UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

IN RE: SOCLEAN, INC., MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION	Master Docket No. 22-MC-00152-JFC
This Document Relates to:	MDL No. 3021
SoClean, Inc. v. Koninklijke Philips N.V., et al., 2:22-cv-542	JURY TRIAL DEMANDED

SECOND AMENDED COMPLAINT

Plaintiff SoClean, Inc. ("SoClean" or "Plaintiff"), by and through its undersigned counsel, brings this action against Koninklijke Philips N.V. ("Royal Philips"), Philips North America LLC ("Philips NA"), and Philips RS North America LLC ("Philips RS") (collectively, "Defendants"), and alleges as follows:

NATURE OF THE ACTION

1. Philips RS has initiated a massive product recall of millions of ventilator, continuous positive airway pressure (CPAP), and bi-level positive airway pressure (BiPAP) devices due to safety concerns related to foam degradation and volatile organic compound (VOC) emissions. The Food and Drug Administration (FDA) classified the process as a Class 1 recall, the most serious type of recall, because the devices at issue may cause serious injuries or death. Since the recall announcement, Royal Philips has lost over 70% of its value. The company has also parted ways with its Chief Executive Officer, Frans van Houten. Defendants are currently under investigation by the United States Department of Justice and French criminal authorities. When this ugly chapter closes, history will judge Royal Philips and its subsidiaries among the most unscrupulous corporate actors in recent memory.

2. Philips RS first became aware of the foam degradation issue in or around 2015. Internal documents show that, from 2014 to 2017, Philips RS received numerous complaints and reports related to degradation of the sound abatement foam used in Trilogy ventilator devices. Specifically, disintegrated foam made its way into the ventilator and the patients' air pathways. Testing conducted by Philips RS revealed that the polyester-based polyurethane foam breaks down when exposed to heat and humidity. Further testing by Philips RS confirmed that the affected foam breaks down by a process called hydrolysis, a chemical reaction involving water. These results were consistent with complaints about foam degradation in Florida and other hot, humid environments. Higher degradation risk also existed with devices that have increased use, evidencing that moisture generated inside the devices during operation also degrades the foam.

3. Philips RS emailed with its foam supplier about the degradation issue between October 30, 2015 and August 6, 2016. The supplier confirmed the susceptibility of polyester-based polyurethane foam to break down in the presence of water and provided information about alternative foam materials (*e.g.*, *polyether*-based polyurethane) that would not degrade under hot and humid conditions. Nonetheless, Philips RS decided not to change its designs and continued using polyester-based polyurethane foam for sound abatement in ventilators and other respiratory products, including its top-selling CPAP machine, called the "DreamStation," which, coincidentally, launched in 2015, when Philips RS first became aware of the degradation issue.

4. Separately, Philips RS knew that its DreamStation product failed emissions testing for volatile organic compounds and aldehydes (*e.g.*, formaldehyde) no later than January 2019. Among the "compounds of concern" identified by Philips RS was dimethyl diazene and phenol 2, 6-bis (1,1-dimethylethyl)-4-(1-methylpropyl), an antioxidant and stabilizer for materials like polyurethanes that resists degradation by oxidation.

5. Company management, including management with executive responsibilities, became aware of the safety issues that led to the Class 1 product recall no later than January 2020. But they did nothing for over a year. The reason was simple: Philips RS had not yet released its next-generation CPAP machine, which was still under development at the time. To hold onto customers and mitigate financial losses, Royal Philips, Philips NA and Philips RS needed to redirect existing business to safe products with alternative designs. So executive management stayed quiet and did not alert the public about the known safety risks, despite knowing that people could be seriously injured or killed.

6. On April 26, 2021, Royal Philips announced publicly for the first time that it had identified "possible risks to users" associated with the polyester-based polyurethane foam. The announcement mentioned foam degradation but said nothing about VOC emissions. The public warning came two weeks after Philips RS released its next-generation DreamStation 2 CPAP device. On information and belief, Royal Philips delayed the safety announcement so that Philips RS could redirect existing business from CPAP users, distributors, and resellers to the next-generation CPAP product. The DreamStation 2 uses a different type of foam.

7. Facing an existential threat, Royal Philips and its subsidiaries needed a scapegoat. Royal Philips, together with Philips NA and Philips RS, conspired as part of a coordinated public relations campaign to deflect blame, avoid accountability, and mitigate reputational damage. In stark contrast to the investigational analysis conducted by Philips RS, which had identified the cause of foam degradation (hydrolysis) and the source of VOC off-gassing (the foam manufacturing process), Defendants attributed responsibility to ozone and ozone cleaners, obfuscating the truth about the product recall. On information and belief, Defendants used one or more crisis management firms to help develop and employ their communications strategy.

8. The recall notification issued by Royal Philips and Philips RS ("Recall Notice")[1] misled customers, distributors, and the general public about the cause of the product recall. The Recall Notice deflected blame to ozone and ozone cleaners by using misleading language to suggest that ozone was responsible for both foam degradation and the off-gassing of harmful chemicals. The Recall Notice stated: "The foam degradation may be exacerbated by use of unapproved cleaning methods, such as ozone (see FDA safety communication on use of Ozone cleaners), and off-gassing may occur during initial operation and may possibly continue throughout the device's useful life."

9. Remarkably, the Recall Notice said nothing about foam degradation under hot and humid conditions, outside or inside the CPAP machine. Philips RS had already conducted an investigational analysis and reached the conclusion that the cause of foam degradation was long-term exposure to environmental conditions of high temperature combined with high humidity. Philips RS was aware of numerous tests since at least August 2016 that identified foam degradation in the absence of ozone cleaning agents. Philips RS also knew about information, including peer-reviewed scientific literature, regarding the susceptibility of polyester-based polyurethane foam to degrade under relatively mild environmental conditions, without the involvement of ozone. Indeed, Philips RS first observed foam degradation in Trilogy ventilators, which are not even compatible with ozone cleaners. Moreover, internal testing confirmed that the affected foam contained a potent antioxidant that would resist oxidation by ozone (*i.e.*, activated oxygen). Despite all of this, the Recall Notice highlighted ozone and said nothing about the mountain of evidence associating foam degradation with hydrolysis.

[1] Royal Philips and Philips NA each published the Recall Notice on their respective company websites (philips.com and usa.philips.com).

10. The Recall Notice discussed ozone and the off-gassing of potentially harmful VOCs in the same sentence, without any clarification. The off-gassing issue was an independent basis for the product recall, separate and apart from foam degradation. At the time of the recall, Defendants knew that the off-gassing of VOCs was unrelated to ozone. In fact, Royal Philips and Philips RS have expressly acknowledged that the off-gassing issue was "associated with the production process of the foam." If anything, the use of ozone cleaners would help mitigate the off-gassing of harmful chemicals by destroying them through chemical reactions.

11. The Recall Notice also misled customers, distributors, and the general public by citing to a FDA safety communication from 2020 that had nothing to do with safety issues related to foam degradation or VOC emissions. The FDA later refuted this incorrect and misleading citation, telling Philips RS that (i) "the safety communication addressed risks wholly unrelated to the potential degradation of sound abatement foam," and (ii) "[t]he safety communication thus did not give device users reason to anticipate that . . . the use of ozone cleaners in ventilated spaces (and utilizing procedures that permitted the circulation of fresh air through the devices) would necessarily present significant risks."

12. SoClean, the dominant market leader for ozone cleaners, was the primary focus of Defendants' coordinated smear campaign.

13. Defendants also had an ulterior motive for disparaging ozone cleaners and harming SoClean. On or around April 12, 2021, Defendants launched a new product, the Philips UV Light Sanitizer Box, which competes directly with SoClean. The Philips UVC Sanitizer Box purports to "disinfect[] surfaces and objects in just minutes," including "a wide range of items like toys, keys, cell phones and wallets." Likewise, SoClean's O3 Smarthome Cleaning System and Device Disinfector disinfects household items, such as smartphones, glasses, keys and earbuds.

14. Further, Royal Philips has intellectual property directed to competing technologies for cleaning and sanitizing sleep and respiratory equipment. On June 4, 2021, just 10 days before the product recall, Royal Philips filed a patent application on a process for disinfecting CPAP and other respiratory equipment using vaporized hydrogen peroxide, a gaseous disinfection technology. Royal Philips also owns patents on the use of ultraviolet (UV) light—and even ozone—to clean and disinfect respiratory equipment.

15. Royal Philips and Philips NA continued to mislead customers and deflect blame to ozone cleaners after the product recall. In numerous public statements and press releases published on their respective company websites, Royal Philips and Philips NA consistently associated ozone and ozone cleaners with the product recall. Both Royal Philips and Philips NA have instructed customers and patients not to use ozone-based cleaning products under any circumstances. Royal Philips and Philips NA knew that their statements regarding the product recall and, in particular, any public remarks by the CEO, would be picked up and disseminated by news and media outlets, including publishers that cater to the sleep and respiratory care industry, such as HME News.

16. Meanwhile, Philips RS made false and misleading statements about ozone to distributors and resellers of medical equipment. On information and belief, Philips RS concealed the truth about its own investigation and blamed ozone for the recall in order to preserve its reputation and prevent a loss of business to competitors, like Resmed. On information and belief, Philips RS falsely assigned blame to SoClean for the product recall in both written and oral statements to distributors and resellers, many of which service both Philips RS and SoClean.

17. High-level executives persisted with the negative attacks against SoClean and ozone cleaners in interviews, appearances on cable news, and highly-produced videos published on the company's website. For example, the CEO of Royal Philips made false and misleading

statements to Bloomberg in a recent television appearance on July 25, 2022: "It is clear by now that for those people that use ozone cleaning methodologies to clean their machine that that has massively aggravated the [foam degradation] issue, and that is more so in the United States than anywhere else in the world where, in fact, we have seen even lower incident rates." This was not true. In the same interview, Mr. van Houten was asked when Royal Philips found out about the safety issues that led to the recall. He responded: "Yeah, when we found out we immediately took the field safety notice out last year in April [2021]." This was another lie.

18. In a moment of candor, Mr. van Houten told the audience at the 2022 Annual General Meeting of Royal Philips that the "origin" of the recall was not ozone, but rather "the choice of sound abatement material in the design of the products many years ago." The next month, on or around on June 28, 2022, Mr. van Houten was quoted by Reuters, saying that Defendants' prior statements concerning ozone cleaners and foam degradation in 2021 were based on unproven assertions that the company "assumed" to be true at the time.

19. Mr. van Houten is a material witness in this case.

20. On November 12, 2021, the FDA issued an update on the Philips recall and a report from an inspection of Philips RS that took place from August 26 to November 9, 2021. According to the FDA, the purpose of the inspection was to "determine what may have caused or contributed to the foam issues and assess adherence to the agency's requirements for quality manufacturing." The report revealed details about the events leading to the recall, including what Philips RS and other related entities knew and when. The FDA found that "there were at least fourteen instances, assessments, and/or test reports, dated from 04/01/2016 to 01/22/2021, where [Philips RS] was aware of issues and concerns related to potential foam degradation and/or Volatile Organic

Compound (VOC) emissions, with various Sleep and Respiratory care devices . . . ." The public version of the FDA's inspection report does not include a single reference to ozone.

21. Later, the FDA eliminated any doubt on the issue of causation. In a Notice of Opportunity for a Hearing, dated May 2, 2022, the FDA told Philips RS that "***the unreasonable risk presented by the recalled devices was not caused by*** a failure to exercise due care in the installation, maintenance, repair, or ***use of the devices related to the use of ozone cleaning agents***." (emphasis added.) The FDA also said that "the risk associated with the devices ***was not caused by the failure of a person other than Philips*** to exercise due care in the installation, maintenance, repair, or use of the devices at issue." (emphasis added.)

22. On information and belief, Defendants misled the FDA before the product recall by telling the Agency that foam degradation may be "exacerbated" by ozone cleaners, without any reliable testing or other valid scientific evidence to validate those statements. It has been over 15 months since the recall. Yet, Defendants have not come forward with any public evidence or actual testing showing that ozone has a degradative effect on polyester-based polyurethane foam.

23. To the contrary, Philips RS conducted internal testing on SoClean devices for at least six months in or around 2017 and 2018. An employee familiar with the testing told one of SoClean's distributors that "[e]arly signs were favorable that SoClean did not affect our DreamStation devices."

24. Defendants' self-serving narrative about ozone cleaners has no basis in science. Ozone is widely recognized in peer-reviewed scientific literature as "one of the safest [biocides] for humans" and a "safe, fast, and economical alternative when compared to other low-temperature sterilization methods for the disinfection and/or sterilization of medical devices and environments." *See* Luis Alberto Breda Mascarenhas, et al., *Technological Advances in Ozone*

and Ozonized Water Spray Disinfection Devices, 11 Appl. Sci. 3081, at 1, 15 (2021). Among the reported advantages of ozone as a disinfectant are (i) "[h]igh efficacy," (ii) "[h]igh material compatibility," (iii) "[n]o toxic residues or emissions," (iv) "[n]o manual handling of the sterilant," and (v) a "[l]ow temperature process." *See* Meenakshi Sundaram Muthuraman et al., *Systematic Review on Sterilization Methods of Implants and Medical Devices*, 8 Int. J. ChemTech Res. 2, 897-911, at 906-7 (2015). Useful applications include "[r]eusable medical devices" made of "materials like stainless steel, titanium, anodized aluminum, ceramic, glass, silica, PVC, Teflon, silicone, polypropylene, polyethylene and acrylics." *Id.*

25. One "major advantage" of polyurethanes is that their chemical structure is "resistant to ozone and exudative aging." M. Szycher, Szycher's Handbook on Polyurethanes (2d ed. 2013), at 63. It is also well-established, however, that "[w]ater absorption and hydrolysis, especially at higher temperature, cause aging problems in polyurethane, particularly polyester urethane." *Id.*

26. The true reason for the product recall was an obvious design flaw. Philips RS chose a foam material that was known to degrade in the presence of heat and humidity. At the same time, many of the recalled products operate under hot and humid conditions, often with the use of a heated humidifier. The foam also happens to emit potentially harmful chemicals. Simply put, there was no good reason for Philips RS to use polyester-based polyurethane foam in the recalled products, or to put the foam in the direct path of the air being inhaled by users.

27. Defendants' false and misleading statements about ozone cleaners have had a devastating impact on SoClean. SoClean's sales have plummeted, its brand reputation has been tarnished, and the company has lost an enormous amount of goodwill. Total damages suffered by SoClean as a result of Defendants' illegal conduct exceed $200 million.

PARTIES

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

29. Defendant Koninklijke Philips N.V. is a Dutch multinational company headquartered in Amsterdam, Netherlands.

30. Defendant Philips North America LLC is a Delaware company with its principal place of business in Andover, Massachusetts.

31. Defendant Philips RS North America LLC (formerly Respironics, Inc.) is a Delaware company headquartered in Pittsburgh, Pennsylvania.

JURISDICTION AND VENUE

32. The Court has subject matter jurisdiction under 28 U.S.C. § 1331 because this action arises, in part, under 15 U.S.C. § 1125(a). The Court also has supplemental jurisdiction over other claims under 28 U.S.C. § 1367.

33. The Court has personal jurisdiction over Defendants because Defendants have conducted substantial business and have promoted their products, including sleep and respiratory care devices, in the Commonwealth of Massachusetts and in this District. Defendants have purposefully availed themselves of the privilege of conducting business in Massachusetts. Defendants have purposefully directed their activities at Massachusetts residents, and this litigation results from injuries that arise out of and relate to those activities. The assertion of personal jurisdiction over Defendants in the District of Massachusetts is both reasonable and fair.

34. Personal jurisdiction over Defendant Philips North America LLC exists because the company's headquarters and principal place of business are located in the Commonwealth of Massachusetts.

35. Personal jurisdiction over Defendant Philips RS North America LLC exists because Philips RS North America LLC is a citizen of Massachusetts. Philips RS North America LLC is wholly owned by a single member, Philips RS North America Holding Corporation, which has a principal place of business located at 222 Jacobs Street, Cambridge, MA 02141.

36. Defendant Koninklijke Philips N.V. is the parent company of Defendant Philips North America LLC, its largest subsidiary in the United States, and Defendant Philips RS North America LLC. Philips NA is a wholly-owned subsidiary of Royal Philips. Philips NA manages the operation of Royal Philips and its various lines of business operating within the United States, including Philips RS. Philips NA and Philips RS regularly carry out the business interests of Royal Philips in the United States. The sole member of Philips NA is Philips Holding USA Inc. Philips NA is 100% owned by Philips RS North America Holding Corporation which, in turn, is 100% owned by Philips Holding USA Inc.

37. Royal Philips has consented to jurisdiction as a defendant in the District of Massachusetts, and it has filed multiple lawsuits in the District of Massachusetts.

38. On information and belief, Royal Philips has overseen and directed the company's public response and communications strategy in the United States related to the product recall initiated on June 14, 2021. On information and belief, Philips NA and Philips RS acted on behalf of, and with the apparent authority of, Royal Philips in response to the product recall, including, for example, by issuing the Recall Notice and coordinating the repair and replace program.

39. On information and belief, Royal Philips exercises pervasive control over Philips NA and Philips RS with regard to the day-to-day operations of the subsidiaries and the conduct underlying this dispute.

40. On information and belief, the head of Philips NA is on the Executive Committee and Board of Management for Royal Philips.

41. Public statements and updates concerning the product recall, including statements published on the company websites and in the press releases, do not distinguish between the corporate entities and refer to Royal Philips, Philips NA, and Philips RS collectively as "Philips." Many of these same public statements and updates were also published concurrently on the respective public websites for Royal Philips (www.philips.com) Philips NA (www.usa.philips.com).

42. Royal Philips has engaged in a common enterprise with Philips NA and Philips RS with substantial disregard of the separate nature of the corporate entities, or at least with serious ambiguity about the manner and capacity in which the various corporate entities and their respective representatives are acting, with regard to the public response to product recall in the United States.

43. On information and belief, Philips NA and Philips RS are agents of Royal Philips with regard to activities related to the product recall in the United States, which is merely one example of Philips NA and Philips RS acting as agents of Royal Philips.

44. Venue is proper under 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to this action occurred in the District of Massachusetts.

45. On the subject of class action litigation concerning the product recall, Philips NA and Philips RS have admitted that "[t]he venue with the strongest nexus to the litigation is the District of Massachusetts," and that "[r]elevant witnesses and documents are located in Massachusetts." *See In Re: Philips Recalled CPAP, Bi-Level PAP, and Mechanical Ventilator Products Liability Litigation*, Case MDL No. 3014, Dkt. No. 47, at 3, 7.

FACTUAL ALLEGATIONS

CPAP, BiPAP, and Continuous Ventilator Machines

46. Sleep apnea is a potentially dangerous sleep disorder in which a person's breathing is interrupted during sleep. People with untreated sleep apnea stop breathing repeatedly during the night, such that the brain and the rest of the body may not get enough oxygen. If left untreated, serious complications may result, including high blood pressure, diabetes, and heart problems.

47. CPAP machines deliver enough air pressure to keep upper airway passages open, thereby preventing snoring and sleep apnea. The pressurized air is delivered through a mask that seals on the mouth or nose.

48. Sleep apnea can also be treated with BiPAP machines. Like CPAP devices, BiPAP machines generate and deliver positive airway pressure through a system of masks, hoses, and other accessories. The primary difference is that BiPAP machines have two pressure settings for inhalation and exhalation, allowing for lower pressure during exhalation.

49. Philips RS sells both CPAP and BiPAP machines.

50. Philips RS launched its DreamStation product line in October 2015.

51. Philips RS also sells ventilators for respiratory care. Examples include the Trilogy series and Omnilab ventilator products.

SoClean's Cleaning and Sanitizing Products

52. The dirty secret of the CPAP industry is that the manufacturer instructions for keeping the devices clean do not properly sanitize the devices. The Philips NA website acknowledges that "[i]t is vitally important to keep everything as clean as possible, as hoses/tubing and masks can be a prime breeding ground for bacteria and mold," quoting the Director of Communications for Sleep Apnea Treatment Centers of America.

53. Cleaning instructions on the Philips NA website recommend that users wipe down any areas that come into contact with skin on a daily basis, using a damp towel with mild detergent and warm water. For devices with a humidifier, the instructions recommend refilling the humidifier with clean, distilled water each day before bed. On a weekly basis, the instructions tell users to clean the CPAP tubing, nasal mask, and headgear in "a bathroom sink filled with warm water and a few drops of ammonia-free, mild dish detergent." Users are told to remove and rinse the filter with warm tap water and to clean the humidifier with warm soapy water each week.

54. On information and belief, the cleaning instructions recommended by CPAP device manufacturers are inadequate to properly clean and disinfect the devices. Wiping down the mask and hosing with mild detergent and soapy water is not sufficient to kill all bacteria, mold, and other pathogens that may accumulate during the lifespan of the device. Internal components can serve as a breeding ground for bacteria, mold, and other pathogens. This is notable because, on information and belief, microbial enzymes can accelerate degradation of the polyester-based polyurethane foam that Philips RS used for sound abatement, particularly in the absence of a biocide additive.

55. The lack of cleanliness is compounded by the fact that CPAP machines are often returned, refurbished, and then shipped to other customers, all within a matter of weeks. This cycle could repeat itself up to 5-10 times with "new" CPAP equipment. Absent any cleaning standards or regulations for the refurbished equipment, it is not possible to trace what happens to the devices before they find a permanent home and what, if anything, has been done to sanitize the devices in between users. On information and belief, CPAP machines being sold to consumers as "new" could easily have multiple prior owners, without any cleaning or sanitization from one user to the next.

56. Ozone cleaners provide the best available technology on the market to thoroughly clean and sanitize sleep and other respiratory equipment to rid them of bacteria, mold, and viruses.

57. SoClean is the dominant market leader for ozone cleaners. SoClean's lead product, the SoClean 3.0, is an automated cleaning device that cleans and sanitizes sleep equipment within minutes. Its patent-protected technology kills up to 99.9% of germs and bacteria that can build up in CPAP and BiPAP equipment without having to disassemble the device.

58. SoClean products generate and pump ozone through the supply tube and into the humidifier reservoir, cleaning not only the water, but also the inner walls of the reservoir. The ozone then moves through the CPAP hose, eliminating potentially harmful pathogens in the process. Ozone also passes in and out of the mask, cleaning it in the same manner as the hose and reservoir. When the short cleaning cycle is over, the ozone gas exits the chamber through a special filter that converts it back into common oxygen.

SoClean's Correspondence and Cooperation with FDA

59. SoClean has interacted extensively with the FDA since it launched the SoClean 2 device in 2014. Since that time, the company consistently maintained its establishment registration and device listing with the FDA.

60. From January 29, 2018 to February 1, 2018, the FDA conducted a thorough inspection of SoClean's manufacturing facility. The FDA did not issue any Form 483 observations following the inspection. Nor did the FDA raise any concerns about the marketing or distribution of SoClean's products.

61. SoClean representatives also worked collaboratively and openly with federal officials and law enforcement in 2018 regarding the importation of counterfeit and knock-off filter cartridges.

62. SoClean received a letter from the FDA on September 10, 2019. The letter stated: "[Y]our devices appear to use ozone and are intended to disinfect and sanitize mask and other accessories for Continuous Positive Airway Pressure (CPAP) therapy devices." The FDA pointed to various "effectiveness and safety medical claims" on SoClean's website and requested information, including the company's rationale to support marketing the SoClean devices as Class I exempt medical devices. The FDA also requested copies of all current product labeling, including operating instructions and promotional materials. In addition, the FDA requested a summary of certain testing related to ozone generated by the devices and the performance of the devices in reducing microbial contamination of CPAP devices.

63. SoClean responded to the FDA's letter on October 16, 2019. SoClean explained how and why it had been operating under the good-faith belief that the company's product was a Class I medical device. SoClean also explained how it revised the company's website and labeling

to address the FDA's comments. Specifically, SoClean outlined how it removed claims pertaining to the cleaning, sanitizing, or disinfection of CPAP machines.

64. SoClean met with the FDA on March 30, 2020. Several days before the meeting, the FDA sent written feedback in response to questions submitted in advance by SoClean. The first question related to whether the FDA concurred with the labeling of SoClean devices as Class 1, 510(k) exempt medical devices under 21 C.F.R. 880.6890 as a General Purpose Disinfectant. On March 25, 2020, the FDA told SoClean that "we believe your device may be more appropriately regulated as a Class II medical device under CFR 880.6992 Medical Device Disinfector," and that "we believe that your device may be appropriate for classification through the De Novo pathway."

65. Discussions with the FDA continued. On June 17, 2020, SoClean submitted a pre-submission to FDA for SoClean 3, which is the latest version of the device and an update to the SoClean 2. The pre-submission materials included (i) a description of the SoClean 3 device, (ii) an overview of the anticipated product development plan for SoClean 3, (iii) several test plans describing testing intended to evaluate the safety and efficacy characteristics of SoClean 3, and (iv) a number of questions for FDA's consideration.

66. On August 10, 2020, the FDA provided SoClean with a notification containing written responses to the questions posed in the pre-submission package, as well as additional guidance. A subsequent teleconference between the FDA and SoClean took place on August 17, 2020 to discuss the FDA's feedback and guidance in further detail.

67. SoClean met with the FDA again on March 1, 2021 to discuss questions and areas for clarification related to SoClean's submission for regulatory approval. SoClean and the FDA discussed multiple issues, including product labeling and microbial performance. The FDA acknowledged through several interactions in the pre-submission process that "a lot of progress

has been made." The FDA also indicated that the device and relevant testing were "on an appropriate path."

68. Pursuant to the FDA's guidance, SoClean submitted a *de novo* application for regulatory approval. The FDA formally accepted SoClean's submission on or around April 1, 2022. The application is currently under review.

69. SoClean has been fully transparent with and has followed the guidance of the FDA. The FDA has requested and received massive amounts of information regarding SoClean's labeling and promotional claims, as well as testing on the safety and efficacy of SoClean's device. SoClean continues to sell its products today under the guidance of the FDA.

70. On information and belief, the FDA is not currently investigating and has not requested testing about what effect, if any, ozone has on polyester-based polyurethane foam.

71. SoClean legally markets its ozone cleaner products with the knowledge of the FDA, without a requirement for premarket authorization.

February 27, 2020 FDA Safety Communication

72. On February 27, 2020, the FDA issued a safety communication about "potential risks associated with the use of ozone and ultraviolet (UV) light products for cleaning CPAP machines and accessories."

73. On the subject of ozone, the safety communication focused exclusively on the issue of potential risk of ozone leakage. The safety communication stated: "Although products that claim to use ozone gas to clean CPAP machine equipment are designed to keep the ozone generated inside the machine and its accessories, leaks can occur at tubing connections, filters or through fabric containers used to house CPAP accessories. When leaks occur, ozone gas in the nearby space may temporarily rise to unsafe levels, especially if the space is not well ventilated."

74. Independent laboratory testing has confirmed that SoClean's products do not leak ozone into the ambient environment at unsafe levels.

75. The safety communication also warned about potential risks associated with UV light cleaners. Specifically, the FDA warned that "unintentional or excessive exposure to UV light during cleaning may put a user at risk of eye injury, skin burns or even an increased risk of skin cancer." The FDA also warned that "UV light may be unable to penetrate all areas of the CPAP accessories such as the hoses, masks and connectors." Accordingly, "[t]his may result in inadequately disinfected CPAP devices and accessories that may not be safe for reuse."

76. The FDA safety communication also addressed the Agency's ongoing activities: "The FDA is working with manufacturers of products that claim to clean, sanitize or disinfect CPAP machines and accessories with either ozone gas or UV light to submit the recommended testing to support use of these devices as claimed."

77. On information and belief, SoClean is the only manufacturer of ozone cleaners to submit the recommended testing requested by the FDA.

78. On information and belief, manufacturers of UV light cleaning products either decided not to submit the recommended testing to support use to clean and disinfect CPAP machines, or they have had their applications for marketing approval denied by the FDA.

79. On February 27, 2020, the FDA issued a press release to accompany the safety communication. The press release stated, in part: "While these devices claiming to clean, sanitize or disinfect CPAP machines and accessories have not been FDA cleared or approved for marketing in the U.S., the FDA conducted its own preliminary lab testing on several of those illegally marketed products." At the time of this statement, SoClean had already removed any marketing

claims about cleaning and disinfecting CPAP machines from its website and promotional materials based on the FDA's prior guidance.

80. The FDA later clarified the scope and content of the February 27, 2020 safety communication. In a Notice of Opportunity for a Hearing, issued to Philips RS on May 2, 2022, the FDA clarified that (i) "the safety communication addressed risks wholly unrelated to the potential degradation of sound abatement foam," and (ii) "[t]he safety communication thus did not give device users reason to anticipate that . . . the use of ozone cleaners in ventilated spaces (and utilizing procedures that permitted the circulation of fresh air through the devices) would necessarily present significant risks."

81. On or about March 6, 2020, about a week after the FDA's safety communication, Philips RS issued a statement to HME News, a leading source of business news for home medical equipment providers. Philips RS told the news outlet that it "does not formally validate the use of SoClean with the DreamStation, but as of Jan. 6, Philips has not denied a warranty claim associated with the use of SoClean with a DreamStation." Notably, Philips RS equated ozone cleaners with SoClean, the dominant market leader in the space.

82. Philips RS also told HME News: "Philips is in communication with SoClean to further analyze the potential compatibility of the SoClean with DreamStation therapy devices, and will provide further information as it becomes available."

83. In fact, Philips RS and Philips NA had been in cooperative discussions with SoClean for years, including talks about a potential partnership.

84. Philips RS conducted over six months of testing on SoClean devices in or around 2017 to 2018. According to one employee familiar with the testing: "Early signs were favorable that SoClean did not affect our DreamStation devices."

First Public Announcement on Safety Concerns

85. Philips RS, Philips NA, and Royal Philips knew for years that the polyester-based polyurethane foam used to dampen sound in Philips ventilator, CPAP, and other respiratory care devices was susceptible to degradation and off-gassed potentially harmful VOCs. Executive management learned about the safety concerns associated with the sound abatement foam no later than January 2020. Despite the known health and safety risks, Defendants took no corrective action until April 2021.

86. On April 26, 2021, Royal Philips acknowledged publicly for the first time that the company had identified "possible risks" associated with "the sound abatement foam used in certain of Philips' sleep and respiratory care devices currently in use." The announcement appeared as part of a regulatory update included in the company's Q1 2021 Quarterly Report. Despite reference to multiple risks, Royal Philips only addressed the risk of foam degradation. Royal Philips wrote that degradation was "influenced by factors including use of unapproved cleaning methods, such as ozone, and certain environmental conditions involving high humidity and temperature." Royal Philips did not mention the health risks associated with VOC emissions, despite knowledge that the DreamStation had failed emissions tests.

87. On information and belief, Defendants used one or more crisis management and/or public relations firms to develop and employ the communications strategy related to public announcement and the product recall.

88. On information and belief, on or around April 23, 2021, Defendants misled the FDA in its initial notification about potential health risks by telling the Agency that foam degradation may be "exacerbated" by ozone cleaners, without any reliable testing or other valid

scientific evidence to validate those statements. On information and belief, Defendants repeated similar statements to the FDA in or around May 2021.

89. The April 26, 2021 announcement noted that "[t]he majority of the affected devices are in the first-generation DreamStation product family." But Royal Philips also assured that "Philips' recently launched next-generation CPAP platform, DreamStation 2, is not affected."

90. Philips RS launched the next-generation DreamStation 2 product on or about April 13, 2021, roughly two weeks before the first public acknowledgement of safety concerns associated with its sound abatement foam. On information and belief, Philips RS chose a different, more stable sound abatement foam for the DreamStation 2 machine long before the first public announcement about safety concerns associated with polyester-based polyurethane foam.

91. On information and belief, Royal Philips delayed the public announcement so that Philips RS could redirect existing business from CPAP users, distributors, and resellers to the next-generation CPAP product.

92. HME News picked up the public safety warning. The news outlet for home medical equipment providers published a short article titled, "Philips Reports Possible Safety Issue," on April 27, 2021. The article quoted the misleading statement by Royal Philips identifying ozone as the primary cause of foam degradation. The article also highlighted the promotional angle of the announcement, telling medical equipment providers that "Philips' recently launched next-generation CPAP platform, DreamStation 2, is not affected."

93. On April 26, 2021, the CEO of Royal Philips, Frans van Houten made public comments about ozone during a webcast and conference call concerning the company's Q1 earnings. Mr. van Houten said: "In the US[,] there's quite a lot of locations that have started to use ozone to disinfect the [DreamStation] machine. And in fact, that has an impact on the foam

used in the machine which makes it degrade." In response to a follow-up question about ozone, Mr. van Houten said: "I mean, if we look around the world, then there's use of ozone is typically a US issue. And then within the US it is related to certain regions where certain companies have been very active in marketing that message. But that's all, let's say, 20/20 hindsight. The FDA observed this and also put out a safety notice to say, don't use ozone for CPAP machines." Here again, Mr. van Houten promoted the company's next-generation CPAP product: "The good thing is, is that we have launched Dream Station 2. That product is already authorized in the United States and is of a different design and is not affected by this [foam] component."

94. HME News also picked up and disseminated the CEO's public remarks made during the webcast and conference call. The news outlet published another article titled, "Philips Gets in Front of Possible Safety Issue," on April 30, 2021. The article quoted Mr. van Houten extensively, including his remarks about ozone. The article began by paraphrasing Mr. van Houten's public comments as follows: "There's only a 'small risk' that the sound abatement foam in the first-generation DreamStation is being compromised by outside factors, including ozone cleaners, but Philips has chosen to be proactive and fix or replace these CPAP devices in the U.S., says CEO Frans van Houten."

95. On information and belief, Mr. van Houten's statements on April 26, 2021 concerning ozone cleaners and the safety risks associated with the DreamStation and other respiratory care products were made for the purpose of influencing customers to buy and continue buying Defendants' products, including the DreamStation 2 CPAP machine and the Philips UV Light Sanitizer Box.

96. On information and belief, in or around April 2021 and beyond, Mr. van Houten and Royal Philips knew that any public comments about safety risks associated with the company's

respiratory care devices would be picked up by HME News and disseminated to home medical equipment providers and the general public through articles published by the news outlet. Indeed, Royal Philips and Philips RS had previously provided statements to HME News on stories that may impact sales and revenue. On information and belief, Royal Philips was aware that HME News is a trusted source of business news for the home medical equipment industry, including distributors and resellers of medical equipment that serve as customers and potential customers of both Philips RS and SoClean.

97. Royal Philips and Philips NA published all of the company's earnings reports, presentations, and transcripts from webcasts and conference calls on their respective public websites. In addition, Royal Philips and Philips NA concurrently issued press releases, which were also published on their respective websites, to publicize, promote, and disseminate those earnings materials to influential media outlets, consumers, and the general public.

The Product Recall

98. On June 14, 2021, Royal Philips and Philips RS issued the Recall Notice in the United States for multiple sleep and respiratory care devices. The Recall Notice had two parts.

99. The first letter in the Recall Notice, which was addressed to patients and users of sleep and respiratory care devices, focused on CPAP and BiPAP devices, including the flagship DreamStation product family. The first letter identified two reasons for the product recall, both related to the polyester-based polyurethane foam sound abatement foam used in the CPAP and BiPAP devices: "1) PE-PUR foam may degrade into particles which may enter the device's air pathway and be ingested or inhaled by the user, and 2) the PE-PUR foam may off-gas certain chemicals." The first letter continued: "The foam degradation may be exacerbated by use of unapproved cleaning methods, such as ozone (see FDA safety communication on use of Ozone

cleaners), and off-gassing may occur during initial operation and may possibly continue throughout the device's useful life." The preceding sentence included a footnote with a URL guiding customers and CPAP users to the FDA's February 27, 2020 safety communication about ozone leakage and risks associated with UV light.

100. The second letter in the Recall Notice focused on other recalled devices, including the Trilogy ventilators. The second letter identified the same two reasons for the recall: (1) degradation of the sound abatement foam, and (2) VOC emissions. The second letter then used slightly different language regarding ozone: "The foam degradation may be exacerbated by use of unapproved cleaning methods, such as ozone (see FDA safety communication on use of Ozone cleaners), and off-gassing may occur during operation." But the second letter included the same footnote, directing customers and users to the FDA's February 27, 2020 safety communication.

101. Both letters in the Recall Notice were signed by Rodney Mell, Head of Quality at Philips RS.

102. The Recall Notice mentioned ozone in the same sentence as foam degradation and off-gassing. But the Recall Notice did not identify hydrolysis (or exposure to heat and humidity) as the cause of foam degradation in the first instance. Nor did the Recall Notice clarify that the off-gassing issue had nothing whatsoever to do with ozone cleaners, despite the fact that VOC exposure could be "life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment."

103. On June 14, 2021, Royal Philips and Philips NA issued press releases attaching the Recall Notice. The press releases stated: "The foam degradation may be exacerbated by use of unapproved cleaning methods, such as ozone,** and high heat and high humidity environments may also contribute to foam degradation." While the press releases associated heat and humidity

with foam degradation, unlike the Recall Notice, Royal Philips and Philips NA falsely and misleadingly identified ozone as the primary cause of the foam degradation. The press releases also included a footnote with a hyperlink to the FDA's February 27, 2020 safety communication, despite the fact it was completely unrelated to the safety issues that led to the product recall.

104. The June 14, 2021 press releases contained promotional language, including a quote from then-CEO of Royal Philips, Frans van Houten, who told customers and users of respiratory devices that "Patient safety is at the heart of everything we do at Philips." In addition, the press releases reassured customers and users that "Philips' recently launched next-generation CPAP platform, DreamStation 2, [was] not affected by the issue," and that "Philips is increasing the production of its DreamStation 2 CPAP devices, that are available in the US and selected countries in Europe." In sum, the press releases issued by Royal Philips and Philips NA promoted the company and directed existing customers to the DreamStation 2 product.

105. On information and belief, the false and misleading statements in the Recall Notice and the accompanying press releases were made for the purpose of influencing customers to buy and continue buying Defendants' products, including the next-generation DreamStation 2 machine and the Philips UV Light Sanitizer Box.

106. Royal Philips and Philips NA published the Recall Notice and the accompanying press releases on their respective public websites.

107. In total, Royal Philips, Philips NA, and Philips RS recalled 20 different respiratory care products, the vast majority of which are not compatible with SoClean's products or other ozone cleaners.

Royal Philips Makes False and Misleading Statements about Testing

108. On July 26, 2021, Royal Philips and its CEO spread false and misleading information about ozone during its webcast and conference call regarding Q2 results.

109. In response to a question, in which the Royal Philips CEO was asked "[h]ave you got any data that shows how ozone is accelerating a foam degradation perhaps," Mr. van Houten responded as follows:

> 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.

110. On information and belief, Royal Philips had no scientifically-valid testing, evidentiary support, or data showing a 40-fold acceleration of polyester-based polyurethane foam degradation in the presence of ozone. Royal Philips has not come forward with any test results or data showing that ozone has *any* degradative effect on polyester-based polyurethane foam.

111. To the extent Royal Philips (or any other Philips entity) has done any testing of polyester-based polyurethane foams in the presence of ozone, on information and belief, such testing did not account for real-world conditions, including, but not limited to, (i) the concentration of ozone at the surface of the foam during the cleaning cycle, (ii) the short duration of ozone exposure during the cleaning cycle, (iii) confounding variables, including heat, pH, and microbial enzymes, all of which would accelerate hydrolytic degradation of the foam, and/or (iv) the fact that high humidity can reduce ozone generation by as much as 50%.

112. On information and belief, Royal Philips and Mr. van Houten had no good-faith basis for his statement that ozone cleaners "should not be used on medical devices at all." At the time of this statement, Royal Philips owned U.S. Patent No. 9,937,275, titled "Gas

Sterilization/Disinfection System and Method for Fluid Conduits." The patent, which issued on April 10, 2018, touts the benefits of using ozone as a treatment gas to disinfect ventilator devices, and it has three separate dependent claims directed to using ozone as the treatment gas.

113. In response to Mr. van Houten's false and misleading statements about ozone, one questioner asked: "And as a follow up here, the ozone is clearly a part of the problem, the ozone cleaning; is there a case to start legal action against the companies that have marketed ozone cleaning and try to recoup some of the costs that you are incurring for this thing?"

114. Royal Philips and Mr. van Houten later recanted. On October 18, 2021, after SoClean filed this lawsuit, Mr. van Houten admitted, "When we went out in April and May, it was on a relatively narrow set of data, taking a worse-case scenario, as to potential risk." He then declared for the first time that "further research and testing" and "expert assessments" were not expected until the fourth quarter of 2021.

115. On information and belief, Mr. van Houten's false and misleading comments about ozone and ozone cleaners during the July 26, 2021 webcast and conference call were made for the purpose of influencing customers to buy and continue buying Defendants' products, including the next-generation DreamStation 2 CPAP machine and the Philips UV Light Sanitizer Box.

116. Royal Philips and Philips NA published the transcripts from the July 26, 2021 and October 18, 2021 webcasts and conference calls, together with press releases, on their respective public websites.

July 8, 2021 Update

117. On July 8, 2021, Royal Philips published an update to physicians and health care providers ("July Update") on its public website.

118. In the July Update, Royal Philips acknowledged that the off-gassing of harmful VOCs was "associated with the production process of the foam." Royal Philips identified "two compounds of concern" emanating from its devices: dimethyl diazene and phenol 2, 6-bis (1,1-dimethylethyl)-4-(1-methylpropyl). The latter compound—phenol 2, 6-bis (1,1-dimethylethyl)-4-(1-methylpropyl)—is an antioxidant and stabilizer used in a wide range of organic materials, including polyurethanes. This antioxidant would resist oxidative breakdown of the foam by ozone.

119. On information and belief, the foam supplier used by Philips RS adds phenol 2, 6-bis (1,1-dimethylethyl)-4-(1-methylpropyl) to resist oxidation and stabilize the polyester-based polyurethane foam material.

120. The health and safety risks associated with VOC chemical emissions from the sound abatement foam were serious enough to serve as an independent basis for the product recall, separate and apart from any foam degradation.

121. The product recall due to the off-gassing of VOCs was unrelated to the use of ozone or ozone cleaners.

122. On information and belief, the use of ozone cleaners would help mitigate the emission of the VOCs and effectively destroy them through chemical reactions.

123. In the July Update, Royal Philips confirmed that it had determined from a combination of user reports and lab testing that the degradation of the foam was caused by "a process called hydrolysis"—*i.e.*, the chemical breakdown of a compound due to a reaction with water. Royal Philips cited a "research study reported in the literature" that identified diethylene glycol (DEG) as one of the "degradative by-products" from a hydrolysis reaction involving polyester-based polyurethane foam. Royal Philips acknowledged that its own "[l]ab analysis of the degraded foam positively confirmed the presence of DEG as well as other compounds." The

positive confirmation of DEG in the degraded foam samples confirmed that the degradation observed by Philips was due to hydrolysis, not reactions involving ozone, which, on information and belief, would not leave a chemical signature.

124. Royal Philips cited a 2011 research study in the July Update. The paper stated: "***It is now accepted that hydrolysis predominates for polyester based polyurethane PU(ES)*** whereas oxidation is the principal cause of degradation for polyether-based polyurethane PU(ET) variety." Lattuati-Derieux, A. et al., *Assessment of the degradation of polyurethane foams after artificial and natural ageing by using pyrolysis-gas chromatography/mass spectrometry and headspace-solid phase microextraction-gas chromatography/mass spectrometry*, J. Chromatogr., A 1218, 4498-4508 (2011) (emphasis added). This was true in 2011. It remains true today.

125. On information and belief, Royal Philips and Philips RS knew before the public announcement on April 26, 2021 that hydrolysis is the dominant source of degradation for polyester-based polyurethane foam.

126. Despite all evidence to the contrary, Royal Philips still told physicians and providers for CPAP, BiPAP, and ventilator devices that "Philips is recommending that customers and patients do not use ozone-related cleaning products."

Frequently Asked Questions

127. Royal Philips published "Frequently Asked Questions" with answers about the product recall for the benefit of customers and patients on its public website. The answers reference ozone nine times in association with the product recall.

128. On four separate occasions, Royal Philips recommended that "customers and patients halt use of ozone-related cleaning products . . . ."

129. The answers published by Royal Philips also flatly assert that degradation was caused by ozone: "Possible health risks include exposure to degraded sound abatement foam, for example caused by unapproved cleaning methods such as ozone, and exposure to chemical emissions from the foam material."

130. Further, Royal Philips told customers and patients: "Philips has determined that the foam may degrade under certain circumstances, influenced by factors including use of unapproved cleaning methods, such as ozone*, and certain environmental conditions involving high humidity and temperature." Here again, Royal Philips directed customers to the FDA's Safety Communication about ozone leakage and UV light, which was unrelated to the product recall.

131. The answers included self-promotional language designed to reassure customers and retain business, while deflecting blame to SoClean and ozone cleaners. For example, Royal Philips told customers and patients: "Philips has a robust Quality Management System and has followed our review and analysis processes to help identify and address this issue." In addition, Royal Philips identified products that were unaffected by the recall, including the DreamStation 2.

132. In the answers, Royal Philips stated: "Products that are not affected may have different sound abatement foam materials, as new materials and technologies are available over time. Also, sound abatement foam in unaffected devices may be placed in a different location due to device design." This is notable for two reasons. First, Royal Philips intentionally misled customers and patients by suggesting "new" alternative foam materials just recently became "available over time." In fact, viable alternative foam materials, including polyether-based silicone-based foams, existed long before the product recall. Second, Royal Philips acknowledged alternative design choices were available to Philips RS, where the sound abatement foam "may be placed in a different location due to device design."

MedTrade West and Distributors

133. On July 12-14, 2021, Medtrade West, the largest home medical equipment trade show and conference in the United States, took place in Phoenix, AZ. The largest distributors and resellers of both Philips RS and SoClean products were in attendance. On information and belief, MedTrade conferences typically have over 500,000 attendees from around the globe.

134. On information and belief, Philips RS cancelled its public booth on the floor of the conference during the MedTrade West conference in July 2021. Instead, on information and belief, Philips RS rented a hotel suite and invited multiple select partners, including distributors and sellers of medical device equipment that service both Philips RS and SoClean.

135. On information and belief, Philips RS, under the direction of Royal Philips and Philips NA, made false and misleading statements about ozone cleaners to SoClean's distributors and resellers during the MedTrade West conference. On information and belief, Philips RS told these distributors and resellers during meetings in the hotel suite and elsewhere that "SoClean was the problem," and that SoClean was to blame for the product recall one month earlier. On information and belief, Philips RS made these statements to deflect blame and avoid accountability for the product recall and to entice distributors and resellers to continue doing business with them.

136. On information and belief, Philips RS made additional statements to multiple SoClean distributors and resellers, under the direction of Royal Philips and Philips NA, in both oral and written communications, which have negatively impacted SoClean's economic, business, and contractual relationships. On information and belief, Philips RS made these statements to deflect blame and avoid accountability for the product recall and to entice distributors and resellers to continue doing business with them.

137. Resellers and distributors have cited Defendants' false and misleading statements about ozone cleaners as the reason for not placing orders with SoClean. Sales to distributors and resellers once accounted for the majority of SoClean's sales and revenue.

138. On or around June 14, 2021, when Royal Philips and Philips RS announced the recall and issued the Recall Notice, one SoClean distributor said, on the subject of SoClean sales, that the "Philips news is killing us."

139. In or around July 2021, another SoClean distributor reported that customers were returning unopened SoClean units, citing unfounded assertions linking ozone cleaners to the product recall. This same distributor reported a decline in monthly unit volume by about 50% since May 2021.

140. By the end of July 2021, all but one of SoClean's top distributors and resellers had stopped placing orders with SoClean because of the false and misleading ozone-related statements made and published by Royal Philips, Philips NA, and Philips RS.

FDA Inspection Report

141. On November 12, 2021, the FDA issued an update on the product recall, together with a report from an inspection of Philips RS that took place from August 26 to November 9, 2021. The FDA stated that the purpose of the inspection was to "determine what may have caused or contributed to the foam issues and assess adherence to the agency's requirements for quality manufacturing."

142. Among other things, the FDA report confirmed that Philips RS had been aware of issues related to both the off-gassing of harmful chemicals and foam degradation for years, but took no corrective action while the company's executives concealed damaging information and problematic test results from the public. The report also confirmed that Philips RS had been

receiving customer complaints about its foam long before SoClean machines were even on the market and with respect to ventilator devices for which SoClean is not compatible.

143. The report "lists observations made by the FDA representative(s) during the inspection of [the Philips RS] facility." The following eight observations describe conduct by Philips RS with respect to the issues that led to the product recall:

i. Risk analysis is inadequate.

ii. Procedures for corrective and preventative action have not been adequately established.

iii. Design validation did not ensure the device conforms to defined user needs and intended uses.

iv. Procedures for design change have not been adequately established.

v. A correction or removal, conducted to reduce a risk to health posed by a device, was not reported in writing to FDA.

vi. Management with executive responsibility has not ensured that the quality policy is understood, implemented and maintained at all levels of the organization.

vii. Procedures to ensure that all purchased or otherwise received product and services conform to specified requirements have not been adequately established.

viii. Potential consultants were not evaluated and selected based on their ability to meet specified requirements.

144. The FDA report begins with the following statement: "There is no documented investigation, risk analysis, or design failure mode effect analysis to support your firm's rationale

for which polyester polyurethane foam-containing products were affected, included, or not included in your firm's ongoing recalls."

145. The FDA observed that Philips RS failed to conduct an appropriate risk analysis when it became aware of concerns regarding either foam degradation or the off-gassing of harmful chemicals: "A risk analysis is inadequate or was not performed when appropriate or within an appropriate time frame of [Philips RS] becoming aware of potential polyester polyurethane foam degradation and/or Volatile Organic Compound (VOC) emission concerns regarding various CPAP, BiPAP, and ventilator devices."

146. The FDA report described numerous instances dating back to April 2016, when Philips became aware of issues and concerns regarding foam degradation and the off-gassing of VOCs: "Specifically, there were at least fourteen instances, assessments, and/or test reports, dated from 04/01/2016 to 01/22/2021, where [Philips RS] was aware of issues and concerns related to potential foam degradation and/ or Volatile Organic Compound (VOC) emissions, with various Sleep and Respiratory care devices . . . ."

147. The FDA found that Philips RS initiated no formal investigation, risk analysis, or corrective measures in response to at least 222,000 complaints between 2008 and 2017 that "could potentially be related to foam degradation." According to the FDA, over 20,000 of those complaints occurred between 2008 and 2017 and involved Trilogy ventilator devices. This means that many of the consumer complaints related to foam degradation pre-dated SoClean's introduction to the market. Also, Trilogy ventilators are not compatible with SoClean machines, eliminating any possibility that ozone cleaners were somehow responsible for the foam degradation in the Trilogy devices.

148. The FDA reviewed email correspondence between Philips RS and its raw foam supplier. The email correspondence revealed that Philips RS was "made aware of polyester polyurethane foam degradation issues in/around October 2015, which was later confirmed by your foam supplier on 08/05/2016, via email."

149. Internal email correspondence at Philips RS from August 2018 described testing that showed "the affected foam breaks down in high heat and high humidity environments." According to the FDA, these test results "concurred with Trilogy ventilator related complaints" received by Philips RS. Despite clear evidence of foam degradation, the same email exchange, dated August 24, 2018, revealed that Philips RS "made the decision not to change the design, and continue to include polyester polyurethane foam, in the Trilogy ventilator platform of devices."

150. Philips RS initiated a "field correction" of Trilogy 100 and 200 ventilator devices and failed to report the event to the FDA. According to the FDA report, "[t]his field correction was implemented as a corrective action in response to CAPA INV 0988, which was initiated due to multiple field complaints and at least 1 Trilogy unit failure, caused by polyester polyurethane foam degradation." Trilogy ventilators are not compatible with SoClean devices. Thus, the foam degradation in the recalled ventilators had nothing whatsoever to do with ozone or ozone cleaners.

151. According to the FDA: "Th[e] affected foam was later found to be mutagenic, cytotoxic, carcinogenic, and non-biocompatible." Philips RS knew of a potential cancer risk and said nothing.

152. The FDA observed that Philips RS management, including company executives, concealed known health risks associated with foam degradation from the public: "[F]irm management, including management with executive responsibility, were aware of potential foam

degradation issues concerning CPAPs, BiPAPs, and Trilogy ventilators since at least 01/31/2020, or earlier, and implemented no further corrective actions until April 2021."

153. On the issue of off-gassing, the FDA inspection report stated that the DreamStation products failed emissions testing for VOCs as early as 2019, based on compounds not previously or publicly disclosed by Philips RS. For example, the report revealed that DreamStation devices failed emissions testing by exceeding tolerable limits of formaldehyde.

154. The FDA inspection report did not contain a single reference to ozone.

FDA's 518(a) Notification Order

155. On or about March 10, 2022, the FDA issued a 518(a) Notification Order to address certain inadequacies in Philips RS's communications with health professionals and others who prescribe or use the recalled products. In the Order, the FDA expressed concerns that Philips RS was not providing patients and consumers with sufficient information regarding the progress of the recall and the process for obtaining a replacement device.

156. Pursuant to section 518(a) of the Food, Drug, and Cosmetic Act (FDCA), the FDA ordered Philips RS to take several actions. Among them, the FDA ordered Philips RS to "[p]rovide a link for healthcare providers and registrants to access all available testing results and third party confirmed conclusions on results and findings from testing PUR-PE foam used in devices manufactured by Philips for VOCs and particulates, regardless of the Philips device that the foam may have been tested in." The FDA also noted that the information on the Philips website was "vague" and did "not provide healthcare providers with the facts necessary for them to make informed decisions regarding the risks associated with the continued use of the Recalled Products for their patients."

157. The FDA ordered Philips RS to "[m]aintain prominently displayed information on the risk of using ozone cleaners on the Recalled Products on the Philips Recall main landing page." On information and belief, the FDA has not conducted any independent testing to determine what effect, if any, ozone cleaners have on the polyester-based polyurethane foam in the recalled devices. On information and belief, Philips RS misled the FDA into believing that Philips RS had a good-faith scientific basis when it repeatedly told the Agency that ozone may exacerbate foam degradation. On information and belief, Philips RS misled the FDA about ozone at the direction of Royal Philips and Philips NA to avoid accountability for the product recall and influence customers to continue buying products from Philips RS.

FDA's 518(b) Notice of Opportunity for a Hearing

158. On May 2, 2022, the FDA issued to Philips RS a Notice of Opportunity for a Hearing pursuant to section 518(b) of the FDCA.

159. In the 518(b) Notice, the FDA called out Philips RS for not being forthright about test results and the health risks posed by polyester-based polyurethane foam. Previously, Philips RS had shared with the FDA a table and narrative summary of all testing done as of April 25, 2022. According to the FDA, Philips RS emphasized test results identifying no risks, while trying to discount "results supporting the conclusion that the recalled devices present a significant risk."

160. The FDA observed: "Philips' Health Hazard Evaluations (HHEs) regarding the foam degradation risk reported potential degradation products identified with the recalled devices, including toluene diisocyanate isomers (TDI), toluene diamine isomers (TDA), and diethylene glycol (DEG)." These are known and well-established biomarkers of degradation by hydrolysis.

161. The FDA also debunked Defendants' weaponization of the 2020 FDA safety communication. The 518(b) Notice stated: "[A]lthough FDA issued a safety communication in

February 2020 stating that the safety and effectiveness of using ozone to clean CPAP machines had not been evaluated by the Agency, and warning of risks associated with using ozone for this purpose, the safety communication addressed risks wholly unrelated to the potential degradation of sound abatement foam." Further, the FDA made clear that the safety communication did not describe any negative effects on the CPAP devices themselves: "These risks focused on the potential for ozone gas leaks, or the temporary build-up of ozone, and did not describe any negative effects of ozone cleaners on the safety or efficacy of CPAP devices themselves." The FDA then concluded: "The safety communication thus did not give device users reason to anticipate that the use of ozone cleaners might significantly impact the safety of the devices themselves, or that the use of ozone cleaners in ventilated spaces (and utilizing procedures that permitted the circulation of fresh air through the devices) would necessarily present significant risks." Last, the FDA pointed out that "Philips' own analysis identified hundreds of complaints confirmed to be related to foam degradation across affected products that were received between 2014 and 2019, before the safety communication was issued."

162. Laboratory testing conducted by or on behalf of Philips RS in 2021 identified VOCs emitted from the foam above acceptable levels, including dimethyl diazine, phenol, 2,6-bis (1,1-dimethylethyl)-4-(1-methylpropyl), and formaldehyde. According to the 518(b) Notice, "Philips has acknowledged that, in a worst-case scenario, exposure to VOCs as a class may cause possible toxic and carcinogenic effects, as well as irritation of the respiratory tract, eyes, nose, and skin, nausea or vomiting, hypersensitivity reactions, dizziness, and headache." These potentially harmful VOC emissions were a separate, independent basis for the recall.

163. The FDA ultimately concluded that "the unreasonable risk associated with the products was not caused by the use of ozone cleaning agents, nor did the use of ozone to clean the

products constitute a failure to exercise due care." The FDA continued: "FDA is not aware of any information unrelated to the use of ozone which may suggest that the unreasonable risk associated with the recalled devices was caused by a failure to exercise due care in the installation, maintenance, repair, or use of the devices by anyone other than Philips." Put another way, Defendants have only themselves to blame for creating an unreasonable risk to patients and users.

June 28, 2022 Update

164. On June 28, 2022, Royal Philips and Philips NA issued identical press releases with an update on the foam testing and research program, together with a written summary of test results and video messages from then-CEO Frans van Houten, future CEO Roy Jakobs, and Jan Bennik, the Technical Project Manager for the company's test and research program. The stated purpose of the update was to "provide healthcare providers, patients, and other stakeholders with updated information on the testing results to date."

165. The press release acknowledged that, at the time of the Recall Notice, Defendants relied on "an initial limited data set and toxicological risk assessment." The press release then touted the subsequent use of "five certified, independent testing laboratories in US and Europe, as well as other qualified third-party experts" to conduct a "comprehensive test and research program" to assess the potential health risks associated with polyester-based polyurethane foam.

166. The press release included a statement by Mr. van Houten. In his statement, Mr. van Houten misled healthcare providers, patients, consumers and other stakeholders in several ways. First, Mr. van Houten highlighted favorable results showing little to no risk, while discounting or flat out ignoring test results showing that the foam tested positive for genotoxicity and cytotoxicity. Second, Mr. van Houten said: "Results to date also indicate that ozone cleaning significantly exacerbates foam degradation." This unfounded statement is demonstrably false. In

reality, Royal Philips, Philips NA, and Philips RS have not released any actual test results involving ozone, let alone from an independent third-party laboratory.

167. On information and belief, Royal Philips and Philips NA intended to mislead the public with unfounded claims about ozone. Reuters was misled, for example, when it reported on Mr. van Houten's statements by citing "aggressive" ozone cleaners as the cause of degradation: "The 'very encouraging' tests showed that the foam degradation was very rare and was linked to aggressive, unauthorised ozone-based cleaning products, Chief Executive Frans van Houten said."

168. In his highly-produced video message posted on the public websites of Royal Philips and Philips NA, Mr. van Houten repeated the unfounded and misleading claim that "ozone cleaning significantly exacerbates foam degradation."

169. In other statements quoted by Reuters, Mr. van Houten went even further. On or about June 28, 2022, he stated: "The correlation between the use of ozone and foam degradation that we ***assumed*** last year has been proven." (emphasis added.) Not only did Mr. van Houten advance the false and misleading assertion that Defendants had somehow "proven" a correlation (not causation) between ozone and foam degradation, he openly admitted that Defendants' prior statements about ozone in 2021 were based on nothing more than on an unfounded assumption.

170. The first "results" identified in the press release purported to speak to the "impact of repeated ozone cleaning." The press release stated: "Devices with self-reported ozone use were 14x more likely to have significant visible foam degradation than those with self-reported no ozone use: 777 of 11,309 devices (7%) showed significant visible foam degradation." This statement and "data" were deeply flawed and wildly misleading.

171. The press release stated that "a visual assessment of the foam ***was performed*** on a sample of 60,847 returned/used first-generation DreamStation devices from the US and Canada."

(emphasis added.) It also stated: "The visual inspection ***was conducted*** according to a specific protocol as part of the repair process." (emphasis added.)

172. Royal Philips and Philips NA used the passive voice to conceal the truth and mislead healthcare providers, patients, consumers, and other stakeholders into believing that Philips RS had independent third-party testing on ozone and polyester-based polyurethane foam. To the contrary, the truth was buried on page 19 of the written summary, in "footnote h," and in fine print: "Visual inspection performed internally."

173. The press release also stated that Philips RS relied on users to "self-report" the use of ozone cleaners. What Royal Philips and Philips NA failed to point out was that by self-reporting the use of an ozone cleaner, patients and users knew they could move to the front of the line and receive repairs or a replacement device more quickly.

174. On information and belief, Philips RS prioritized certain patients for repair and replacement in the United States based on "high risk" using data that the company collected through the "US Patient Portal." The prioritization webpage included a series of questions to support "efforts to prioritize fulfillment of registered devices for patients with the most urgent medical needs." The last question on the prioritization page to expedite repair and replacement was: "Has Ozone or Activated Oxygen been used to sterilize the device?"

175. On information and belief, the inclusion of a question about ozone on the prioritization page created a strong incentive for patients and users to self-report ozone usage to get a replacement device sooner. Consequently, on information and belief, patients and users significantly over-reported ozone usage to get to the front of the line.

176. On information and belief, as of mid-April 2022, Philips RS had repaired or replaced roughly 840,000 units out of 2.8 million registered units in the United States and Canada,

and processed about 33,000 units each week. At that pace, it would take over a year, until the middle of 2023 to repair or replace the registered units in the United States and Canada alone. The slow pace of the repair and replace program created an additional incentive for patients and users to self-report ozone usage, even when none had occurred.

177. The "visual inspections" were also done internally by Philips RS employees, not by an independent third-party lab. On information and belief, Philips RS conducted the visual inspections after this lawsuit was filed, creating bias and a strong incentive to skew the results to favor Defendants and harm SoClean.

178. In the section addressing VOC testing, the press release states: "It is important to note that these tested new and lab aged first-generation DreamStation devices were not exposed to ozone cleaning, in accordance with the instructions for use." Here again, Royal Philips and Philips NA created a false and misleading impression that ozone cleaners were somehow responsible for VOC emissions from the sound abatement foam, despite all evidence to the contrary.

179. In another highly-produced video message posted on the public websites of Royal Philips and Philips NA, along with the June 28, 2022 testing update, Jan Bennik said that "we are also testing the impact of repeated ozone cleaning on VOC emission and foam degradation." Thus, even as of June 28, 2022, Defendants did not have reliable test results involving ozone capable of withstanding public scrutiny. To date, no such test results have been released.

180. Mr. Bennik also acknowledged in his video message that when Philips RS issued the Recall Notice "we were relying on an initial and limited set of data."

Defendants Create Widespread Confusion

181. Defendants' conduct and statements have created widespread confusion in the marketplace, including with SoClean's actual and prospective customers and distributors. SoClean's actual and prospective customers and distributors have been wrongfully led to believe that SoClean devices were the reason for the product recall, should not be used to sanitize CPAP machines or other medical devices, and are unsafe.

182. On June 14, 2021, for example, the day after Philips RS issued the Recall Notice, the Oregon Sleep Association (OSA) issued a notice stating that "[t]here is a slight risk of [the] foam degrading into particles which may be inhaled or ingested during use," and that "[t]he highest risk of exposure appears to be in conjunction with ozone cleaning machines such as SoClean Devices."

183. The OSA later issued another notice stating that "Philips has advised that patients who have reported these rare symptoms may be users of the ozone cleaning systems, such as SoClean. If you are currently using such a system to clean your PAP machine, we suggest you stop doing so . . . ."

184. On June 16, 2021, the Pulmonary and Critical Care of Baltimore (PCCB) issued a notice notifying its patients of the Philips recall. The notice incorrectly stated: "It appears that [the foam degradation issue] has been found predominantly when such machines have been cleaned with ozone cleaning machine device." The PCCB noted that "Philips is recommending that customers and patients halt use of ozone-related cleaning products." The notice also said that the PCCB "recommends that all of our patients discontinue the use of ozone or UV cleaners until we have learned more about this."

185. The Minnesota Sleep Institute issued a similar notice, instructing patients and members to "stop using ozone cleaning products such as SoClean."

186. The U.S. Department of Veteran Affairs, which had distributed nearly 600,000 recalled devices to veterans for home use and another 2,000 devices used within VA hospitals or clinic settings, issued a similar notice, stating that "Philips Respironics testing indicates that the breakdown [of the foam] is primarily caused by the devices being used in high heat and high humidity environments or using unapproved cleaning methods such as ozone." The notice further stated incorrectly that "[m]ost of the devices found with this issue have been in use for more than three years and have been routinely cleaned with an ozone cleaner."

187. On July 16, 2021, the American Academy of Sleep Medicine—which has a combined membership of 11,000 accredited member sleep centers and individual members, including physicians, scientists, and other health care professionals—issued a notice directing its members to "[i]nform patients that Philips has stated that ozone-related products should not be used to clean PAP equipment."

188. On information and belief, many health care providers, associations, agencies, and other groups have issued similar notices or communications to their patients, members, and the broader public. These organizations have wrongfully represented the reason for the product recall and the risks associated with ozone cleaners based on false and misleading statements made and published by Royal Philips, Philips NA, and Philips RS.

189. Numerous media outlets and websites have misrepresented the reason for the product recall and the risks associated with ozone cleaners based on Defendants' false and misleading statements.

190. Prior to Defendants' wrongful conduct, SoClean enjoyed an exceptionally high customer satisfaction rate, with more than 90% ranking their experience with SoClean as "Very Satisfying" or "Extremely Satisfying."

191. Following the product recall and misleading public statements about ozone, however, SoClean has been inundated with messages from customers, distributors, and others who have been misled to believe that SoClean devices are the reason for the product recall, should not be used to clean their medical devices, and are unsafe.

192. SoClean has received customer complaints following Defendants' false and misleading statements alleging, among other things, that SoClean "ruins" the CPAP machine and that ozone is "not safe."

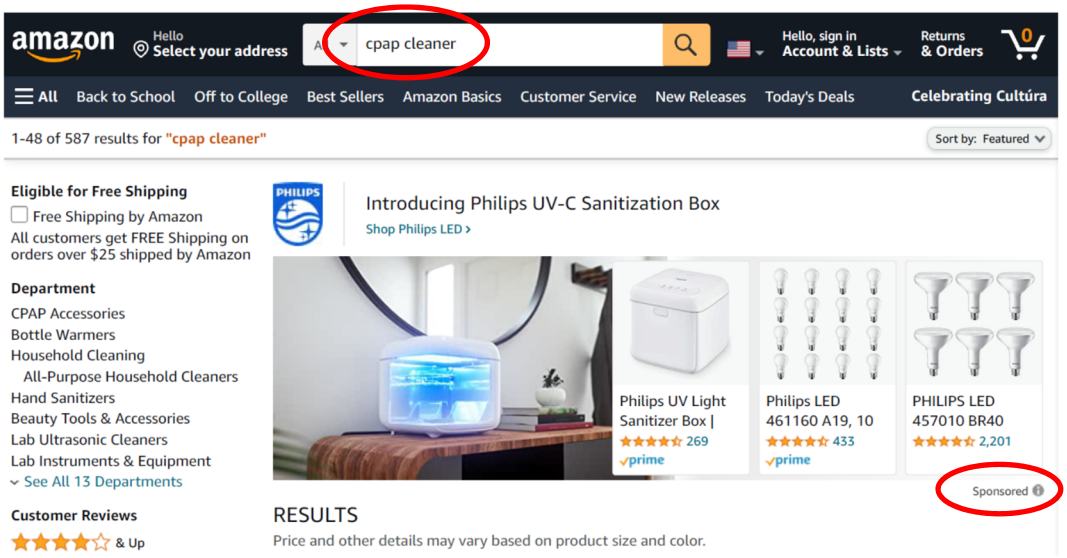
Defendants Compete with SoClean

193. SoClean sells a product called the "SoClean's O3 Smarthome Cleaning System and Device Disinfector." The product uses ozone to clean and disinfect everyday household items, such as television remotes, smartphones, glasses, keys, and earbuds. It is available for purchase on the SoClean website for $99.

194. On or around April 12, 2021, Defendants publicly launched a new product, the Philips UV Light Sanitizer Box. On information and belief, the Philips UV Light Sanitizer Box became available for purchase on Amazon.com on or about April 19, 2021. The product is available for purchase on Amazon for $99.99.

195. The Philips UV Sanitization Box competes directly with SoClean's ozone cleaning products. The product purports to "disinfect[] surfaces and objects in just minutes." On information and belief, the Philips UV Sanitizer Box is sold under the direction of Philips NA and/or Royal Philips. Promotional materials with the Philips logo state that the product is intended to "disinfect small items and objections" and is "suitable for a wide range of items like toys, keys, cell phones and wallets."

196. On information and belief, the Philips UV Sanitizer Box is being marketed using keywords specifically targeted to CPAP consumers (*e.g.*, "CPAP cleaner," "CPAP sanitizer," and "CPAP disinfector"). For example, a search for "cpap cleaner" on Amazon results in sponsored ad banners for the Philips UV Sanitizer Box.



197. On information and belief, one or more of the Defendants selected and paid for dozens of keywords that include the words "CPAP," "BIPAP," "DreamStation," and "Resmed" to sell and market the Philips UV Sanitizer Box.

198. Defendants do not have approval to market the Philips UV Sanitizer Box to clean or disinfect CPAP equipment and accessories.

199. On information and belief, Defendants are aware that consumers purchase and use the Philips UV Sanitizer Box to clean their CPAP devices. For example, customer reviews and comments on the Amazon.com product page include extensive discussions regarding the use of the Philips UV Sanitizer Box to clean and disinfect CPAP devices. The Philips UV Sanitizer Box is large enough to fit CPAP accessories, including the mask and tubing, as shown below.

200. Defendants launched a UV light sanitizer and covertly marketed the product for use with CPAP equipment and accessories, despite knowledge that the FDA had previously warned in its 2020 safety communication that "UV light may be unable to penetrate all areas of the CPAP accessories such as the hoses, masks and connectors." According to the FDA, "[t]his may result in inadequately disinfected CPAP devices and accessories that may not be safe for reuse."

201. Royal Philips also owns intellectual property directed to technologies for cleaning and sanitizing sleep and respiratory equipment that compete with ozone. For example, on June 4, 2021, just 10 days before the product recall, Royal Philips filed a patent application (U.S. Patent App. No. 2022/0001059) on a process for disinfecting CPAP and other respiratory equipment using vaporized hydrogen peroxide, a competing gaseous disinfection technology. Royal Philips also owns patents on the use of ozone (U.S. Patent No. 9,937,275) and ultraviolet (UV) light to clean and disinfect respiratory equipment (*e.g.*, U.S. Patent No. 10,130,726). On information and belief, Royal Philips owns the rights to other patents and applications directed to cleaning and disinfecting technologies that compete with ozone.

Damage to SoClean

202. SoClean has experienced devastating damage to its brand reputation and a loss of goodwill as a result of Defendants' illegal conduct.

203. On information and belief, users, distributors, and resellers of CPAP devices have stopped using and buying SoClean products in response to Defendants' false and misleading statements and other wrongful conduct. As a direct result of Defendants' coordinated smear campaign against ozone cleaners, SoClean's sales to distributors, resellers, and end-users have plummeted.

204. SoClean sells its devices in a variety of ways, including via indirect sales through distributors, as well as direct sales to consumers, online Durable Medical Equipment suppliers (DMEs), and other DMEs. In some cases, SoClean sells it devices to distributors, which in turn sell the devices to, among others, DMEs, which, in turn sell, the devices to consumers. SoClean has historically accepted as returns devices that are returned to DMEs by consumers.

205. SoClean has had economic and contractual relationships with third-party distributors, resellers, and DMEs. Defendants knew about these contractual and business relationships because, among other reasons, they too have contractual and business relationships with many of the same distributors, resellers, and DMEs. Defendants also know that many of these distributors, resellers, and DMEs sell both SoClean and Philips RS products, and that Philips RS is a much larger account, which provides more leverage and negotiating power to Philips RS.

206. On information and belief, Philips RS sells its CPAP machines in a variety of ways, including sales to DMEs. Philips RS recently agreed to pay $24 million to resolve False Claim Act allegations by the Department of Justice that Philips RS provided kickbacks to its DME customers in the form of data on the prescribing decisions of U.S. physicians. According to a DOJ

press release, dated September 1, 2022, Philips RS allegedly "caused DME suppliers to submit claims for ventilators, oxygen concentrators, CPAP and BiPAP machines, and other respiratory-related equipment that were false because Respironics provided illegal inducements to the DME suppliers." The press release continued: "Respironics allegedly gave the DME suppliers physician prescribing data free of charge that could assist their marketing efforts to physicians." This was yet another source of undue influence that Philips RS held over DME suppliers and resellers.

207. As of July 30, 20201, SoClean lost 5 of its top 6 distributors. These customers stopped buying from SoClean while promoting competing disinfection devices, including devices using UV light, as a result of Defendants' unlawful conduct.

208. Historically, SoClean's sales to distributors and resellers once accounted for over half of the company's total revenue.

209. On information and belief, customers have continued using and selling CPAP devices made by both Philips RS and its competitors but have stopped using or selling SoClean devices due to Defendants' false and misleading statements and other wrongful conduct.

210. On information and belief, the damage to SoClean caused by Defendants exceeds $200 million.

CLAIM I

(Lanham Act Violation: 15 U.S.C. § 1125(a)(1)(B))

211. SoClean repeats each of the allegations above as if fully set forth herein.

212. Defendants have made false and misleading factual representations about their own products and SoClean's products. Specifically, Defendants have made false and misleading factual representations about (i) Philips RS sleep and respiratory care products, including the flagship DreamStation CPAP products, and (ii) ozone cleaners sold by SoClean, in commercial advertising or promotion.

213. Each Defendant has published false and misleading information and misrepresented facts regarding the cause of degradation and VOC emissions associated with the polyester-based polyurethane foam that Philips RS used for sound abatement in its sleep and respiratory care products, including the original DreamStation CPAP machine.

214. Separately, each Defendant has also published false and misleading information and misrepresented facts related to SoClean's ozone cleaner products in communications directed at consumers, distributors, and resellers of sleep and respiratory care products, with an intent to influence their purchasing decisions.

215. Defendants have deceived a substantial portion of their intended audience—namely, users, distributors, resellers, and prescribers of Philips respiratory care devices and the Philips UV Light Sanitation Box.

216. Defendants' misrepresentations deceived CPAP machine users, resellers, distributors, and prescribers about the cause of safety risks associated with Philips RS products, including foam degradation and VOC emissions, and the general safety of ozone cleaners. Countless distributors, resellers, users, and prescribers of CPAP machines are now under the false

impression that SoClean and its ozone cleaners are responsible for the product recall and unsafe for use. As a direct result of Defendants' false and misleading statements, customers have continued using Philips brand respiratory care and disinfection products and stopped using SoClean's products due to unfounded safety concerns.

217. Defendants targeted and deceived a specific class and category of purchasers and potential purchasers to deflect blame and responsibility for the recall so that customers would continue to purchase and prescribe sleep and respiratory care devices made by Philips RS. In addition, Defendants also deceived customers and potential customers of SoClean's with false and misleading information about the safety of ozone in an effort to direct sales to the competing Philips UV Light Sanitation Box.

218. Defendants' misrepresentations about ozone advanced their collective economic, business, and commercial interests. Defendants had an improper motive and economic incentives to preserve the company's brand and reputation, maintain the existing customer relationships of Philips RS and Philips NA, and shift responsibility for the safety concerns associated with the sound abatement foam to anyone other than Royal Philips or its subsidiaries.

219. Defendants also had an improper motive and economic incentive to damage the reputation of SoClean, the market leader for ozone cleaners accounting for the vast majority of sales. SoClean is a direct competitor that sells competing disinfection products, including SoClean's O3 Smarthome Cleaning System and Device Disinfector.

220. Defendants' misrepresentations about ozone cleaners and the reasons for the product recall were material in that they were likely to influence, and have influenced, the purchasing decisions of distributors, resellers, and individual consumers.

221. The alleged misrepresentations (i) constituted commercial speech, (ii) were made with the intent of influencing customers and potential customers to continue purchasing sleep and respiratory care products sold by Philips RS, including the next-generation DreamStation 2 product and the Philips UV Sanitizer Box, and (iii) were disseminated to the consuming public in such a way to constitute advertising or promotion.

222. Actionable statements include, at least, (a) the Recall Notice and accompanying press releases and other contemporaneous materials, (b) false and misleading statements published on the public websites of Royal Philips and Philips RS related to product recall and ozone cleaners, including press releases, updates, and statements by the company's CEO Frans van Houten during webcasts and media interviews, and (c) statements to SoClean's distributors, resellers, and other customers that SoClean was the "problem," and that its products were unsafe for use and to blame for the safety issues that led to product recall.

223. Defendants intentionally waited to take corrective action to address safety concerns associated with polyester-based polyurethane foam until they could redirect existing business to the DreamStation 2 product. In multiple statements related to the recall, Defendants promoted the DreamStation 2 product, noting that it was not affected by the recall.

224. Defendants placed their false and misleading statements in interstate commerce, for example, through press releases and on the public websites of Royal Philips and Philips NA.

225. Defendants knew that their false statements about the safety of ozone cleaners, as well as their public admonitions not to use or purchase ozone cleaners, would result injury to SoClean in the form of declining sales and loss of goodwill.

226. SoClean has been injured severely as a direct result of Defendants' Lanham Act violations. The injuries suffered by SoClean have been in the form of a dramatic decline in sales, damage to brand reputation, and a loss of goodwill.

CLAIM II

(New Hampshire Consumer Protection Act)

227. SoClean repeats each of the allegations above as if fully set forth herein.

228. Defendants used unfair methods of competition and committed unfair and deceptive acts in the conduct of trade or commerce within the state of New Hampshire.

229. Defendants conduct both trade and commerce within the state of New Hampshire.

230. Specifically, Defendants have violated the New Hampshire Consumer Protection Act, for example, by "[d]isparaging the goods, services, or business of another by false or misleading representation[s] of fact." *See* N.H. Rev. Stat. Ann. § 358-A:2, VIII.

231. Each Defendant has disparaged SoClean's products by publishing and widely disseminating false and misleading representations about SoClean's products that have misled consumers within the state of New Hampshire. Specifically, Defendants have misled consumers about the safety of SoClean's products and the cause of the safety issues that led to the recall.

232. Among other things, Defendants' statements led reasonable consumers, including consumers in New Hampshire, to mistakenly believe that ozone cleaners are the reason for the product recall and are unsafe for use.

233. On information and belief, Defendants' false and misleading representations of fact were intended to disparage SoClean's products and influence customers to continue buying Defendants' products, including the next-generation DreamStation 2 machine and the Philips UV Light Sanitizer Box.

234. Defendants' unlawful conduct (i) has offended established public policy, (ii) was immoral, unethical, and unscrupulous, and (iii) has caused substantial injury to SoClean, all within the state of New Hampshire.

235. Defendants' unlawful conduct has caused direct and indirect injury to both consumers and SoClean within the state of New Hampshire.

236. Harm suffered by SoClean, a company based in the town of Peterborough, occurred within the state of New Hampshire.

237. New Hampshire commerce and citizens have been affected by Defendants' unfair and deceptive conduct.

238. SoClean is entitled to enhanced damages and attorney's fees under the statute.

CLAIM III

(Tortious Interference with Advantageous and Prospective Business Relationships)

239. SoClean repeats each of the allegations above as if fully set forth herein.

240. SoClean has business, economic, and contractual relationships with customers, including third-party distributors, resellers, and DMEs that purchase SoClean's ozone cleaners. SoClean has entered into written contracts with distributors, resellers, and DMEs.

241. Defendants had knowledge of SoClean's business, economic, and contractual relationships with third-party distributors, resellers, and DMEs because, among other reasons, numerous distributors and resellers of sleep equipment and DMEs purchase and sell devices for both SoClean and Philips RS.

242. Defendants knew that consumers of the DreamStation machines and the Philips UV Light Sanitizer Box also use SoClean's ozone cleaners.

243. Defendants knew that the Philips UV Light Sanitizer Box competes directly with SoClean's ozone cleaning product designed for household items.

244. On information and belief, Defendants communicated directly and indirectly with SoClean's distributors, resellers, and DMEs about ozone cleaners, blaming SoClean and ozone cleaners for the product recall.

245. SoClean is the dominant market leader for ozone cleaners, accounting for the vast majority of sales. Thus, on information and belief, even when Defendants made false and misleading to SoClean's customers, including distributors, resellers, and DMEs, about ozone cleaners, in general, such statements were made with reference to SoClean's products.

246. Defendants knowingly, intentionally, and purposefully interfered with SoClean's business, economic, and contractual relationships with third-party distributors, resellers, and DMEs, acting with an improper motive and means to preserve Defendants' sales and reputation and to prevent SoClean from continuing its existing business and contractual relationships.

247. Defendants' highly publicized false and misleading statements regarding the product recall and ozone cleaners also interfered with SoClean's business, economic, and contractual relationships with third-party distributors, resellers, and DMEs. Defendants knew any public statements about safety issues and the product recall, including statements by the CEO, would picked up and widely disseminated by news outlets like HME News, a media source that caters to home medical equipment providers.

248. Absent interference by Defendants, SoClean's business and contractual relationships with its distributors, resellers, and DMEs would have continued unabated.

249. Defendants have no privilege or justification to excuse their interference with SoClean's business, economic, and contractual relationships.

250. SoClean has suffered actual damages as a result of Defendants' interference in the form of a decline in sales, damage to its brand reputation, and a loss of goodwill.

CLAIM IV

(Defamation)

251. SoClean repeats each of the allegations above as if fully set forth herein.

252. Defendants have each made statements about SoClean that are false and defamatory in character to third parties, including SoClean's actual and prospective distributors, resellers, DMEs, and consumers, including statements regarding (i) the reasons for the product recall, (ii) the cause of degradation and VOC emissions associated with the polyester-based polyurethane foam, (iii) purported "testing" related to ozone cleaners, and (iv) and the use and safety of ozone cleaners including SoClean's ozone cleaner products.

253. Defendants were negligent and/or failed to exercise reasonable care in publishing their false and defamatory statements.

254. The recipients of Defendants' false and defamatory statements, including SoClean's actual and prospective distributors, resellers, DMEs, and consumers, understood the defamatory meaning of the statements and that the statements applied to SoClean.

255. Defendants did not have a valid privilege permitting them to make false and defamatory statements about SoClean to third parties, including SoClean's actual and prospective distributors, resellers, DMEs, and consumers.

256. Defendants' publication of the false and defamatory statements was a substantial factor in causing actual injury to SoClean, including damage to SoClean's business, brand, goodwill, and reputation. Defendants' defamatory statements have caused actual harm and substantial economic loss to SoClean.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff SoClean respectfully requests that the Court enter an Order:

A. That Defendants have violated 15 U.S.C. § 1125(a)(1)(B) and N.H. Rev. Stat. Ann. § 358-A:1 *et seq.*;

B. That Defendants are liable for tortious interference and defamation;

C. That SoClean be awarded all monetary relief available under the laws of the United States and applicable state law, including, but not limited to, actual damages, pre- and post-judgment interest, enhanced damages, costs, and attorneys' fees pursuant to 15 U.S.C. § 1117(a) and N.H. Rev. Stat. Ann. § 358-A;

D. That this is an exceptional case under 15 U.S.C. § 1117(a); and

E. For such other and further relief as the Court deems just and proper.

Dated: October 10, 2022

Respectfully submitted,

/s/ Colin Cabral

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