. Marsh asked whether exposure to oxygen, higher temperature, and higher humidity could accelerate deterioration of PE-PUR foam.[120]

135. Mr. Lawler responded that he did "not believe that exposure to oxygen will cause any significant damage to polyurethane foam unless elevated temperature and/or humidity is also present."[121]

136. On May 3, 2018, Mr. Testa from Philips admitted in a follow-up email to Mr. Marsh from PolyTech, that:

> We [Philips] are evaluating our options regarding the foam. We could switch to the PAF [ether-based foam], or we could indicate a preventative maintenance cycle in which they would replace the PAFS [ester-based] foam pieces. . . . The environmental conditions for our device are a maximum of 40C and 95% R.H. Note the difference in temperature.[122]

137. Mr. Testa at Philips asked Mr. Marsh from PolyTech the following:

1. Please ask your foam supplier to calculate the service life based on this higher temperature (40C vs. 27C).
    a. It would also be useful if they could provide a graph depicting failure over time. For example, if tensile strength reduced over time, they would plot strength vs. time.
2. At the end of the service life, what is the failure mode of this material?[123]

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[119] *See* Email from Bob Marsh to Lee Lawler dated 5/2/2018 (Lawler Aff. Exh. H) (Exhibit "F" hereto), at WTB 000069.

[120] *Id.*

[121] *See* Email from Lee Lawler to Bob Marsh dated 5/2/2018 (Lawler Aff. Exh. H) (Exhibit "F" hereto), at WTB 000069.

[122] *See* Email from Vincent Testa to Bob Marsh dated 5/3/2018 (Lawler Aff. Exh. H) (Exhibit "F" hereto), at WTB 000068-69).

[123] *Id*.

138. Mr. Marsh again forwarded these questions to Mr. Lawler at Burnett, who responded:

> I am unable to answer Question Number 1. We would not recommend using **polyester** foam in such an environment and have no direct data to use to calculate the rate of hydrolysis. **Polyether** foam lifetime would not be expected to reduce significantly at the stated conditions. Use with pure oxygen could shorten the lifetime some by promoting more rapid oxidation. I do not know the extent of the reduction, but do not expect it to be overly significant.
>
> Polyester foam will lose tensile strength and overall integrity as it hydrolyzes. It will eventually decompose to a sticky powder. That will happen very rapidly at 40C, 95% R.H.[124]

139. Mr. Lawler from Burnett added: "Is it one of our data sheets that states foam lifetime being 10 years at 95% R.H? I do not think I have seen a sheet with that statement."[125] Mr. Marsh at PolyTech responded that he would pass along the information to Philips and that "[w]e have no idea where that statement came from. It has been on our data sheets for probably 20 years. We are removing it."[126]

140. On May 23, 2018, Mr. Marsh from PolyTech forwarded to Mr. Lawler from Burnett another question from Mr. Testa at Philips about the degradation of the foam it was using in its Recalled Devices.[127] Mr. Testa explained that Philips had "sent samples to a local lab for

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[124] *See* Email from Lee Lawler to Bob Marsh dated 5/4/2018 (Lawler Aff. Exh. H) (Exhibit "F" hereto), at WTB 000067-68 (emphasis in original).

[125] *Id.* at WTB 000068.

[126] *See* Email from Bob Marsh at PolyTech to Lee Lawler at Burnett dated 5/4/2018 (Lawler Aff. Exh. H) (Exhibit "F" hereto), at WTB 000067. Notably, PolyTech still advertises on its website that PE-PUR foam is resistant to heat and humidity. *See* https://www.polytechinc.com/products/polymer-acoustic-foam (last accessed Aug. 15, 2022) ("Ester foams have superior physical properties and offer excellent resistance to heat, moisture, and chemicals.").

[127] *See* Email from Bob Marsh to Lee Lawler dated 5/23/2018 (Lawler Aff. Exh. H) (Exhibit "F" hereto), at WTB 000066-67.

analysis."[128] The local lab concluded that the degradation was a result of cleavage of the bonds in the base polymer, and Mr. Testa stated that "[f]urther investigation concluded that prolonged exposure to high humidity causes the foam to degrade."[129] Mr. Testa noted that "[a]s the foam degrades it breaks down into small particulate" and asked whether the foam "maintain[s] its UL 94 Flame Resistance rating if it is broken down into particulate?"[130]

141. Mr. Lawler replied: "I am sure the degraded foam will not perform well in UL94 testing, though I cannot imagine how one would actually perform the test on such degraded material."[131]

142. On June 7, 2018, Mr. Testa at Philips again emailed Mr. Marsh at PolyTech:

> As we continue our investigation of the deterioration of the PAFS foam, a few questions has [*sic*] been posed regarding the material. Can you please reach out to your foam supplier regarding the following.
>
> 1. What is the actual composition of the polyurethane-ester foam PAFS-038? (CAS #s/percentages/weight percent/reactive groups etc. any chemistry is very appreciated)
> 2. What kind of diisocynate is used in the polyurethane foam synthesis process and how much?
> 3. Is diethylene glycol or another polyol utilized in the foam synthesis process?
> 4. Have you tested to see if all diisocyanate groups are reacted in your foam or are there unreacted groups even after manufacturing?[132]

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[128] *Id.* at WTB 000066.

[129] *Id.* at WTB 000067.

[130] *Id.*

[131] *See* Email from Lee Lawler to Bob Marsh dated 5/23/2018 (Lawler Aff. Exh. H) (Exhibit "F" hereto), at WTB 000066.

[132] *See* Email from Vincent Testa to Bob Marsh dated 6/7/2018 (Lawler Aff. Exh. I) (attached hereto as Exhibit "G"), at WTB 000076-77.

143. Mr. Marsh (PolyTech) forwarded the questions to Mr. Lawler (Burnett), who asked why Mr. Testa (Philips) needed this information. Mr. Marsh did not provide a definitive answer but said, "What Vince [Testa] told us is that they are investigating alternatives to polyurethane foam (ester and ether)."[133] Mr. Lawler ultimately did not answer Mr. Testa's questions because they touched on Burnett's confidential, proprietary information.

144. On June 20, 2018, Philips closed CAPA INV 0988.[134] According to the FDA, Philips implemented "a preventative maintenance procedure for Trilogy devices, but Philips did not verify the effectiveness of this measure."[135] Yet "after CAPA INV 0988, Philips modified its CAPA procedures to include 'requirements to help ensure that CAPAs are fully complete [and] appropriately scoped,' and that 'processing the issue [that was the subject of CAPA INV 0988] through the current CAPA program would have result[ed] in an appropriate horizontal assessment.'"[136]

145. The FDA pointed out that Philips' informal CAPA INV[137] related to these Trilogy devices did "not include, investigate, or examine all of [Philip's] CPAP and BiPAP medical devices, which also include similar air path assemblies and/or the affected polyester polyurethane [PE-PUR] foam, which is susceptible to degradation."[138] But Philips had acknowledged to the

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[133] *See* Email from Bob Marsh to Lee Lawler dated 6/14/2018 (Lawler Aff. Exh. I) (Exhibit "G" hereto), at WTB 000075.

[134] 483 Report at 15.

[135] 518(b) Notice at 8.

[136] *Id.*

[137] The 483 Report explained that Philips's practice at the time was to first open CAPA requests—called "CAPA INVs"—as a precursor to a formal CAPA, but this could only occur if approved by a "CAPA Review Board" or delegate. *See* 483 Report at 14-15.

[138] *Id.* at 15.

FDA that it had "received approximately eighty complaints related to foam degradation, **on non-Trilogy ventilator devices**, from 2014 to 2017."[139]

146. The FDA concluded that Philips had not "adequately established" procedures for initiating CAPA procedures.[140] Specifically, the FDA faulted Philips for not initiating a "formal" CAPA after receiving "various complaints alleging foam degradation in Trilogy ventilator devices" and then closing its informal investigation just two months later without "verify[ing] the effectiveness" of the limited "preventative maintenance procedure for Trilogy devices."[141]

147. Philips continued to receive more information suggesting that the PE-PUR foam was prone to degradation. According to the FDA, "[a] follow-up email amongst [Philips'] personnel, dated 08/24/2018, states that testing confirmed that the affected foam breaks down in high heat and high humidity environments, which concurred with Trilogy ventilator related complaints . . . ."[142]

148. Further, "[o]n December 12, 2018, several months after CAPA INV 0988 was closed, a report from additional testing conducted for Philips found that '[p]olyester polyurethane foam showed clear disintegration after 2 weeks."[143]

149. Nonetheless, Philips continued manufacturing and selling the Recalled Devices containing PE-PUR foam.

150. Philips failed to apprise the FDA of the facts and problems it learned from its foam suppliers about premature foam degradation risks.

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[139] *Id.* at 16 (emphasis added).

[140] *Id.* at 14.

[141] 518(b) Notice at 8.

[142] 483 Report at 18.

[143] 518(b) Notice at 8.

151. Philips failed to apprise the FDA of consumer, medical provider and durable medical equipment company reports of the presence of foam particles and other device failures.

3. Philips Finally Opened A Formal CAPA In 2019 – But Did Not Initiate A Recall For Two More Years.

152. In April 2019, Philips received two complaints that "sound abatement foam 'is degrading and entering the air path[.]'"[144]

153. In response, in June 2019, Philips finally initiated a formal CAPA, numbered CAPA 7211, related to the issues associated with the PE-PUR foam. But as the FDA explains:

> Even then, that CAPA failed to evaluate all relevant data. Philips' search of FDA's Manufacturer and User Facility Device Experience (MAUDE) database in connection with CAPA 7211 identified only three medical device reports (MDRs) associated with potential foam degradation involving Trilogy ventilators between January 2011 and January 2021. Yet an MDR analysis conducted by Philips in 2018 had already identified 17 documented complaints related to foam degradation in Trilogy ventilators, and at least 14 of those 17 complaints had related MDRs. Similarly, Philips' analysis of foam degradation-related complaints conducted in connection with CAPA 7211 identified 1,254 complaints confirmed to be related to foam degradation between 2014 and April 2021 across all affected products, yet this analysis failed to include several complaints confirmed to be related to foam degradation in Trilogy ventilators that were documented in 2018 in connection with CAPA INV 0988.[145]

154. Philips continued to test the PE-PUR foam while the CAPA was underway. A Biological Risk Assessment dated July 2, 2020, found that "the biological and toxicological risks from exposure to degraded PE-PUR foam are of concern…."[146]

155. Another internal "Biological Risk Assessment" dated December 10, 2020 – and "conducted as a result of field reports/complaints regarding degraded sound abatement foam in

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[144] *Id.*

[145] *Id*. at 8-9.

[146] 483 Report at 7; *see also id.* ("Philips Respironics Inc. (PRI) was made aware in May 2019 that four CPAP units were returned to a service center with degraded sound abatement foam.").

various CPAP and ventilator products"[147] – described the risks that degraded polyurethane foam posed to humans in no uncertain terms:

> The cytotoxicity and positive genotoxicity results observed from degraded PE-PUR foam samples **indicate a potential patient risk. Potential cytotoxicity and genotoxicity leading to carcinogenicity are possible outcomes from degraded PE-PUR foam exposure.** Overall, based on an understanding of the toxicological significance of the foam degradants and the results of the ISO 10993 testing to include mutagenic responses in both a bacterial and mammalian system, **the degraded PE-PUR foam is not considered biocompatible and presents a significant biological risk to those patient populations who are exposed to degraded PE-PUR foam.**[148]

156. An additional Philips' Biocompatibility Risk Assessment dated January 11, 2021, concurred that degraded PE-PUR foam "presents a significant biological risk to patients," and goes on to state that "[p]otential cytotoxicity and genotoxicity leading to carcinogenicity are possible outcomes from degraded PE-PUR foam exposure."[149]

157. Ultimately, in CAPA 7211, Philips concluded that "the cause of the foam degradation condition is long-term exposure to environmental conditions of high temperature combined with high humidity" and restated that "the cause of degradation was due to chemical breakdown of the foam due to exposure to water caused by long-term exposure to environmental conditions."[150]

158. Based on its investigation, the FDA concluded that Philips' upper management was aware of the foam degradation issues, discussed it at numerous management review meetings, and yet delayed doing anything about it:

> [F]irm management, including management with executive responsibility, were aware of potential foam degradation issues concerning CPAPs, BiPAPs, and

[147] *Id.* at 8.

[148] *Id.* at 7-8 (emphasis added).

[149] *Id.* at 8.

[150] 518(b) Notice at 10.

> Trilogy ventilators since at least 01/31/2020, or earlier, and implemented no further corrective actions until April 2021.
>
> Polyester polyurethane foam degradation issues concerning CPAPs, BiPAPs, and Trilogy Ventilators were discussed at all [redacted] management review meetings, since the 2019 [redacted], dated 01/31/2020 . . . . Additionally, your firm [Philips] became aware of this issue and related field complaints in at least 2015 or earlier.[151]

F. PHILIPS CONSISTENTLY MARKETED ITS BREATHING MACHINES AS SAFE AND EFFECTIVE EVEN WHEN IT KNEW OF THE PROBLEMS WITH PE-PUR FOAM DEGRADATION AND ASSOCIATED HEALTH RISKS.

1. Philips Never Hinted at the Dangerous Condition of the Recalled Devices.

159. At no point prior to April 2021, when Philips first disclosed foam issues to its shareholders, did Philips even hint that there was a dangerous condition in its recalled CPAP, BiPAP, and ventilator devices. Instead, Philips held itself out as a trusted brand and "global leader in the sleep and respiratory markets."[152] Its branding promises consumers that they will "[b]reath easier, sleep more naturally[.]"[153] Philips further assures consumers that its "sleep therapy systems are designed with the needs of care practitioners and patients in mind," and that its "quality systems reflect [Philips'] commitment to providing enhanced patient comfort," among other things.[154] And it has long advertised its CPAP and BiPAP Machines as "clinically proven" treatment for sleep disorders.[155]

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[151] 483 Report at 24.

[152] http://www.respironics.com/product_library (last accessed Aug. 15, 2022).

[153] *Id*.

[154] *Id.*

[155] https://www.usa.philips.com/healthcare/solutions/sleep/sleep-therapy (last accessed Aug. 15, 2022).

160. Philips boasts that it has the "most prescribed CPAP systems by U.S. sleep physicians."[156]

2. Philips Knew Some of its Customers Were Using the SoClean Zone Cleaning Technology with its Devices and Assented to Such Use.

161. Philips was fully cognizant that many users were utilizing the So-Clean Ozone product in conjunction with its device.

162. For example, on March 6, 2020, in a letter responding to a customer's request for written guidance, Philips Respironics said using SoClean on its DreamStation will not automatically void the warranty, but the company "reserves the right to void a warranty if it is determined that the use of SoClean caused a defect for which a device otherwise under warranty was returned." The company said in a statement to HME News that it "does not formally validate the use of SoClean with the DreamStation, but as of Jan. 6, Philips has not denied a warranty claim associated with the use of SoClean with a DreamStation." Philips told HME News it wrote the letter "to limit confusion and misinformation." The article in HME News further quoted Philips stating that "Philips is in communication with SoClean to further analyze the potential compatibility of the SoClean with DreamStation therapy devices, and will provide further information as it becomes available," the company told HME News.[157]

163. By virtue of that communication to a trade journal, Philips not only acknowledged its awareness of the use of the product, but also acknowledged it received warranty complaints amongst users of the DreamStation who also used SoClean, and honored the warranties and communicated with SoClean.

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[156] *Id.*

[157] *Business News For Home Medical Equipment Providers*, March 6, 2020 at https://www.hmenews.com/article/cpap-manufacturers-address-certain-cleaning-devices (last accessed August 22, 2022).

164. Additional evidence that Philips was aware that SoClean was selling a product specifically designed to be used in conjunction with the DreamStation is the website of CPAPDIRECT.COM, a major internet provider of CPAP machines and related paraphernalia which advertised an express adapter kit for So Clean and Dream Station products.[158] Similarly numerous other internet and durable medical equipment companies and retail suppliers of Philips CPAP devices also sold SoClean to be used in conjunction with the Devices, and Philips was expressly and impliedly was aware of this combined use.

165. Given that Philips was on notice since at least 2008 of a foam degradation concern, and was also aware of the combined use of its Devices with SoClean, to the extent there is any validity to Philips recent claims attributing foam degradation to SoClean ozone treatment, Philips should have and could have made the same attributions and affirmatively stepped up to expressly warn medical providers, Durable Medical Equipment companies and patients against the combined use of the products in allegedly contributing to premature foam degradation.

166. Instead, recognizing that SoClean consumers seemingly liked having this additional cleaning modality, Philips declined to dissuade patients and customers from the combined use due to a concern that they would lose business to alternative CPAP manufacturers who also tacitly or expressly condoned such joint use.

3. Philips Sold Its Humidifier Accessory Allowing Warm Storage Conditions and Contributing to Humidity of the Foam.

167. Philips sold humidifiers to accompany its CPAP devices, especially the DreamStation, stating in the humidifier's User Manual under the heading "Intended Use": "The

[158] https://www.cpapdirect.com/cleaning/soclean-respironics-system-one-and-dreamstation-adapter (last accessed August 22, 2022).

DreamStation Heated Humidifier is an accessory for the Philips Respironics DreamStation therapy devices to provide moisture to the patient circuit."[159]

168. The humidifier manual quoted above had, under the heading "DreamStation Heated Humidifier Specifications" had environmental specifications that included an "Operating Temperature: 5° to 35° C (41° to 95° F")" as well as "Storage Temperature: -20° to 60° C (-4° to 140° F)" and "Relative Humidity (operating & storage): 15 to 95% (non-condensing)."[160]

169. Philips provided the humidifier option explaining in the DreamStation User Manual that "[y]ou can use the heated humidifier and the heated tube with your device. They are available from your home care provider. A humidifier may reduce nasal dryness and irritation by adding moisture to the airflow."[161]

170. Philips not only knew but recommended the use of the humidifier, and also advised that the device could be stored in a room as warm as 140° F despite their knowledge that warm, hot and humid conditions contributed to rapid degradation of its sound insulating foam.

G. PHILIPS FINALLY RECALLED ITS DEFECTIVE DEVICES CONTAINING HAZARDOUS PE-PUR FOAM, BUT ONLY AFTER LAUNCHING ITS NEWEST DEVICE WITHOUT PE-PUR FOAM.

1. Prior to the Recall, In April And May 2021, Philips Launched The DreamStation 2 (Which Does Not Contain PE-PUR Foam).

171. Two months prior to the Recall, Philips announced on April 13, 2021, that it was launching the DreamStation 2, a next-generation machine in its DreamStation product family. The DreamStation 2 does not contain PE-PUR foam.

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[159] https://www.documents.philips.com/doclib/enc/11410694/DreamStation_Humidifier_User_Manual.pdf, at 1 (last accessed August 22, 2022).

[160] *Id.* at 12.

[161] *See, e.g.*, Exh. C-1 (DreamStation User Manual), at 22.

172. Philips, acting with willful, wanton, and reckless disregard for the safety of its consumers, chose to defer even warning patients about the foam degradation, particle debris and off gassing of toxic fumes, and also deferred the recall until such time as it had its new product commercially available so as to not lose market share to competitors.

173. Not coincidentally, less than two weeks after its launch of the DreamStation 2, on April 26, 2021, Philips announced that its previous generation DreamStation products and other Recalled Devices posed serious health risks to users and, in the same release, Philips started trying to convince consumers to purchase and use its new DreamStation 2 device:

> Philips has determined from user reports and testing that there are possible risks to users related to the sound abatement foam used in certain of Philips' sleep and respiratory care devices currently in use. The risks include that the 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. The majority of the affected devices are in the first-generation DreamStation product family. ***Philips' recently launched next-generation CPAP platform, DreamStation 2, is not affected***. Philips is in the process of engaging with the relevant regulatory agencies regarding this matter and initiating appropriate actions to mitigate these possible risks. Given the estimated scope of the intended precautionary actions on the installed base, Philips has taken a provision of EUR 250 million.[162]

2. <u>Testing Continued To Confirm The Recalled Devices Were Defective and the FDA received additional MDRs.</u>

174. Even as it launched the DreamStation 2 device and announced publicly that its previous generation DreamStation products posed serious health risks to users, Philips continued to conduct tests that confirmed some of its breathing products were defective.

175. For example, on May 17, 2021, Ken Cole from RJ Lee, an industrial forensics analytical laboratory and scientific consulting firm, produced a presentation analyzing the foam in

[162] https://www.philips.com/a-w/about/news/archive/corpcomms/news/press/2021/philips-first-quarter-results-2021.html (last accessed Aug. 15, 2022) (emphasis added).

Philips' Trilogy EVO devices. The presentation states that the investigation was "prompted by staff observation of color variance across both current production and previous builds."[163]

176. The analysis involved six samples of foam, two from units built in 2018 and four taken from Philips' current production stock in May 2021.[164] Some of the samples from 2021 showed "differing cell structure" which is an "[i]ndication of poor process control."[165] The 2021 foam had "significant contaminants."[166] The foam was supposed to be ether-based,[167] but testing revealed indications that some of the foam was actually ester-based.[168]

177. In addition, MDRs associated with the PE-PUR foam breakdown increased significantly.[169] From 2011 to April 2021 when Philips first notified the FDA of their intention to conduct a field action due to concerns pertaining to foam degradation (breakdown) in certain ventilators, BiPAP machines, and CPAP machines, Philips submitted only 30 MDRs that they

[163] *See* RJ Lee Analysis Review of Trilogy EVO Foam (Lawler Aff. Exh. A) (attached hereto as Exhibit "H"), at (WTB 000003).

[164] *Id.* at WTB 000006.

[165] *Id.* at WTB 000008.

[166] *Id.* at WTB 000009; *see also* WTB 000010 ("Indication of poor process control and/or contamination.").

[167] *Id.* at WTB 000002.

[168] *Id.* at WTB 000013.

[169] As stated above, manufacturers, such as Philips, are required to submit medical device reports (MDRs) when information reasonably suggests that their device may have caused or contributed to a death or serious injury, or has malfunctioned, and that device or a similar device they manufacture would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. Health professionals, consumers, and patients may voluntarily submit reports of device adverse events and malfunctions to the FDA. *See, e.g.*, 21 C.F.R. § 803.20.

identified as associated with the PE-PUR foam breakdown and there were no reports of patient injury or death among those 30 MDRs.[170] Eight of those reports were from the United States.

178. After Philips notified the FDA of its intention to conduct a field action in April 2021 through July 31, 2022, the amount of MDRs the FDA received increased significantly as did the "reports of death, associated with the PE-PUR foam breakdown or suspected foam breakdown."[171] Specifically, the FDA reported:

- From April 2021 through April 30, 2022, the FDA received more than 21,000 MDRs, including 124 reports of death, associated with the PE-PUR foam breakdown or suspected foam breakdown.

- From May 1, 2022, through July 31, 2022, the FDA received more than 48,000 MDRs, including 44 reports of death, associated with the PE-PUR foam breakdown or suspected foam breakdown.

179. The FDA continued: "A wide range of injuries have been reported in these MDRs, including cancer, pneumonia, asthma, other respiratory problems, infection, headache, cough, dyspnea (difficulty breathing), dizziness, nodules, and chest pain."[172]

3. Finally, In June 2021, Philips Recalled Its Defective Devices.

180. Finally, on June 14, 2021, Philips issued a recall notice directed to its customers in the United States, stating:

> To date, Philips has produced millions of Bi-Level PAP, CPAP and mechanical ventilator devices using the PE-PUR sound abatement foam. Despite a low complaint rate (0.03% in 2020), Philips determined based on testing that there are possible risks to users related to this type of foam. The risks include that the PE-

[170] The FDA's latest information about medical device reports (MDRs) associated with the Recalled Devices on August 16, 2022 is available here: https://www.fda.gov/medical-devices/safety-communications/update-certain-philips-respironics-ventilators-bipap-machines-and-cpap-machines-recalled-due?utm_medium=email&utm_source=govdelivery#mdr (last accessed Aug. 17, 2022) ("FDA MDR Update").

[171] *Id*. (stating "The MDRs received included both mandatory reports from Philips and voluntary reports from health professionals, consumers, and patients.").

[172] *Id*.

> 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. The foam degradation may be exacerbated by use of unapproved cleaning methods, such as ozone,** and high heat and high humidity environments may also contribute to foam degradation.
>
> Therefore, Philips has decided to voluntarily issue a recall notification* to inform patients and customers of potential impacts on patient health and clinical use related to this issue, as well as instructions on actions to be taken.[173]

181. Philips stated that "[t]he majority of the affected devices within the advised 5-year service life are in the first-generation DreamStation product family."[174] Philips elaborated:

> Based on the latest analysis of potential health risks and out of an abundance of caution, the recall notification advises patients and customers to take the following actions:
>
> For patients using affected BiLevel PAP and CPAP devices: Discontinue use of your device and work with your physician or Durable Medical Equipment (DME) provider to determine the most appropriate options for continued treatment. To continue use of your device due to lack of alternatives, consult with your physician to determine if the benefit of continuing therapy with your device outweighs the risks identified in the recall notification.
>
> For patients using affected life-sustaining mechanical ventilator devices: Do not stop or alter your prescribed therapy until you have talked to your physician. Philips recognizes that alternate ventilator options for therapy may not exist or may be severely limited for patients who require a ventilator for life-sustaining therapy, or in cases where therapy disruption is unacceptable. In these situations, and at the discretion of the treating clinical team, the benefit of continued usage of these ventilator devices may outweigh the risks identified in the recall notification.
>
> **Possible health risks**
>
> The company continues to monitor reports of potential safety issues as required by medical device regulations and laws in the markets in which it operates. To date, there have been no reports of death as a result of these issues. Philips has received reports of possible patient impact due to foam degradation. The potential risks of particulate exposure include headache, irritation, inflammation, respiratory issues, and possible toxic and carcinogenic effects. The potential risks of chemical exposure due to off-gassing include headache, irritation, hypersensitivity,

[173] Recall Notices (Exhibit "B" hereto).

[174] *Id.*

> nausea/vomiting, and possible toxic and carcinogenic effects. Philips has received no reports regarding patient impact related to chemical emissions.[175]

182. Corroborating the dangerous nature of the Recalled Devices, on July 22, 2021, the FDA upgraded Philips' recall of the Recalled Devices to its most serious classification, Class I, which according to the FDA means: "A situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death."[176]

183. Philips' Recall announcement instructed users to not use the Recalled Devices because of the health risks. This confirmed the true nature of the products, which at all times were adulterated and worthless.

184. Philips took similar action with respect to its defective CPAP, BiPAP, and ventilator devices across the globe.

185. Also, on June 14, 2021, Philips' main competitor, ResMed, issued "[a] message from ResMed's CEO" to the public regarding the Philips Recall. In this notice, ResMed CEO, Mick Farrell, stated that "ResMed devices are safe to use and are not subject to Philips' recall. ResMed devices use a different material than what Philips uses in their recalled machines."[177]

186. ResMed devices and ventilators use polyether polyurethane or silicone-based foam, not PE-PUR foam, for sound abatement purposes.[178]

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[175] *Id.*

[176] https://www.fda.gov/safety/industry-guidance-recalls/recalls-background-and-definitions (last accessed Aug. 15, 2022).

[177] https://www.resmed.com/en-us/healthcare-professional/other-manufacturer-recall-2021/ (last accessed Aug. 15, 2022).

[178] https://www.resmed.com/en-us/other-manufacturer-recall-2021/ (last accessed Aug. 15, 2022).

H. THE MEASURES TAKEN BY PHILIPS TO RECALL THE DEFECTIVE DEVICES WERE INEFFECTIVE.

187. Philips' CEO, Frans van Houten, stated in the Recall announcement: "We deeply regret any concern and inconvenience that patients using the affected devices will experience because of the proactive measures we are announcing today to ensure patient safety."[179]

188. But Philips' "recall" was a recall in name only and did not effectively provide patients with notice of the risks of the Recalled Devices nor did it provide them with new Philips CPAP, BiPAP, or ventilator devices.

1. Many Patients, Providers, And Others Were Not Notified About The Recall.

189. On March 10, 2022, the FDA issued a Notification Order under § 518(a) of the FDCA.[180] The Notification Order stated that the "FDA has received a number of calls from patients and consumers who contacted FDA to report problems and/or concerns regarding the Recalled Products, but were unaware of the recall and had not been informed of the health risks presented by the Recalled Products."[181]

190. The FDA estimated that, after nine months of the Recall, "approximately 50% of patients and consumers who have purchased or received the Recalled Products (excluding ventilators) within the last five years (the service life of the devices) have registered with Philips to obtain a replacement device."[182] But it was "unclear whether the remaining patients and

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[179] https://www.usa.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 (last accessed Aug. 15, 2022).

[180] See 518(a) Notification Order, available at: https://www.fda.gov/media/156811/download (last accessed Aug. 15, 2022).

[181] 518(a) Notification Order at 2.

[182] *Id.*

consumers have not registered because they are unaware of the need to register, or because they do not want or need a replacement device from Philips."[183]

191. The FDA surveyed 182 consignees to determine whether they had been notified of the Recall and found 28 "who had reported to FDA that they were not aware of the recall."[184] The FDA reported its results to Philips on September 8, 2021 and October 29, 2021, and Philips did not respond. On November 22, 2021, Philips stated that it had notified 23 of the 28 consignees of the Recall, but Philips did not "indicate whether the consignees identified by FDA had been sent notification before, or only after, they had been identified by FDA as being unaware of the recall."[185] Moreover, Philips' evidence of notification consisted of delivery confirmation receipts, reflecting that written correspondence was delivered to the consignees. As the FDA explained, "[t]ypically, firms demonstrate the effectiveness of its recall communications through evidence more meaningful than a delivery confirmation receipt, such as a returned response form or a documented telephone conversation."[186]

192. Throughout the Recall, the FDA "on multiple occasions has informed Philips that FDA was concerned that Philips' efforts to notify patients and consumers, healthcare providers, and consignees regarding the recall have been insufficient" and has expressed concern that "it is likely that a significant portion of patients and consumers using the Recalled Products are unaware of the health risks presented by those products."[187]

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[183] *Id.*

[184] *Id.*

[185] *Id.*

[186] *Id.* at 3.

[187] *Id.*

193. Noting "Philips' failure to timely provide effective notice to health professionals who prescribe or use the Recalled Products and other persons (including consignees, distributors, retailers, and device users) who should be notified, of the recall and the health risks presented by the Recalled Products," the FDA issued an order under Section 518(a) of the FDCA ordering Philips to "notify all health professionals who prescribe or use the Recalled Products, and other persons (including consignees, distributors, retailers, and device users) who should be notified, of the recall and the health risks presented by the Recalled Products **within the next 45 days**[.]"[188]

2. Philips' Repair/Replacement Program Has Been Extremely Slow.

194. Those patients who registered their Recalled Devices with Philips for the Recall did not immediately receive replacement devices and were not told when a replacement device would be provided.

195. As Philips' June 14, 2021 announcement explained:

> **Repair and replacement program**
>
> Philips is providing the relevant regulatory agencies with required information related to the launch and implementation of the projected correction. The company will replace the current sound abatement foam with a new material and has already begun the preparations, which include obtaining the relevant regulatory clearances. Philips aims to address all affected devices in scope of this correction as expeditiously as possible.
>
> As part of the program, the first-generation DreamStation product families will be modified with a different sound abatement foam and shipped upon receipt of the required regulatory clearances. Philips' recently launched next-generation CPAP platform, DreamStation 2, is not affected by the issue. To support the program, Philips is increasing the production of its DreamStation 2 CPAP devices, that are available in the US and selected countries in Europe.[189]

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[188] *Id.* at 4 (emphasis in original).

[189] https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/philips-issues-recall-notification-mitigate-potential-health-risks-related-sound-abatement-foam (last accessed Aug. 15, 2022).

196. In reality, patients may register their DreamStation Recalled Device with Philips for the Recall, but Philips has not immediately replaced the defective PE-PUR foam in the DreamStation Recalled Devices. Rather, patients have had to wait, sometimes for many months, for Philips to repair or replace their devices, and many patients are still waiting for a replacement device.

197. As of the date of this Complaint—over a year after the Recall was announced—Philips continues to repair or replace defective DreamStation 1 Recalled Devices. In other words, the Recall remains ongoing.

198. The replacement program for the Trilogy devices has been even slower. Philips has only just begun the rework of affected Trilogy 100/200 devices and Philips projects that the process will take approximately 12-14 months to complete.[190]

199. There is no repair or replacement program for any of the other Recalled Devices recalled by Philips.

200. Due to the design of the Recalled Devices, it is prohibitively difficult for patients to remove or replace the PE-PUR foam themselves. Also, the FDA warns:

> Do **not** try to remove the foam from your device. Trying to or successfully removing the foam may damage the device or change how the device works. It may also lead to more foam or chemicals entering the air tubing of the device.[191]

201. As a result, the Recall leaves patients without safe, free options. Instead, patients may simply be forced to buy Philips' next-generation product or a competitor's product—at full price, and indeed, thousands of patients have already done so.

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[190] https://www.usa.philips.com/healthcare/resource-catalog/landing/experience-catalog/sleep/communications/src-update/news/ventilation-news-and-updates (last accessed Aug. 12, 2022).

[191] https://www.fda.gov/medical-devices/safety-communications/faqs-philips-respironics-ventilator-bipap-machine-and-cpap-machine-recalls (emphasis in original) (last accessed Aug. 15, 2022).

202. Thus, Philips intends to, and is, profiting from its "recall" by selling more of its next generation product, the DreamStation 2, whose launch appears intentionally timed to coincide with the "recall," to affected patients.

203. The FDA also believes that the Recall is not proceeding quickly enough. It recently stated:

> Based on the status of Philips' recall as of the date of this letter [May 2, 2022], CDRH believes that, if an order were to be issued to Philips under section 518(b), the plan submitted by Philips in response to that order should provide for significant improvements to Philips' ongoing repair and replacement activities to speed the pace of remediation and address other deficiencies identified by CDRH and communicated to Philips, to the extent such improvements are achievable by Philips.[192]

V. EQUITABLE TOLLING OF STATUTES OF LIMITATIONS

204. The running of any statute of limitations has been equitably tolled by Philips' fraudulent concealment and/or omissions of critical safety information. Through its affirmative misrepresentations and omissions, Philips actively concealed from Plaintiffs and their physicians the true risks associated with the Recalled Devices.

205. As a result of Philips' actions, Plaintiffs were unaware, and could not have reasonably known or learned through reasonable diligence, that they had been exposed to the risks and harms set forth herein and that those risks and harms were the direct and proximate result of Philips' acts and omissions.

206. Plaintiffs did not have the technical, scientific or medical knowledge and information sufficient to ascertain the cause of their injury prior to learning of the recall and the basis for the recall.

[192] 518(b) Notice at 13.

VI. CAUSES OF ACTION

COUNT I
NEGLIGENCE

207. Plaintiffs re-allege and incorporate by reference the allegations set forth throughout the Complaint as if set forth herein and further allege as follows:

208. Philips and PolyTech owed a duty to Plaintiffs to use and exercise reasonable and due care in the design, materials procurement, manufacturing, testing, distribution, labeling, marketing, warnings, instructions for use and storage, disclosures, regulatory compliance, and sale of the Recalled Devices.

209. Philips and PolyTech owed a duty to Plaintiffs to ensure that the Recalled Devices it sold in the United States were safe, did not expose patients using the devices to toxic substances, and/or complied with current best manufacturing practices and regulatory requirements.

210. Philips and PolyTech owed a duty of care to Plaintiffs; because they were the foreseeable, reasonable, and probable users of the Recalled Devices. Philips and PolyTech knew, or should have known, that the Recalled Devices were not safe, exposed their users to toxic and carcinogenic compounds, and/or did not comply with best manufacturing practices and regulatory requirements. Philips and PolyTech were in the best position to uncover and remedy these shortcomings.

211. Philips and PolyTech negligently designed and manufactured the Recalled Devices, causing patients using the Recalled Devices to be exposed to the Foam Toxins and degraded particulate matter which are harmful, carcinogenic and/or toxic.

212. Philips and PolyTech failed to discharge their duties of reasonable care. Philips and PolyTech inadequately conducted or oversaw the design, materials procurement, manufacturing, testing, labeling, distribution, marketing, warnings, disclosures, instructions for use and storage,

regulatory compliance and sale of the Recalled Devices. Philips and PolyTech knew or should have known that the aforesaid wrongdoing would damage Plaintiffs.

213. Philips and PolyTech negligently failed to promptly and immediately warn and disclose to Plaintiffs, and the medical and regulatory communities, of the potential and actual danger posed by the PE-PUR foam in the Recalled Devices as soon as it was discovered, delaying notice of this harmful and potentially fatal toxic exposure to carcinogens and thus causing continued exposure to the carcinogenic and/or hazardous compounds, and delaying cessation of use, necessary medical testing, examinations, surveillance, and treatment.

214. Philips and PolyTech failed to discharge their duties of reasonable care. Philips and PolyTech failed to warn or instruct that the Recalled Devices should not be stored in warm climates and conditions; and that warm temperatures and humidity would hasten the degradation of the foam, and make the Recalled Devices especially dangerous; and further failed to warn or instruct that the Recalled Devices should not be used in conjunction with the SoClean ozone cleaning system which Philips now claims can hasten or cause the degradation of the foam and make the Recalled Devices especially dangerous.

215. Philips' and PolyTech's negligent or grossly negligent conduct created and then exacerbated an unreasonable and dangerous condition for Plaintiffs.

216. Philips and PolyTech acted with recklessness and willful and wanton disregard for the health of Plaintiffs.

217. Philips' and PolyTech's unreasonable, negligent actions and inactions were taken or not taken with willful and wanton disregard for the health of Plaintiffs and created a foreseeable risk of harm to Plaintiffs.

218. As a direct and proximate result of Philips' and PolyTech's negligence, Plaintiffs have suffered serious and debilitating injuries.

219. In addition, as a direct and proximate cause of Philips' and PolyTech's negligence, Plaintiffs may suffer additional serious and debilitating illnesses or injuries, including various cancers, in the future as a result of exposure to the Foam Toxins.

220. Plaintiffs demand judgment against Philips and PolyTech and request compensatory damages, punitive damages, medical monitoring, interest, costs of suit, attorneys' fees, and such other relief as the Court deems equitable and just.

COUNT II
STRICT LIABILITY: DESIGN DEFECT

221. Plaintiffs re-allege and incorporate by reference the allegations set forth throughout the Complaint as if set forth herein and further allege as follows:

222. At all times mentioned herein, Philips and PolyTech were involved in researching, designing, developing, manufacturing, testing, selling and/or distributing the Recalled Devices, which were defective and unreasonably dangerous.

223. Plaintiffs were foreseeable users of the Recalled Devices and Philips and PolyTech knew that Plaintiffs would use the Recalled Devices.

224. The Recalled Devices are defective in design because the PE-PUR foam comprising part of the devices is subject to degradation and off-gassing and the PE-PUR foam contains toxic and carcinogenic materials. The Recalled Devices release particles and off-gas chemicals, including TDA, TDI, DEG. These chemicals and particles are then inhaled and ingested by Plaintiffs using the Recalled Devices and cause, among other problems, cancer, COPD, kidney injuries, cardiac injuries, pulmonary injuries, liver damage, inflammation, respiratory issues, asthma, adverse effects to organs, and toxic and carcinogenic effects.

225. Philips and PolyTech knew or should have known that the defective conditions of the Recalled Devices made the Recalled Devices unreasonably dangerous to Plaintiffs.

226. The Recalled Devices were unreasonably dangerous when used by ordinary users, such as Plaintiffs, who used the Recalled Devices as they were intended to be used.

227. The Recalled Devices are dangerous to an extent beyond what would be contemplated by the ordinary user of the Recalled Devices.

228. The defective condition of the subject Recalled Devices rendered them unreasonably dangerous and/or not reasonably safe, and the devices were in this defective condition at the time they left the hands of Philips and PolyTech. The Recalled Devices reached Plaintiffs without substantial change in the condition in which they were designed, manufactured, labeled, sold, distributed, marketed, promoted, supplied, and otherwise released into the stream of commerce.

229. Plaintiffs were not able to discover, nor could they have discovered through the exercise of reasonable diligence, the defective nature of the subject devices. Further, in no way could Plaintiffs have known that Philips had designed, developed, and manufactured the subject devices in a way as to make the risk of harm or injury outweigh any benefits.

230. Safer alternative machines and designs were available which did not have an unreasonable risk of harm that the Recalled Devices and their unsafe PE-PUR foam did; for example, devices that included non-PE-PUR foam and designs that included other types of sound abatement technologies.

231. At the time the Recalled Devices left Philips' and PolyTech's possession and continuing through when they were used by Plaintiffs, the Recalled Devices were in a condition that made them unreasonably dangerous to Plaintiffs.

232. The Recalled Devices used by Plaintiffs were expected to, and did, reach Plaintiffs without substantial change in the condition in which the Recalled Devices were manufactured, sold, distributed, and marketed by Philips and PolyTech.

233. At all relevant times, Plaintiffs used the Recalled Devices in the manner in which the devices were intended to be used.

234. Philips and PolyTech researched, designed, manufactured, tested, advertised, promoted, marketed, sold, and distributed the defective Recalled Devices which, when used in their intended or reasonably foreseeable manner, created an unreasonable risk to the health of consumers, such as Plaintiffs, and Philips is therefore strictly liable for the injuries sustained by Plaintiffs.

235. As a direct and proximate cause of Philips' and PolyTech's conduct, Plaintiffs have suffered serious and debilitating injuries.

236. In addition, as a direct and proximate cause of Philips' and PolyTech's conduct, Plaintiffs may suffer additional serious and debilitating illnesses or injuries, including various cancers, in the future as a result of exposure to the Foam Toxins.

237. Plaintiffs demand judgment against Philips and PolyTech and request compensatory damages, punitive damages, interest, costs of suit, attorneys' fees, and such other relief as the Court deems equitable and just.

238. Plaintiffs demand judgment against Philips and PolyTech and request compensatory damages, punitive damages, medical monitoring, interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT III
NEGLIGENT DESIGN

239. Plaintiffs re-allege and incorporate by reference the allegations set forth throughout the Complaint as if set forth herein and further allege as follows:

240. At all times mentioned herein, Philips and PolyTech were involved in researching, designing, developing, manufacturing, testing, selling and/or distributing the Recalled Devices.

241. At all times relevant to this action, Philips and PolyTech had a duty to design, manufacture, formulate, test, package, label, produce, create, make, construct, assemble, market, advertise, promote, distribute, and sell the Recalled Devices with reasonable and due care for the safety and well-being of users, including Plaintiffs who used the Recalled Devices.

242. Plaintiffs were foreseeable users of the Recalled Devices, and Philips and PolyTech knew that Plaintiffs would use the Recalled Devices.

243. It was foreseeable that the Recalled Devices would be used with the Accessory Humidifiers contributing to humidity; and that they could be used in many climates, and stored in very warm settings, as noted by their own environmental specifications, with said condition contributing to rapid foam degradation.

244. The Recalled Devices are defective in design because the PE-PUR foam comprising part of the devices is subject to degradation and off-gassing and the PE-PUR foam contains toxic and carcinogenic materials. The Recalled Devices release chemicals and particles, including but not limited to TDA, TDI, and DEG. These chemicals and particles are then inhaled and ingested by Plaintiffs using the Recalled Devices and cause, among other problems, cancer, COPD, kidney injuries, cardiac injuries, pulmonary injuries, liver damage, inflammation, respiratory issues, asthma, adverse effects to organs, and toxic and carcinogenic effects.

245. The foreseeable risks of using the Recalled Devices, particularly respiratory illnesses up to and including death, significantly outweigh the benefits conferred upon patients using the subject devices.

246. Philips and PolyTech knew or should have known that the defects of the Recalled Devices made the Recalled Devices unreasonably dangerous.

247. Philips and PolyTech continued to manufacture and distribute the Recalled Devices after Philips and PolyTech knew or should have known of the Recalled Devices adverse effects or the availability of safer designs.

248. The Recalled Devices were unreasonably dangerous when used by Plaintiffs, who followed the instructions provided by Philips and used the Recalled Devices with common knowledge of their characteristics and according to their common usage.

249. At the time the Recalled Devices left Philips' and PolyTech's possession and continuing through when they were used by Plaintiffs, the Recalled Devices were in a condition that made them unreasonably dangerous to Plaintiffs.

250. The Recalled Devices used by Plaintiffs were expected to and did reach Plaintiffs without substantial change in the condition in which the Recalled Devices were manufactured, sold, distributed, and marketed by Philips and PolyTech.

251. At all relevant times, Plaintiffs used the Recalled Devices in the manner in which the Recalled Devices were intended to be used.

252. Philips and PolyTech had superior knowledge of the Recalled Devices and owed a duty of care to Plaintiffs.

253. Reasonable alternative designs existed for the Recalled Devices which would have eliminated or reduced the risk of inhalation of carcinogenic materials and VOCs including, but not

limited to the use of non-PE-PUR foam or other sound abatement technologies such as those used by other manufacturers.

254. Philips and PolyTech failed to exercise reasonable and due care under the circumstances and breached their duty of care.

255. As a direct and proximate cause of Philips' and PolyTech's negligence, Plaintiffs have suffered serious and debilitating injuries.

256. In addition, as a direct and proximate cause of Philips' and PolyTech's negligence, Plaintiffs may suffer additional serious and debilitating illnesses or injuries, including various cancers, in the future as a result of exposure to the Foam Toxins.

257. Plaintiffs demand judgment against Philips and PolyTech and request compensatory damages, punitive damages, medical monitoring, interest, costs of suit, attorneys' fees, and such other relief as the Court deems equitable and just.

COUNT IV
STRICT LIABILITY – FAILURE TO WARN

258. Plaintiffs re-allege and incorporate by reference the allegations set forth throughout the Complaint as if set forth herein and further allege as follows:

259. At all times mentioned herein, Philips and PolyTech designed, manufactured, and sold the Recalled Devices.

260. Plaintiffs were foreseeable users of the Recalled Devices.

261. The Recalled Devices are defective because the PE-PUR foam comprising part of the devices is subject to degradation and off-gassing and the PE-PUR foam contains toxic and carcinogenic materials. The Recalled Devices release chemicals and particles, including but not limited to TDA, TDI, DEG. These chemicals and particles are then inhaled and ingested by Plaintiffs using the Recalled Devices and cause, among other problems, cancer, COPD, kidney

injuries, cardiac injuries, pulmonary injuries, liver damage, inflammation, respiratory issues, asthma, adverse effects to organs, and toxic and carcinogenic effects.

262. Philips and PolyTech knew that the defective condition of the Recalled Devices made the devices unreasonably dangerous to users such as Plaintiffs.

263. The Recalled Devices were dangerous when used by ordinary users, such as Plaintiffs, who used the devices as they were intended to be used.

264. The Recalled Devices are dangerous to an extent beyond what would be contemplated by the ordinary user of the device.

265. Philips and PolyTech knew or should have known of the defects in the Recalled Devices at the time Philips and PolyTech sold or provided the Recalled Devices that were used by Plaintiffs.

266. At the time the Recalled Devices left Philips' and PolyTech's possession, the Recalled Devices were defective and in a condition that made them unreasonably dangerous to Plaintiffs.

267. At the time Plaintiffs used the Recalled Devices, the devices were defective and in a condition that made them unreasonably dangerous to Plaintiffs.

268. The Recalled Devices used by Plaintiffs were expected to, and did, reach Plaintiffs without substantial change in the condition in which the devices were manufactured, sold, distributed, and marketed by Philips and PolyTech.

269. At all relevant times, Plaintiffs used the Recalled Devices in the manner in which the devices were intended to be used.

270. The Recalled Devices are defective because Philips and PolyTech failed to warn or instruct that the PE-PUR foam in the Recalled Devices can degrade and off-gas dangerous and carcinogenic chemicals and particles, posing a serious risk to users.

271. Philips and PolyTech further failed to warn or instruct that the Recalled Devices had been adequately or properly tested.

272. The warning and instructions that accompanied the Recalled Devices failed to provide the level of information that ordinary consumers, including Plaintiffs, would expect when using the product in a manner reasonably foreseeable to Philips and PolyTech.

273. Philips and PolyTech further failed to warn or instruct that the Recalled Devices, when used in conjunction with the Accessory Humidifiers, would hasten the degradation of the foam and make the Recalled Devices especially dangerous.

274. Philips and PolyTech further failed to warn or instruct that the Recalled Devices should not be stored in warm climates and conditions, and that warm temperatures and humidity would hasten the degradation of the foam, and make the Recalled Devices especially dangerous.

275. Philips and PolyTech further failed to warn or instruct that the Recalled Devices should not be used in conjunction with the SoClean ozone cleaning system which Philips now claims can hasten or cause the degradation of the foam and make the Recalled Devices especially dangerous.

276. Had Plaintiffs received proper or adequate warnings or instructions as to the risks of using the Recalled Devices, Plaintiffs would not have used the Recalled Devices.

277. Had Plaintiffs received proper or adequate warnings or instructions as to the storage, climate and cleaning conditions and protocols, they would have heeded such warnings to mitigate the risk of premature foam degradation.

278. Philips and PolyTech researched, designed, manufactured, tested, advertised, promoted, marketed, sold, and distributed the defective Recalled Devices which, when used in their intended or reasonably foreseeable manner, created an unreasonable risk to the health of consumers, such as Plaintiffs, and Philips and PolyTech are therefore strictly liable for the injuries sustained by Plaintiffs.

279. As a direct and proximate cause of Philips' and PolyTech's conduct, Plaintiffs have suffered serious and debilitating injuries.

280. In addition, as a direct and proximate cause of Philips' and PolyTech's conduct, Plaintiffs may suffer additional serious and debilitating illnesses or injuries, including various cancers, in the future as a result of exposure to the Foam Toxins.

281. Plaintiffs demand judgment against Philips and PolyTech and request compensatory damages, punitive damages, medical monitoring, interest, costs of suit, attorneys' fees, and such other relief as the Court deems equitable and just.

COUNT V
NEGLIGENT FAILURE TO WARN

282. Plaintiffs re-allege and incorporate by reference the allegations set forth throughout the Complaint as if set forth herein and further allege as follows:

283. At all times mentioned herein, Philips and PolyTech designed, manufactured, and sold the Recalled Devices.

284. At all times relevant to this action, Philips and PolyTech had a duty to manufacture, design, formulate, test, package, label, produce, create, make, construct, assemble, market, advertise, promote, distribute, and sell the Recalled Devices with reasonable and due care for the safety and well-being of Plaintiffs, who were subject to and used the devices.

285. In addition, Philips and PolyTech owed a duty of care to Plaintiffs because, among other things, it had superior knowledge with respect to the Recalled Devices including, but not limited to critical safety issues associated with foam degradation, off-gassing, and related health risks.

286. Plaintiffs were foreseeable users of the Recalled Devices.

287. The Recalled Devices are defective because the PE-PUR foam comprising part of the devices is subject to degradation and off-gassing and the PE-PUR foam contains toxic and carcinogenic materials. The Recalled Devices release chemicals and particles, including but not limited to TDA, TDI, DEG. These chemicals and particles are then inhaled and ingested by Plaintiffs using the Recalled Devices and cause, among other problems, cancer, COPD, kidney injuries, cardiac injuries, pulmonary injuries, liver damage, , inflammation, respiratory issues, asthma, adverse effects to organs, and toxic and carcinogenic effects.

288. The foreseeable risks of using the Recalled Devices significantly outweigh the benefits conferred upon patients using the Recalled Devices.

289. Philips and PolyTech knew that the defective condition of the Recalled Devices made the devices unreasonably dangerous to users such as Plaintiffs.

290. The Recalled Devices were unreasonably dangerous when used by ordinary users, such as Plaintiffs, who used the devices as they were intended to be used.

291. The Recalled Devices are dangerous to an extent beyond what would be contemplated by the ordinary user of the device.

292. Philips and PolyTech knew or should have known of the defects in the Recalled Devices at the time Philips sold or provided the Recalled Devices that were used by Plaintiffs.

293. At the time the Recalled Devices left Philips' and PolyTech's possession and continuing through when they were used by Plaintiffs, the Recalled Devices were defective and in a condition that made them unreasonably dangerous to Plaintiffs.

294. The Recalled Devices used by Plaintiffs were expected to, and did, reach Plaintiffs without substantial change in the condition in which the devices were manufactured, sold, distributed, and marketed by Philips and PolyTech.

295. At all relevant times, Plaintiffs used the Recalled Devices in the manner in which the devices were intended to be used.

296. Philips and PolyTech breached their duty to Plaintiffs by failing to warn of the risks and dangers of using the Recalled Devices as they are intended to be used. The Recalled Devices did not contain warnings of the risks of the PE-PUR foam and the risks of degradation, off-gassing, and related health risks.

297. Philips and PolyTech further breached their duty to Plaintiffs because it failed to warn or instruct that the Recalled Devices had not been adequately or properly tested.

298. Philips and PolyTech further failed to warn or instruct that the Recalled Devices, when used in conjunction with the Accessory Humidifiers would hasten the degradation of the foam and make the Recalled Devices especially dangerous.

299. Philips and PolyTech further failed to warn or instruct that the Recalled Devices should not be stored in warm climates and conditions; and that warm temperatures and humidity would hasten the degradation of the foam, and make the Recalled Devices especially dangerous.

300. Philips and PolyTech further failed to warn or instruct that the Recalled Devices should not be used in conjunction with the SoClean ozone cleaning system which Philips now

claims can hasten or cause the degradation of the foam and make the Recalled Devices especially dangerous.

301. The warnings and instructions of the Recalled Devices did not provide the amount of information that ordinary consumers, including Plaintiffs, would expect when using the devices in a reasonably foreseeable manner.

302. Had Plaintiffs received proper or adequate warnings or instructions as to the risks of using the Recalled Devices, Plaintiffs would not have used the Recalled Devices.

303. Had Plaintiffs received proper or adequate warnings or instructions as to the storage, climate and cleaning conditions and protocol, they would have heeded such warnings to mitigate the risk of premature foam degradation.

304. As a direct and proximate cause of Philips' and PolyTech's conduct, Plaintiffs have suffered serious and debilitating injuries.

305. In addition, as a direct and proximate cause of Philips' and PolyTech's conduct, Plaintiffs may suffer additional serious and debilitating illnesses or injuries, including various cancers, in the future as a result of exposure to the Foam Toxins.

306. Plaintiffs demand judgment against Philips and PolyTech and request compensatory damages, punitive damages, medical monitoring, interest, costs of suit, attorneys' fees, and such other relief as the Court deems equitable and just.

COUNT VI
NEGLIGENT RECALL

307. Plaintiffs re-allege and incorporate by reference the allegations set forth throughout the Complaint as if set forth herein and further allege as follows:

308. In issuing a voluntary recall, Philips assumed duties to exercise reasonable care in issuing and implementing the Recall.

309. Philips breached its duties by failing to adequately warn, notify, and promptly replace the Recalled Devices.

310. As a direct result of Philips' breach of duty, Plaintiffs have suffered harm in an amount to be determined at trial.

311. In addition, as a direct and proximate cause of Philips' breach of duty, Plaintiffs may suffer additional serious and debilitating illnesses or injuries, including various cancers, in the future as a result of continued exposure to the Foam Toxins.

312. Plaintiffs demand judgment against Philips and request compensatory damages, punitive damages, medical monitoring, interest, costs of suit, attorneys' fees, and such other relief as the Court deems equitable and just.

COUNT VII
BATTERY

313. Plaintiffs re-allege and incorporate by reference the allegations set forth throughout the Complaint as if set forth herein and further allege as follows:

314. Philips engaged in acts that resulted in harmful and offensive contact with Plaintiffs.

315. Plaintiffs each used a Recalled Device and unknowingly had unwanted and dangerous particles and gases blown into their bodies, including into their respiratory systems.

316. Philips designed, manufactured, marketed, and sold the Recalled Devices with the defects discussed herein including foam degradation and resulting off-gassing. Thus, Philips did acts that caused the harmful and offensive touching of Plaintiffs to occur.

317. The acts engaged in by Philips that caused the unwanted and dangerous particles and gases to touch and enter Plaintiffs' bodies were all done intentionally, and with full knowledge that they would result in harmful and offensive contact.

318. The touching was harmful and offensive to Plaintiffs because they are dangerous and can cause serious health problems. Any reasonable person in Plaintiffs' situation would have been offended by the touching under the circumstances.

319. Plaintiffs did not consent to the touching. Any ostensible "consent" provided was not done knowingly and was otherwise vitiated under the circumstances and not effective.

320. Plaintiffs agreed to use the Recalled Devices and have air circulated through their respiratory systems, but, as alleged herein, they each did so without knowledge of the dangerous particles and gases caused by the Defect in the Recalled Devices.

321. As alleged herein, Philips knew about the Defect and that it was substantially certain to result in the harmful touching of Plaintiffs. Despite this knowledge, Philips did not disclose the Defect to Plaintiffs, their doctors, the FDA, or others.

322. As alleged herein, while Philips knew of the Defect for many years, Philips failed to disclose and concealed it from Plaintiffs and the public. Philips thus knew the offensive touching would occur and that Plaintiffs were under the mistaken impression that the products were safe and that no such offensive touching would occur.

323. Philips willfully, knowingly and tortiously battered Plaintiffs.

324. Plaintiffs were harmed and injured by this harmful and offensive touching.

325. As a foreseeable, proximate, and direct result of Philips' conduct, Plaintiffs each have suffered a battery and have been damaged, including as otherwise set forth in this Complaint and the individual Short Form Complaints, and by invasion of their privacy and bodily integrity without their consent, severe emotional stress and anxiety, and harm to their human dignity and corresponding damages therefrom.

326. Plaintiffs demand judgment against Philips and request compensatory damages, punitive damages, medical monitoring, interest, costs of suit, attorneys' fees, and such other relief as the Court deems equitable and just.

COUNT VIII
STRICT LIABILITY - MANUFACTURING DEFECT

327. Plaintiffs re-allege and incorporate by reference the allegations set forth throughout the Complaint as if set forth herein and further allege as follows:

328. At all times mentioned herein, Philips and PolyTech were involved in researching, designing, developing, manufacturing, testing, selling and/or distributing the Recalled Devices, which were unreasonably dangerous, unsafe and defective in their manufacturing when they left Philips' and PolyTech's possession.

329. The Recalled Devices were expected to, and did, reach the Plaintiffs without substantial change or adjustment to their mechanical function and condition in which they were sold.

330. Plaintiffs used the Recalled Devices as directed and for the purpose for which they were intended.

331. The Recalled Devices are inherently dangerous for their intended used due to manufacturing defects. Philips and PolyTech therefore are strictly liable.

332. Philips failed to ensure that a subset of the purchased, or otherwise received, Recalled Devices and services conformed to specified requirements.

333. Specifically, Philips used defective, incorrect and non-specified PE-PUR, raw foam product, not intended for use in Recalled Devices, to manufacture some of the Recalled Devices including certain recalled Trilogy Evo ventilators.

334. This incorrect and non-specified PE-PUR foam was sourced from Philips' raw foam supplier, used in the muffler assembly of the affected Recalled Devices, including Trilogy Evo ventilators, and resulted in non-conforming Recalled Devices being approved, released and distributed by Philips to Plaintiffs.

335. Per design specifications, this foam was required to be polyether based, not polyester based foam.

336. Upon information and belief, the Recalled Devices contain a manufacturing defect that differed from other typical units of the same product line.

337. Philips sold the Recalled Devices in this defective condition.

338. Philips failed to conduct proper and regular quality control sampling and testing.

339. The Recalled Devices, as manufactured, were unsafe and unreasonably dangerous to Plaintiffs.

340. The Recalled Devices did not perform as safely as an ordinary consumer would expect.

341. Philips and PolyTech knew or should have known of the manufacturing defects and the risks of serious bodily injury exceeded the benefits associated with the Recalled Devices.

342. Furthermore, the Recalled Devices and their defects presented an unreasonably dangerous risk beyond what the ordinary consumer would reasonably expect.

343. As a direct and proximate cause of Philips' and PolyTech's manufacturing defect, Plaintiffs suffered injuries and damages.

344. In addition, as a direct and proximate cause of Philips' and PolyTech's manufacturing defect, Plaintiffs may suffer additional serious and debilitating illnesses or injuries, including various cancers, in the future as a result of their exposure to the Foam Toxins.

345. Plaintiffs demand judgment against Philips and PolyTech and request compensatory damages, punitive damages, medical monitoring, interest, costs of suit, attorneys' fees, and such other relief as the Court deems equitable and just.

COUNT IX
NEGLIGENT MANUFACTURING

346. Plaintiffs re-allege and incorporate by reference the allegations set forth throughout the Complaint as if set forth herein and further allege as follows:

347. At all times mentioned herein, Philips and PolyTech were involved in researching, designing, developing, manufacturing, testing, selling and/or distributing the Recalled Devices.

348. At all times relevant to this action, Philips and PolyTech had a duty to design, manufacture, formulate, test, package, label, produce, create, make, construct, assemble, market, advertise, promote, distribute, and sell the Recalled Devices with reasonable and due care for the safety and well-being of users, including Plaintiffs who used the Recalled Devices.

349. The Recalled Devices were expected to, and did, reach the Plaintiffs without substantial change or adjustment to their mechanical function and condition in which they were sold.

350. Plaintiffs were foreseeable users of the Recalled Devices, and Philips and PolyTech knew that Plaintiffs would use the Recalled Devices.

351. It was foreseeable that the Recalled Devices would be used with the Accessory Humidifiers contributing to humidity; and that they could be used in many climates, and stored in very warm settings, as noted by their own environmental specifications, with said condition contributing to rapid foam degradation.

352. The Recalled Devices are defective in manufacture because the PE-PUR foam comprising part of the devices is subject to degradation and off-gassing and the PE-PUR foam

contains toxic and carcinogenic materials. The Recalled Devices release chemicals and particles, including but not limited to TDA, TDI, and DEG. These chemicals and particles are then inhaled and ingested by Plaintiffs using the Recalled Devices and cause, among other problems, cancer, kidney injuries, cardiac injuries, headaches, inflammation, respiratory issues, asthma, adverse effects to organs, and toxic and carcinogenic effects.

353. The foreseeable risks of using the Recalled Devices, particularly respiratory illnesses up to and including death, significantly outweigh the benefits conferred upon patients using the subject devices.

354. The Recalled Devices, as manufactured, were unsafe and unreasonably dangerous to Plaintiffs.

355. The Recalled Devices did not perform as safely as an ordinary consumer would expect.

356. At all relevant times, Plaintiffs used the Recalled Devices in the manner in which the Recalled Devices were intended to be used.

357. Philips and PolyTech had superior knowledge of the Recalled Devices and owed a duty of care to Plaintiffs.

358. Philips and PolyTech knew or should have known that the manufacturing defects and the attendant risks of serious bodily injury exceeded the benefits associated with the Recalled Devices.

359. Philips and PolyTech failed to exercise reasonable and due care under the circumstances and breached their duty of care.

360. As a direct and proximate cause of Philips' and PolyTech's negligent manufacture, Plaintiffs have suffered serious and debilitating injuries.

361. In addition, as a direct and proximate cause of Philips' and PolyTech's negligent manufacture, Plaintiffs may suffer additional serious and debilitating illnesses or injuries, including various cancers, in the future as a result of exposure to the Foam Toxins.

362. Plaintiffs demand judgment against Philips and PolyTech and request compensatory damages, punitive damages, medical monitoring, interest, costs of suit, attorneys' fees, and such other relief as the Court deems equitable and just.

COUNT X
BREACH OF EXPRESS WARRANTY

363. Plaintiffs re-allege and incorporate by reference the allegations set forth throughout the Complaint as if set forth herein and further allege as follows:

364. Philips warranted that all of the Recalled Devices "shall be free from defects of workmanship and materials and will perform in accordance with the product specifications for a period of two (2) years from the date of sale."[193]

365. Philips breached this express warranty in connection with the sale and distribution of the Recalled Devices. At the point of sale, the Recalled Devices, while appearing normal, contained latent defects as set forth herein, rendering them unsuitable and unsafe for personal use.

366. Further, through Philips' public statements, descriptions, and promises relating to the Recalled Devices, Philips expressly warranted that the products were safe and effective for their intended use.

367. Had Plaintiffs known the Recalled Devices were unsafe for use, they would not have purchased or leased the Recalled Devices nor would they have used them.

[193] *See, e.g.,* Warranty Exemplars: Dreamstation (Exhibit "C-1" hereto), at 29; REMstar SE (Exhibit "C-2" hereto), at 21; Trilogy 100 (Exhibit "C-3" hereto), at 163.

368. Philips has breached its warranty and refused to provide appropriate warranty relief notwithstanding the risks of using the Recalled Devices. Plaintiffs reasonably expected, at the time of use, that the Recalled Devices were safe for their ordinary and intended use.

369. To the extent privity may be required, Plaintiffs can establish privity with Philips or alternatively, Plaintiffs can establish that they fall into an exception to a privity requirement. Plaintiffs relied on Philips' warranties and dealt directly with Philips through the exchange of warranty and recall information.

370. Alternatively, Plaintiffs were foreseeable third-party beneficiaries of Philips' sale of the Recalled Devices.

371. Plaintiffs are not required to give notice to Philips, a remote manufacturer, and Philips has had notice of the type and source of claims in this matter for nearly a year.

372. As a direct and proximate result of Philips' breach of its express warranties, Plaintiffs have suffered serious and debilitating injuries.

373. In addition, as a direct and proximate cause of Philips' breach of its express warranties, Plaintiffs may suffer additional serious and debilitating illnesses or injuries, including various cancers, in the future as a result of exposure to the Foam Toxins.

374. Plaintiffs demand judgment against Philips and request compensatory damages, punitive damages, medical monitoring, interest, costs of suit, attorneys' fees, and such other relief as the Court deems equitable and just.

COUNT XI
BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY

375. Plaintiffs re-allege and incorporate by reference the allegations set forth throughout the Complaint as if set forth herein and further allege as follows:

376. By operation of law, Philips, as the manufacturer of the Recalled Devices and as the provider of a limited warranty for the Recalled Devices, impliedly warranted to Plaintiffs that the Recalled Devices were of merchantable quality and safe for their ordinary and intended use.

377. Such implied warranty of merchantability, contained in U.C.C. § 2-314, has been codified in each state. *See, e.g.*, Ala. Code §§ 7-2-314, *et seq*.; Alaska Stat. §§ 45.02.314, *et seq.*; Ariz. Rev. Stat. Ann. §§ 47-2314, *et seq.*; Ark. Code Ann. §§ 4-2-314, *et seq*.; Cal. Com. Code §§ 2314, *et seq*.; Colo. Rev. Stat. §§ 4-2-314, *et seq*.; Conn. Gen. Stat. Ann. §§ 42a-2-314, *et seq*.; Del. Code Ann. tit. 6, §§ 2-314, *et seq*.; D.C. Code Ann. §§ 28:2-314, *et seq*.; Fla. Stat. Ann. §§ 672.314, *et seq*.; O.C.G.A. §§ 11-2-314, *et seq*.; Haw. Rev. Stat. §§ 490:2-314, *et seq*.; Idaho Code §§ 28-2-314, *et seq*.; Ill. Comp. Stat. Ann. Ch. 810, 5/2-314, *et seq*.; Ind. Code Ann. §§ 26-1-2-314, *et seq*.; Iowa Code Ann. §§ 554.2314, *et seq*.; Kan. Stat. Ann. §§ 84-2-314, *et seq*.; Ky. Rev. Stat. Ann. §§ 355.2-314, *et seq*.; La. Civ. Code Ann. art. 2520, *et seq.*; Me. Rev. Stat. Ann. tit. 11, §§ 2-314, *et seq*.; Md. Code Ann., Com. Law §§ 2-314, *et seq*.; Mass. Gen. Laws Ann. Ch. 106, §§ 2-314, *et seq*.; Mich. Comp. Laws Ann. §§ 440.2314, *et seq*.; Minn. Stat. Ann. §§ 336.2-314, *et seq*.; Miss. Code Ann. §§ 75-2-314, *et seq*.; Mo. Rev. Stat. §§ 400.2-314, *et seq*.; Mont. Code Ann. §§ 30-2-314, *et seq*.; Neb. Rev. Stat. §§ 2-314, *et seq*.; Nev. Rev. Stat. §§ 104.2314, *et seq*.; N.H. Rev. Stat. Ann. §§ 382-A:2-314, *et seq*.; N.J. Stat. Ann. §§ 12A:2-314, *et seq*.; N.M. Stat. Ann. § 55-2-314, *et seq.*; N.Y. U.C.C. Law §§ 2-314, *et seq*.; N.C. Gen. Stat. Ann. §§ 25-2-314, *et seq*.; N.D. Cent. Code §§ 41-02-314, *et seq*.; Ohio Rev. Code Ann. §§ 1302.27, *et seq*.; Okla. Stat. tit. 12A, §§ 2-314, *et seq*.; Or. Rev. Stat. §§ 72.3140, *et seq*.; 13 Pa. Stat. Ann. §§ 2314, *et seq*.; R.I. Gen. Laws §§ 6A-2-314, *et seq*.; S.C. Code Ann. §§ 36-2-314, *et seq*.; S.D. Codified Laws §§ 57A-2-314, *et seq*.; Tenn. Code Ann. §§ 47-2-314, *et seq*.; Tex. Bus. & Com. Code §§ 2.314, *et seq*.; Utah Code Ann. §§ 70A-2-314, *et seq*.; Va. Code Ann. §§ 8.2-314, *et seq*.; Vt. Stat.

Ann. tit. 9A, §§ 2-314, *et seq*.; Wash. Rev. Code §§ 62A.2-314, *et seq*.; W. Va. Code §§ 46-2-314, *et seq*.; Wis. Stat. Ann. §§ 402.314, *et seq*.; and Wyo. Stat. Ann. §§ 34.1-2-314, *et seq*.

378. Philips breached the implied warranty of merchantability in connection with the sale and distribution of the Recalled Devices. At the point of sale, the Recalled Devices, while appearing normal, contained latent defects as set forth herein rendering them unsuitable and unsafe for personal use.

379. Had Plaintiffs known the Recalled Devices were unsafe for use, they would not have purchased or leased the Recalled Devices nor would they have used them.

380. To the extent privity may be required, Plaintiffs can establish privity with Philips or alternatively, Plaintiffs can establish that they fall into an exception to a privity requirement. Plaintiffs relied on Philips' warranties and dealt directly with Philips through the exchange of warranty and recall information.

381. Alternatively, Plaintiffs were foreseeable third-party beneficiaries of Philips' sale of the Recalled Devices.

382. Plaintiffs are not required to give notice to Philips, a remote manufacturer, and Philips has had notice of the type and source of claims in this matter for nearly a year.

383. As a direct and proximate cause of Philips' conduct, Plaintiffs have suffered serious and debilitating injuries.

384. In addition, as a direct and proximate cause of Philips' conduct, Plaintiffs may suffer additional serious and debilitating illnesses or injuries, including various cancers, in the future as a result of exposure to the Foam Toxins.

385. Plaintiffs demand judgment against Philips and request compensatory damages, punitive damages, medical monitoring, interest, costs of suit, attorneys' fees, and such other relief as the Court deems equitable and just.

COUNT XII
BREACH OF THE IMPLIED WARRANTY OF USABILITY

386. Plaintiffs re-allege and incorporate by reference the allegations set forth throughout the Complaint as if set forth herein and further allege as follows:

387. By operation of law, Philips, as the manufacturer of the Recalled Devices and as the providers of a limited warranty for the Recalled Devices, impliedly warranted to Plaintiffs that the Recalled Devices were usable for their ordinary and intended use.

388. Such implied warranty of usability, contained in U.C.C. § 2-314, has been codified in each state. *See, e.g.*, Ala. Code §§ 7-2-314, *et seq.*; Alaska Stat. §§ 45.02.314, *et seq.*; Ariz. Rev. Stat. Ann. §§ 47-2314, *et seq.*; Ark. Code Ann. §§ 4-2-314, *et seq.*; Cal. Com. Code §§ 2314, *et seq.*; Colo. Rev. Stat. §§ 4-2-314, *et seq.*; Conn. Gen. Stat. Ann. §§ 42a-2-314, *et seq.*; Del. Code Ann. tit. 6, §§ 2-314, *et seq.*; D.C. Code Ann. §§ 28:2-314, *et seq.*; Fla. Stat. Ann. §§ 672.314, *et seq.*; O.C.G.A. §§ 11-2-314, *et seq.*; Haw. Rev. Stat. §§ 490:2-314, *et seq.*; Idaho Code §§ 28-2-314, *et seq.*; Ill. Comp. Stat. Ann. Ch. 810, 5/2-314, *et seq.*; Ind. Code Ann. §§ 26-1-2-314, *et seq.*; Iowa Code Ann. §§ 554.2314, *et seq.*; Kan. Stat. Ann. §§ 84-2-314, *et seq.*; Ky. Rev. Stat. Ann. §§ 355.2-314, *et seq.*; La. Civ. Code Ann. art. 2520, *et seq.*; Me. Rev. Stat. Ann. tit. 11, §§ 2-314, *et seq.*; Md. Code Ann., Com. Law §§ 2-314, *et seq.*; Mass. Gen. Laws Ann. Ch. 106, §§ 2-314, *et seq.*; Mich. Comp. Laws Ann. §§ 440.2314, *et seq.*; Minn. Stat. Ann. §§ 336.2-314, *et seq.*; Miss. Code Ann. §§ 75-2-314, *et seq.*; Mo. Rev. Stat. §§ 400.2-314, *et seq.*; Mont. Code Ann. §§ 30-2-314, *et seq.*; Neb. Rev. Stat. §§ 2-314, *et seq.*; Nev. Rev. Stat. §§ 104.2314, *et seq.*; N.H. Rev. Stat. Ann. §§ 382-A:2-314, *et seq.*; N.J. Stat. Ann. §§ 12A:2-314, *et seq.*; N.M. Stat. Ann. § 55-2-314,

et seq.; N.Y. U.C.C. Law §§ 2-314, *et seq.*; N.C. Gen. Stat. Ann. §§ 25-2-314, *et seq.*; N.D. Cent. Code §§ 41-02-314, *et seq.*; Ohio Rev. Code Ann. §§ 1302.27, *et seq.*; Okla. Stat. tit. 12A, §§ 2-314, *et seq.*; Or. Rev. Stat. §§ 72.3140, *et seq.*; 13 Pa. Stat. Ann. §§ 2314, *et seq.*; R.I. Gen. Laws §§ 6A-2-314, *et seq.*; S.C. Code Ann. §§ 36-2-314, *et seq.*; S.D. Codified Laws §§ 57A-2-314, *et seq.*; Tenn. Code Ann. §§ 47-2-314, *et seq.*; Tex. Bus. & Com. Code §§ 2.314, *et seq.*; Utah Code Ann. §§ 70A-2-314, *et seq.*; Va. Code Ann. §§ 8.2-314, *et seq.*; Vt. Stat. Ann. tit. 9A, §§ 2-314, *et seq.*; Wash. Rev. Code §§ 62A.2-314, *et seq.*; W. Va. Code §§ 46-2-314, *et seq.*; Wis. Stat. Ann. §§ 402.314, *et seq.*; and Wyo. Stat. Ann. §§ 34.1-2-314, *et seq*.

389. Through usage of trade, manufacturers of prescription drugs and medical devices impliedly warrant that their products are usable for the end consumer.

390. Philips breached the implied warranty of usability in connection with the sale and distribution of the Recalled Devices. At the point of sale, the Recalled Devices while appearing normal—contained defects as set forth herein rendering them unusable.

391. Philips, its agents and employees knew or should have known that the Recalled Devices suffer from a defect that causes negative health effects and/or places persons at risk for negative health effects to such an extent that the products are unusable.

392. Philips' Recall announcement instructed Plaintiffs to not use Recalled Devices because of the health risks. This confirmed the true nature of the products, which at all times were adulterated and worthless.

393. To the extent privity may be required, Plaintiffs can establish privity with Philips or alternatively, Plaintiffs can establish that they fall into an exception to a privity requirement. Plaintiffs relied on Philips' warranties and dealt directly with Philips through the exchange of warranty and recall information.

394. Alternatively, Plaintiffs were foreseeable third-party beneficiaries of Philips' sale of the Recalled Devices.

395. Had Plaintiffs known that Philips had breached the implied warranty of usability for their Recalled Devices, they would not have purchased or leased the Recalled Devices nor would they have used the Recalled Devices.

396. As a direct and proximate cause of Philips' conduct, Plaintiffs have suffered serious and debilitating injuries.

397. In addition, as a direct and proximate cause of Philips' conduct, Plaintiffs may suffer additional serious and debilitating illnesses or injuries, including various cancers, in the future as a result of exposure to the Foam Toxins.

398. Plaintiffs demand judgment against Philips and request compensatory damages, punitive damages, medical monitoring, interest, costs of suit, attorneys' fees, and such other relief as the Court deems equitable and just.

COUNT XIII
FRAUD

399. Plaintiffs re-allege and incorporate by reference the allegations set forth throughout the Complaint as if set forth herein and further allege as follows:

400. Philips and PolyTech knew the Recalled Devices posed serious health risks to users.

401. Philips and PolyTech failed to advise Plaintiffs of the material fact that the Recalled Devices posed serious health risks to users. Philips and PolyTech concealed from Plaintiffs information regarding the adverse health effects posed by the Recalled Devices. Philips and PolyTech misrepresented to Plaintiffs that the Recalled Devices were safe for use.

402. Philips and PolyTech were under a duty to disclose to Plaintiffs the serious health risks posed to users because: (a) Philips and PolyTech were in a superior position to Plaintiffs to

know the risks associated with the use of the Recalled Devices; (b) Philips and PolyTech were in a superior bargaining position to Plaintiffs in determining whether or not to disclose or conceal information regarding the Recalled Devices in its packaging, labels, advertising, and websites; (c) Philips and PolyTech made representations regarding the safety of the Recalled Devices and had a duty to fully disclose all facts related to the serious health risks to users posed by the Recalled Devices, once Philips and PolyTech became aware of such serious health risks; (d) Philips and PolyTech knew that the Plaintiffs could not reasonably have been expected to learn or discover the serious health risks posed by use of the Recalled Devices prior to using the Recalled Devices, given the representations, concealed material information, and omissions by Philips in its packaging, labels, advertising, and websites; and (e) Philips and PolyTech had a duty to disclose information related to the health and safety of its products.

403. Philips and PolyTech intentionally, knowingly, and recklessly allowed their packaging, labels, advertisements, promotional materials, and websites to mislead Plaintiffs to believe that the Recalled Devices were safe for use.

404. Philips and PolyTech knew that their omissions, concealment, and representations in its packaging, labels, advertisements, promotional materials, and websites regarding the Recalled Devices were false, deceptive, inadequate, and misleading, and that the Recalled Devices contained PE-PUR foam and thus could cause adverse health effects to users of the Recalled Devices.

405. Philips and PolyTech concealed from Plaintiffs and misrepresented to Plaintiffs material information regarding the serious health risks posed to users of the Recalled Devices, by failing to include material information in its packaging, labels, advertisements, promotional materials, and websites.

406. The information undisclosed and concealed by Philips and PolyTech to Plaintiffs was material, as a reasonable consumer would find information regarding serious adverse health risks associated with the use of the Recalled Devices important when deciding whether to use the Recalled Devices.

407. As a result of such fraudulent and/or deceptive packaging, labels, advertisements, promotional materials, and websites, Plaintiffs justifiably and reasonably believed the Recalled Devices were safe for use.

408. Philips and PolyTech intentionally, knowingly, and recklessly made these material omissions and misrepresentations, and concealed material information regarding the adverse health risks associated with the Recalled Devices in its packaging, labels, advertisements, promotional materials, and websites regarding the Recalled Devices to induce Plaintiffs to use the Recalled Devices.

409. Plaintiffs relied on Philips' and PolyTech's deceptive packaging, labels, advertisements, promotional materials, and websites and purchased and used the Recalled Devices to their detriment. Given the deceptive manner in which Philips advertised, represented, and promoted the Recalled Devices, such reliance by Plaintiffs was reasonable and justified.

410. As a direct and proximate result of Philips' and PolyTech's material omissions, misrepresentations, and concealment of material information regarding the adverse health effects to users of the Recalled Devices, Plaintiffs have suffered serious and debilitating injuries and other economic harm.

411. In addition, as a direct and proximate cause of Philips' and PolyTech's material omissions, misrepresentations, and concealment of material information regarding the adverse health effects to users of the Recalled Devices, Plaintiffs may suffer additional serious and

debilitating illnesses or injuries, including various cancers, in the future as a result of exposure to the Foam Toxins.

412. Plaintiffs demand judgment against Philips and PolyTech and request compensatory damages, punitive damages, medical monitoring, interest, costs of suit, attorneys' fees, and such other relief as the Court deems equitable and just.

COUNT XIV
NEGLIGENT MISREPRESENTATION

413. Plaintiffs re-allege and incorporate by reference the allegations set forth throughout the Complaint as if set forth herein and further allege as follows:

414. Philips and PolyTech had a duty to tell Plaintiffs, and the public, the truth of the risks and harms associated with the Recalled Devices.

415. Philips and PolyTech failed to advise Plaintiffs of the material fact that the Recalled Devices posed serious health risks to users. Philips and PolyTech concealed from Plaintiffs information regarding the adverse health effects posed by the Recalled Devices. Philips and PolyTech misrepresented to Plaintiffs that the Recalled Devices were safe for use.

416. Philips and PolyTech were under a duty to disclose to Plaintiffs the serious health risks posed to users because: (a) Philips and PolyTech were in a superior position to Plaintiffs to know the risks associated with the use of the Recalled Devices; (b) Philips and PolyTech were in a superior bargaining position to Plaintiffs in determining whether or not to disclose or conceal information regarding the Recalled Devices in its packaging, labels, advertising, and websites; (c) Philips and PolyTech made representations regarding the safety of the Recalled Devices; and had a duty to fully disclose all facts related to the serious health risks to users posed by the Recalled Devices, once Philips and PolyTech became aware of such serious health risks; (d) Philips and PolyTech knew that the Plaintiffs could not reasonably have been expected to learn or discover

the serious health risks posed by use of the Recalled Devices prior to using the Recalled Devices, given the representations, concealed material information, and omissions by Philips and PolyTech in their packaging, labels, advertising, and websites; and (e) Philips and PolyTech had a duty to disclose information related to the health and safety of its products.

417. Philips and PolyTech breached their duty by falsely representing to Plaintiffs and the public that the Recalled Devices were safe for use when Defendants knew or should have known that the Recalled Devices were defective, and had not been properly or adequately tested.

418. Philips and PolyTech failed to exercise ordinary care in the representation of the Recalled Devices during its manufacturing, sale, testing, quality assurance, quality control, and/or distribution into interstate commerce, in that Philips and PolyTech negligently misrepresented the safety and efficacy of the devices.

419. As a direct and proximate result of Philips' and PolyTech's material omissions, misrepresentations, and concealment of material information regarding the adverse health effects to users of the Recalled Devices, Plaintiffs have suffered serious and debilitating injuries and other economic harm.

420. In addition, as a direct and proximate cause of Philips' and PolyTech's material omissions, misrepresentations, and concealment of material information regarding the adverse health effects to users of the Recalled Devices, Plaintiffs may suffer additional serious and debilitating illnesses or injuries, including various cancers, in the future as a result of exposure to the Foam Toxins.

Plaintiffs demand judgment against Philips and PolyTech and request compensatory damages, punitive damages, medical monitoring, interest, costs of suit, attorneys' fees, and such other relief as the Court deems equitable and just.

COUNT XV
NEGLIGENCE PER SE

421. Plaintiffs re-allege and incorporate by reference the allegations set forth throughout the Complaint as if set forth herein and further allege as follows:

422. At all times, Philips had an obligation to comply with applicable statutes and regulations, including relevant and applicable statues and regulations promulgated by the FDA.

423. Philips utilized the 510(k) process to receive clearances for each of its Recalled Devices except the E30 ventilator which was marketed under an EUA.

424. Philips' actions as described herein violated applicable statutes and regulations related to, at a minimum, the 510(k) application process, including but not limited to 21 C.F.R. § 807 *et seq.*, and parallel state law requirements.

425. Philips' actions as described herein violated applicable statutes and regulations related to its duty to monitor, investigate, evaluate and timely report issues with foam degradation, including 21 C.F.R. part 803 and 21 C.F.R. § 820.198, and parallel state law requirements.

426. Plaintiffs are within the class of persons that these statutes and regulations are intended to protect.

427. Plaintiffs' injuries and/or symptoms are the type of harm that these statutes and regulations are intended to prevent.

428. Philips' violations of the foregoing statutes and regulations, among others, constitutes negligence per se.

429. As a direct and proximate result of Philips' negligence per se, Plaintiffs have suffered serious and debilitating injuries.

430. In addition, as a direct and proximate cause of Philips' negligence per se, Plaintiffs may suffer additional serious and debilitating illnesses or injuries, including various cancers, in the future as a result of exposure to the Foam Toxins.

431. Plaintiffs demand judgment against Philips and request compensatory damages, punitive damages, medical monitoring, interest, costs of suit, attorneys' fees, and such other relief as the Court deems equitable and just.

COUNT XVI
CONSUMER FRAUD AND/OR UNFAIR AND DECEPTIVE PRACTICES UNDER STATE LAW

432. Plaintiffs re-allege and incorporate by reference the allegations set forth throughout the Complaint as if set forth herein and further allege as follows:

433. Certain Plaintiffs herein will bring a cause of action for consumer fraud and/or unfair and deceptive trade practices under applicable state law.

434. Philips is on notice that such claims may be asserted by those Plaintiffs.

435. Plaintiffs used the Recalled Devices and suffered ascertainable losses as a result of Philips' actions in violation of these consumer protection laws.

436. Had Philips not engaged in the deceptive conduct described herein, Plaintiffs would not have purchased, leased, or used the Recalled Devices nor would Plaintiffs have incurred related medical costs and injuries from using the Recalled Devices.

437. Fraudulent, unfair, and/or deceptive practices that violate consumer protection laws include the following: (a) representing that goods or services have approval, characteristics, uses, or benefits that they do not have; (b) advertising goods or service with the intent not to sell them as advertised; and (c) engaging in fraudulent or deceptive conduct that creates a likelihood of confusion.

438. Plaintiffs were injured and suffered ascertainable losses of money or property by Philips' unlawful conduct.

439. Philips' deceptive, unconscionable, unfair, and/or fraudulent representations and material omissions to Plaintiffs constitute consumer fraud and/or unfair and deceptive acts and trade practices in violation of consumer protection statutes, including but not limited to:

a. Ala. Code § 8-19-1, *et seq.*;

b. Alaska Stat. § 45.50.471, *et seq.*;

c. Ariz. Rev. Stat. Ann. § 44-1521, *et seq.*;

d. Ark. Code Ann. § 4-88-101, *et seq.*;

e. Cal. Civ. Code § 1770, *et seq.*;

f. Cal. Bus. & Prof. Code § 17200, *et seq.*;

g. Cal. Bus. & Prof. Code § 17500, *et seq.*;

h. Colo. Rev. Stat. § 6-1-101, *et seq.*;

i. Conn. Gen. Stat. § 42-110a, *et seq.*;

j. Del. Code Ann. tit. 6, § 2511, *et seq.*, § 2531, *et seq.*;

k. D.C. Code Ann. § 28-3901, *et seq.*;

l. Fla. Stat. Ann. § 501.201, *et seq.*;

m. Fla. Stat. Ann. § 817.06, 817.41, *et seq.*;

n. Ga. Code Ann. § 10-1-390, *et seq.*;

o. Ga. Code. Ann. § 10-1-370, *et seq.*;

p. Haw. Rev. Stat. § 480-1, *et seq.*;

q. Id. Code Ann. § 48-601, *et seq.*;

r. Ill. Comp. Stat. Ann. Ch. 815, 505/1, *et seq.*;

s. 815 Ill. Comp. Stat. Ann. § 510/1, *et seq.*;

t. Ind. Code Ann. § 24-5-0.5-1, *et seq.*;

u. Iowa Code Ann. § 714H.1, *et seq.*;

v. Kan. Stat. Ann. § 50-623, *et seq.*;

w. Ky. Rev. Stat. Ann. § 367.110, *et seq.*;

x. La. Rev. Stat. Ann. § 51:1401, *et seq.*;

y. La. Civ. Code art. 2520, *et seq.*;

z. Me. Rev. Stat. Ann. tit. 5, § 205A, *et seq.*;

aa. 10 Me. Rev. Stat. tit. § 1211, *et seq.*;

bb. Md. Code Ann., Com. Law § 13-101, *et seq.*;

cc. Mass. Gen. Laws Ann. Ch. 93A, *et seq.*;

dd. Mich. Comp. Laws § 445.901, *et seq.*;

ee. Minn. Stat. § 325D.43, *et seq.*, §§ 325F.67-325F.69, *et seq.*;

ff. Miss. Code Ann. § 75-24-1, *et seq.*;

gg. Mo. Ann. Stat. § 407.010, *et seq.*;

hh. Mont. Code Ann. § 30-14-101, *et seq.*;

ii. Neb. Rev. Stat. § 59-1601, *et seq.*;

jj. Neb. Rev. Stat. § 87-301, *et seq.*;

kk. Nev. Rev. Stat. § 598.0915, *et seq.*;

ll. N.H. Rev. Stat. Ann. § 358-A:1, *et seq.*;

mm. N.J. Stat. Ann. § 56:8-2, *et seq.*;

nn. N.M. Stat. Ann. § 57-12-1, *et seq.*;

oo. N.Y. Gen. Bus. Law § 349, *et seq.*, § 350-e, *et seq.*;

pp. N.C. Gen. Stat. § 75-1.1, *et seq.*;

qq. N.D. Cent. Code § 51-12-01, *et seq.*, § 51-15-01, *et seq.*;

rr. Ohio Rev. Code Ann. § 1345.01, *et seq.*;

ss. Okla. Stat. tit. 15 § 751, *et seq.*;

tt. Or. Rev. Stat. § 646.605, *et seq.*;

uu. 73 Pa. Stat. § 201-1, *et seq.*;

vv. R.I. Gen. Laws § 6-13.1-1, *et seq.*;

ww. S.C. Code Ann. § 39-5-10, *et seq.*;

xx. S.D. Codified Laws § 37-24-1, *et seq.*;

yy. Tenn. Code Ann. § 47-18-101, *et seq.*;

zz. Tex. Bus. & Com. Code Ann. §17.41, *et seq.*;

aaa. Utah Code Ann. § 13-11-1, *et seq.*;

bbb. Utah Code Ann. § 13-11a-1, *et seq.*;

ccc. Vt. Stat. Ann. tit. 9, § 2451, *et seq.*;

ddd. Va. Code Ann. § 59.1-196, *et seq.*;

eee. Wash. Rev. Code § 19.86.010, *et seq.*;

fff. W. Va. Code § 46A-6-101, *et seq.*;

ggg. Wis. Stat. Ann. § 100.18, *et seq.*;

hhh. Wyo. Stat. Ann. § 40-12-101, *et seq.*

440. Under these and other consumer protection statutes, Philips is the supplier, manufacturer, advertiser, and seller of the Recalled Devices, subject to liability under such legislation from fraudulent, unfair, deceptive, and unconscionable consumer sales practices.

441. The actions and omissions of Philips are uncured or incurable.

442. Philips was put on notice of these issues by the investigation of the FDA, numerous complaints filed against Philips, and individual letters and communications from certain Plaintiffs and others within a reasonable amount of time after Philips' conduct was publicly disclosed.

443. Philips had actual knowledge of the defective and dangerous condition of the Recalled Devices and failed to take any action to cure those conditions.

444. Plaintiffs relied upon Philips' misrepresentations and omissions in deciding to use the Recalled Devices.

445. By reason of the fraudulent, deceptive, unfair, and/or otherwise unlawful acts engaged in by Philips, and as a direct and proximate result thereof, Plaintiffs have sustained injuries and other damages.

446. Plaintiffs demand judgment against Philips and request compensatory damages, punitive damages, medical monitoring, interest, costs of suit, attorneys' fees, and such other relief as the Court deems equitable and just.

COUNT XVII
UNJUST ENRICHMENT (in the alternative)

447. Plaintiffs re-allege and incorporate by reference the allegations set forth throughout the Complaint as if set forth herein and further allege as follows:

448. Plaintiffs conferred a tangible and material economic benefit upon Philips and PolyTech by using the Recalled Devices that were purchased or leased on their behalf. Plaintiffs would not have used the Recalled Devices had they known the true risks of using the Recalled Devices.

449. Philips and PolyTech readily accepted and retained these benefits. Philips and PolyTech profited from the sale of the Recalled Devices to the detriment and expense of Plaintiffs.

450. Philips and PolyTech appreciated these benefits. These benefits were the expected result of Philips and PolyTech acting in their pecuniary interest at the expense of their customers. Philips and PolyTech knew of these benefits because Philips and PolyTech were aware of the defective nature of the Recalled Devices. Philips and PolyTech failed to disclose this knowledge, and thereby misled Plaintiffs regarding the nature and quality of the Recalled Devices while profiting from this deception.

451. Under these circumstances, it would be unjust, inequitable, and unconscionable for Philips and PolyTech to retain benefits it received at the expense of Plaintiffs, including because they were procured as a result of Philips' and PolyTech's wrongful conduct alleged herein. Failing to require Philips and PolyTech to provide remuneration under these circumstances would result in Philips and PolyTech being unjustly enriched at the expense of Plaintiffs who have suffered injuries as a result of using the Recalled Devices.

452. Philips' and PolyTech's retention of the benefits conferred upon it by Plaintiffs would be unjust and inequitable.

453. Plaintiffs are entitled to restitution of the benefits Philips and PolyTech unjustly retained and/or any amounts necessary to return Plaintiffs to the position they occupied prior to dealing with Philips and PolyTech, such as compensatory damages, punitive damages, medical monitoring, interest, costs of suit, attorneys' fees, and such other relief as the Court deems equitable and just.

454. Plaintiffs plead this claim separately as well as in the alternative to their other claims, as without such claims they would have no adequate legal remedy.

COUNT XVIII
LOSS OF CONSORTIUM

455. Plaintiffs re-allege and incorporate by reference the allegations set forth throughout the Complaint as if set forth herein and further allege as follows:

456. At all relevant times, certain Plaintiffs were married to spouses or had minor children.

457. As a result of the injuries and damages sustained by certain Plaintiffs, their spouses and minor children have suffered the loss of care, comfort, society, and affection from Plaintiffs.

458. Plaintiffs demand judgment against Philips and PolyTech and request compensatory damages, punitive damages, interest, costs of suit, attorneys' fees, and such other relief as the Court deems equitable and just.

COUNT XIX
SURVIVORSHIP AND WRONGFUL DEATH

459. Plaintiffs re-allege and incorporate by reference the allegations set forth throughout the Complaint as if set forth herein and further allege as follows:

460. Certain Plaintiffs suffered and incurred a premature and untimely death as a result of the Recalled Devices.

461. Plaintiff-Decedent would not have used the Recalled Devices but for the wrongful conduct of Philips and PolyTech. Similarly, as alleged throughout this Master Long Form Complaint and as incorporated herein, Philips and PolyTech are liable for the Plaintiff-Decedent's suffering and death, for each Plaintiff-Decedent's survivors' damages, for damages sustained by the Plaintiff-Decedent's estate, and all other injuries and damages flowing from Plaintiff-Decedent's death.

462. Plaintiff-Decedent's demand judgment against Philips and PolyTech and request compensatory damages, punitive damages, interest, costs of suit, attorneys' fees, and such other relief as the Court deems equitable and just.

COUNT XX
MEDICAL MONITORING

463. Plaintiffs re-allege and incorporate by reference the allegations set forth throughout the Complaint as if set forth herein and further allege as follows:

464. Plaintiffs bring an independent claim of medical monitoring against Philips and PolyTech.

465. As alleged above, Philips' and PolyTech's Recalled Devices contained defective PE-PUR foam that exposed patients using the devices to the Foam Toxins. The Foam Toxins are hazardous, life-threatening, toxic substances that are known to cause cancer and other illnesses, diseases, and disease processes in humans.

466. Philips and PolyTech understood, at all relevant times, that a chemical that causes cancer in animal studies must be presumed to present a risk of cancer to humans, except in extraordinarily limited circumstances; specifically, when (1) the precise mechanism of action that causes tumors is known, and (2) it is also known that the mechanism of action is either not operative or cannot occur in humans. That extraordinary circumstance does not exist here.

467. Studies show that the persistent exposure to the Foam Toxins results in their presence, accumulation, toxic invasion, and/or persistence in the human bloodstream, including the bloodstream of Plaintiffs; resulting in injurious, physically harmful, unwanted, unconsented-to, and deleterious alterations, changes, and/or other presently-existing physical injuries and/or adverse impacts to the blood and/or bodies of Plaintiffs, including but not limited to subcellular injuries.

468. Moreover, based on available scientific literature, exposure to the Foam Toxins places Plaintiffs at risk of developing a number of serious illnesses and diseases, including but not limited to the following: cancer, including cancer as of the head, neck, kidneys, liver, brain, pancreas, blood-forming tissue, respiratory system, gastrointestinal system, reproductive system, and lymphatic system; respiratory diseases such as asthma, chronic bronchitis, chronic obstructive pulmonary disease, constrictive bronchiolitis or obliterative bronchiolitis, emphysema, interstitial lung disease, pleuritis, pulmonary fibrosis, sarcoidosis; and chronic sinusitis, chronic rhinitis, and other forms of chronic inflammation. The Foam Toxins are cytotoxic and genotoxic; as such, exposure causes widespread damage to DNA as well as the reproductive system, neurological system, and other critical systems.

469. Plaintiffs have been significantly exposed to the proven hazardous Foam Toxins released by PE-PUR foam in the Recalled Devices. Plaintiffs have inhaled and/or ingested these Foam Toxins through their respiratory tract and gut, where they were absorbed into tissue and into Plaintiffs' bloodstream, producing subcellular or other physiological changes in Plaintiffs.

470. Philips and PolyTech did not seek or obtain permission or consent from Plaintiffs before engaging in such acts and/or omissions that caused, allowed, and/or otherwise resulted in the contamination of Plaintiffs' bloodstream and/or bodies with the Foam Toxins.

471. As a proximate result of Philips' and PolyTech's acts and omissions, Plaintiffs are at an increased risk of developing cancer and other illnesses, diseases, and disease processes above the normal base-level risk.

472. Plaintiffs are at this increased risk of cancer and other serious health conditions because they were exposed to, inhaled, consumed, and/or ingested the Foam Toxins in quantities, and over periods of time, sufficient to establish levels of exposure that are hazardous to health; and

sufficient to cause cancer and other serious ailments; or increase the risk of developing cancer and other serious ailments.

473. Plaintiffs may not develop all, or some, of the forms of cancer or various adverse health conditions for many years.

474. In addition to the injuries they have already suffered, Plaintiffs are reasonably concerned and fearful of the worsening, or additional, effects from exposure to the Foam Toxins. This includes the synergistic effects of having multiple toxic and carcinogenic materials in their blood at the same time; and what such effects will and/or are reasonably likely or probable to do to them and their children, including the well-founded and reasonable fear of cancer and other serious diseases that have long latency periods after such exposures.

475. The exposure was solely and proximately caused by Philips' and PolyTech's acts and omissions, including: their failure to adequately design and manufacture their Recalled Devices to satisfy applicable standards imposed by law and regulation; their failure to address known issues with the PE-PUR foam during quality control testing; their material misrepresentations, false statements, and other deceptive practices in continuing to claim that the Recall Devices were safe for use.

476. Philips and PolyTech owed duties to the Plaintiffs: to ensure and warrant that the Recalled Devices were indeed designed and manufactured to satisfy applicable standards imposed by law and regulation; to disclose to Plaintiffs any defect or other potential health hazard known or discoverable by Philips; and to ensure that the Recalled Devices were safe, reliable, and non-hazardous for human consumption-their intended purpose.

477. As alleged in this Complaint, Philips' and PolyTech's negligent acts and omissions resulted in an increased risk for all Plaintiffs of developing cancer or other serious health

conditions. Cancer is a serious disease that causes life-threatening illness and debilitating cellular, genetic, and physical injury. Technology, analytical tools, test and/or monitoring procedures exist and are readily available to detect cancer and other deleterious health conditions in patients. These technologies, tools tests and/or monitoring procedures are accepted and widely used by the scientific and medical community. The existing scientific methods include, but are not limited to: blood and laboratory tests; physical examinations; imaging; colonoscopies, endoscopies, and other similar methods for examination; biopsies; pathologic, histologic, and oncologic evaluations; and oncologic, histologic, surgical and other necessary medical consultations.

478. Early detection of cancer and other serious health conditions in patients is one of the best, and sometimes the only, means to treat cancer and other ailments such that they do not cause lasting, permanent injury, illness, or death.

479. Early detection of cancer and other serious health conditions in patients necessarily allows patients to avail themselves of myriad forms of treatment, each of which is capable to altering the course of the illness, such as bringing the cancer into remission, removal of any malignant tumors, and other treatment to alleviate injury.

480. The tests and treatments for the early detection and treatment of cancer and other serious health conditions must be prescribed by a qualified physician, and are conducted according to the latest, contemporary, and widely accepted scientific principles. Because screenings for cancer and other serious health conditions associated with the Foam Toxins may not be conducted with the frequency necessary to identify those illnesses in the absence of exposure to the Foam Toxins, the prescribed monitoring regime is different from that normally recommended in the absence of exposure. Further, Plaintiffs require more frequent screenings not within the purview of routine medical exams.

481. Plaintiffs seek injunctive and monetary relief, including compensatory damages for, and the creation of a fund to adequately finance the costs of: (1) providing necessary testing, evaluations, examinations, screenings, and other necessary medical consultations; (2) providing all necessary medical and surgical procedures including consultation, diagnosis, and treatment; and (3) providing for all necessary attorneys' fees, costs, interest, and such further relief as the Court deems equitable and just.

COUNT XXI
PUNITIVE DAMAGES

482. Plaintiffs re-allege and incorporate by reference the allegations set forth throughout the Complaint as if set forth herein and further allege as follows:

483. Philips' and PolyTech's conduct as set forth herein constitutes intentional, fraudulent, malicious and/or reckless conduct; and wanton and willful disregard of the rights and health of the Plaintiffs.

484. Plaintiffs are thus entitled to punitive damages.

485. Plaintiffs demand judgment against Philips and PolyTech and request punitive damages, and such other relief as the Court deems equitable and just.

VII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request that this Court:

A. award all damages to which Plaintiffs are entitled (including, without limitation, compensatory damages for pain and suffering, emotional distress damages, past and future medical expenses, past and future loss of wages and wage earning capacity, and other economic damages; loss of consortium, medical monitoring; statutory damages; punitive, exemplary and treble damages; and loss of services, support and consortium);

B. award pre-judgment and post-judgment interest on such monetary relief;

C. award reasonable attorneys' fees and costs; and

D. grant such further and other relief that this Court deems appropriate.

VIII. JURY DEMAND

Plaintiffs demand a trial by jury on all issues so triable.

Dated: August 22, 2022

Respectfully submitted,

/s/ Sandra L. Duggan
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