UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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SALVATORE DIGRAZIA AND MARYANN DIGRAZIA,

Plaintiffs,

-against-

KONINKLIJKE PHILIPS N.V.; PHILIPS RS NORTH AMERICA LLC; PHILIPS NORTH AMERICA LLC; PHILIPS HOLDING USA, INC.; PHILIPS RS NORTH AMERICA HOLDING CORPORATION; WM. T. BURNETT FOAM, LLC; WM. T. BURNETT & CO.; WM. T. BURNETT MANAGEMENT, INC.; WM. T. BURNETT HOLDING LLC; WM. T. BURNETT & CO., INCORPORATED; WM. T. BURNETT FIBER, LLC; WM. T. BURNETT IP LLC; and SOCLEAN, INC.,

Defendants.

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CIVIL ACTION NO.:

COMPLAINT

JURY TRIAL DEMANDED

The plaintiffs, SALVATORE DIGRAZIA AND MARYANN DIGRAZIA, residing in Elmont in the State of New York, by their attorneys, Danzi Law Partners, LLC hereby submit the following Complaint and Demand for Jury Trial against Defendants Koninklijke Philips N.V. ("Royal Philips"), Phillips RS North America LLC ("Philips RS" or "Respironics"), Philips North America LLC ("Philips NA"), Philips Holding USA, Inc., ("Philips USA") and Philips RS North America Holding Corporation ("Philips RS NA Holding") (hereinafter collectively referred to as "Philips") and Defendants Wm. T. Burnett Foam LLC ("Burnett Foam"), WM. T. Burnett & Co. ("Burnett & Co."), Wm. T. Burnett Management, Inc. ("Burnett Management"), Wm. T. Burnett & Co., Incorporated ("Burnett & Co., Inc."), Wm. T. Burnett Holding LLC ("Burnett Holding"), Wm. T. Burnett Fiber LLC ("Burnett Fiber"), Wm. T. Burnett IP LLC ("Burnett IP") (hereinafter, collectively referred to as "Burnett") and SoClean, Inc, ("SoClean") and respectfully allege as follows upon information and belief:

NATURE OF ACTION

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

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

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

4. On April 26, 2021, as part of its Quarterly Report for Q1 2021, under the section entitled "Regulatory Update," Philips disclosed for the first time that the sound abatement foam in Philips' CPAP, BiPAP and mechanical ventilator devices posed serious health risks to their users.

5. On June 14, 2021, Philips issued a recall notification for many of its CPAP, BiPAP, and mechanical ventilator devices.

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

7. Philips' recall advised patients using these affected devices of potential risks from exposure to chemicals released from the sound abatement foam via degradation and/or off-gassing

8. Specifically, Philips recall notification stated that the risks related to exposure to chemicals given off by the sound abatement foam could include headache, irritation, inflammation, respiratory issues, and possible toxic and carcinogenic effects.

9. Upon information and belief, Burnett manufactures the polyester-based polyurethane (PE-PUR) sound abatement foam used in Philips' recalled CPAP and BiPAP Devices.

10. Upon information and belief, So Clean manufactures and markets devices used to clean continuous positive airway pressure ("CPAP") machines, which treat sleep apnea since approximately 2012.

11. Upon information and belief, So Clean has used false and misleading representations about its devices to market the SoClean 2 CPAP Sanitizing Machine, the SoClean 2 Go CPAP Sanitizing machine, and their predecessor devices (collectively "the SoClean Devices").

12. The SoClean Devices work by generating ozone to sterilize and deodorize CPAP machines. Ozone (O3) is an unstable toxic gas with a pungent characteristic odor - sometimes described as "clean" smelling - that can kill bacteria and viruses. To be effective as a germicide, ozone must be present in a concentration far greater than can be safely tolerated by people or animals.

13. SoClean's marketing materials fail to disclose that its devices emit ozone, which is a longstanding requirement of federal law. Instead, SoClean falsely represent that its devices use "activated oxygen" to clean CPAP machines. SoClean markets the Sevices as "safe" and "healthy," which is false given that they generate toxic ozone gas at levels that substantially exceed federal regulations. SoClean falsely represents that its devices use "no water or chemicals" or "no harsh chemicals" to clean CPAP machines, despite using ozone gas - a harsh chemical that causes respiratory problems in humans. SoClean represents that its devices use the same sanitizing process found in "hospital sanitizing," however, hospitals cannot and do not use

ozone sanitizers in spaces occupied by patients. SoClean also claims that separately sold filters convert "activated oxygen" into "regular oxygen," which is false because SoClean's filters have no measurable effect on the Device's ozone output. Finally, SoClean falsely claims that its devices are "sealed" such that "activated oxygen" (i.e., ozone) does not escape the devices. SoClean Devices are so dangerous and destructive that several of the largest manufactures of CPAP machines in the United States require purchasers to acknowledge that they have been informed that if the purchaser uses a SoClean Device to clean their CPAP machine, the warranty of their CPAP machine will be voided.

14. SoClean's misrepresentations have allowed it to command ninety percent of the relevant market. Due to the nature of SoClean's business, its customers all have breathing problems for which they are receiving medical treatment in the form of CPAP therapy. If CPAP users knew that the SoClean Devices generate unsafe levels of toxic gas, which is then pumped into their CPAP machines and into their bedrooms, they would find this risk material to their purchasing decisions.

15. SoClean's representations are designed to mislead consumers into believing that the machine uses a benign form of oxygen to clean CPAP machines rather than a harsh gas that is generally only suitable for commercial sanitization under highly controlled conditions. These representations are made more egregious because the SoClean Devices are designed and marketed for use on the consumer's bedside table and because CPAP users suffer from many symptoms that ozone exacerbates - making the falsehoods especially reprehensible and dangerous.

16. Upon information and belief, Plaintiff Salvatore DiGrazia was prescribed the use of and purchased/rented one of Philips' recalled devices, the REMstar Plus machine (Serial

Number SN P11040538D0AE) to treat Plaintiff's sleep apnea in March of 2014 from Apria Healthcare, LLC located at 265 Executive Drive, Plainview, New York 11803.

17. Plaintiff used Philips' REMstar Plus CPAP device (hereinafter the "Philips Device" or "Device"), one of Philips' recalled Devices, on a daily basis for a number of years.

18. After using the Philips Device for a number of years. Plaintiff was diagnosed with brain cancer in December of 2021.

19. Upon information and belief, Plaintiff Salvatore DiGrazia was prescribed the use of and purchased/rented one of SoClean's recalled devices, the SoClean 2, CPAP sanitizing equipment (Serial Number SC120016120602455) to clean and sterilize Plaintiff's CPAP device, the REMstar Plus in or about 2016.

20. Plaintiff used SoClean's SoClean2 Device (hereinafter the "SoClean Device" or "Device"), one of SoClean's recalled devices, on a daily basis for a number of years.

21. After using the SoClean Device for a number of years. Plaintiff was diagnosed with brain cancer in December of 2021.

22. In December of 2021, the plaintiff underwent surgical removal of a brain mass and the pathology report dated December 18, 2021, revealed a diagnosis of brain cancer (glioblastoma/glioma).

23. Due to his diagnosis of brain cancer, the plaintiff, Salvatore DiGrazia, has undergone brain surgery on two separate occasions and suffers from the sequelae of his diagnosis.

24. As a direct and proximate result of Defendants' conduct, Plaintiff, Salvatore DiGrazia, has suffered serious and substantial life-altering injuries.

25. As a direct and proximate result of the subject devices manufactured, marketed, sold, and distributed by Defendants, Plaintiff, Salvatore DiGrazia has suffered physical and emotional injuries, including brain cancer and the invasive treatment of the cancer and the sequelae of the cancer, its treatment including surgical intervention, radiation, and seizures.

26. Defendants have long known that the polyester-based polyurethane (PE-PUR) sound abatement foam in Defendants' CPAP, BiPAP and mechanical ventilator devices had a tendency to release toxic and carcinogenic microparticles that can be inhaled by users like Plaintiff, Salvatore DiGrazia, causing serious injury or death.

27. Defendants have long known that the use of the SoClean Device can cause degradation of the polyester-based polyurethane (PE-PUR) sound abatement foam in Philips' CPAP, BiPAP and mechanical ventilator devices (including the REMstar Plus) causing it to release toxic and carcinogenic microparticles that can be inhaled by users like the Plaintiff, Salvatore DiGrazia, causing serious injury or death.

28. As a result of the Philips and SoClean Devices' defects and Defendants' tortious acts and/or omissions, Plaintiff, Salvatore DiGrazia had developed serious and life-threatening conditions and has endured unnecessary pain and suffering.

29. Plaintiff, Salvatore DiGrazia, has suffered from unnecessary pain, debilitation, hospitalization, and the development of recurrent brain cancer because Defendants defectively designed and manufactured the Devices and failed to adequately warn of the dangers of the Devices.

PARTIES

30. At all relevant times, the Plaintiffs, Salvatore DiGrazia and MaryAnn DiGrazia were over the age of majority and were residents and citizens of Nassau County in the State of

New York. Plaintiff Salvatore DiGrazia was injured due to defective medical devices manufactured by the Defendants. Plaintiff, Maryann DiGrazia has a derivative claim for loss of services.

31. Defendant Koninklijke Philips ("Royal Philips") is a public limited liability company established under the law of The Netherlands, having its principal executive offices at Philips Center, Amstelplein 2, 1096 BC Amsterdam, The Netherlands. Royal Philips is the parent company of Philips North America LLC, Philips Holding USA Inc., Philips RS North America, and Philips RS North America Holding Corporation. Royal Philips can be served with process via the Convention on the Service Abroad of Judicial and Extrajudicial Documents in Civil or Commercial Matters ("Hague Service Convention"). Defendant Royal Philips is subject to the jurisdiction and venue of this Court.

32. Defendant Philips RS North America LLC ("Philips RS") is a Delaware corporation with its principal place of business located at 6501 Living Place, Pittsburgh, Pennsylvania 15206. Philips RS was formerly operated under the business name Respironics, Inc. ("Respironics"). Royal Philips acquired Respironics in 2008.

33. Defendant Philips North America LLC ("Philips NA") is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. Philips NA is a wholly owned subsidiary of Koninklijke Philips ("Royal Philips"), a Dutch corporation. Upon information and belief, Philips NA manages the operation of Royal Philips' various lines of business, including Philips RS, in North America. The sole member of Philips NA is Philips USA.

34. Defendant Philips Holding USA, Inc. ("Philips USA") is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Floor 3, Cambridge,

Massachusetts 02141. Philips USA is a holding company that is the sole member of Defendant Philips NA.

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

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

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

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

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

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

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

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

43. Defendant SoClean, Inc. is a Delaware corporation with its principal place of business at 12 Vose Farm Road, Peterborough, New Hampshire 03458.

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

STATEMENT OF JURISDICTION & VENUE

45. This Court has subject matter jurisdiction over the Parties pursuant to 28 U.S.C. §1332(a) because Plaintiff and Defendants are citizens of different States and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

46. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b) and (c).

47. This Court has personal jurisdiction over Defendants because Defendants conduct substantial business in this District, and the events giving rise to Plaintiffs' claims arise out of and relate to Defendants' contacts with this District.

PLAINTIFF'S REMSTAR PLUS CPAP DEVICE

48. Plaintiffs bring this product liability personal injury action as Plaintiff, Salvatore DiGrazia was a recipient of defective medical devices, i.e., a CPAP Device designed, manufactured, and distributed by the Philips and Burnett Defendants.

49. In March of 2014, Plaintiff, Salvatore DiGrazia was prescribed and purchased/rented a Philips REMstar Plus CPAP Device (Serial Number SN P11040538D0AE).

50. Defendants, directly or through their subsidiaries or affiliates, designed, manufactured, distributed, and sold the Philips REMstar Plus CPAP Device prescribed to and purchased by Plaintiff Salvatore DiGrazia.

51. Based upon the patient population that Defendants intended its Philips REMstar Plus CPAP Device to be used by, when Plaintiff Salvatore DiGrazia used the Device, Plaintiff was an appropriate patient to use the Device.

52. At all times subsequent to the date of first use, Plaintiff Salvatore DiGrazia used the Device in a normal and expected manner.

53. Subsequent to Plaintiff's normal use of the Device, Plaintiff Salvatore DiGrazia suffered symptoms including but not limited to brain cancer.

54. At the time the Device was purchased / rented by Plaintiff Salvatore DiGrazia, it was in the same condition in all relevant respects as when it left Philips' control.

55. Prior to Plaintiff Salvatore DiGrazia's purchase /rental of the Device, Philips did not warn patients, including Plaintiff, physicians, its customers, or its sales representative/distributors that the Device was known to emit toxic and/or carcinogenic particles from its PE-PUR sound abatement foam via degradation and/or off-gassing, which could then be directly inhaled by the user, causing severe injury or death.

56. Plaintiff Salvatore DiGrazia's use of the Device has subjected him to much greater risks of future harm than he had before using the Device.

57. Had Plaintiff Salvatore DiGrazia or Plaintiff's physician known that the Device would release carcinogenic particles causing Plaintiff Salvatore DiGrazia's development of brain cancer, then neither Plaintiff nor Plaintiff's physician or medical supplier would have chosen the Device for treatment of Plaintiff Salvatore DiGrazia's sleep apnea.

58. As a direct and proximate result of use of Philips' REMstar Plus CPAP Device, Plaintiff Salvatore DiGrazia has suffered significant harm, including but not limited to:

a. the development of brain cancer and attendant hospitalizations;

b. the development of life-threatening glioblastoma/glioma and its invasive treatment;

c. past and future pain and suffering, both in mind and in body;

d. permanent diminishment of Plaintiff's ability to participate in and enjoy the affairs of life;

e. medical bills associated with the treatment of brain cancer and recovery therefrom;

f. future medical expenses;

g. loss of enjoyment of life;

h. disfigurement; and

i. physical impairment.

59. As a direct and proximate result of Plaintiff Salvatore DiGrazia's use of Philips' REMstar Plus CPAP Device, Plaintiff Maryann DiGrazia has suffered significant harm, including but not limited to the loss of care, comfort, society, and affections from Plaintiff.

PLAINTIFF'S SO CLEAN 2 DEVICE

60. Plaintiffs bring this product liability personal injury action as Plaintiff, Salvatore DiGrazia was a recipient of defective medical devices, i.e., a SoClean2 Device designed, manufactured, and distributed by the SoClean Defendants.

61. SoClean manufactures and sells medical devices that clean continuous positive airway pressure ("CPAP") machines. Plaintiff is the owner of a SoClean 2 CPAP cleaning Device and has used that Device on a regular basis since he purchased the Device.

62. In or about 2016, Plaintiff, Salvatore DiGrazia was prescribed and purchased a SoClean 2 Device (Serial Number SC120016120602455).

63. Defendants, directly or through their subsidiaries or affiliates, designed, manufactured, distributed, and sold the SoClean 2 Device prescribed to and purchased by Plaintiff Salvatore DiGrazia.

64. Based upon the patient population that Defendants intended its SoClean Device to be used by, when Plaintiff Salvatore DiGrazia used the Device, Plaintiff was an appropriate patient to use the Device.

65. At all times subsequent to the date of first use, Plaintiff Salvatore DiGrazia used the Device in a normal and expected manner.

66. Subsequent to Plaintiff's normal use of the Device, Plaintiff Salvatore DiGrazia suffered symptoms including but not limited to brain cancer.

67. At the time Plaintiff Salvatore DiGrazia purchased the Device, it was in the same condition in all relevant respects as when it left SoClean's control.

68. Prior to Plaintiff Salvatore DiGrazia's purchase of the Device, SoClean did not warn patients, including Plaintiff, physicians, its customers, or its sales representative/distributors that the Device was known to release ozone and/or cause degradation of the PE-PUR sound abatement foam of the Philips CPAP machines and/or off-gassing, which could then be directly inhaled by the user, causing severe injury or death.

69. Plaintiff Salvatore DiGrazia's use of the Device has subjected him to much greater risks of future harm than he had before using the Device.

70. Had Plaintiff Salvatore DiGrazia or Plaintiff's physician known that the SoClean 2 Device would release ozone and/or contribute to the release carcinogenic particles from his Philips REMstar Plus CPAP machine causing Plaintiff Salvatore DiGrazia's development of brain cancer, then neither Plaintiff nor Plaintiff's physician or medical supplier would have chosen the Device to clean and sterilize his CPAP Device.

71. As a direct and proximate result of use of the SoClean Device, Plaintiff Salvatore DiGrazia has suffered significant harm, including but not limited to:

(a) the development of brain cancer and attendant hospitalizations;

(b) the development of life-threatening glioblastoma/glioma and its invasive treatment;

(c) past and future pain and suffering, both in mind and in body;

(d) permanent diminishment of Plaintiff's ability to participate in and enjoy the affairs of life;

(e) medical bills associated with the treatment of brain cancer and recovery therefrom;

(f) future medical expenses;

(g) loss of enjoyment of life;

(h) disfigurement; and

(i) physical impairment.

72. As a direct and proximate result of Plaintiff Salvatore DiGrazia's use of the SoClean Device, Plaintiff Maryann DiGrazia has suffered significant harm, including but not limited to the loss of care, comfort, society, and affections from Plaintiff.

FIRST CAUSE OF ACTION

STRICT PRODUCTS LIABILITY
DEFECTIVE DESIGN

73. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

A. AS TO THE PHILIPS AND BURNETT DEFENDANTS

74. At all times herein mentioned, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed the Philips REMstar Plus CPAP Device as hereinabove described that was prescribed to and used by Plaintiff Salvatore DiGrazia.

75. Defendants each had a duty to place into the stream of commerce, manufacture, distribute, market, promote and sell the Philips REMstar CPAP Device so that it was neither defective nor unreasonably dangerous when used for which it was designed, manufactured, distributed, marketed, and sold.

76. At all times herein mentioned, the Philips REMstar CPAP Device was in an unsafe, defective, and inherently dangerous condition for users such as Plaintiff Salvatore DiGrazia.

77. At all times of use of the Device by Plaintiff Salvatore DiGrazia, the Device was being used for the purposes and in a manner normally intended, namely for use as treatment for sleep apnea.

78. At the time the Devices left the possession of Defendants and the time the Philips REMstar CPAP Devices entered the stream of commerce, they were in an unreasonably dangerous or defective condition. These defects include, but are not limited to, the following:

(a) the Devices were not reasonably safe as intended to be used;

(b) the Devices had an inadequate design for the purpose of treatment of sleep apnea, in that the sound abatement foam should not release toxic and carcinogenic particles and should not have been placed in the Device's airpath where such particles would then travel directly into patients' lungs and bodies;

(c) the Devices contained unreasonably dangerous design defects, including an inherently defective design, i.e., placement of a sound abatement foam that releases toxic and carcinogenic particles directly in the airpath of the Device, from where such particles could easily travel to the user;

(d) the Devices' defective design resulted in a CPAP Device which had risks that far exceeded the benefits of the medical device;

(e) the Devices were not appropriately or adequately tested before their distribution; and

(f) the Devices have an unreasonably high propensity for the release of toxic and carcinogenic particles under normal and expected use of the Devices.

(g) the Devices have built-in settings for heat and humidity that are expected to be utilized during normal use, and according to Philips such environmental factors may exacerbate the release of toxic and carcinogenic particles from the sound abatement foam in the Devices.

79. At all times herein mentioned, the Devices were expected to and did reach the usual consumers, handlers, and persons coming into contact with said products without substantial change in the condition in which it was designed, produced, manufactured, sold, distributed, and marketed by Defendants.

80. The Philips REMstar Plus CPAP Device's unsafe, defective, and inherently dangerous conditions were the cause of injury to Plaintiff.

81. The Devices failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner.

82. Plaintiffs' injuries resulted from use of the Device that was both intended and reasonably foreseeable by Defendants.

83. At the time of Defendants' initial design, manufacture, marketing and sale of the Devices, a feasible, alternative safer design for the Devices was known and available to Philips.

84. At the time of and subsequent to Defendants' initial design, manufacture, marketing and sale of the Devices, including prior to the time of Plaintiff's initial purchase and use of the Device, Defendants had the ability to eliminate the unsafe character of the Devices without impairing their usefulness, as by either using non-toxic, non-carcinogenic sound abatement foam, or by simply placing the sound abatement foam anywhere else in the Device besides the Device's airpath, among other reasonable alternatives.

85. Had Defendants properly and adequately tested the Devices, Defendants would have discovered that the sound abatement foam had a high propensity for releasing toxic and carcinogenic particles when used normally by patients.

86. The Philips REMstar CPAP Devices, manufactured and supplied by Defendants, were, therefore, defective in design or formulation in that, when they left the hands of Defendants, the foreseeable risk of harm from the product exceeded or outweighed the benefit or utility of the Devices' particular design or formulation, and/or it was unreasonably dangerous to the user or consumer, and/or it failed to comply with federal requirements for these medical devices.

87. The foreseeable risks associated with the design or formulation of the Philips REMstar Plus CPAP Devices include, but are not limited to, the fact that the design or formulation of these Devices are more dangerous than a reasonably prudent consumer would

expect when used in an intended or reasonably foreseeable manner, and/or it failed to comply with federal requirements.

88. At all times herein mentioned, the Defendants knew, or should have known, that the Devices were in a defective condition, and were inherently dangerous and unsafe for use.

89. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed defective products which, when used in their intended or reasonably foreseeable manner, created an unreasonable risk to the health of consumers and to Plaintiff Salvatore DiGrazia, in particular, and Defendants are therefore strictly liable for the injuries sustained by Plaintiffs Salvatore DiGrazia.

90. As a direct and proximate result of Plaintiff's use of Defendants' REMstar Plus CPAP Device, as manufactured, designed, sold, supplied, marketed and introduced into the stream of commerce by Defendants and/or their failure to comply with federal requirements, Plaintiff Salvatore DiGrazia has suffered serious physical injury, harm, damages, and economic loss and will continue to suffer such harm, damages and economic loss in the future, and is entitled to compensatory damages, and seeks a monetary award and damages as set forth below.

B. AS TO THE SOCLEAN DEFENDANTS

91. At all times herein mentioned, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed the SoClean 2 Device as hereinabove described that was prescribed to and used by Plaintiff Salvatore DiGrazia.

92. Defendants each had a duty to place into the stream of commerce, manufacture, distribute, market, promote and sell the SoClean 2 Device so that it was neither defective nor unreasonably dangerous when used for which it was designed, manufactured, distributed, marketed, and sold.

93. At all times herein mentioned, the SoClean 2 Device was in an unsafe, defective, and inherently dangerous condition for users such as Plaintiff Salvatore DiGrazia.

94. At all times of use of the Device by Plaintiff Salvatore DiGrazia, the Device was being used for the purposes and in a manner normally intended, namely for cleaning and sterilizing CPAP Devices/machines.

95. At the time the Devices left the possession of Defendants and the time the SoClean Devices entered the stream of commerce, they were in an unreasonably dangerous or defective condition. These defects include, but are not limited to, the following:

(a) the Devices were not reasonably safe as intended to be used;

(b) the Devices had an inadequate design for the purpose of cleaning and sterilizing CPAP machines in that they emit high levels of ozone and cause degradation of the sound abatement foam in Philips CPAP machines which caused the release of toxic and carcinogenic particles which would then travel directly into patients' lungs and bodies;

(c) the Devices contained unreasonably dangerous design defects, including an inherently defective design;

(d) the Devices' defective design resulted in a SoClean 2 Device which had risks that far exceeded the benefits of the medical device;

(e) the Devices were not appropriately or adequately tested before their distribution; and

(f) the Devices have an unreasonably high propensity for the release of toxic and carcinogenic particles under normal and expected use of the Devices because they

release high levels of ozone and/or cause the degradation of the sound abatement foam in Philips CPAP machines.

96. At all times herein mentioned, the Devices were expected to and did reach the usual consumers, handlers, and persons coming into contact with said products without substantial change in the condition in which it was designed, produced, manufactured, sold, distributed, and marketed by Defendants.

97. The SoClean 2 Device's unsafe, defective, and inherently dangerous conditions were the cause of injury to Plaintiff.

98. The Devices failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner.

99. Plaintiffs' injuries resulted from use of the Device that was both intended and reasonably foreseeable by Defendants.

100. At the time of Defendants' initial design, manufacture, marketing and sale of the Devices, a feasible, alternative safer design for the Devices was known and available to SoClean.

101. At the time of and subsequent to Defendants' initial design, manufacture, marketing and sale of the Devices, including prior to the time of Plaintiff's initial purchase and use of the Device, Defendants had the ability to eliminate the unsafe character of the Devices without impairing their usefulness.

102. Had Defendants properly and adequately tested the Devices, Defendants would have discovered that the Device emitted ozone and/or contributed to the degradation of sound abatement foam in Philips CPAP machines thereby causing a high propensity for releasing toxic and carcinogenic particles when used normally by patients.

103. The SoClean Devices, manufactured and supplied by Defendants, were, therefore, defective in design or formulation in that, when they left the hands of Defendants, the foreseeable risk of harm from the product exceeded or outweighed the benefit or utility of the Devices' particular design or formulation, and/or it was unreasonably dangerous to the user or consumer, and/or it failed to comply with federal requirements for these medical devices.

104. The foreseeable risks associated with the design or formulation of the SoClean Devices include, but are not limited to, the fact that the design or formulation of these Devices are more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner, and/or it failed to comply with federal requirements.

105. At all times herein mentioned, the Defendants knew, or should have known, that the Devices were in a defective condition, and were inherently dangerous and unsafe for use.

106. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed defective products which, when used in their intended or reasonably foreseeable manner, created an unreasonable risk to the health of consumers and to Plaintiff Salvatore DiGrazia, in particular, and Defendants are therefore strictly liable for the injuries sustained by Plaintiff Salvatore DiGrazia.

107. As a direct and proximate result of Plaintiff's use of Defendants' SoClean 2 Device, as manufactured, designed, sold, supplied, marketed and introduced into the stream of commerce by Defendants and/or their failure to comply with federal requirements, Plaintiff Salvatore DiGrazia has suffered serious physical injury, harm, damages, and economic loss and will continue to suffer such harm, damages and economic loss in the future, and is entitled to compensatory damages, and seeks a monetary award and damages as set forth below.

SECOND CAUSE OF ACTION

STRICT PRODUCTS LIABILITY
FAILURE TO WARN

108. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

A. AS TO THE PHILIPS AND BURNETT DEFENDANTS

109. At all times relevant herein, Defendants were engaged in the design, development, testing, manufacturing, marketing, and sale of the Philips REMstar Plus CPAP Device.

110. Defendants designed, manufactured, assembled, and sold the Philips REMstar Plus CPAP Device to medical distributors and patients knowing that they would then be used by patients to treat sleep apnea.

111. The Devices placed into the stream of commerce by Defendants were defective due to inadequate warnings, because Defendants knew or should have known that the Device could release toxic and/or carcinogenic particles in patients when used and therefore give rise to serious physical injury, pain and suffering, debilitation, and death, but failed to give consumers adequate warning of such risks.

112. Defendants had a duty to warn their sales representatives/distributors, prescribing sleep doctors, and patients such as Plaintiff, and Defendants breached their duty in that they failed to provide adequate and timely warnings or instructions regarding their Philips REMstar Plus CPAP Device, and its known defects and potential risks, including its propensity to release toxic and/or carcinogenic particles when used normally.

113. Adequate efforts to communicate an adequate warning to the ultimate users were not made by Defendants (or Defendants' sales representatives/distributors).

114. Defendants are strictly liable to Plaintiff because the warnings to Plaintiff, Plaintiff's medical equipment supplier and Plaintiff's prescribing physician about the dangers the Philips REMstar Plus CPAP Device posed to consumers when used were inadequate. Examples of the lack and/or inadequacy of Defendants' warnings include, but are not limited to, one or more of the following particulars:

(a) the Devices contained warnings insufficient to alert Plaintiff, Plaintiff's medical equipment supplier and Plaintiff's physicians as to the risk of adverse events, i.e., respiratory issues, development of disease like cancer, and even death, associated with use of the Philips REMstar Plus CPAP Device, subjecting the Plaintiff to risks which exceeded the benefits of the Devices;

(b) the Devices contained warnings insufficient to alert Plaintiff and Plaintiff's physicians as to the release of toxic and carcinogenic particles when used normally;

(c) the Devices contained misleading warnings emphasizing the efficacy of the Device while downplaying the risks associated with its use, thereby making use more dangerous than the ordinary consumer would expect;

(d) the Devices contained insufficient and/or incorrect warnings to alert consumers, including Plaintiff, the medical supplier, and the prescribing physicians, regarding the risk, scope, propensity, frequency, duration and severity of the adverse events associated with use of Device;

(e) the Devices did not disclose that they were inadequately tested;

(f) the Devices failed to convey adequate post-marketing warnings regarding the risk, severity, propensity, frequency, scope and/or duration of the dangers posed by normal use of the Devices to treat sleep apnea;

(g) the Devices failed to contain instructions sufficient to alert consumers to the dangers they posed and to give them the information necessary to avoid or mitigate those dangers.

115. Further, Philips REMstar Plus CPAP Device is unreasonably dangerous because it was sold to Plaintiff Salvatore DiGrazia without an adequate warning that when used normally, the PE-PUR sound abatement foam will release toxic and carcinogenic particles that can lead to serious injury or death.

116. There are other manufacturers of sleep apnea machines on the market that do not contain this foam design defect and Plaintiff Salvatore DiGrazia could have chosen to acquire a different model and brand had this defect been disclosed.

117. The Devices placed into the stream of commerce by Defendants were used by patients like Plaintiff in a manner reasonably anticipated by Defendants.

118. As a direct and proximate result of Defendants' failure to adequately communicate a warning and/or failure to provide an adequate warning and other wrongful conduct as set forth herein, Plaintiff Salvatore DiGrazia has suffered serious physical injury, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future, and is entitled to compensatory damages, and seeks a monetary award and damages as set forth below.

B. AS TO THE SOCLEAN DEFENDANTS

119. At all times relevant herein, Defendants were engaged in the design, development, testing, manufacturing, marketing, and sale of the SoClean 2 Device.

120. Defendants designed, manufactured, assembled, and sold the SoClean 2 Device to medical distributors and patients knowing that they would then be used by patients to clean and sterilize CPAP machines.

121. The Devices placed into the stream of commerce by Defendants were defective due to inadequate warnings, because Defendants knew or should have known that the Device released ozone and contributed to the degradation of sound abatement foam in Philips CPAP machines thereby causing a high propensity for releasing toxic and/or carcinogenic particles when used normally by patients and therefore gives rise to serious physical injury, pain and suffering, debilitation, and death, but failed to give consumers adequate warning of such risks.

122. Defendants had a duty to warn their sales representatives/distributors, prescribing sleep doctors, and patients such as Plaintiff, and Defendants breached their duty in that they failed to provide adequate and timely warnings or instructions regarding their SoClean 2 Device, and its known defects and potential risks, including its propensity to release toxic and/or carcinogenic particles when used normally.

123. Adequate efforts to communicate an adequate warning to the ultimate users were not made by Defendants (or Defendants' sales representatives / distributors).

124. Defendants are strictly liable to Plaintiff because the warnings to Plaintiff, Plaintiff's medical equipment supplier and Plaintiff's prescribing physician about the dangers the SoClean 2 Device posed to consumers when used were inadequate. Examples of the lack and/or

inadequacy of Defendants' warnings include, but are not limited to, one or more of the following particulars:

(a) the Devices contained warnings insufficient to alert Plaintiff, Plaintiff's medical equipment supplier and Plaintiff's physicians as to the risk of adverse events, i.e., respiratory issues, development of disease like cancer, and even death, associated with use of the SoClean 2 Device, subjecting the Plaintiff to risks which exceeded the benefits of the Devices;

(b) the Devices contained warnings insufficient to alert Plaintiff and Plaintiff's physicians as to the release of toxic ozone and carcinogenic particles when used normally;

(c) the Devices contained misleading warnings emphasizing the efficacy of the Device while downplaying the risks associated with its use, thereby making use more dangerous than the ordinary consumer would expect;

(d) the Devices contained insufficient and/or incorrect warnings to alert consumers, including Plaintiff, the medical supplier, and the prescribing physicians, regarding the risk, scope, propensity, frequency, duration and severity of the adverse events associated with use of Device;

(e) the Devices did not disclose that they were inadequately tested;

(f) the Devices failed to convey adequate post-marketing warnings regarding the risk, severity, propensity, frequency, scope and/or duration of the dangers posed by normal use of the Devices to clean and sterilize CPAP machines;

(g) the Devices failed to contain instructions sufficient to alert consumers to the dangers they posed and to give them the information necessary to avoid or mitigate those dangers.

125. Further, the SoClean 2 Device is unreasonably dangerous because it was sold to Plaintiff Salvatore DiGrazia without an adequate warning that when used normally, the Device released ozone and/or caused and/or contributed to the degradation of sound abatement foam in Philips CPAP machines thereby causing a high propensity for releasing toxic and/or carcinogenic particles when used normally by patients that can lead to serious injury or death.

126. There are other manufacturers of CPAP cleaning devices on the market that do not release ozone and/or that do not cause degradation of sound abatement foam and Plaintiff Salvatore DiGrazia could have chosen to acquire a different model and brand had this defect been disclosed.

127. The Devices placed into the stream of commerce by Defendants were used by patients like Plaintiff in a manner reasonably anticipated by Defendants.

128. As a direct and proximate result of Defendants' failure to adequately communicate a warning and/or failure to provide an adequate warning and other wrongful conduct as set forth herein, Plaintiff Salvatore DiGrazia has suffered serious physical injury, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future, and is entitled to compensatory damages, and seeks a monetary award and damages as set forth below.

THIRD CAUSE OF ACTION

STRICT PRODUCTS LIABILITY MANUFACTURING DEFECT and FAILURE TO ADHERE TO QUALITY CONTROLS

129. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

A. AS TO THE PHILIPS AND BURNETT DEFENDANTS

130. The recalled Devices, including Plaintiff's Device, are defectively manufactured because the foreseeable risks of cancer and other serious injury and illness outweigh the benefits associated with the Devices.

131. The Philips REMstar Plus CPAP Device was designed and/or manufactured in a manner violative of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321 et seq., and the Medical Devices Amendment thereto (hereafter "FDCA"). The facilities or controls used by defendants in the manufacture, testing, packing, storage, or installation of the Devices were not in conformity with applicable requirements of the FDCA.

132. The Philips REMstar Plus CPAP Device was expected to and did reach the Plaintiff without substantial change or adjustment to its function.

133. Defendants knew or should have known of the manufacturing defects and the risk of serious bodily injury that exceeded the benefits associated with the Philips REMstar Plus CPAP Device.

134. Furthermore, the Philips REMstar Plus CPAP Device and its defects presented an unreasonably dangerous risk beyond what the ordinary consumer would reasonably expect.

135. The Philips REMstar Plus CPAP Device is inherently dangerous for its intended use due to a manufacturing defect or defects and improper functioning. Defendants are therefore strictly liable to the Plaintiff for their breach of duty to the Plaintiff.

136. As a direct and proximate result of Defendants' wrongful conduct, the Plaintiff Salvatore DiGrazia has sustained and will continue to sustain severe physical injuries, and the Plaintiff has suffered and will continue to suffer severe emotional distress, mental anguish, and other damages, and is entitled to compensatory damages and seeks a monetary award and damages as set forth below.

137. The recalled Devices, including Plaintiff's Device, are defectively manufactured because the foreseeable risks of cancer and other serious injury and illness outweigh the benefits associated with the Devices.

138. The SoClean 2 Device was designed and/or manufactured in a manner violative of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321 et seq., and the Medical Devices Amendment thereto (hereafter "FDCA"). The facilities or controls used by defendants in the manufacture, testing, packing, storage, or installation of the Devices were not in conformity with applicable requirements of the FDCA.

139. The SoClean 2 Device was expected to and did reach the Plaintiff without substantial change or adjustment to its function.

140. Defendants knew or should have known of the manufacturing defects and the risk of serious bodily injury that exceeded the benefits associated with the SoClean 2 Device.

141. Furthermore, the SoClean Device 2 and its defects presented an unreasonably dangerous risk beyond what the ordinary consumer would reasonably expect.

142. The SoClean 2 Device is inherently dangerous for its intended use due to a manufacturing defect or defects and improper functioning. Defendants are therefore strictly liable to the Plaintiff for their breach of duty to the Plaintiff.

143. As a direct and proximate result of Defendants' wrongful conduct, the Plaintiff Salvatore DiGrazia has suffered serious physical injury, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future, and is entitled to compensatory damages, and seeks a monetary award and damages as set forth below.

FOURTH CAUSE OF ACTION

NEGLIGENCE

144. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

A. AS TO THE PHILIPS AND BURNETT DEFENDANTS

145. While the focus of Plaintiff's strict liability claims (Claims I-III) is on the condition of the product, the focus of Plaintiff's negligence claim is instead on Defendants' conduct. Defendants had a duty to exercise reasonable care in the design, formulation, manufacture, testing, quality assurance, quality control, labeling, warning, sale and/or distribution of the Philips REMstar Plus CPAP Device, including a duty to assure that their products did not pose a significantly increased risk of life-threatening bodily harm and disease.

146. Defendants failed to exercise reasonable care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, warning, marketing, promotions, and distribution of the Philips REMstar Plus CPAP Device in that Defendants knew or should have known that these products caused significant bodily harm and were not safe for use by consumers.

147. The negligence of Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

(a) Negligently designing the recalled Devices' PE-PUR sound abatement foam such that it has a high propensity to release toxic and carcinogenic particles during normal use of the Device;

(b) Negligently designing the recalled Devices such that the sound abatement foam is placed in the airpath of the Devices, where the foam's propensity to release toxic and carcinogenic particles is most deleterious to a patient's health because they will directly inhale such toxins and carcinogens;

(c) Negligently designing the recalled products such that they contain built-in settings for use that allow a user to increase the heat and humidity of the air being convected through the Devices' airpaths, despite Defendants knowing that heat and humidity can exacerbate the release of the toxic and carcinogenic particles from the PE-PUR sound abatement foam;

(d) Designing, manufacturing, producing, creating, and/or promoting the Devices for use in treating sleep apnea without adequately, sufficiently, or thoroughly testing them, including both pre-market testing and post-market surveillance;

(e) Not conducting sufficient testing programs to determine whether or not the PE-PUR sound abatement foam was safe for use in the Devices;

(f) Selling the Devices without making proper and sufficient tests to determine the dangers when used in a reasonably foreseeable and normal manner;

(g) Negligently failing to adequately and correctly warn Plaintiff or Plaintiff's physicians, hospitals, healthcare providers, and medical device distributors of the dangers of using the recalled Devices, including:

1) Negligently failing to warn of an increased risk of release of toxic and carcinogenic particles;

2) Negligently failing to warn of the risk of development of serious disease such as cancer or even death;

3) Negligently failing to recall their dangerous and defective CPAP Devices at the earliest date it became known that the Devices were, in fact, dangerous and defective;

4) Negligently advertising and recommending the use of the Devices despite the fact Defendants knew or should have known of their dangerous propensities;

5) Negligently representing that the Devices were safe for their intended use, when in fact, they were unsafe;

6) Negligently manufacturing the Devices in a manner which was dangerous to those individuals who used them;

(h) Defendants under-reported, underestimated, and downplayed the serious dangers associated with the PE-PUR sound abatement foam used in all of the recalled Devices;

(i) Defendants failed to use due care in designing and manufacturing the Devices so as to ensure good performance and durability and reduce the risk of

degradation and off-gassing of toxic and carcinogenic particles that could be directly inhaled by the user;

(j) Failed to accompany their products with proper warnings;

(k) Failed to accompany their products with proper instructions for use;

(l) Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of the recalled Devices when used normally;

(m) Were otherwise careless and/or negligent.

148. Despite the fact that Defendants knew or should have known that use of the Philips REMstar Plus CPAP Device caused harm to individuals that used the Devices, Defendants continued to market, manufacture, distribute and/or sell the Philips REMstar CPAP Device for use in treating sleep apnea.

149. Defendants knew or should have known that consumers such as Plaintiff would suffer foreseeable injury, and/or be at increased risk of suffering injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

150. Defendants, furthermore, in advertising, marketing, promoting, packaging, and selling the Devices negligently misrepresented material facts regarding their safety, efficacy and fitness for human use by claiming the Devices were fit for their intended purpose of use when, in fact, they were not.

151. Defendants' negligence was the proximate cause of Plaintiff's physical, mental and emotional injuries and harm, and economic loss which Plaintiff has suffered and/or will continue to suffer.

152. By reason of the foregoing, Plaintiff experienced and will continue to experience severe harmful effects as a result of the Defendants' negligence as set forth above.

153. Defendants' conduct, as described above, including, but not limited to, Defendants' failure to adequately test and warn, as well as their continued marketing and distribution of the Philips REMstar Plus CPAP Device when they knew or should have known of the serious health risks these Devices created when used normally by patients such as Plaintiff was negligent.

154. As a direct and proximate result of Defendants' negligence, including negligent testing, failure to warn and misrepresentations, Plaintiff Salvatore DiGrazia has suffered serious physical injury, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future, and is entitled to compensatory damages, and seeks a monetary award and damages as set forth below.

B. AS TO THE SOCLEAN DEFENDANTS

155. While the focus of Plaintiff's strict liability claims (Claims I-III) is on the condition of the product, the focus of Plaintiff's negligence claim is instead on Defendants' conduct. Defendants had a duty to exercise reasonable care in the design, formulation, manufacture, testing, quality assurance, quality control, labeling, warning, sale and/or distribution of the SoClean 2 Device, including a duty to assure that their products did not pose a significantly increased risk of life-threatening bodily harm and disease.

156. Defendants failed to exercise reasonable care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, warning, marketing, promotions, and distribution of the SoClean 2 Device in that Defendants knew or should have

known that these products caused significant bodily harm and were not safe for use by consumers.

157. The negligence of Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

(a) Negligently designing the recalled Devices to emit toxic levels of ozone such that it has a high propensity to release toxic and carcinogenic particles during normal use of the Device;

(b) Negligently designing the recalled Devices such that they cause the degradation of the sound abatement foam of CPAP Devices, thereby causing the foam to release toxic and carcinogenic particles and is most deleterious to a patient's health because they will directly inhale such toxins and carcinogens;

(c) Designing, manufacturing, producing, creating, and/or promoting the Devices for use in cleaning and sterilizing CPAP machines without adequately, sufficiently, or thoroughly testing them, including both pre-market testing and post-market surveillance;

(d) Not conducting sufficient testing programs to determine whether or not the SoClean 2 Device was safe to use;

(e) Selling the Devices without making proper and sufficient tests to determine the dangers when used in a reasonably foreseeable and normal manner;

(f) Negligently failing to adequately and correctly warn Plaintiff or Plaintiff's physicians, hospitals, healthcare providers, and medical device distributors of the dangers of using the recalled Devices, including:

1) Negligently failing to warn of an increased risk of release of ozone and/or toxic and carcinogenic particles;

2) Negligently failing to warn of the risk of development of serious disease such as cancer or even death;

3) Negligently failing to recall their dangerous and defective SoClean 2 Devices at the earliest date it became known that the Devices were, in fact, dangerous and defective;

4) Negligently advertising and recommending the use of the Devices despite the fact Defendants knew or should have known of their dangerous propensities;

5) Negligently representing that the Devices were safe for their intended use, when in fact, they were unsafe;

6) Negligently manufacturing the Devices in a manner which was dangerous to those individuals who used them;

(g) Defendants under-reported, underestimated, and downplayed the serious dangers associated with the release of ozone and the degradation of PE-PUR sound abatement foam used in CPAP Devices in all of the recalled Devices;

(h) Defendants failed to use due care in designing and manufacturing the Devices so as to ensure good performance and durability and reduce ozone release and the risk of degradation sound abatement foam in CPAP machines and off-gassing of toxic and carcinogenic particles and/or ozone that could be directly inhaled by the user;

(i) Failed to accompany their products with proper warnings;

(j) Failed to accompany their products with proper instructions for use;

(k) Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of the recalled Devices when used normally;

(l) Were otherwise careless and/or negligent.

158. Despite the fact that Defendants knew or should have known that use of the SoClean 2 Device caused harm to individuals that used the Devices, Defendants continued to market, manufacture, distribute and/or sell the SoClean 2 Device for use in cleaning and sterilizing CPAP machines.

159. Defendants knew or should have known that consumers such as Plaintiff would suffer foreseeable injury, and/or be at increased risk of suffering injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

160. Defendants, furthermore, in advertising, marketing, promoting, packaging, and selling the Devices negligently misrepresented material facts regarding their safety, efficacy and fitness for human use by claiming the Devices were fit for their intended purpose of use when, in fact, they were not.

161. Defendants' negligence was the proximate cause of Plaintiff's physical, mental, and emotional injuries and harm, and economic loss which Plaintiff has suffered and/or will continue to suffer.

162. By reason of the foregoing, Plaintiff experienced and will continue to experience severe harmful effects as a result of the Defendants' negligence as set forth above.

163. Defendants' conduct, as described above, including, but not limited to, Defendants' failure to adequately test and warn, as well as their continued marketing and distribution of the SoClean 2 Devices when they knew or should have known of the serious

health risks these Devices created when used normally by patients such as Plaintiff was negligent.

164. As a direct and proximate result of Defendants' negligence, including negligent testing, failure to warn and misrepresentations, Plaintiff Salvatore DiGrazia has suffered serious physical injury, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future, and is entitled to compensatory damages, and seeks a monetary award and damages as set forth below.

FIFTH CAUSE OF ACTION

NEGLIGENT MISREPRESENTATION

165. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

A. AS TO THE PHILIPS AND BURNETT DEFENDANTS

166. Defendants supplied false information to the public, to Plaintiff and to Plaintiff's physicians regarding the high-quality, safety and effectiveness of the Philips REMstar Plus CPAP Device. Defendants provided this false information to induce the public, Plaintiff and Plaintiff's physicians to purchase and use the Philips REMstar Plus CPAP Device.

167. Defendants knew or should have known that the information they supplied regarding the purported high-quality, safety and effectiveness of the Devices would induce Plaintiff and Plaintiff's physicians to purchase/rent and use the Philips REMstar Plus CPAP Device was false and misleading.

168. Defendants were negligent in obtaining or communicating false information regarding the purported high-quality, safety and effectiveness of the Philips REMstar Plus CPAP Device.

169. Plaintiff and Plaintiff's physicians relied on the false information supplied by Defendants to Plaintiff's detriment by causing the Philips REMstar CPAP Device to be purchased/rented and used by Plaintiff.

170. Plaintiff and Plaintiff's physicians were justified in their reliance on the false information supplied by Defendants regarding the purported high-quality, safety and effectiveness of the Philips REMstar Plus CPAP Device.

171. As a direct and proximate result of Defendants' negligent misrepresentations, Plaintiff Salvatore DiGrazia has suffered serious physical injury, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future, and is entitled to compensatory damages, and seeks a monetary award and damages as set forth below.

B. AS TO THE SOCLEAN DEFENDANTS

172. Defendants supplied false information to the public, to Plaintiff and to Plaintiff's physicians regarding the high-quality, safety and effectiveness of the SoClean 2 Device. Defendants provided this false information to induce the public, Plaintiff and Plaintiff's physicians to purchase and use the SoClean 2 Device.

173. Defendants knew or should have known that the information they supplied regarding the purported high-quality, safety and effectiveness of the Devices would induce Plaintiff and Plaintiff's physicians to purchase and use the SoClean 2 Device was false and misleading.

174. Defendants were negligent in obtaining or communicating false information regarding the purported high-quality, safety and effectiveness of the SoClean 2 Device.

175. Plaintiff and Plaintiff's physicians relied on the false information supplied by Defendants to Plaintiff's detriment by causing the SoClean 2 Device to be purchased and used by Plaintiff.

176. Plaintiff and Plaintiff's physicians were justified in their reliance on the false information supplied by Defendants regarding the purported high-quality, safety and effectiveness of the SoClean 2 Device.

177. As a direct and proximate result of Defendants' negligent misrepresentations, Plaintiff Salvatore DiGrazia has suffered serious physical injury, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future, and is entitled to compensatory damages, and seeks a monetary award and damages as set forth below.

SIXTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY

178. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

A. AS TO THE PHILIPS AND BURNETT DEFENDANTS

179. Defendants expressly warranted that the Philips REMstar Plus CPAP Device was a safe and effective medical device to be used for patients suffering from sleep apnea.

180. At the time Defendants marketed, sold and/or distributed the Philips REMstar Plus CPAP Device, they knew that the Devices were intended for human use, and that Plaintiff was a foreseeable user of the Devices.

181. The express warranties represented by Defendants were a part of the basis for Plaintiff's use of the Device, and Plaintiff and Plaintiff's physician relied on these warranties in deciding to use the Device.

182. At the time of the making of the express warranties, Defendants had knowledge of the purpose for which the Devices were to be used and warrantied the same to be in all respects safe, effective, and proper for such purpose.

183. The Devices do not conform to these express representations as shown by the development of brain cancer in Plaintiff Salvatore DiGrazia.

184. At the time Defendants marketed, sold and/or distributed the recalled Devices, Defendants expressly warranted that the recalled Devices were safe for their intended use.

185. Plaintiff and Plaintiff's prescribing physician reasonably relied upon Defendants' express warranties.

186. Plaintiff used the Device for its intended purpose, and in a reasonably foreseeable manner.

187. The Philips REMstar Plus CPAP Device manufactured and sold by Defendants did not conform to Defendants' express representations because the Device caused serious injury to Plaintiff when used as recommended and directed.

188. As a direct and proximate result of Defendants' breach of express warranty, Plaintiff Salvatore DiGrazia has suffered serious physical injury, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future, and is entitled to compensatory damages, and seeks a monetary award and damages as set forth below.

B. AS TO THE SOCLEAN DEFENDANTS

189. Defendants expressly warranted that the SoClean Device was a safe and effective medical device to be used by patients to clean and sterilize their CPAP machines.

190. At the time Defendants marketed, sold and/or distributed the SoClean Device, they knew that the Devices were intended for human use, and that Plaintiff was a foreseeable user of the Devices.

191. The express warranties represented by Defendants were a part of the basis for Plaintiff's use of the Device, and Plaintiff and Plaintiff's physician relied on these warranties in deciding to use the Device.

192. At the time of the making of the express warranties, Defendants had knowledge of the purpose for which the Devices were to be used and warrantied the same to be in all respects safe, effective, and proper for such purpose.

193. The Devices do not conform to these express representations as shown by the development of brain cancer in Plaintiff Salvatore DiGrazia.

194. At the time Defendants marketed, sold and/or distributed the recalled Devices, Defendants expressly warranted that the recalled Devices were safe for their intended use.

195. Plaintiff and Plaintiff's prescribing physician reasonably relied upon Defendants' express warranties.

196. Plaintiff used the Device for its intended purpose, and in a reasonably foreseeable manner.

197. The SoClean 2 Device manufactured and sold by Defendants did not conform to Defendants' express representations because the Device caused serious injury to Plaintiff when used as recommended and directed.

198. As a direct and proximate result of Defendants' breach of express warranty, Plaintiff Salvatore DiGrazia has suffered serious physical injury, harm, damages, and economic

loss and will continue to suffer such harm, damages, and economic loss in the future, and is entitled to compensatory damages, and seeks a monetary award and damages as set forth below.

SEVENTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTIES OF MERCHANTABILITY AND FOR A PARTICULAR PURPOSE

199. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

A. AS TO THE PHILIPS AND BURNETT DEFENDANTS

200. At the time Defendants designed, manufactured, marketed, sold, and distributed the Philips REMstar Plus CPAP Device for use by Plaintiff, Defendants knew of the use for which these Devices were intended and impliedly warranted these products to be of merchantable quality and safe for such use and that their design, manufacture, labeling and marketing complied with all applicable federal requirements.

201. The Philips REMstar Plus CPAP Device manufactured and supplied by Defendants were not of merchantable quality and were not fit for the ordinary and/or particular purpose for which they were intended as, among other defects, the risks included an unreasonably high risk of developing cancer or other serious illness due to the release of toxic and carcinogenic particles from the Device's PE-PUR sound abatement foam.

202. Plaintiff and/or Plaintiff's physician reasonably relied upon the skill and judgment of Defendants as to whether the Philips REMstar Plus CPAP Device were of merchantable quality and safe for their intended and particular use and purpose, and upon Defendants' implied warranty as to such matters.

203. Contrary to such implied warranties, the Philips REMstar Plus CPAP Device was not of merchantable quality or safe for its intended and particular use and purpose, because the product was defective when used normally as described above, and/or failed to comply with federal requirements.

204. As a direct and proximate result of Defendants' breach of implied warranties, Plaintiff Salvatore DiGrazia has suffered serious physical injury, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future, and is entitled to compensatory damages, and seeks a monetary award and damages as set forth below.

B. AS TO THE SOCLEAN DEFENDANTS

205. At the time Defendants designed, manufactured, marketed, sold, and distributed the SoClean 2 Device for use by Plaintiff, Defendants knew of the use for which these Devices were intended and impliedly warranted these products to be of merchantable quality and safe for such use and that their design, manufacture, labeling, and marketing complied with all applicable federal requirements.

206. The SoClean 2 Device manufactured and supplied by Defendants were not of merchantable quality and were not fit for the ordinary and/or particular purpose for which they were intended as, among other defects, the risks included an unreasonably high risk of developing cancer or other serious illness due to the release of ozone and/or toxic and carcinogenic particles as a result of degradation of the PE-PUR sound abatement foam from CPAP Devices.

207. Plaintiff and/or Plaintiff's physician reasonably relied upon the skill and judgment of Defendants as to whether the SoClean 2 Device was of merchantable quality and

safe for their intended and particular use and purpose, and upon Defendants' implied warranty as to such matters.

208. Contrary to such implied warranties, the SoClean 2 Device was not of merchantable quality or safe for its intended and particular use and purpose, because the product was defective when used normally as described above, and/or failed to comply with federal requirements.

209. As a direct and proximate result of Defendants' breach of implied warranties, Plaintiff Salvatore DiGrazia has suffered serious physical injury, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future, and is entitled to compensatory damages, and seeks a monetary award and damages as set forth below.

EIGHTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE

210. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

A. AS TO THE PHILIPS AND BURNETT DEFENDANTS

211. Defendants designed, manufactured, tested, marketed, and distributed into the stream of commerce the Philips REMstar Plus CPAP Device.

212. At the time Defendants designed, manufactured, tested, marketed, and distributed into the stream of commerce the Philips REMstar Plus CPAP Device. Defendants knew the use for which the Philips REMstar Plus CPAP Device was intended, and impliedly warranted the Philips REMstar Plus CPAP Device to be safe for such use.

213. Plaintiff and/or Plaintiff's physician reasonably relied upon the skill and judgment of Defendants as to whether the Philips REMstar Plus CPAP Device were safe for its intended use.

214. Contrary to Defendants' implied warranties, the Philips REMstar Plus CPAP Device was not fit for its intended and particular use and purpose, because the Device was defective when used as described above, and/or failed to comply with federal requirements.

215. As a direct and proximate result of Defendants' breach of implied warranties, Plaintiff Salvatore DiGrazia has suffered serious physical injury, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future, and is entitled to compensatory damages, and seeks a monetary award and damages as set forth below.

B. AS TO THE SOCLEAN DEFENDANTS

216. Defendants designed, manufactured, tested, marketed, and distributed into the stream of commerce the SoClean 2 Device.

217. At the time Defendants designed, manufactured, tested, marketed, and distributed into the stream of commerce the SoClean 2 Device. Defendants knew the use for which the SoClean 2 Device was intended, and impliedly warranted the SoClean 2 Device to be safe for such use.

218. Plaintiff and/or Plaintiff's physician reasonably relied upon the skill and judgment of Defendants as to whether the SoClean 2 Device was safe for its intended use.

219. Contrary to Defendants' implied warranties, the SoClean 2 Device was not fit for its intended and particular use and purpose, because the Device was defective when used as described above, and/or failed to comply with federal requirements.

220. As a direct and proximate result of Defendants' breach of implied warranties, Plaintiff Salvatore DiGrazia has suffered serious physical injury, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future, and is entitled to compensatory damages, and seeks a monetary award and damages as set forth below.

NINTH CAUSE OF ACTION

VIOLATION OF THE NEW YORK DECEPTIVE PRACTICES ACT (NY Gen. Bus. Law Section 349 and 350, et. seq.) and THE PENNSYLVANIA UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION LAW (73 Pa. Cons. Stat. Ann. §§ 201-1, et seq.)

221. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

A. AS TO THE PHILIPS AND BURNETT DEFENDANTS

222. Defendants unfairly, unconscionably, and deceptively advertised, marketed, sold, and represented the Philips REMstar Plus CPAP Device as a high-quality, safe, and effective medical device for treatment of sleep apnea to Plaintiff and Plaintiff's physicians.

223. Before they advertised, marketed, sold, and represented the Philips REMstar Plus CPAP Device that were used by Plaintiff, Defendants knew or should have known of the unreasonable dangers and serious health risks that such a Device posed to patients like Plaintiff.

224. Plaintiff purchased/rented and used the Philips REMstar Plus CPAP Device for personal use and thereby suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

225. Had Defendants not engaged in the deceptive conduct described herein, Plaintiff would not have purchased/rented and/or paid for the Philips REMstar Plus CPAP Device and would not have incurred related medical costs and injury.

226. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiff for the Philips REMstar Plus CPAP Device that would not have been paid had Defendants not engaged in unfair and deceptive conduct.

227. Unfair methods of competition or deceptive acts or practices that are proscribed by law, include the following:

(a) Representing that goods or services have characteristics, ingredients, uses, benefits or quantities that they do not have;

(b) Advertising goods or services with the intent not to sell them as advertised; and

(c) Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

228. Plaintiff was injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and consumers was to create demand for and sell the Philips REMstar Plus CPAP Device. Each aspect of Defendants' conduct combined to artificially create sales of the Philips REMstar Plus CPAP Device.

229. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, development, manufacture, promotion, and sale of the Philips REMstar Plus CPAP Device.

230. Had Defendants not engaged in the deceptive conduct described above, Plaintiff would not have purchased and/or paid for the Philips REMstar Plus CPAP Device, and would not have incurred related medical costs.

231. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians, and consumers, including Plaintiff, constituted unfair and deceptive acts and trade practices in violation of the state consumer protection statutes listed.

232. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive, or fraudulent acts, or trade practices in violation of state consumer protection statutes, as listed below.

233. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation of the New York Deceptive Practices Act (NY Gen. bus. Law Sections 349 and 350, et. seq.), and the Pennsylvania Unfair Trade Practices and Consumer Protection Law, (73 Pa. Cons. Stat. Ann. §§ 201-1, et seq.).

234. Under the statutes listed above to protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices and false advertising, Defendants are the suppliers, manufacturers, advertisers, and sellers, who are subject to liability under such legislation for unfair, deceptive, fraudulent, and unconscionable consumer sales practices.

235. Defendants violated the statutes that were enacted to protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the Philips REMstar CPAP Device were fit to be used for the purpose for which they were intended, when in fact these Devices were defective and dangerous, and by other acts alleged herein. These representations were made in uniform promotional materials.

236. The actions and omissions of Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted to protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices and false advertising.

237. Defendants had actual knowledge of the defective and dangerous condition of the Philips REMstar CPAP Device and failed to take any action to cure such defective and dangerous conditions.

238. Plaintiff and the medical community relied upon Defendants' misrepresentations and omissions in determining which CPAP / sleep apnea treatment Device to use and recommend.

239. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians, and consumers, constituted unfair and deceptive acts and practices.

240. By reason of the unlawful acts engaged in by Defendants, and as a direct and proximate result thereof, Plaintiffs have suffered ascertainable losses and damages.

241. As a direct and proximate result of Defendants' violations of New York and Pennsylvania's consumer protection laws, Plaintiffs have sustained economic losses and other damages and is entitled to statutory and compensatory, damages in an amount to be proven at trial.

242. As specifically described in detail above, Defendants knew that the Philips REMstar Plus CPAP Device subjected patients to the release of toxic and carcinogenic particles leading to serious illness, injury, and even death.

243. As a direct and proximately result of Defendants' representations, Plaintiff Salvatore DiGrazia has suffered serious physical injury, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future, and is entitled to compensatory damages, and seeks a monetary award and damages as set forth below.

B. AS TO THE SOCLEAN DEFENDANTS

244. Defendants unfairly, unconscionably, and deceptively advertised, marketed, sold, and represented the SoClean 2 Device as a high-quality, safe, and effective medical device for cleaning and sanitizing CPAP Devices.

245. Before they advertised, marketed, sold, and represented the SoClean 2 Device that was used by Plaintiff, Defendants knew or should have known of the unreasonable dangers and serious health risks that such a Device posed to patients like Plaintiff.

246. Plaintiff purchased and used the SoClean 2 Device for personal use and thereby suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

247. Had Defendants not engaged in the deceptive conduct described herein, Plaintiff would not have purchased and/or paid for the SoClean 2 Device and would not have incurred related medical costs and injury.

248. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiff for the SoClean 2 Device that would not have been paid had Defendants not engaged in unfair and deceptive conduct.

249. Unfair methods of competition or deceptive acts or practices that are proscribed by law, include the following:

(a) Representing that goods or services have characteristics, ingredients, uses, benefits or quantities that they do not have;

(b) Advertising goods or services with the intent not to sell them as advertised; and

(c) Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

250. Plaintiff was injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and consumers was to create demand for and sell the SoClean 2 Device. Each aspect of Defendants' conduct combined to artificially create sales of the SoClean 2 Device.

251. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, development, manufacture, promotion, and sale of the SoClean 2 Device.

252. Had Defendants not engaged in the deceptive conduct described above, Plaintiff would not have purchased and/or paid for the SoClean 2 Device and would not have incurred related medical costs.

253. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians, and consumers, including Plaintiff, constituted unfair and deceptive acts and trade practices in violation of the state consumer protection statutes listed.

254. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive, or fraudulent acts, or trade practices in violation of state consumer protection statutes, as listed below.

255. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation of the New York Deceptive Practices Act (NY Gen. bus. Law Sections 349 and 350, et. seq.), the Pennsylvania Unfair Trade Practices and Consumer Protection Law, (73 Pa. Cons. Stat. Ann. §§ 201-1, et seq.), and the California Consumer Legal Remedies Act, (Cal. Civ. Code § 1770, et seq.).

256. Under the statutes listed above to protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices and false advertising, Defendants are the suppliers, manufacturers, advertisers, and sellers, who are subject to liability under such legislation for unfair, deceptive, fraudulent, and unconscionable consumer sales practices.

257. Defendants violated the statutes that were enacted to protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the SoClean 2 Device was fit to be used for the purpose for which they were intended, when in fact these Devices were defective and dangerous, and by other acts alleged herein. These representations were made in uniform promotional materials.

258. The actions and omissions of Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted to protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices and false advertising.

259. Defendants had actual knowledge of the defective and dangerous condition of the SoClean 2 Device and failed to take any action to cure such defective and dangerous conditions.

260. Plaintiff and the medical community relied upon Defendants' misrepresentations and omissions in determining which CPAP cleaning and sterilizing Device to use and recommend.

261. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians, and consumers, constituted unfair and deceptive acts and practices.

262. By reason of the unlawful acts engaged in by Defendants, and as a direct and proximate result thereof, Plaintiffs have suffered ascertainable losses and damages.

263. As a direct and proximate result of Defendants' violations of New York and Pennsylvania's consumer protection laws, Plaintiffs have sustained economic losses and other damages and is entitled to statutory and compensatory, damages in an amount to be proven at trial.

264. As specifically described in detail above, Defendants knew that the SoClean 2 Device subjected patients to the release of ozone and toxic and carcinogenic particles leading to serious illness, injury, and even death.

265. As a direct and proximately result of Defendants' representations, Plaintiff Salvatore DiGrazia has suffered serious physical injury, harm, damages, and economic loss and will continue to suffer such harm, damages, and economic loss in the future, and is entitled to compensatory damages, and seeks a monetary award and damages as set forth below.

TENTH CAUSE OF ACTION

PUNITIVE DAMAGES

266. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

A. AS TO THE PHILIPS AND BURNETT DEFENDANTS

267. Defendants risked the safety of recipients of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public.

268. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting recipients of its recalled Devices despite knowledge that these Devices were defective and unreasonably dangerous in nature.

269. Defendants knew or ought to have known that this conduct would result in injury or damage, but continued to mislead both the medical community and the public at large, including Plaintiff, by making false representations about the safety and efficacy of the recalled Devices.

270. These acts are wanton and reckless in that the Defendants demonstrated conscious indifference and utter disregard of the consequences of their actions upon the health, safety, and rights of others, including Plaintiff.

271. Additionally, Defendants delayed the recall of the defective Devices while seeking clearance for the next-generation DreamStation 2 Device, which is significantly more expensive than the recalled Devices, and did not disclose to the public any of the risks described herein until after the DreamStation 2 had been made commercially available. Thus, Defendants allowed patients like Plaintiff to continue to be exposed to toxic and carcinogenic particles for a significantly longer period of time while Defendants were attempting to monetize this public health crisis of their own creation.

272. As a direct and proximate result of Defendants' conscious and deliberate disregard for the rights and safety of consumers such as Plaintiff. Plaintiff Salvatore DiGrazia suffered severe and permanent physical injuries as set forth above. Defendants' outrageous conduct warrants an award of punitive damages.

B. AS TO THE SOCLEAN DEFENDANTS

273. Defendants risked the safety of recipients of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public.

274. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting recipients of its recalled Devices despite knowledge that these Devices were defective and unreasonably dangerous in nature.

275. Defendants knew or ought to have known that this conduct would result in injury or damage, but continued to mislead both the medical community and the public at large, including Plaintiff, by making false representations about the safety and efficacy of the recalled Devices.

276. These acts are wanton and reckless in that the Defendants demonstrated conscious indifference and utter disregard of the consequences of their actions upon the health, safety, and rights of others, including Plaintiff.

277. Additionally, Defendants delayed the recall of the defective Devices while seeking clearance for the next-generation Devices, and did not disclose to the public any of the risks. Thus, Defendants allowed patients like Plaintiff to continue to be exposed to toxic and carcinogenic particles for a significantly longer period of time while Defendants were attempting to monetize this public health crisis of their own creation.

278. As a direct and proximate result of Defendants' conscious and deliberate disregard for the rights and safety of consumers such as Plaintiff., Plaintiff Salvatore DiGrazia suffered severe and permanent physical injuries as set forth above. Defendants' outrageous conduct warrants an award of punitive damages.

279. By reason of the foregoing, plaintiffs have been damaged and are entitled to compensatory damages, and seek a monetary award and damages as set forth below.

ELEVENTH CAUSE OF ACTION

LOSS OF SERVICES

280. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

281. At all times hereinafter mentioned the Plaintiff, Salvatore DiGrazia and Maryann DiGrazia were and still are husband and wife.

282. That as a result of the injuries and damages sustained by the Plaintiff, Salvatore DiGrazia, the plaintiff, Maryann DiGrazia has suffered the of care, comfort, services, society and affection of the Plaintiff, Salvatore DiGrazia and has incurred and will continue to incur medical expenses on his behalf for his medical care and treatment.

283. By reason of the foregoing, plaintiff, Maryann DiGrazia has been damaged and is entitled to compensatory damages and seek a monetary aware as set forth below.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment as follows:

1a. against the Philips and Burnett Defendants on the first cause of action in the sum of Fifteen Million ($15,000,000.00) Dollars;

1b. against the SoClean Defendants on the first cause of action in the sum of Fifteen Million ($15,000,000.00) Dollars;

2a. against the Philips and Burnett Defendants on the second cause of action in the sum of Fifteen Million ($15,000,000.00) Dollars;

2b. against the SoClean Defendants on the second cause of action in the sum of Fifteen Million ($15,000,000.00) Dollars;

3a. against the Philips and Burnett Defendants on the third cause of action in the sum of Fifteen Million ($15,000,000.00) Dollars;

3b. against the SoClean Defendants on the third cause of action in the sum of Fifteen Million ($15,000,000.00) Dollars;

4a. against the Philips and Burnett Defendants on the fourth cause of action in the sum of Fifteen Million ($15,000,000.00) Dollars;

4b. against the SoClean Defendants on the fourth cause of action in the sum of Fifteen Million ($15,000,000.00) Dollars;

5a. against the Philips and Burnett Defendants on the fifth cause of action in the sum of Fifteen Million ($15,000,000.00) Dollars;

5b. against the SoClean Defendants on the fifth cause of action in the sum of Fifteen Million ($15,000,000.00) Dollars;

6a. against the Philips and Burnett Defendants on the sixth cause of action in the sum of Fifteen Million ($15,000,000.00) Dollars;

6b. against the SoClean Defendants on the sixth cause of action in the sum of Fifteen Million ($15,000,000.00) Dollars;

7a. against the Philips and Burnett Defendants on the seventh cause of action in the sum of Fifteen Million ($15,000,000.00) Dollars;

7b. against the SoClean Defendants on the seventh cause of action in the sum of Fifteen Million ($15,000,000.00) Dollars;

8a. against the Philips and Burnett Defendants on the eighth cause of action in the sum of Fifteen Million ($15,000,000.00) Dollars;

8b. against the SoClean Defendants on the eighth cause of action in the sum of Fifteen Million ($15,000,000.00) Dollars;

9a. against the Philips and Burnett Defendants on the ninth cause of action in the sum of Fifteen Million ($15,000,000.00) Dollars;

9b. against the SoClean Defendants on the ninth cause of action in the sum of Fifteen Million ($15,000,000.00) Dollars;

10a. against the Philips and Burnett Defendants on the tenth cause of action in the sum of Fifteen Million ($15,000,000.00) Dollars;

10b. against the SoClean Defendants on the tenth cause of action in the sum of Fifteen Million ($15,000,000.00) Dollars;

11a. against the Philips and Burnett Defendants on the eleventh cause of action in the sum of Fifteen Million ($15,000,000.00) Dollars;

11b. against the SoClean Defendants on the eleventh cause of action in the sum of Fifteen Million ($15,000,000.00) Dollars;

12. Attorneys' fees and costs;

13. Interest; and

14. Any and all further relief, both legal and equitable, that the Court may deem just and proper.

JURY DEMAND

284. Plaintiffs demand a trial by jury on all issues.

Dated: December 12, 2022
Jericho, New York

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