UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW HAMPSHIRE

LEONARD BRADLEY & CHINEDU EKWEOZOH, on behalf of themselves and all others similarly situated, *Plaintiffs*, v. SOCLEAN, INC., *Defendant*.	**Case No. 1:21-cv-1029** **CLASS ACTION COMPLAINT** **DEMAND FOR JURY TRIAL**

Plaintiffs Leonard Bradley and Chinedu Ekweozoh ("Plaintiffs"), on behalf of themselves, the class, and subclasses of all others similarly situated as defined below, for their complaint against Defendant SoClean, Inc. ("SoClean"), allege the following based on (a) personal knowledge, (b) the investigation of counsel, and (c) information and belief.

INTRODUCTION

1. Plaintiffs bring this action on behalf of themselves and proposed class and subclasses of purchasers and users of SoClean's ozone cleaning devices (the "SoClean Devices"), which are used to clean Continuous Positive Airway Pressure (CPAP), Bi-Level Positive Airway Pressure (BiPAP) devices, and mechanical ventilators manufactured by Philips (collectively, the "Philips Devices").[1]

2. The Philips Devices contain polyester-based polyurethane sound abatement foam ("PE-PUR Foam"). The Philips Devices are commonly used to treat sleep apnea (CPAP and BiPAP) and respiratory failure (ventilators). In general, Philips Devices blow air into patients'

[1] "Philips" collectively refers to herein as the following entities: Koninklijke Philips N.V., Philips North America LLC, and Philips RS North America LLC.

airways. CPAP and BiPAP machines are intended for daily use, and ventilators are used continuously while needed. Without these devices, some patients may experience severe symptoms, including heart attack, stroke, and death by asphyxiation.

3. On April 26, 2021, Philips made a public announcement disclosing it had determined there were risks that the PE-PUR Foam used in certain Philips Devices it manufactured may degrade or off-gas under certain circumstances.

4. On June 14, 2021, Philips issued a recall (hereinafter referred to as the "Recall Notice") in the United States of its Philips Devices containing PE-PUR Foam, because Philips had determined that (a) the PE-PUR Foam was at risk for degradation into particles that may enter the devices' pathway and be ingested or inhaled by users, and (b) the PE-PUR Foam may off-gas certain chemicals during operation.[2] Philips further disclosed the potential risks created by the degradation and off-gassing include "headache, irritation, inflammation, respiratory issues[,] . . . hypersensitivity, nausea/vomiting, and possible toxic and carcinogenic effects."[3]

5. Notably, Philips further informed consumers that cleaning devices, such as SoClean Devices, were responsible for the recall: "The foam degradation may be exacerbated by use of unapproved cleaning methods, such as ozone . . ."[4]

6. Philips has disclosed that the absence of visible particles in the devices does not mean that PE-PUR Foam breakdown has not already begun. Philips reported that lab analysis of

[2] *Philips issues recall notification* to mitigate potential health risks related to the sound abatement foam component in certain sleep and respiratory care devices,* Philips (June 14, 2021), https://www.philips.com/a-w/about/news/archive/standard/news/press/2021/20210614-philips-is sues-recall-notification-to-mitigate-potential-health-risks-related-to-the-sound-abatement-foam-c omponent-in-certain-sleep-and-respiratory-care-devices.html (last visited Nov. 22, 2021) ("*Recall Notice*").
[3] *Id.*
[4] *Id.*

the degraded foam reveals the presence of harmful chemicals, including: Toluene Diamine ("TDA"), Toluene Diisocyanate ("TDI"), and Diethylene Glycol ("DEG").[5]

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

8. In the Recall Notice, Philips recommended that patients using the recalled Philips Devices immediately discontinue using their devices and that patients using the recalled ventilators for life-sustaining therapy consult with their physicians regarding alternative ventilator options.[6]

9. Each of the Plaintiffs received confirmation that their respective Philips Devices were subject to recall.

10. Each of the Plaintiffs used SoClean Devices to clean their Philips Devices.

11. If Plaintiffs knew that that the SoClean Devices would damage their Phillips Devises by degrading the PE-PUR Foam, they would have not purchased the SoClean Devices.

12. Further, the SoClean Devices have caused injury to other property, i.e., the Phillips Devices.

13. Plaintiffs seek to recover damages based on, *inter alia*, SoClean's misrepresentations, omissions, and breaches of state consumer protection laws in connection with its manufacture, marketing, and sales of the SoClean Devices on behalf of themselves and the proposed Class Members. In addition, Plaintiffs seek medical monitoring damages for users of the

[5] *Sleep and Respiratory Care update; Clinical information for physicians*, Philips (June 14, 2021), https://www.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/philips-recall-clinical-information-for-physicians-and-providers.pdf (last accessed Nov. 22, 2021).

[6] *Recall Notice*, *supra*, n.2.

SoClean Devices, who are at risk of suffering from serious injury, including irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (*e.g.*, kidneys and liver) and toxic carcinogenic affects.

PARTIES

14. Unless otherwise indicated, all Plaintiffs identified below purchased and used the SoClean Devices for personal use in connection with a sleep apnea diagnosis. All Plaintiffs were harmed and suffered damages.

15. For ease of reference, the following chart identifies and organizes the named Plaintiffs by the state in which they purchased or used the SoClean Devices:

Plaintiff Name	State
Chinedu Ekweozoh	Maryland
Leonard Bradley	Nebraska

Maryland Plaintiff, Chinedu Ekweozoh

16. Plaintiff Chinedu Ekweozoh ("Ekweozoh") resides in Oxen Hill, Maryland. Plaintiff Ekweozoh purchased a SoClean Device in or about June 2020, from CVS.

17. Plaintiff Ekweozoh used the SoClean Device to clean his Philips Device as instructed by SoClean.

18. Since using the devices, Plaintiff Ekweozoh has experienced headaches, irritation, nausea, respiratory issues, and coughing.

19. Plaintiff Ekweozoh would not have purchased and/or used the SoClean Devices on her Philips Device if he had known it would cause damage to his Phillips Device.

20. Plaintiff Ekweozoh is seeking a refund for his SoClean Device, replacement of his Philips Device, and costs for ongoing medical monitoring, and all other appropriate damages for all the injuries he has suffered as a result of the defective SoClean Devices.

Nebraska Plaintiff, Leonard Bradley

21. Plaintiff Leonard Bradley ("Bradley") resides in Omaha, Nebraska. Plaintiff Bradley was provided a SoClean Device in May 2019 by the Veterans' Administration.

22. Plaintiff Bradley used the SoClean Device to clean his Philips Device as instructed by SoClean.

23. Since using the devices, Plaintiff Bradley has experienced irritation and respiratory issues.

24. Plaintiff Bradley would not have purchased and/or used the SoClean Devices on his Philips Device if he had known it would cause damage to his Phillips Device.

25. Plaintiff Bradley is seeking replacement of his Philips Device, and costs for ongoing medical monitoring, and all other appropriate damages for all the injuries he has suffered as a result of the defective SoClean Devices.

Defendant SoClean, Inc.

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

JURISDICTION AND VENUE

27. This Court has subject matter jurisdiction over this class action pursuant to 28 U.S.C. § 1332, as amended by the Class Action Fairness Act of 2005, because the matter in controversy exceeds $5 million, exclusive of interest and costs, and is a class action in which

Plaintiffs and some members of the Class are citizens of states different than Defendant. *See* 28 U.S.C. § 1332(d)(2)(A).

28. Venue is proper in this District because SoClean is headquartered in this District and because a substantial part of the events or omissions giving rise to the claim occurred in this District.

29. The Court has personal jurisdiction over SoClean because it conducts substantial business in this District, and the events giving rise to Plaintiffs' claims arise out of and relate to Defendant's contacts with this District. Moreover, SoClean has its principal place of business in this District. Further, SoClean has transacted business, maintained substantial contacts, purposefully targeted consumers, and medical professionals for sales of its devices and/or committed overt acts in furtherance of the unlawful acts alleged in this Complaint in this District, as well as throughout the United States. The unlawful acts of SoClean have been directed at, targeted, and have had the effect of causing injury to persons residing in, located in, or doing business in this District, as well as throughout the United States.

COMMON GENERAL FACTS

I. Continuous Positive Airway Pressure Therapy

30. Continuous Positive Airway Pressure ("CPAP") therapy is a common nonsurgical treatment primarily used to treat sleep apnea. CPAP therapy typically involves the use of a hose and a nasal or facemask device that delivers constant and steady air pressure to an individual's throat to help individuals breathe.

31. Sleep apnea is a common sleep disorder characterized by repeated interruptions in breathing throughout an individual's sleep cycle. These interruptions, called "apneas," are caused when the soft tissue in an individual's airway collapses. The airway collapse prevents oxygen from

reaching the individual's lungs which can cause a buildup of carbon dioxide. If the individual's brain senses the buildup of carbon dioxide, it will briefly rouse the individual from sleep so that the individual's airway can reopen. Often, these interruptions are so brief that the individual will not remember. Despite the brevity of the interruptions, the sleep cycle disruption caused by sleep apnea can dramatically impact a person's lifestyle, including negatively impacting energy, mental performance, and long-term health. CPAP therapy helps treat sleep apnea by preventing the person's airway from collapsing while breathing during sleep cycles, which can help prevent interruptions in breathing.

II. Bi-Level Positive Airway Pressure Therapy

32. Bi-Level Positive Airway Pressure ("BiPAP") therapy is a common alternative to CPAP therapy for treating sleep apnea. Similar to CPAP therapy, BiPAP therapy is nonsurgical and involves the use of a nasal or facemask device to maintain air pressure in an individual's airway. BiPAP therapy is distinguishable from CPAP therapy because BiPAP devices deliver two alternating levels—inspiratory and expiratory—of pressurized air into a person's airway, rather than the single continuous level of pressurized air delivered by a CPAP device. The inspiratory positive airway pressure assists a person as a breath is taken in. Conversely, the expiratory positive airway pressure is applied to allow a person to comfortably breathe out. BiPAP devices deliver one level of pressurize air (the inspiratory positive level) to assist as a person inhales, and another level (the expiratory level) as a person exhales.

III. Mechanical Ventilation

33. Mechanical ventilation is a treatment to help people breathe when they find it difficult or are unable to breathe on their own. A mechanical ventilator pushes airflow into the patient's lungs to help them breathe. Mechanical ventilation may be invasive ventilation with a

tube inserted into the patient's airway, performed in the intensive care unit in the hospital or a long-term institutional setting. Non-invasive ventilation can be used at home by people with respiratory difficulties.

COMMON SUBSTANTIVE ALLEGATIONS

34. Philips developed, marketed, and sold a variety of CPAP and BiPAP respirator devices and mechanical ventilators under its "Sleep & Respiratory Care" segment of its business designed to assist individuals with a number of sleep, breathing, and respiratory conditions, including obstructive sleep apnea, central sleep apnea, complex sleep apnea syndrome, and Chronic Obstructive Pulmonary Disease ("COPD"), as well as to assist those individuals requiring invasive and non-invasive ventilators for acute and sub-acute hospital environments. Philips's CPAP and BiPAP respirator devices and its mechanical ventilators typically cost hundreds, if not thousands, of dollars. Philips has sold millions of these devices in the United States.

35. Because of their daily usage, many consumers of the Philips Devices sought out methods to clean and sanitize their Philips Devices.

36. SoClean manufactured and marketed the SoClean Devices as a product that could be used to generate ozone to sterilize and sanitize the Philips Devices.

37. SoClean marketed the SoClean Devices as a "safe" and "healthy" way to sterilize and sanitize sleeping devices, including the Philips Devices.[7]

38. The SoClean Devices utilize ozone to sterilize and sanitize the Philips Devices. Specifically, the SoClean Devices generate ozone and circulate it throughout the Philips Devices during a cleaning cycle.

39. The cleaning cycle for a SoClean Device lasts between 7 and 14 minutes.

[7] SoClean, https://www.soclean.com/ (last visited Nov. 22, 2021).

40. Users can manually initiate a cleaning cycle, or they can opt to run a cleaning every day.

41. When a cleaning cycle initiates, the SoClean Device begins emitting ozone gas throughout the Philips Device through a black hose connecting the two devices.

42. SoClean markets the SoClean Devices as an effective way to sterilize and sanitize the Philips Devices.

43. SoClean markets the SoClean Devices as free of "harsh chemicals."

44. For example, the packaging on the SoClean 2 SoClean Device states "Breathe Healthy, Breathe Clean."

45. The packaging further states "No water or chemicals."

46. In addition, on information and belief, SoClean has aired the television commercial "Getting Sick from a Dirty CPAP" at least 10,929 times nationwide since 2018, representing that the SoClean Devices are safe, healthy, and free of harsh chemicals.

47. Similar representations as to the ones described in the preceding paragraphs are prominently made throughout SoClean's website.

48. Contrary to these representations, the SoClean Devices are not "safe" and healthy, are not an effective way to sterilize and sanitize the Philips Devices, and are not free of "harsh chemicals."

49. On April 26, 2021, in its Quarterly Report for Q1 2021, Philips disclosed for the first time, under a section entitled "Regulatory Update," that reports from users of Philips Machines had led to the discovery that the type of PE-PUR Foam Philips used to minimize noise in several CPAP and BiPAP respirators and mechanical ventilators posed health risks to its users. Specifically, Philips disclosed that "the [PE-PUR] foam may degrade under certain circumstances, influenced by factors ***including use of unapproved cleaning methods, such as ozone[]*** . . . ."[8]

50. Seven weeks later, on June 14, 2021, Philips announced a recall of numerous models of CPAP and BiPAP devices, as well as a variety of its mechanical ventilators "to address identified potential health risks related to the polyester-based polyurethane (PE-PUR) sound abatement foam component in these devices."[9] Specifically, Philips announced that it had determined that the "PE-PUR foam may degrade into particles which may enter the device's air pathway and be ingested or inhaled by the user, and the foam may off-gas certain chemicals."[10] In total, Philips announced that "[b]etween 3 million and 4 million" devices are targeted in the recall.[11]

51. According to Philips, the degraded PE-PUR Foam used in Philips Devices put users at risk of suffering from: "[i]rritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (*e.g.*, kidneys and liver) and toxic carcinogenic affects."[12]

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[8] *First Quarter Results*, Philips (Apr. 26, 2021), https://www.results.philips.com/publications/q121/downloads/pdf/en/philips-first-quarter-results-2021-report.pdf (last accessed Nov. 22, 2021).
[9] *Recall Notice*, *supra* note 2.
[10] *Id.*
[11] Associated Press, *Philips recalls ventilators, sleep apnea machines due to health risks*, NBC News (June 14, 2021), https://www.nbcnews.com/business/consumer/philips-recalls-ventilators-sleep-apnea-machines-due-health-risks-n1270725 (last accessed Nov. 22, 2021).
[12] *Id.*

52. Philips reported to physicians that PE-PUR Foam particles "may cause irritation and airway inflammation, and this may be particularly important for patients with underlying lung diseases or reduced cardiopulmonary reserve."[13]

53. Further, Philips reported that "based on lab testing and evaluations, it may be possible that these potential health risks could result in a wide range of potential patient impact, from transient potential injuries, symptoms and complications, as well as possibly serious injury which can be life-threatening or cause permanent impairment, or require medical intervention to preclude permanent impairment."[14]

54. Philips announced that it has received reports of "patient impact" in the Philips Devices, and announced risks of exposure as including "headache, irritation, inflammation, and respiratory issues."[15]

55. In no uncertain terms, Philips blamed the need to recall the Philips Devices on ozone cleaners, including SoClean Devices which, on information and belief, account for 90% of the market for CPAP sanitizing / sterilization devices.

56. In a Q&A about the product recall on its public website, Philips referenced ozone cleaners at least *nine* times, suggesting they were responsible for the issues that led to the recall. Included among those statements: "Philips is recommending that customers and patients do not use ozone-related cleaning products."[16] Also: "Philips is recommending that customers and

[13] *Sleep and Respiratory Care update; Clinical information for physicians, supra* note 5.
[14] *Id.*
[15] *Recall Notice, supra* note 2.
[16] *Medical Device Recall Notification,* https://www.usa.philips.com/healthcare/e/sleep/communications/src-update#questions_and_answers (last visited Nov. 22, 2021).

patients halt use of ozone-related cleaning products, and adhere to their device Instructions for Use for approved cleaning methods."[17]

57. During Philips' Q2 Earnings Call, Philips' CEO unilaterally condemned the use of ozone cleaners for Philips' Philips Devices. In response to a question from an analyst, who asked if Philips had "any data that shows how ozone is accelerating foam degradation," Philips's CEO responded:

> Yeah, that we do. **We have tested that, and we see a 40 times factor of acceleration of degradation when ozone is being used.** And that's on an average use of ozone cleaning. And if people do that every day, of course, it goes even faster, right? But the acceleration factor caused by ozone cleaning is very, very significant, right? And otherwise, we would not call it out. It's a very aggressive cleaning method that should not be used on medical devices at all.

58. Simply put, the SoClean Devices cause the PE-PUR Foam used in the Philips Devices to degrade or off-gas harmful chemicals.

59. SoClean does not warn users that using the SoClean Devices may cause or will cause the PE-PUR Foam used in their Philips Devices to degrade or off-gas harmful chemicals.

60. SoClean does not warn users that the potential risks of foam degradation and off-gassing include "headache, irritation, inflammation, respiratory issues[,] . . . hypersensitivity, nausea/vomiting, and possible toxic and carcinogenic effects."[18]

61. As a result of the health risks associated with the use of the SoClean Devices, the SoClean Devices have been rendered completely worthless or, at the very least, have been substantially diminished in value.

62. As a result of the recall, the Plaintiffs' and Class members' SoClean Devices and Philips Devices are of no value; further, the Plaintiffs and Class Members have spent money to

[17] https://www.mypmahealth.com/wp-content/uploads/2021/06/Recall.pdf (last visited Nov. 22, 2021)
[18] *Recall Notice*, *supra* note 2.

purchase new devices and incurred additional expenses in connection with the replacement of their SoClean Devices.

TOLLING AND ESTOPPEL

I. DISCOVERY RULE TOLLING

63. Plaintiffs and the Class Members had no way of knowing about SoClean's conduct with respect to the health risks associated with the use of the SoClean Devices.

64. Neither Plaintiffs nor any other members of the Classes, through the exercise of reasonable care, could have discovered the conduct by SoClean alleged herein. Further, Plaintiffs and members of the Class and Subclasses did not discover and did not know of facts that would have caused a reasonable person to suspect that SoClean was engaged in the conduct alleged herein.

65. For these, reasons, all applicable statutes of limitation have been tolled by the discovery rule with respect to claims asserted by Plaintiffs, the Class, and Subclasses.

II. FRAUDULENT CONCEALMENT TOLLING

66. By failing to provide immediate notice of the adverse health effects associated with continued use of the SoClean Devices, SoClean concealed its conduct and the existence of the claims asserted herein from Plaintiff and the members of the Class and Subclasses.

67. Upon information and belief, SoClean intended its acts to conceal the facts and claims from Plaintiffs and members of the Class and Subclasses. Plaintiffs and the members of the Class and Subclasses were unaware of the facts alleged herein without any fault or lack of diligence on their part and could not have reasonably discovered Defendant's conduct. For this reason, any statute of limitations that otherwise may apply to the claims of Plaintiffs or members of the Classes should be tolled.

CLASS ACTION ALLEGATIONS

68. Plaintiffs bring this action as a class action pursuant to Federal Rules of Civil Procedure 23(a) and 23(b)(3). Plaintiffs seek class certification on behalf of a class defined as follows (the "Class"):

> **NATIONWIDE CLASS**: All persons in the United States who purchased or used a SoClean Device to clean and sanitize a recalled Phillips Device.

69. In addition to a Nationwide Class, Plaintiff Ekweozoh seeks certification on behalf of a subclass defined as follows (the "Maryland Subclass"):

> **MARYLAND SUBCLASS**: All persons who were or are citizens of the State of Maryland who purchased or used a SoClean Device to clean and sanitize a recalled Phillips Device.

70. In addition to a Nationwide Class, Plaintiff Bradley seeks certification on behalf of a subclass defined as follows (the "Nebraska Subclass"):

> **NEBRASKA SUBCLASS**: All persons who were or are citizens of the State of Nebraska who purchased or used a SoClean Device to clean and sanitize a recalled Phillips Device.

71. Plaintiffs reserve the right to modify or refine the definitions of the Class or Subclasses based upon discovery of new information and in order to accommodate any of the Court's manageability concerns.

72. Excluded from the Class and Subclasses are: (a) any Judge or Magistrate Judge presiding over this action and members of their staff, as well as members of their families; (b) Defendant and Defendant's predecessors, parents, successors, heirs, assigns, subsidiaries, and any entity in which any Defendant or its parents have a controlling interest, as well as Defendant's current or former employees, agents, officers, and directors; (c) persons who properly execute and

file a timely request for exclusion from the Class or Subclasses; (d) persons whose claims in this matter have been finally adjudicated on the merits or otherwise released; (e) counsel for Plaintiffs and Defendant; and (f) the legal representatives, successors, and assigns of any such excluded persons.

73. **Numerosity (Rule 23(a)(1))**. The members of the Class and Subclasses are so numerous that joinder of individual members herein is impracticable. The exact number of members of the Class and Subclasses, as herein identified and described, is not known, but sales figures and the Recall Notice indicate that millions of individuals have purchased the Philips Devices and millions of individuals use ozone machines, like the SoClean Devices, to clean their Philips Machines.

74. **Commonality (Rule 23(a)(2))**. Common questions of fact and law exist for each cause of action and predominate over questions affecting only individual members of the Class and Subclasses, including the following:

- whether Defendant owed a duty of care to Plaintiffs and the Class and Subclasses;
- whether Defendant knew or should have known that the SoClean Devices cause the PE-PUR Foam used in the Philips Devices to degrade or off-gas harmful chemicals.
- whether Defendant wrongfully represented that the SoClean Devices were healthy and safe to use;
- whether the SoClean Devices rendered the Philips Devices worthless;
- whether the SoClean Devices have any value;
- whether Defendant's representations and omissions in advertising, packaging, and/or labeling were false, deceptive, and/or misleading;

- whether those representations and omissions were likely to deceive a reasonable consumer;
- whether a reasonable consumer would consider the presence, or risk of, health risks as a material fact in purchasing one of the SoClean Devices;
- whether Defendant had knowledge that those representations and omissions were false, deceptive, and misleading;
- whether Defendant engaged in unfair trade practices;
- whether Defendant engaged in false advertising;
- whether Defendant's conduct was negligent per se;
- whether Defendant made negligent and/or fraudulent misrepresentations and/or omissions; and
- whether Plaintiffs and the members of the Class and Subclasses are entitled to actual, statutory, and punitive damages.

75. **Typicality (Rule 23(a)(3))**. Plaintiffs' claims are typical of the claims of the other members of the proposed Class and Subclasses. Plaintiffs and members of the Class and Subclasses (as applicable) suffered injuries as a result of Defendant's wrongful conduct that is uniform across the Class and Subclasses.

76. **Adequacy (Rule 23(a)(4))**. Plaintiffs' interests are aligned with the Class and Subclasses that they seek to represent. Plaintiffs have and will continue to fairly and adequately represent and protect the interests of the members of the Class and Subclasses. Plaintiffs have retained competent counsel highly experienced in complex litigation and class actions and the types of claims at issue in this litigation, with the necessary resources committed to protecting the interests of the Class and Subclasses. Plaintiffs have no interests that are antagonistic to those of

the Class and Subclasses, and Defendant has no defenses unique to Plaintiffs. Plaintiffs and their counsel are committed to vigorously prosecuting this action on behalf of the members of the Class and Subclasses. Neither Plaintiffs nor Plaintiffs' counsel have any interest adverse to those of the other members of the Class and Subclasses.

77. **Superiority**. This class action is appropriate for certification because class proceedings are superior to other available methods for the fair and efficient adjudication of this controversy, and joinder of all members of the Class and Subclasses is impracticable. The prosecution of separate actions by individual members of the Class and Subclasses would impose heavy burdens upon the Courts and Defendant, would create a risk of inconsistent or varying adjudications of the questions of law and fact common to members of the Class and Subclasses, and would be dispositive of the interests of the other members not parties to the individual adjudications or would substantially impair or impede their ability to protect their interests. Class treatment will create economies of time, effort, and expense and promote uniform decision-making.

78. **Manageability.** This proposed class action presents fewer management difficulties than individual litigation, and provides the benefits of single adjudication, economies of scale, and comprehensive supervision by a single court.

79. Class certification, therefore, is appropriate under Fed. R. Civ. P. 23(b)(3) because the above common questions of law or fact predominate over any questions affecting individual members of the Class, and a class action is superior to other available methods for the fair and efficient adjudication of this controversy.

CAUSES OF ACTION

COUNT 1

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY
(On behalf of the Nationwide Class and each State Class)

80. Plaintiffs incorporate by reference and reallege all paragraphs previously alleged herein.

81. Plaintiffs bring this claim for breach of implied warranty against Defendant on behalf of the Nationwide Class and each State Class.

82. Defendant manufactured, marketed, sold, and distributed the SoClean Devices.

83. At the time Defendant marketed, sold, and distributed the SoClean Devices, Defendant knew of the purpose for which the SoClean Devices were intended and impliedly warranted that the SoClean Devices were of merchantable quality and safe and fit for such use.

84. Plaintiffs and the Class and Subclass members reasonably relied upon the skill, superior knowledge, and judgment of Defendant as to whether the SoClean Devices were of merchantable quality and safe and fit for their intended use.

85. Plaintiffs and the Class and Subclass members could not have known about the risks associated with the SoClean Devices until after the recall of Philips Devices. Contrary to Defendant's implied warranty, the SoClean Devices were not of merchantable quality and were not safe or fit for their intended use.

86. As a direct and proximate result of Defendant's breach of implied warranty, Plaintiffs and the Class members suffered damages as alleged herein.

87. Therefore, Plaintiffs pray for relief as set forth below.

COUNT 2

BREACH OF EXPRESS WARRANTY
(On behalf of the Nationwide Class and each State Class)

88. Plaintiffs incorporate by reference and reallege all paragraphs previously alleged herein.

89. Plaintiffs bring this claim for breach of express warranty against Defendant on behalf of the Nationwide Class and each State Class.

90. Defendant expressly warranted to Plaintiffs and the Class members that the SoClean Devices were safe and healthy.

91. The SoClean Devices did not conform to these express representations because the SoClean Devices are not safe and cause serious side effects.

92. As a direct and proximate result of Defendant's breaches of its express warranties to Plaintiffs and the Class members, and as the direct and legal result of the defective condition of the SoClean Devices as manufactured and/or supplied by Defendant, and other wrongdoing of Defendant described herein, Plaintiffs and the Class members suffered damages.

93. Therefore, Plaintiffs pray for relief as set forth below.

COUNT 3

NEGLIGENCE
(On behalf of each State Class)

94. Plaintiffs incorporate by reference and reallege all paragraphs previously alleged herein.

95. Plaintiffs bring this claim for negligence against Defendant on behalf of each State Class.

96. Plaintiffs and the Class, as owners of Philips Devices, were within the foreseeable zone of risk of injury or other losses in the event Defendant's SoClean Devices were defective or otherwise negligently formulated, manufactured, or produced, which risks Defendant knew or should have known.

97. Defendant owed Plaintiffs and the Class members a duty to offer only safe and healthy products for use by Plaintiffs and the Subclass members.

98. Through its failure to exercise due care, Defendant breached this duty by producing, manufacturing, and offering for sale the SoClean Devices in a defective condition that was unhealthy and injurious to Plaintiffs and the Subclass members.

99. Additionally, Defendant breached its duty of care to Plaintiffs and the Class members by failing to use sufficient quality control, perform adequate testing, proper manufacturing or production.

100. Defendant knew, or in the exercise of reasonable care should have known, that the SoClean Devices presented an unacceptable risk of harm to the owners and users of Philips Devices and would result in damage that was foreseeable and reasonably avoidable.

101. As a direct and proximate result of Defendant's negligence, Plaintiffs and the Class members have suffered loss and damages.

102. Therefore, Plaintiffs pray for relief as set forth below.

COUNT 4

STRICT PRODUCT LIABILITY
(On behalf of each State Class)

103. Plaintiffs incorporate by reference and reallege all paragraphs previously alleged herein.

104. Plaintiffs bring this claim for strict product liability design defect against Defendant on behalf of each State Class.

105. Defendant is the producer, manufacturer, and/or distributor of the SoClean Devices.

106. Defendant's SoClean Devices left Defendant's possession in an unreasonably dangerous condition.

107. Defendant's products reached Plaintiffs and the Class members without substantial change in condition, as expected.

108. The SoClean Devices, which, among other potential defects, created toxic levels of ozone, were in an unreasonably dangerous condition because (a) they failed to perform as safely as an ordinary consumer would expect when used as intended or when used in a manner reasonably foreseeable to Defendant; and (b) because the foreseeable risks of using the SoClean Devices outweighed the benefits of their use.

109. Plaintiffs and the Subclass members used the products as intended and in a manner reasonably foreseeable to Defendant.

110. As the direct and foreseeable result of the defective condition of the SoClean Devices as produced, manufactured, and/or distributed by Defendant, Plaintiffs and the Class members suffered damages.

111. Therefore, Plaintiffs pray for relief as set forth below.

COUNT 5

UNJUST ENRICHMENT
(On behalf of each State Class)

112. Plaintiffs incorporate by reference and reallege all paragraphs previously alleged herein.

113. Plaintiffs bring this claim for unjust enrichment against Defendant on behalf of each State Class.

114. As a direct, proximate, and foreseeable result of Defendant's acts and otherwise wrongful conduct, Plaintiffs and the Subclass members conferred a benefit on Defendant and consequently suffered damages. Defendant profited and benefited from the sale of the SoClean Devices, even as the SoClean Devices caused Plaintiffs and the Subclass members to incur damages.

115. Defendant voluntarily accepted and retained these profits and benefits, derived from Plaintiffs and the Class members, with full knowledge and awareness that as a result of Defendant's wrongdoing, consumers including Plaintiffs and the Subclass members were not receiving SoClean Devices of the quality, nature, fitness, or value that had been represented by Defendant or that reasonable consumers expected. Plaintiffs and the Subclass members purchased SoClean Devices that they expected would be safe and healthy would effectively clean their Philips Machines and instead have now had to suffer the expense and inconvenience of replacing or abandoning both their SoClean Devices and Philips Devices. Defendant continues to possess monies paid by Plaintiffs and the Class members to which Defendant is not entitled.

116. Under the circumstances it would be inequitable for Defendant to retain the benefits conferred upon it and Defendant's retention of these benefits violates fundamental principles of justice, equity, and good conscience.

117. Plaintiffs and the Class members hereby seek the disgorgement and restitution of Defendant's wrongful profits, revenue, and benefits, to the extent, and in the amount, deemed appropriate by the Court, and such other relief as the Court deems just and proper to remedy Defendant's unjust enrichment.

118. Therefore, Plaintiffs pray for relief as set forth below.

COUNT 6

VIOLATIONS OF THE MARYLAND CONSUMER PROTECTION ACT, Md. Comm. Code §§ 13-301, *et seq.*
(On behalf of the Maryland Subclass, except for Subclass Members who purchased a Philips Device for business use only)

119. Plaintiff Ekweozoh reasserts and realleges all proceeding factual allegations above as if fully set forth herein.

120. Plaintiff Ekweozoh brings this claim on behalf of himself and the Maryland Subclass Members.

121. Defendant is a person as defined by Md. Comm. Code § 13-101(h).

122. Defendant's conduct as alleged herein related to "sales," "offers for sale," or "bailment" as defined by Md. Comm. Code § 13-101(i) and § 13-303.

123. Maryland Subclass Members are "consumers" as defined by Md. Comm. Code § 13-101(c).

124. Defendant advertises, offers, or sells "consumer goods or "consumer services" as defined by Md. Comm. Code § 13-101(d).

125. Defendant advertised, offered, or sold goods or services in Maryland and engaged in trade or commerce directly or indirectly affecting the people of Maryland.

126. Defendant engaged in unfair and deceptive trade practices, in violation of Md. Comm. Code § 13-301, including:

a. False or misleading oral or written representations that have the capacity, tendency, or effect of deceiving or misleading consumers;

b. Representing that consumer goods or services have a characteristic that they do not have;

c. Representing that consumer goods or services are of a particular standard, quality, or grade that they are not;

d. Failing to state a material fact where the failure deceives or tends to deceive;

e. Advertising or offering consumer goods or services without intent to sell, lease, or rent them as advertised or offer; and

f. Deception, fraud, false pretense, false premise, misrepresentation, or knowing concealment, suppression, or omission of any material fact with the intent that a consumer rely on the same in connection with the promotion or sale of consumer goods or services of the subsequent performance with respect to an agreement, sale, lease, or rental.

127. Defendant engaged in these unfair and deceptive trade practices in connection with offering for sale or selling consumer goods or services or with respect to the extension of consumer credit, in violation of Md. Comm. Code § 13-303.

128. Defendant's representations and omissions were material because they were likely to deceive reasonable consumers.

129. Defendant intended to mislead Plaintiff Ekweozoh and the Maryland Subclass Members and induce them to rely on its misrepresentations and omissions.

130. Defendant should have disclosed the dangerous propensity of the SoClean Devices to cause degradation of PE-PUR Foam in the Philips Devices to Plaintiff Ekweozoh and the Maryland Subclass Members because it was in a superior position to know the true facts related to

that dangerous propensity, and Plaintiff Ekweozoh and Maryland Subclass Members could not reasonably be expected to learn or discover the true facts related to this dangerous propensity.

131. Defendant, by the conduct, statements, and omissions described above, also knowingly and intentionally concealed from Plaintiff Ekweozoh and the Maryland Subclass Members that the SoClean Device are unsafe and unfit for its intended use.

132. These acts and practices have deceived Plaintiff Ekweozoh and are likely to deceive the public. Defendant, by the conduct, statements, and omissions described above, and by knowingly and intentionally concealing from Plaintiff Ekweozoh and the Maryland Subclass Members that the SoClean Devices are unsafe for their intended use, breached their duties to disclose these facts, violated the Maryland Consumer Protection Act ("MCPA"), and caused injuries to Plaintiff Ekweozoh and the Maryland Subclass Members. The omissions and acts of concealment by Defendant pertained to information that was material to Plaintiff Ekweozoh and Maryland Subclass Members, as it would have been to all reasonable consumers.

133. The injuries suffered by Plaintiff Ekweozoh and the Maryland Subclass Members are greatly outweighed by any potential countervailing benefit to consumers or to competition, nor are they injuries that Plaintiff Ekweozoh and the Maryland Subclass Members should have reasonably avoided.

134. Defendant's conduct proximately caused injuries to Plaintiff Ekweozoh and other Maryland Subclass Members. Had Plaintiff Ekweozoh and the Maryland Subclass Members known about the defective nature of the SoClean Devices, they would not have purchased the SoClean Devices.

135. Plaintiff Ekweozoh and the Maryland Subclass Members seek all monetary and non-monetary relief allowed by law, including damages, disgorgement, injunctive relief, and attorneys' fees and costs.

COUNT 7

VIOLATIONS OF NEBRASKA UNIFORM DECEPTIVE TRADE PRACTICES ACT, Neb. Rev. Stat. §§ 87-301, *et seq.*
(On behalf of the Nebraska Subclass, except for Subclass Members who purchased a Philips Device for business use only)

136. Plaintiff Bradley reasserts and realleges all proceeding factual allegations above as if fully set forth herein.

137. The Nebraska Plaintiff and Subclass Members are "persons" as defined by Neb. Rev. Stat. § 87-301(19).

138. Defendant advertised, offered, or sold goods or services in Nebraska and engaged in trade or commerce directly or indirectly affecting the people of Nebraska.

139. Defendant engaged in deceptive trade practices in the course of its business, in violation of Neb. Rev. Stat. §§ 87-302(a)(5),(8) and (10) by representing that goods and services have characteristics, uses, benefits, or qualities that they do not have; representing that goods and services are of a particular standard, quality, or grade if they are of another; and advertising its goods and services with intent not to sell them as advertised and in a manner calculated or tending to mislead or deceive.

140. Defendant's representations and omissions were material because they were likely to deceive reasonable consumers.

141. Defendant intended to mislead the Nebraska Plaintiff and Subclass Members and induce them to rely on its misrepresentations and omissions.

142. As a direct and proximate result of Defendant's deceptive acts and practices, the Nebraska Plaintiff and Subclass Members have suffered and will continue to suffer injury, ascertainable losses of money or property, and monetary and non-monetary damages, including from not receiving the benefit of their bargain in purchasing the SoClean Devices.

143. Defendant's deceptive trade practices complained of herein affected consumers at large, including the large percentage of Nebraskans who purchased and/or used the SoClean Devices.

144. The Nebraska Plaintiff and Subclass Members seek all monetary and non-monetary relief allowed by law, including injunctive relief, other equitable relief, civil penalties, and attorneys' fees and costs.

COUNT 8

MEDICAL MONITORING
(On behalf of the Nationwide Class and each State Class)

145. Plaintiffs incorporate the foregoing allegations as if fully set forth herein.

146. At all relevant times, SoClean designed, manufactured, assembled, inspected, tested, packaged, labeled, marketed, advertised, promoted, supplied, distributed, sold and/or otherwise placed the SoClean Devices into the stream of commerce, and therefore owed a duty of reasonable care to avoid causing harm to those that used them, such as Plaintiffs.

147. It has been reported that users of the SoClean Devices face risks of serious injury that occurs when the SoClean Devices' utilization of ozone degrades the PE-PUR Foam contained in the SoClean Devices during the cleaning cycles of the SoClean Devices. When PE-PUR Foam degrades into particles that may enter the device's pathway and be ingested or inhaled by users of the devices, users face significantly increased risks of serious injury that can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent

impairment. The potential risks of degraded foam exposure include: irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (*e.g.*, kidneys and liver) and toxic carcinogenic effects.

148. The off-gassing of chemicals from the PE-PUR Foam contained in the SoClean Devices, which is caused by the SoClean Devices, poses risks of serious injury that can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment. The potential risks of exposure to off-gassing from PE-PUR Foam include: headache/dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, nausea/vomiting, toxic and carcinogenic effects.

149. The absence of visible particles does not mean that PE-PUR Foam breakdown has not already begun. Philips has reported that lab analysis of the degraded foam reveals the presence of harmful chemicals including: TDA, TDI, and DEG.[19] TDI is a powerful irritant to the mucous membranes of the eyes and gastrointestinal and respiratory tracts,[20] and has been reported to cause Occupational Asthma.[21] Exposure to TDA may result in ataxia, tachycardia, nausea, vomiting, convulsions, and respiratory depression.[22] TDA can cause chemical cyanosis (*i.e.*, bluish

[19] *Sleep and Respiratory Care update; Clinical information for physicians*, *supra* note 5.
[20] Nat'l Inst. for Occupational Safety & Health (NIOSH) Current Intel. Bulletin 53, *Toluene Diisocyanate (TDI) and Toluenediamine (TDA): Evidence of Carcinogenicity*, DHHS (NIOSH) Publication Number 90-101 (Dec. 1989); *see also* Gunnar Skarping, et al., *Biological monitoring of isocyanates and related amines: Test chamber exposure of humans to toluene diisocyanate*, Dep't of Occupational & Env't Med., Univ. Hosp., S-221 85 Lund, Sweden (1990); https://greenfuture.io/sustainable-living/spray-polyurethane-foam-toxic/ (last accessed Nov. 22, 2021).
[21] David I. Bernstein, *Occupational asthma: Definitions, epidemiology, causes, and risk factors*, Wolters Kluwer, UpToDate.com, https://www.uptodate.com/contents/occupational-asthma-definitions-epidemiology-causes-and-risk-factors?search=Occupational%20asthma:%20Definitions,%20epidemiology,%20causes,%20and%20risk%20factors&source=search_result&selectedTitle=1~38&usage_type=default&display_rank=1 (last accessed Nov. 22, 2021).
[22] NIOSH, *Toluene Diisocyanate (TDI) and Toluenediamine (TDA): Evidence of Carcinogenicity*; *see also* Skarping, et al., *Biological monitoring of isocyanates and related amines*, *supra* note 22; Ali Emerson, *Is Polyurethane Foam A Dreamy Comfort Or Toxic* Nightmare, Green Future (Mar. 2, 2017), https://greenfuture.io/sustainable-living/spray-polyurethane-foam-toxic/(last accessed Nov. 22, 2021).

discoloration of the skin) by converting hemoglobin to methemoglobin. This compound can also cause fatty degeneration of the liver.[23] TDA and TDI are potential carcinogens.[24] Repeated exposure to DEG has been associated with damage to the kidneys and renal failure.[25]

150. As a direct and proximate result of SoClean's conduct, Plaintiffs have been exposed to substantially increased risks of serious injury from off-gassing and/or degradation of PE-PUR Foam in the SoClean Devices, all of which is caused by the SoClean Devices.

151. As a direct and proximate result of SoClean's conduct, Plaintiffs have a significantly increased risk of suffering serious injury or contracting a serious latent disease, and suffering further injury at an unknown date in the future. Such injuries include cancer and organ failure, among others currently unknown or just being discovered.

152. Monitoring procedures exist that makes the early detection of damage from degraded and/or off-gassed PE-PUR Foam possible. These procedures are different from that normally recommended in the absence of the exposure. These monitoring procedures include non-routine surveillance studies, laboratory testing, and physical examinations, and would be reasonably necessary according to contemporary scientific principles.

153. Existing medical research indicates that exposure to TDI, TDA, and DEG, which Philips has found to exist in off-gassed or degraded PE-PUR Foam, can cause serious, life-

[23] NIOSH, *Toluene Diisocyanate (TDI) and Toluenediamine (TDA): Evidence of Carcinogenicity, supra*, n. 20.

[24] *Id.* ("The excess cancer risk for workers exposed to TDI and TDA has not yet been quantified, but the probability of developing cancer should be decreased by minimizing exposure.")

[25] Greg M. Landry, *Diethylene glycol-induced toxicities show marked threshold dose response in rats*, Toxicology and Applied Pharmacology 282 (2015) 244–51 ("DEG has recently been involved in several mass epidemics of renal failure and death world-wide (O'Brien et al., 1998; Schier et al., 2013). DEG poisoning clinically manifests in metabolic acidosis, hepatotoxicity, renal failure, and peripheral neuropathy, with the hallmark being acute renal failure involving proximal tubule cell necrosis and cortical degeneration (Schep et al., 2009)"); Jeffrey A. Cohen, *Demyelinating Diseases of the Peripheral Nerves*, Nerves and Nerve Injuries (2015) ("When consumed, DEG causes severe systemic and neurologic complications, including coma, seizures, peripheral neuropathy, and hepatorenal failure.").

threatening, and permanent injuries. Philips has received reports from users of the SoClean Devices of headache, upper airway irritation, cough, chest pressure and sinus infection. The exposure to the defects inherent in the SoClean Devices has occurred for users, such as Plaintiffs, but the full extent of the injuries will not manifest until later in the Plaintiffs' lives. Thus, because of SoClean's conduct, it is reasonably necessary that Plaintiffs be placed under period diagnostic testing beyond that normally recommended in the absence of use of the SoClean Devices.

154. Plaintiffs demand judgment against SoClean for medical monitoring damages to diagnose injuries caused by the SoClean Devices at an earlier date to allow for timely treatment and prevention of exacerbation of injuries, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, individually and on behalf of all others similarly situated, pray for judgment against SoClean as to each and every count, including:

A. An order certifying this action and the Class and Subclasses requested herein as a class action, designating Plaintiffs as the representatives of the Class and Subclasses, and appointing Plaintiffs' counsel as counsel to the Class and Subclasses;

B. An order declaring that Philips's actions constitute: (i) breach of implied warranty; (ii) breach of express warranty; (iii) negligence; (iv) unreasonably dangerous conduct; and (iv) violations of the consumer protection statutes invoked herein, and that SoClean is liable to Plaintiffs and the Subclass and Subclasses, as described herein, for damages arising therefrom;

C. A judgment awarding Plaintiffs and members of the Class and Subclasses all appropriate damages in an amount to be determined at trial;

D. A judgment awarding Plaintiffs and the Class and Subclasses medical monitoring damages;

E. A judgment awarding Plaintiffs and the Class and Subclasses pre- and post-judgment interest, as permitted by law;

F. A judgment awarding Plaintiffs and the Class and Subclasses costs and fees, including attorneys' fees, as permitted by law; and

H. Grant such other legal, equitable or further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

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

DATED: December 1, 2021

Respectfully submitted,

/s/ Matthew V. Burrows
Matthew V. Burrows, Esq. (#20914)
GALLAGHER, CALLAHAN & GARTRELL, P.C.
214 North Main Street
Concord, New Hampshire 03301
Direct: (603) 545-3643
Fax: (603) 224-7588
Email: burrows@gcglaw.com

Gary E. Mason*
MASON LIETZ & KLINGER LLP
5101 Wisconsin Avenue NW, Suite 305
Washington, D.C. 20016
T: (202) 429-2290
F: (202) 429-2294
gmason@masonllp.com

Gary M. Klinger*
MASON LEITZ & KLINGER LLP
227 W. Monroe Street, Suite 2100
Chicago, IL 60606
T: (202) 429-2290
gklinger@masonllp.com

Jonathan Shub*
Kevin Laukaitis*
SHUB LAW FIRM LLC
134 Kings Hwy E., Fl. 2
Haddonfield, NJ 08033
T: 856-772-7200
jshub@shublawyers.com
klaukaitis@shublawyers.com

Jonathan M. Jagher*
FREED KANNER LONDON & MILLEN LLC
923 Fayette Street
Conshohocken, PA 19428
T: (610) 234-6486
jjagher@fklmlaw.com

**Pro Hac Vice* Application Forthcoming

Attorneys for Plaintiffs and the Classes