IN THE 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-152 MDL No. 3021
This Document Relates to:	
SoClean, Inc., plaintiff, v. **Koninklijke Philips N.V., Philips North America LLC, and Philips RS North America LLC**, defendants.	Civil Action No. 22-542

OPINION ON MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM

CONTI, Senior District Judge

I. Introduction

This action is part of multidistrict litigation number 3021 ("MDL 3021") and concerns the sale of a device (the "SoClean 2") by plaintiff SoClean, Inc. ("SoClean"). SoClean filed this action against defendants Koninklijke Philips N.V. ("KPNV" or "Royal Philips")[1], Philips RS North America LLC ("Philps RS"), and Philips North America LLC ("Philips NA" and with KPNV and Philips RS, "Philips defendants" or "defendants") based upon alleged statements made by the Philips defendants about the SoClean 2, which SoClean alleges caused it harm. Currently pending before the court is the Philips defendants' motion with respect to the second

[1] In the second amended complaint, SoClean refers to KPNV as "Royal Philips." (ECF No. 211.)

amended complaint to dismiss it for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6) (ECF No. 273). SoClean opposes the motion.

For the reasons set forth in this opinion, the motion to dismiss will be granted with respect to the claim asserted by SoClean under the Lanham Act, 15 U.S.C. § 1125(a), based upon alleged statements made by the Philips defendants in quarterly reports, on earnings calls, in the recall notice, in a Q&A posted on one of the Philips defendants' websites, an update dated July 2021, and a press release issued on June 28, 2022. The court will deny without prejudice the motion to dismiss with respect to the claim based upon whether SoClean set forth factual allegations sufficient to state a plausible Lanham Act claim with respect to the alleged statements made by Philips RS—at the direction of the other Philips defendants—during the MedTrade West tradeshow in July 2021. The motion to dismiss will be denied in all other respects.

II. Procedural History

On October 12, 2021, plaintiff SoClean filed a complaint against the Philips defendants. (ECF No. 1.) On December 2, 2021, SoClean filed the first amended complaint against the Philips defendants. (ECF No. 5.) SoClean in the first amended complaint asserted the following claims against the Philips defendants:

- Count I—Lanham Act Violation, 15 U.S.C. § 1125(a)(1)(B);
- Count II—M.G.L. Chapter 93A;
- Count III—Commercial Disparagement;
- Count IV—Tortious Interference with Business Relationships; and
- Count V—Unfair Competition.

(ECF No. 5.)

On April 11, 2021, the United States Judicial Panel on Multidistrict Litigation issued a transfer order, pursuant to which this case was transferred to this court as part of MDL 3021, In re: SoClean, Inc. Marketing, Sales Practices, and Products Liability Litigation. (ECF Nos. 16, 17.)

On May 11, 2022, the Philips defendants filed a motion to dismiss the amended complaint (ECF No. 33) and two briefs in support of the motion (one asserting the court lacked personal jurisdiction over KPNV and one attacking the claims in the complaint under Rule 12(b)(6)). (ECF Nos. 34, 35.) On June 21, 2022, SoClean filed a response in opposition to each of the briefs in support of the motion to dismiss. (ECF Nos. 43, 44.) On July 14, 2022, the Philips defendants filed a reply brief to each of SoClean's responses. (ECF Nos. 48, 49.) On August 5, 2022, the parties filed a joint motion to enter order preserving KPNV's jurisdictional defense and permitting the parties 90 days of discovery. (ECF No. 50 at 1.) This court held a hearing on the motion to dismiss for failure to state a claim under Rule 12(b)(6). The court gave its preliminary assessment of the motion to dismiss on the record. On that basis, SoClean informed the court that it intended to file a second amended complaint, which would moot out the motion to dismiss. The court ordered the parties to discuss a staged briefing schedule for the filing of future motions to dismiss.

On October 10, 2022, SoClean filed a second amended complaint. (ECF No. 211.) SoClean asserts the following claims against the Philips defendants:

- Count I—Lanham Act Violation, 15 U.S.C. § 1125(a)(1)(B);
- Count II—violation of New Hampshire Consumer Protection Act, N.H. Rev. Stat. Ann. § 358-A:2, VIII;
- Count III—Tortious Interference with Advantageous and Prospective Business Relationships; and

– Count IV—Defamation.

(ECF No. 211 at 52-58.)

On November 1, 2022, SoClean and the Philips defendants filed a joint motion to enter order setting briefing scheduled for the Philips defendants' motions to dismiss the second amended complaint. (ECF No. 223.) The court granted the motion and entered the following order:

> Defendants shall first move on the question of the Court's subject-matter jurisdiction and Plaintiff's standing. Defendants shall file their motion(s) by November 18, 2022; Plaintiff shall file its opposition(s) by December 16, 2022; and Defendants shall file their reply(ies) by January 20, 2023. Oral argument shall occur on February 21, 2023.
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> Separately, Defendants shall move on the question of whether the Second Amended Complaint states a claim. Defendants shall file their motion(s) by December 16, 2022; Plaintiff shall file its opposition(s) by January 20, 2023; and Defendants shall file their reply(ies) by February 10, 2023. Oral argument shall occur on March 21, 2023.
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> …
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> The parties agree that in participating in further proceedings before its jurisdictional challenge is briefed and decided, KPNV is not waiving, and is expressly preserving, its jurisdictional defense in all respects. See ECF No. 178.

(ECF No. 228.)

The parties completed their briefing with respect to the motion to dismiss for lack of subject-matter jurisdiction, the court held a hearing on the motion, and the parties filed supplemental briefing and exhibits with respect to that motion.

On December 16, 2022, the Philips defendants filed the pending motion to dismiss for failure to state a claim. (ECF No. 273.) SoClean filed its response in opposition to the motion. (ECF No. 299.) The Philips defendants filed a reply brief in support of their motion. (ECF No. 313.) On April 27, 2023, this court held a hearing on the pending Rule 12(b)(6) motion to dismiss. (H.T. 4/27/2023 (ECF No. 385).)

On June 15, 2023, the court and the parties addressed the supplemental submissions of the parties with respect to the Philips defendants' motion to dismiss for lack of subject-matter jurisdiction. The court on the record explained that the motion to dismiss for lack of subject-matter jurisdiction would be denied without prejudice because the record before the court was insufficient for the court to conclude—as a matter of law—that SoClean did not have a legally protected interest in marketing the device at issue in the second amended complaint, i.e., the SoClean 2. (H.T. 6/15/2023 (ECF No. 413) at 47.) Specifically, the court required additional information about the Food and Drug Administration ("FDA") and determined it would appoint an expert to opine on certain FDA matters.

The motion to dismiss for failure to state a claim having been fully briefed is now ripe to be decided by the court.

III. Factual Allegations in the Complaint[2]

A. CPAP, BiPAP, and Continuous Ventilator Machines

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. (ECF No. 211 ¶ 46.) Sleep apnea can be treated with: (1) continuous positive airway pressure ("CPAP") machines, which deliver pressurized air via a mask that seals on the mouth or nose to

[2] The factual allegations are taken as true for purposes of resolving the motion to dismiss. U.S. Express Lines Ltd. v. Higgins, 281 F.3d 383, 388 (3d Cir. 2002). Factual allegations pertinent to only certain claims will be reviewed in the discussion of those claims. When the factual allegations are intertwined with legal conclusions, the court will not consider those conclusions in resolving the motion. Fowler v. UPMC Shadyside, 578 F.3d 203, 210 (3d Cir. 2009) ("The District Court must accept all of the complaint's well-pleaded facts as true, but may disregard any legal conclusions.").

keep upper airway passages open and to prevent snoring and sleep apnea, (id. ¶ 47); or (2) bi-level positive airway pressure ("BiPAP") machines, which generate and deliver positive airway pressure through a system of masks, hoses, and other accessories, (id. ¶ 48). Philips RS sells both CPAP and BiPAP machines. (Id. ¶ 49.) In 2015, Philips RS launched its DreamStation product line. (Id. ¶ 50.) Philips RS also sells ventilators for respiratory care; examples include the Trilogy series and Omnilab ventilator products. (Id. ¶ 51.)

B. SoClean's Cleaning and Sanitizing Products

According to SoClean, the "dirty secret" of the CPAP industry is that the manufacturer instructions for keeping the devices clean do not properly sanitize the devices. (Id. ¶ 52.) Cleaning instructions on the Philips NA website recommend that users wipe down any areas that contact skin on a daily basis with a damp towel, mild detergent, and warm water. For devices with a humidifier, the instructions recommend refilling the humidifier with clean, distilled water each day before bed. (Id. ¶ 53.) According to SoClean, the cleaning instructions recommended by CPAP device manufacturers are inadequate to clean and disinfect properly the devices; indeed, 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. (Id. ¶ 54.)

Ozone cleaners provide the best available technology on the market to clean and sanitize thoroughly sleep and other respiratory equipment to rid them of bacteria, mold, and viruses. (Id. ¶ 56.) SoClean is the dominant market leader for ozone cleaners. SoClean's lead product, the SoClean 3.0,[3] is an automated cleaning device that cleans and sanitizes sleep equipment within

[3] SoClean 3.0 is not in issue in this litigation.

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. (Id. ¶ 57.)

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. (Id. ¶ 58.)

C. SoClean's Correspondence and Cooperation with the FDA

SoClean has interacted extensively with the FDA since it launched in 2014 the SoClean 2 device, the device in issue in this litigation. Since that time, SoClean maintained its registration and device listing for the SoClean 2 with the FDA. (Id. ¶ 59.) SoClean's interaction with the FDA is summarized, in pertinent part, as follows:

- from January 29, 2018, to February 1, 2018, the FDA conducted a thorough inspection of SoClean's manufacturing facility, after which the FDA did not raise any concerns about the marketing or distribution of SoClean's products, (id. ¶ 60);

- SoClean received a letter from the FDA on September 10, 2019, in which the FDA requested information about SoClean marketing its devices as Class I exempt medical devices, copies of all current product labeling, and 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, (id. ¶ 62);

- SoClean responded to the FDA's letter on October 16, 2019, and explained how it had been operating under the good-faith belief that the company's product was a Class I medical device, revised the company's website and labeling to address the FDA's comments, and removed claims pertaining to the cleaning, sanitizing, or disinfection of CPAP machines, (id. ¶ 63);

- in or about March 2020, the FDA wrote to SoClean and explained that it "believe[d] …[the SoClean 2] may be more appropriately regulated as a Class II medical device," and that the SoClean 2 "may be appropriate for classification through the De Novo pathway[,]" (id. ¶ 64);

- on June 17, 2020, SoClean submitted a presubmission to FDA for SoClean 3, which included a description of the SoClean 3 device, an overview of the anticipated product development plan for SoClean 3, several test plans describing testing intended to evaluate the safety and efficacy characteristics of SoClean 3, and a number of questions for the FDA's consideration, (id. ¶ 65);

- on August 10, 2020, the FDA provided SoClean with written responses to the questions posed in the presubmission package, and, on August 17, 2020, a teleconference between the FDA and SoClean took place during which SoClean and the FDA discussed the FDA's feedback (id. ¶ 66);

- on March 1, 2021, SoClean and the FDA discussed SoClean's submission of the SoClean 3.0 device for regulatory approval and FDA acknowledged that SoClean had made "a lot of progress" and that the device and relevant testing were "on an appropriate path" (id. ¶ 67); and

- pursuant to the FDA's guidance, SoClean submitted a de novo application for regulatory approval of the SoClean devices, which the FDA formally accepted on or about April 1, 2022, and is currently under review (id. ¶ 68.)

D. The FDA Safety Communication

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." (Id. ¶ 72.) The safety communication focused exclusively on the issue of potential risk of ozone leakage and provided:

> 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.

(Id. ¶ 73.) Independent laboratory testing has confirmed, however, that SoClean's products do not leak ozone into the ambient environment at unsafe levels. (Id. ¶ 74.)

The FDA safety communication addressed the FDA'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." (Id. ¶ 76.) According to SoClean, it is the only manufacturer of ozone cleaners to submit the recommended testing requested by the FDA. (Id. ¶ 77.)

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.

(Id. ¶ 79.) 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. (Id.)

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: (1) "the safety communication addressed risks wholly unrelated to the potential degradation of sound abatement foam;" and (2) "[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." (Id. ¶ 80.)

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. (ECF No. 211 ¶ 81.) 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." (Id.) Notably, Philips RS equated ozone cleaners with SoClean, the dominant market leader in the space. (Id.) 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."[4] (Id. ¶ 82.)

D. First Public Announcement on Safety Concerns

The Philips defendants 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 volatile organic compounds ("VOCs"). (Id. ¶ 85.) By January 2020, executive management learned about the safety concerns associated with the sound abatement foam. Despite the known health and safety risks, the Philips defendants did not take any corrective action until April 2021. (Id. ¶ 85.) On or about April 13, 2021, Philips RS launched the next-generation DreamStation 2 product. 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. (Id. ¶ 90.)

On or around April 23, 2021, the Philips defendants misled the FDA in its initial notification about potential health risks by telling the FDA that foam degradation may be "exacerbated" by ozone cleaners. The Philips defendants, however, did not have any reliable testing or other valid scientific evidence to validate those statements. In or around May 2021, the Philips defendants repeated similar statements to the FDA. (Id. ¶ 88.)

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[4] Philips RS and Philips NA had been in cooperative discussions with SoClean for years, including talks about a potential partnership. (ECF No. 211 ¶ 83.) In or around 2017 and 2018, Philips RS conducted over six months of testing on the SoClean device. According to one employee familiar with the testing: "Early signs were favorable that SoClean did not affect our DreamStation devices." (Id. ¶ 84.)

On April 26, 2021, KPNV 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." (Id. ¶ 86.) The announcement was a part of a regulatory update included in the company's Q1 2021 Quarterly Report. Despite reference to multiple risks, KPNV only addressed the risk of foam degradation. KPNV 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." (Id.) KPNV did not mention the health risks associated with VOC emissions, despite knowledge that the DreamStation had failed emissions tests. (Id. ¶ 86.) The April 26, 2021 announcement provided that "[t]he majority of the affected devices are in the first-generation DreamStation product family." (Id. ¶ 89.) KPNV also assured that "Philips' recently launched next-generation CPAP platform, DreamStation 2, is not affected." (Id.)

On April 26, 2021, the CEO of KPNV, Frans van Houten ("van Houten") made public comments about ozone during a webcast and conference call concerning the company's Q1 earnings. van Houten said: "In the US[,] there's quite a lot of locations that have started to use ozone to disinfect the [DreamStation] machine[,] which has an impact on the foam used in the machine…[and] makes it degrade." (Id. ¶ 93.) In response to a follow-up question about ozone, van Houten promoted the company's next-generation CPAP device and 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.
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> …
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> 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.

(Id. ¶ 93.)

According to SoClean, 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 the Philips defendants' products, including the DreamStation 2 CPAP machine and the Philips UV Light Sanitizer Box. (Id. ¶ 95.) Indeed, the Philips defendants used one or more crisis management or public relations firms to develop and employ the communications strategy related to public announcement and the product recall. (Id. ¶ 87.) van Houten and KPNV 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 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. (Id. ¶ 96.)

KPNV and Philips NA published all the company's earnings reports, presentations, and transcripts from webcasts and conference calls on their respective public websites. KPNV 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. (Id. ¶ 97.)

E. The Product Recall

On June 14, 2021, KPNV and Philips RS issued the Recall Notice in the United States for multiple sleep and respiratory care devices. The Recall Notice had two parts. (Id. ¶ 98.) 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, and provided:

– there were 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[;]"

– "[t]he 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[;]" and

– a "URL"[5] guiding customers and CPAP users to the FDA's February 27, 2020 safety communication about ozone leakage and risks associated with UV light.

(Id. ¶ 99.)

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;

– provided that "[t]he 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[;]" and

– included the URL directing customers and users to the FDA's February 27, 2020 safety communication.

(Id. ¶ 100.)

Both letters in the Recall Notice were signed by Rodney Mell, Head of Quality at Philips RS. (Id. ¶ 101.) The Recall Notice:

- mentioned ozone in the same sentence as foam degradation and off-gassing;

- did not identify hydrolysis (or exposure to heat and humidity) as the cause of foam degradation; and

- did not clarify that the off-gassing issue had nothing to do with ozone cleaners.

[5] A "URL" is a uniform resource locator.

(Id. ¶ 102.)

On June 14, 2021, KPNV and Philips NA issued press releases attaching the Recall Notice. The press releases:

- stated that "[t]he 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[;]"

- falsely and misleadingly identified ozone as the primary cause of the foam degradation;

- included a footnote with a hyperlink to the FDA's February 27, 2020 safety communication;

- contained promotional language, including a quote from van Houten, who told customers and users of respiratory devices that "Patient safety is at the heart of everything we do at Philips[;]"

- 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[;]" and

- promoted the company and directed existing customers to the DreamStation 2 product.

(Id.¶¶ 103-04.)

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 the Philips defendants' products, including the next-generation DreamStation 2 machine and the Philips UV Light Sanitizer Box. (Id.¶ 105.) KPNV and Philips NA published the Recall Notice and the accompanying press releases on their respective public websites. (Id.¶ 106.) In total, KPNV, 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. (Id. ¶ 107.)

F. KPNV Makes False and Misleading Statements about Testing

On July 26, 2021, KPNV and van Houten spread false and misleading information about ozone during its webcast and conference call regarding Q2 results. (Id. ¶ 108.) In response to the question "[h]ave you got any data that shows how ozone is accelerating a foam degradation perhaps," van Houten responded:

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

(Id. ¶ 109.)

KPNV 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. KPNV has not come forward with any test results or data showing that ozone has any degradative effect on polyester-based polyurethane foam. (Id. ¶ 110.) To the extent KPNV (or any other Philips entity) has done any testing of polyester-based polyurethane foams in the presence of ozone, the testing did not account for real-world conditions, e.g., the concentration of ozone at the surface of the foam during the cleaning cycle, the short duration of ozone exposure during the cleaning cycle, confounding variables, including heat, pH, and microbial enzymes, all of which would accelerate hydrolytic degradation of the foam, or the fact that high humidity can reduce ozone generation by as much as 50%. (Id. ¶ 111.) KPNV and van Houten did not have a good-faith basis for the statement that ozone cleaners "should not be used on medical devices at all."[6] (Id. ¶ 112.)

[6] At the time of this statement, KPNV owned U.S. Patent No. 9,937,275, titled "Gas Sterilization/Disinfection System and Method for Fluid Conduits." The patent, which issued on

KPNV and van Houten later recanted. On October 18, 2021, after SoClean filed this lawsuit, 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." (Id. ¶ 114.) He then declared for the first time that "further research and testing" and "expert assessments" were not expected until the fourth quarter of 2021. (Id.) 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 the Philips defendants' products, including the next-generation DreamStation 2 CPAP machine and the Philips UV Light Sanitizer Box. (Id. ¶ 115.) KPNV 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. (Id. ¶ 116.)

G. July 8, 2021 Update

On July 8, 2021, KPNV published an update to physicians and health care providers ("July 2021 Update") on its public website. (Id. ¶ 117.) In the July 2021 Update, KPNV acknowledged that the off-gassing of harmful VOCs was "associated with the production process of the foam." (Id. ¶ 118.) KPNV 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. (Id.) The foam supplier used

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. (Id. ¶ 112.)

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. (Id. ¶ 119.)

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. (Id. ¶ 120.) The product recall due to the off-gassing of VOCs was unrelated to the use of ozone or ozone cleaners. (Id. ¶ 121.) The use of ozone cleaners mitigated the emission of the VOCs and effectively destroy them through chemical reactions. (Id. ¶ 122.)

In the July 2021 Update, KPNV 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. KPNV 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. KPNV acknowledged that its own "[l]ab analysis of the degraded foam positively confirmed the presence of DEG as well as other compounds." (Id. ¶ 123.) The positive confirmation of DEG in the degraded foam samples confirmed that the degradation observed by the Philips defendants was due to hydrolysis, not reactions involving ozone, which would not leave a chemical signature.[7] (Id.)

KPNV 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. (Id. ¶

[7] KPNV cited a 2011 research study in the July 2021 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." (Id. ¶ 124.) According to SoClean, this statement remains true. (Id.)

125.) Despite all evidence to the contrary, KPNV 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." (Id. ¶ 126.)

H. Frequently Asked Questions

KPNV published "Frequently Asked Questions" with answers about the product recall for the benefit of customers and patients on its public website. The answers:

- referenced ozone nine times in association with the product recall. (Id. ¶ 127.)
- recommended that "customers and patients halt use of ozone-related cleaning products" (id.¶ 129);
- asserted 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" (id. ¶ 129);
- provided that "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" (id. ¶ 130);
- directed customers to the FDA's Safety Communication about ozone leakage and UV light, which was unrelated to the product recall (id.);
- included self-promotional language designed to reassure customers and retain business, while deflecting blame to SoClean and ozone cleaners;
- provided "Philips has a robust Quality Management System and has followed our review and analysis processes to help identify and address this issue" (id. ¶ 131);
- identified products that were unaffected by the recall, including the DreamStation 2 (id.); and
- provided that "[p]roducts that are not affected may have different sound abatement foam materials, as new materials and technologies are available over time…[and] sound abatement foam in unaffected devices may be placed in a different location due to device design"[8] (id. ¶ 132).

[8] This statement by the Philips defendants in the FAQs is notable for two reasons: (1) KPNV allegedly intentionally misled customers and patients by suggesting "new" alternative

I. MedTrade West and Distributors

From July 12-14, 2021, MedTrade West, the largest home medical equipment trade show and conference in the United States, took place in Phoenix, Arizona. The largest distributors and resellers of both Philips RS and SoClean products were in attendance. MedTrade conferences typically have over 500,000 attendees from around the globe. (Id. ¶ 133.) Philips RS cancelled its public booth on the floor of the conference during the MedTrade West conference in July 2021, rented a hotel suite, and invited multiple select partners, including distributors and sellers of medical device equipment that service both Philips RS and SoClean, to the suite. (Id. ¶ 134.) Philips RS, under the direction of KPNV and Philips NA, made false and misleading statements about ozone cleaners to SoClean's distributors and resellers during the MedTrade West conference. 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. 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. (Id. ¶ 135.)

Resellers and distributors have cited the Philips defendants' false and misleading statements about ozone cleaners as the reason for not placing orders with SoClean. (Id. ¶ 137.) Sales to distributors and resellers once accounted for the majority of SoClean's sales and revenue. (Id.) On or around June 14, 2021, when KPNV and Philips RS announced the recall and issued the Recall Notice, one SoClean distributor said, on the subject of SoClean sales, that the

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foam materials just recently became "available over time" while viable alternative foam materials, including polyether-based silicone-based foams, existed long before the product recall; and (2) KPNV 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." (Id. ¶ 132.)

"Philips news is killing us." (Id. ¶ 138.) 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. (Id. ¶ 139.) 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 KPNV, Philips NA, and Philips RS. (Id. ¶ 140.)

J. FDA Inspection Report

On November 12, 2021, the FDA issued an update on the product recall, together with a report[9] from an inspection of Philips RS that took place from August 26, 2021, to November 9, 2021. The FDA report:

- 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" (id. ¶ 141);

- confirmed, among other things, 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;

- 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 (id. ¶ 142); and

[9] 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.

(Id. ¶ 144.)

- "list[ed] observations made by the FDA representative(s) during the inspection of [the Philips RS] facility" (id. ¶ 143).[10]

K. FDA's 518(a) Notification Order

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. (Id. ¶ 155.) 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

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[10] 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; and

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

(Id. ¶ 143.)

> 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.

(Id. ¶ 156.) The FDA also noted that the information on the Philips defendants 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." (Id.)

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." (ECF No. 211 ¶ 157.) 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. According to SoClean, Philips RS misled the FDA: (1) into believing that Philips RS had a good-faith scientific basis when it repeatedly told the FDA that ozone may exacerbate foam degradation; and (2) about ozone to avoid accountability for the product recall and influence customers to continue buying products from Philips RS. (Id.)

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

On May 2, 2022, the FDA issued to Philips RS a Notice of Opportunity for a Hearing ("518(b) Notice") pursuant to § 518(b) of the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq. (Id. ¶ 158.) In the 518(b) Notice, the FDA, among other things:

- "called out" Philips RS for not being forthright about test results and the health risks posed by polyester-based polyurethane foam by emphasizing test results identifying no risks, while trying to discount "results supporting the conclusion that the recalled devices present a significant risk" (id. ¶ 159);

- recognized that "Philips" knew there were degradation products identified with the recalled devices, which were known and well-established biomarkers of degradation by hydrolysis (id. ¶ 160);

- "debunked defendants' weaponization of the 2020 FDA safety communication" by stating, among other things, that "the safety communication addressed risks wholly

unrelated to the potential degradation of sound abatement foam[,]…[including]…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" (id. ¶ 161);

- concluded that "[t]he safety communication…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" (id.);

- 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" (id.);

- recognized that the "potentially harmful VOC emissions" from "Philips'" devices were "a separate, independent basis for the recall," and "Philips" had "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" (id. ¶ 162);

- 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" (id. ¶ 163); and

- explained that the "FDA…[was] 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" (id.).

M. June 28, 2022 Update

On June 28, 2022, KPNV and Philips NA issued identical press releases with an update on the foam testing and research program, a summary of test results, and video messages from van Houten, Roy Jakobs, the future CEO, and Jan Bennik ("Bennik"), the technical project manager for KPNV'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." (Id. ¶ 164.) KPNV and Philips NA, however, intended to mislead the public with unfounded claims about ozone. (Id. ¶ 167.) The press releases:

- acknowledged that, at the time of the Recall Notice, the Philips defendants relied on "an initial limited data set and toxicological risk assessment[;]"

- 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 (id. ¶ 165);

- included a misleading statement by van Houten that highlighted favorable results showing little to no risk and discounting or ignoring test results showing that the foam tested positive for genotoxicity and cytotoxicity;

- included a second misleading statement by van Houten that "[r]esults to date also indicate that ozone cleaning significantly exacerbates foam degradation" (id. ¶ 166); and

- stated that with respect to VOCs, "[i]t 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[,]" and, thus, 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 (id. ¶ 178).

N. Philips Defendants Create Widespread Confusion

The conduct and statements by the Philips defendants 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. (Id. ¶ 181.)[11]

[11] For example, on June 14, 2021, 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." (Id. ¶ 182.) 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…." (Id. ¶ 183.)

On June 16, 2021, the Pulmonary and Critical Care of Baltimore ("PCCB") issued a notice notifying its patients about the Philips recall. The notice incorrectly stated: "It appears that [the foam degradation issue] has been found predominantly when such machines have been

Prior to the Philips 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." (Id. ¶ 190.) 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. (Id. ¶ 191.) SoClean has received customer complaints following the Philips defendants' false and misleading statements alleging, among other things, that SoClean "ruins" the CPAP machine and that ozone is "not safe."

O. Damage to SoClean

SoClean has experienced damage to its brand reputation and a loss of goodwill as a result of the Philips defendants' illegal conduct. (Id. ¶ 202.) Because of the false and misleading statements made by the Philips defendants, users of CPAP devices stopped buying and using

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cleaned with ozone cleaning machine device." (Id. ¶ 184.) The PCCB noted that "Philips is recommending that customers and patients halt use of ozone-related cleaning products." (Id.) 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." (Id.)

The Minnesota Sleep Institute issued a similar notice, instructing patients and members to "stop using ozone cleaning products such as SoClean." (Id. ¶ 185.) 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." (Id. ¶ 186.) The notice 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." (Id.)

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." (Id. ¶ 187.)

SoClean products and distributors and resellers stopped buying SoClean products. SoClean's sales to distributors, resellers, and end-users have plummeted. (Id. ¶ 203.) 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 historically accepted as returns devices that are returned to DMEs by consumers. (Id. ¶ 205.) SoClean had economic and contractual relationships with third-party distributors, resellers, and DMEs. The Philips defendants knew about these contractual and business relationships because, among other reasons, they have contractual and business relationships with many of the same distributors, resellers, and DMEs. The Philips defendants also know that many of these distributors, resellers, and DMEs sell SoClean *and* Philips RS products. The Philips RS account, however, is a much larger account than the SoClean account, which provides more leverage and negotiating power to Philips RS. (Id. ¶ 205.)

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 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" (id. ¶ 206); and

- "Respironics allegedly gave the DME suppliers physician prescribing data free of charge that could assist their marketing efforts to physicians[,]…[which] "was yet

another source of undue influence that Philips RS held over DME suppliers and resellers" (id.).

As of July 30, 2021, 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 the unlawful conduct by the Philips defendants. (Id. ¶ 207.) Historically, SoClean's sales to distributors and resellers once accounted for over half of the company's total revenue. (Id. ¶ 208.) 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 the false and misleading statements and other wrongful conduct by the Philips defendants. (Id. ¶ 209.) The damage to SoClean caused by the Philips defendants exceeds $200 million. (Id. ¶ 210.)

IV. Standard of Review

A. Choice of Law Issues

The claims in this action arise under federal law, i.e., the Lanham Act, and state law. This action was transferred to this court as part of a multidistrict litigation. The court must determine which law to apply to the issues raised by the parties. The choice of law is dependent upon whether the issue raised is procedural or substantive and whether the issue arises under federal law or state law. "On matters of procedure, the transferee court must apply federal law as interpreted by the court of the district where the transferee court sits." Various Plaintiffs v. Various Defendants (Oil Field Cases), 673 F. Supp. 2d 358, 362 (E.D. Pa. 2009); In re Johnson & Johnson Talcum Powder Prod. Mktg., Sales Pracs., & Prod. Liab. Litig., 553 F. Supp. 3d 211, 219 (D.N.J. 2021). This court, therefore, will apply the law of the Third Circuit when issues about procedural matters are raised.[12]

[12] With respect to procedural issues, one district court has explained:

With respect to substantive law issues, the court's analysis depends upon whether the claim arises under federal law or state law.[13] With respect to issues of federal law, "the transferee

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> In the context of pre-trial issues such as motions to dismiss or discovery disputes, section 1407 requires the application of the law of the transferee circuit where the motions are being considered….For example, courts have held that the law of the transferee circuit controls pretrial issues such as whether the court has subject matter or personal jurisdiction over the action, or whether the cases should be remanded to state court because the cases were not properly removed….Likewise, the law of the transferee circuit controls discovery issues such as whether to compel a deposition or documents pursuant to a subpoena….
>
> The law of the transferee circuit applies in each of these situations because the "objective of transfer is to eliminate duplication in discovery, avoid conflicting rulings and schedules, reduce litigation costs, and save the time and effort of the parties, the attorneys, the witnesses, and the courts."…Section 1407 is aimed at eliminating "delay, confusion, conflict, inordinate expense and inefficiency" during the pretrial period….In other words, it promotes "just and efficient" resolution of the proceedings to apply the law of the transferee circuit to pretrial issues….

In re Methyl Tertiary Butyl Ether (MTBE) Prod. Liab. Litig., 241 F.R.D. 435, 439 (S.D.N.Y. 2007)

[13] One district court has explained:

> In matters requiring the interpretation of the Constitution, a federal law or a federal rule of procedure, a transferee court applies the law of the circuit where it sits. Therefore, in cases where jurisdiction is based on federal question, this Court, as the transferee court, will apply federal law as interpreted by the Third Circuit.
>
> In matters where the Court has jurisdiction under 28 U.S.C. § 1332 based upon diversity of citizenship, the transferee court applies state substantive law as determined by the choice of law analysis required by the state in which the action was filed.

Various Plaintiffs v. Various Defendants (Oil Field Cases), 673 F. Supp. 2d 358, 362–63 (E.D. Pa. 2009); Flores v. Ethicon, Inc., No. 2:14-CV-24748, 2018 WL 3130421, at *3 (S.D.W. Va. June 25, 2018) ("When analyzing questions of federal law, the transferee court should apply the law of the circuit in which it is located. When considering questions of state law, however, the

court applies the law of the circuit in which it sits (here, the Third Circuit)." In re Johnson & Johnson, 553 F.Supp.3d at 219. This court will, therefore, apply the law of the Third Circuit to analyze the Philips defendants' arguments about SoClean's Lanham Act claims.

With respect to SoClean's state law claims, "the transferee court applies 'the choice of law rules of the transferor courts.'" Id. (quoting Ford Motor Co. Ignition Switch Prod. Liab. Litig., In re, 174 F.R.D. 332, 348 (D.N.J. 1997)). As discussed below, however, the parties did not brief the choice of law issue with respect to SoClean's state law claims. The parties analyze the claims under New Hampshire law. At this stage of the proceedings and because the parties did not properly brief the issue, the court will only address the Philips defendants' arguments about SoClean's state law claims under New Hampshire law.

B. Rule 12(b)(6)

"The manner and details of pleading in the federal courts are governed by the Federal Rules of Civil Procedure regardless of the source of substantive law to be applied in the particular action." 5 CHARLES ALAN WRIGHT & ARTHUR R. MILLER, FEDERAL PRACTICE AND PROCEDURE § 1204 (2d ed. 1990). As discussed above, federal law governs procedural issues raised in this case. Thus, the court will apply the standard of review applicable to Rule 12(b)(6) motions as set forth in the Third Circuit to the pending motion to dismiss.

A motion to dismiss filed pursuant to Federal Rule of Civil Procedure 12(b)(6) tests the legal sufficiency of the complaint. Kost v. Kozakiewicz, 1 F.3d 176, 183 (3d Cir. 1993). In deciding a motion to dismiss, the court is not opining on whether the plaintiff will be likely to prevail on the merits; rather, when considering a motion to dismiss, the court accepts as true all

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transferee court must apply the state law that would have applied to the individual cases had they not been transferred for consolidation.").

well-pled factual allegations in the complaint and views them in a light most favorable to the plaintiff. U.S. Express Lines Ltd. v. Higgins, 281 F.3d 383, 388 (3d Cir. 2002). While a complaint does not need detailed factual allegations to survive a Rule 12(b)(6) motion to dismiss, a complaint must provide more than labels and conclusions. Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007). A "formulaic recitation of the elements of a cause of action will not do." Id. (citing Papasan v. Allain, 478 U.S. 265, 286 (1986)). "Factual allegations must be enough to raise a right to relief above the speculative level" and "sufficient to state a claim for relief that is plausible on its face." Id. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (citing Twombly, 550 U.S. at 556).

> The plausibility standard is not akin to a "probability requirement," but it asks for more than a sheer possibility that a defendant has acted unlawfully.... Where a complaint pleads facts that are "merely consistent with" a defendant's liability, it "stops short of the line between possibility and plausibility of 'entitlement to relief.'"

Id. (quoting Twombly, 550 U.S. at 556) (internal citations omitted).

The Court of Appeals for the Third Circuit has instructed that "a court reviewing the sufficiency of a complaint must take three steps." Connelly v. Lane Constr. Corp., 809 F.3d 780, 787 (3d Cir. 2016). The court of appeals explained:

> First, it must "tak[e] note of the elements [the] plaintiff must plead to state a claim." Iqbal, 556 U.S. at 675. Second, it should identify allegations that, "because they are no more than conclusions, are not entitled to the assumption of truth." Id. at 679. See also Burtch v. Milberg Factors, Inc., 662 F.3d 212, 224 (3d Cir. 2011) ("Mere restatements of the elements of a claim are not entitled to the assumption of truth."(citation and editorial marks omitted)). Finally, "[w]hen there are well-pleaded factual allegations, [the] court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." Iqbal, 556 U.S. at 679.

Id. "Determining whether a complaint states a plausible claim for relief will ... be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." Iqbal, 556 U.S. at 679 (citing Iqbal v. Hasty, 490 F.3d 143, 157-58 (2d Cir. 2007)). A plaintiff must set forth "sufficient factual allegations to raise a reasonable expectation that discovery will reveal evidence" of the elements of the claim for relief. Connelly, 809 F.3d at 789; Trzaska v. L'Oreal USA, Inc., 865 F.3d 155, 162 (3d Cir. 2017).

When ruling on a Rule 12(b)(6) motion to dismiss for "failure to state a claim upon which relief can be granted," courts generally do not consider materials outside the pleadings, but only the allegations of the complaint, attached exhibits, and matters of public record. Pension Benefit Guar. v. White Consol. Indus., Inc., 998 F.2d 1192, 1196 (3d Cir.1993); Pryor v. Nat'l Coll. Athletic Ass'n, 288 F.3d 548, 559–60 (3d Cir.2002). Factual allegations within documents described or identified in the complaint may be considered if the plaintiff's claims are based upon those documents. Id. Documents referred to in a complaint which are central to the claim are considered part of the pleading, even if not attached to the complaint. Pryor, 288 F.3d at 559–60. A document forms the basis of a claim if it is "integral to or explicitly relied upon in the complaint." Lum v. Bank of America, 361 F.3d 217, 222 n. 3 (3d Cir.2004)); U.S. Express Lines Ltd. v. Higgins, 281 F.3d 383, 388 n. 1 (3d Cir.2002) (because the plaintiff alleges breach of an agreement, the agreement is "a document integral to or explicitly relied upon in the complaint [and] may be considered without converting the motion to dismiss into one for summary judgment").

A court may take judicial notice of public records and proceedings in other courts that relate to matters at issue. Grynberg v. Total Compagnie Francaise Des Petroles, 891 F.Supp.2d 663, 675 (D.Del.2012) (citing M & M Stone Co. v. Pa. Dep't of Envt'l Prot., 388 F.App'x 156, 162 (3d Cir.2010)). A district court may consider indisputably authentic documents without

converting a motion to dismiss into a motion for summary judgment. Spruill v. Gillis, 372 F.3d 218, 223 (3d Cir. 2004).

V. Discussion

A. Lanham Act Claim

1. Parties' Arguments

The Philips defendants argue that SoClean's Lanham Act claim should be dismissed with prejudice because—after several attempts—SoClean did not set forth factual allegations to state a plausible Lanham Act claim for relief. Specifically, defendants argue that: (1) SoClean did not plausibly show that it is in the "zone of interests" protected by the Lanham Act because SoClean unlawfully marketed its products and was not in competition with defendants, and, therefore, SoClean lacks statutory standing to assert a claim under the Lanham Act; (2) the alleged statements by the Philips defendants were not made in commercial advertising or promotion; (3) SoClean did not set forth factual allegations to show plausibly it is entitled to relief with respect to the Philips defendants' statements at the MedTrade West tradeshow; and (4) SoClean did not set forth factual allegations to show plausibly that any of the Philps defendants' statements were false or misleading.

SoClean in response argues that: (1) it was not required to plead that its products were lawfully marketed, but, in any event, the factual allegations plausibly show that SoClean registered its device with the FDA and operated with the FDA's knowledge, under the FDA's supervision, and the FDA never ordered SoClean to stop selling the devices or otherwise found they were illegally marketed; (2) SoClean is not required to plead that it was a direct competitor of the Philips defendants, but, in any event, it competed with defendants with respect to defendants' ozone cleaner for household items and KPNV owns intellectual property directed to

technologies for cleaning and sanitizing sleep and respiratory equipment; (3) the Philips defendants' false or misleading statements constituted commercial advertising or promotion because they were intended to and did promote the sale of the Philips defendants' products by influencing the purchasing decisions of distributors, resellers, and consumers; (4) SoClean set forth factual allegations to show plausibly that in July 2021 at the MedTrade West tradeshow the Philips defendants falsely told SoClean's resellers and distributors that SoClean was to blame for the foam degradation problems with the Philips defendants' recalled products; and (5) SoClean set forth factual allegations to show plausibly that the challenged statements deceived SoClean's resellers, distributors, customers, and others into falsely believing ozone cleaners, including SoClean's devices, were responsible for foam degradation in defendants' recalled devices.

The applicable law and the parties' arguments are discussed below.

2. Law Generally

Section 43(a) of the Lanham Act creates a civil cause of action for

> [a]ny person who, on or in connection with any goods or services, or any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which…in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities….

15 U.S.C. § 41(a)(1).

A false advertising claim under the Lanham Act has the following elements:

> "(1) that the defendant has made false or misleading statements as to his own product [or another's];
>
> (2) that there is actual deception or at least a tendency to deceive a substantial portion of the intended audience;
>
> (3) that the deception is material in that it is likely to influence purchasing decisions;

(4) that the advertised goods traveled in interstate commerce; and

(5) that there is a likelihood of injury to the plaintiff in terms of declining sales, loss of good will, etc."

Painaway Australia Pty Ltd. ACN 151 146 977 v. MaxRelief USA, Inc., No. CV 18-3854, 2022 WL 1028024, at *3 (E.D. Pa. Apr. 6, 2022) (quoting Groupe SEB USA, Inc. v. Euro-Pro Operating LLC, 774 F.3d 192, 198 (3d Cir. 2014)). Included within those elements is the need to show "commercial advertising or promotion." Parker v. Google, Inc., 242 F. App'x 833, 839 (3d Cir. 2007).

A plaintiff asserting a false advertising claim under the Lanham Act must also show that it "falls within the class of plaintiffs whom Congress has authorized to sue under § 1125(a)." Lexmark Int'l, Inc. v. Static Control Components, Inc., 572 U.S. 118, 129, 132 (2014).[14] To satisfy that burden, the plaintiff must show: "(1) that its interest 'fall[s] within the zone of interests protected by the [Lanham Act]' and (2) that its injuries are 'proximately caused by violations of the statute.'" Conopco, Inc. v. WBM, LLC, No. CV2114205ZNQRLS, 2023 WL 2570207, at *5 (D.N.J. Mar. 20, 2023) (quoting Lexmark Int'l, Inc. v. Static Control

[14] The Supreme Court of the United States has recognized that whether a plaintiff "falls within the zone of interests protected by the Lanham Act" has been called "statutory standing" or "prudential standing." Lexmark, 572 U.S. at 128 n.4. The Court, however, concluded those standing labels are "misleading" because "'the absence of a valid (as opposed to arguable) cause of action does not implicate subject-matter jurisdiction, i.e., the court's statutory or constitutional power to adjudicate the case.'" Id. (quoting Verizon Md. Inc. v. Public Serv. Comm'n of Md., 535 U.S. 635, 642–643 (2002)). A motion to dismiss based upon a plaintiff's alleged failure to fall within the zone of interests protected by the Lanham Act is properly asserted under Rule 12(b)(6) rather than Rule 12(b)(1). Leyse v. Bank of Am. Nat. Ass'n, 804 F.3d 316, 320 (3d Cir. 2015) (explaining that motion to dismiss for lack of "statutory standing" is properly asserted under Rule 12(b)(6) rather than Rule 12(b)(1) because "[s]tatutory standing goes to whether Congress has accorded a particular plaintiff the right to sue under a statute, but it does not limit the power of the court to adjudicate the case").

Components, Inc., 572 U.S. 118, 129, 132 (2014)). The Court has explained that "whether a plaintiff falls within the zone of interests protected by the Lanham Act" and "its injuries are proximately caused by violations of the statute" are elements of the cause of action for false advertising under the Lanham Act that "must be adequately alleged at the pleading stage in order for the case to proceed." Lexmark, 572 U.S. at 134 n.6.

Here, the Philips defendants raise arguments about the zone of interests, whether the alleged statements were made in commercial advertising or promotion, and whether the alleged statements were false or misleading. The zone of interests argument will be addressed first.

3. Whether SoClean is in the "zone of interests" protected by the Lanham Act

a. Whether the Lanham Act requires SoClean to be a competitor of defendants to sue the Philips defendants for false advertising

In Lexmark, the Court considered whether the plaintiff—a manufacturer of a part that third parties used to remanufacture the plaintiff's specially-made toner cartridges—could sue the defendant—a manufacturer and seller of laser printers and toner cartridges for those printers. Lexmark, 572 U.S. at 131. The plaintiff sued the defendant under, among other statutes, the Lanham Act, 15 U.S.C. § 1125(a). The Court explained the plaintiff's Lanham Act claim as follows:

> First, it alleged that through its Prebate program Lexmark "purposefully misleads end-users" to believe that they are legally bound by the Prebate terms and are thus required to return the Prebate-labeled cartridge to Lexmark after a single use. App. 31, ¶ 39. Second, it alleged that upon introducing the Prebate program, Lexmark "sent letters to most of the companies in the toner cartridge remanufacturing business" falsely advising those companies that it was illegal to sell refurbished Prebate cartridges and, in particular, that it was illegal to use Static Control's products to refurbish those cartridges. *Id.,* at 29, ¶ 35. Static Control asserted that by those statements, Lexmark had materially misrepresented "the nature, characteristics, and qualities" of both its own products and Static Control's products. *Id.,* at 43–44, ¶ 85. It further maintained that Lexmark's misrepresentations had "proximately caused and [we]re likely to cause injury to

> [Static Control] by diverting sales from [Static Control] to Lexmark," and had "substantially injured [its] business reputation" by "leading consumers and others in the trade to believe that [Static Control] is engaged in illegal conduct." *Id.,* at 44, ¶ 88. Static Control sought treble damages, attorney's fees and costs, and injunctive relief.

Id. at 122-23. The district court granted the defendant's motion to dismiss for lack of standing[15] and explained that the remanufactures of the defendant's toner cartridges were the "more direct plaintiffs" that could sue the defendant. The Sixth Circuit Court of Appeals reversed that decision and explained that the plaintiff had standing because the plaintiff "alleged a cognizable interest in its business reputation and sales to remanufacturers and sufficiently alleged that th[o]se interests were harmed by [the defendant's]…statements to the remanufacturers that…[the plaintiff] was engaging in illegal conduct." Id. at 124-25.

The Supreme Court of the United States framed the issue as:

> Whether…[the plaintiff] falls within the class of plaintiffs whom Congress has authorized to sue under § 1125(a). In other words, we ask whether…[the plaintiff] has a cause of action under the statute.

Lexmark, 572 U.S. at 128. To answer that question, the court first looked to whether the plaintiff was within the "zone of interests" of the Lanham Act, and, then, whether the plaintiff's injuries were proximately caused by the defendant's violation of the statute.

With respect to the "zone of interests" inquiry, the Court held "that to come within the zone of interests in a suit for false advertising under § 1125(a), a plaintiff must allege an injury to a commercial interest in reputation or sales." Id. at 131-32. The Court relied upon the following "detailed statement of the…[Lanham Act's] purpose" provided by Congress:

> The intent of this chapter is to regulate commerce within the control of Congress by making actionable the deceptive and misleading use of marks in such commerce; to protect registered marks used in such commerce from interference

[15] As explained above, the zone of interest issue does not concern whether a plaintiff has constitutional standing to assert a claim. See supra n.14.

> by State, or territorial legislation; **to protect persons engaged in such commerce against unfair competition**; to prevent fraud and deception in such commerce by the use of reproductions, copies, counterfeits, or colorable imitations of registered marks; and to provide rights and remedies stipulated by treaties and conventions respecting trademarks, trade names, and unfair competition entered into between the United States and foreign nations.

15 U.S.C. § 1127 (emphasis added). The Court explained that the protections against "unfair competition" included protection "against injuries to business reputation and present and future sales." Lexmark, 572 U.S. at 131.

The Court rejected "a rule categorically prohibiting all suits by noncompetitors" because it "would read too much into the Act's reference to 'unfair competition.'" Id. at 136. The Court explained:

> By the time the Lanham Act was adopted, the common-law tort of unfair competition was understood not to be limited to actions between competitors. One leading authority in the field wrote that "there need be no competition in unfair competition," just as "[t]here is no soda in soda water, no grapes in grape fruit, no bread in bread fruit, and a clothes horse is not a horse but is good enough to hang things on." Rogers, 39 Yale L. J., at 299; accord, Vogue Co. v. Thompson–Hudson Co., 300 F. 509, 512 (C.A.6 1924); 1 H. Nims, The Law of Unfair Competition and Trade–Marks, p. vi (4th ed. 1947); 2 id., at 1194–1205. It is thus a mistake to infer that because the Lanham Act treats false advertising as a form of unfair competition, it can protect *only* the false-advertiser's direct competitors.

Lexmark, 572 U.S. at 136. The law review article relied upon the Court for the contemporary understanding of "unfair competition" at the time the Lanham Act was enacted provided:

> What we are really dealing with and calling unfair competition are trade rights and duties. The right of a business man is to have full benefit of the reputation he has established, a part of which is the trade that, without interference, would normally flow to him; and the duty of others is to refrain from appropriating this reputation or doing anything to divert or obstruct the normal flow of trade which probably would result from it.

Edward S. Rogers, The Law of Unfair Competition and Trade Marks. by Harry D. Nims. (3d Ed.), New York, Baker, Voorhis & Co., 1929. Pp. Cliv, 1293. $20, 39 Yale L.J. 297, 299 (1929).

The article set forth the examples of "unfair competition," i.e., commercial situations that were *unfair*, but in which the parties were not competitors. For example:

> Ingersoll watches are advertised and sold at definite prices suggested by the company producing them. They are recognized as being good value at these prices. A dealer for some ulterior purpose of his own advertises Ingersoll watches at less than cost, with the result that the public gets the impression that the customary prices are excessive and other dealers, being unwilling also to sell at a loss, decline to deal further in Ingersoll watches. There is no competition between the Ingersoll Watch Company and the price-cutting dealer. Or suppose the dealer, to sell other goods, tells people asking for Ingersoll watches that the pinions are made of lead, and for purposes of exhibition and to give verisimilitude puts a lead pinion in an Ingersoll watch, what then? There is no competition between the Ingersoll Watch Company and the dealer, and "unfair" seems much too delicate a term to use.

Id. at 298.

With respect to the proximate cause inquiry, the Court in Lexmark held:

> [A] plaintiff suing under § 1125(a) ordinarily must show economic or reputational injury flowing directly from the deception wrought by the defendant's advertising; and that that occurs when deception of consumers causes them to withhold trade from the plaintiff. That showing is generally not made when the deception produces injuries to a fellow commercial actor that in turn affect the plaintiff. For example, while a competitor who is forced out of business by a defendant's false advertising generally will be able to sue for its losses, the same is not true of the competitor's landlord, its electric company, and other commercial parties who suffer merely as a result of the competitor's "inability to meet [its] financial obligations." *Anza,* 547 U.S., at 458, 126 S.Ct. 1991.

Lexmark, 572 U.S. at 133–34. The Court found that the plaintiff satisfied its burden at the pleading stage to show that its injuries were proximately caused by the defendant's violations of the Lanham Act. First, the Court noted:

> This case, it is true, does not present the "classic Lanham Act false-advertising claim" in which " 'one competito[r] directly injur[es] another by making false statements about his own goods [or the competitor's goods] and thus inducing customers to switch.' " Harold H. Huggins Realty, 634 F.3d, at 799, n. 24. But although diversion of sales to a direct competitor may be the paradigmatic direct injury from false advertising, it is not the only type of injury cognizable under § 1125(a).

Id.

The Court found that the plaintiff satisfied the proximate cause requirement in two ways. The Court explained the first:

> Static Control alleged that Lexmark disparaged its business and products by asserting that Static Control's business was illegal. See 697 F.3d, at 411, n. 10 (noting allegation that Lexmark "directly target[ed] Static Control" when it "falsely advertised that Static Control infringed Lexmark's patents"). When a defendant harms a plaintiff's reputation by casting aspersions on its business, the plaintiff's injury flows directly from the audience's belief in the disparaging statements.

Id. at 138. The Court specifically rejected the district court's holding that because the plaintiff and defendant were not *direct* competitors, the plaintiff could not show injury. The Court explained:

> The District Court emphasized that Lexmark and Static Control are not direct competitors. But when a party claims reputational injury from disparagement, competition is not required for proximate cause; and that is true even if the defendant's aim was to harm its immediate competitors, and the plaintiff merely suffered collateral damage. Consider two rival carmakers who purchase airbags for their cars from different third-party manufacturers. If the first carmaker, hoping to divert sales from the second, falsely proclaims that the airbags used by the second carmaker are defective, both the second carmaker and its airbag supplier may suffer reputational injury, and their sales may decline as a result. In those circumstances, there is no reason to regard either party's injury as derivative of the other's; each is directly and independently harmed by the attack on its merchandise.

Id. at 138–39.

The Court explained the second way in which the plaintiff showed proximate cause:

> Static Control adequately alleged proximate causation by alleging that it designed, manufactured, and sold microchips that both (1) were necessary for, and (2) had no other use than, refurbishing Lexmark toner cartridges. See App. 13, ¶ 31; id., at 37, ¶ 54…It follows from that allegation that any false advertising that reduced the remanufacturers' business necessarily injured Static Control as well. Taking Static Control's assertions at face value, there is likely to be something very close to a 1:1 relationship between the number of refurbished Prebate cartridges sold (or not sold) by the remanufacturers and the number of Prebate microchips sold (or not sold) by Static Control. "Where the injury alleged is so integral an aspect of the [violation] alleged, there can be no question" that proximate cause is satisfied. Blue Shield of Va. v. McCready, 457 U.S. 465, 479, 102 S.Ct. 2540, 73 L.Ed.2d 149 (1982).

Id. at 139.

Having found the plaintiff satisfied its burden to show it was in the zone of interests the Lanham Act sought to protect and that its injuries were proximately caused by the defendant's violation of the Lanham Act, the Court held:

> To invoke the Lanham Act's cause of action for false advertising, a plaintiff must plead (and ultimately prove) an injury to a commercial interest in sales or business reputation proximately caused by the defendant's misrepresentations. Static Control has adequately pleaded both elements. The judgment of the Court of Appeals is affirmed.

Id. at 140.

Following Lexmark, courts have explained that a plaintiff need not be in competition with the defendant to sue the defendant under the Lanham Act. See e.g., Syngenta Seeds, Inc. v. Bunge N. Am., Inc., 773 F.3d 58, 64 (8th Cir. 2014) ("The Supreme Court [in Lexmark] also expressly rejected the requirement that challenged commercial speech be made by a competitor."); Moreland v. Kladeck, Civ. A. No. 21-1975, 2022 WL 1501122, at *4 (D. Minn. May 12, 2022) ("Kladeck argues that Plaintiffs' interests are not within in zone of interests protected by the Lanham Act because Plaintiffs were not competitors of the club….But the parties need not be competitors for Plaintiffs to have standing."); Bayer Healthcare Pharmaceuticals Inc., v. RJ Health Systems International LLC, Civ. A. No. 15-6952, 2016 WL 3574325, at *3 (D.N.J. June 30, 2016) (explaining that the parties (the seller of pharmaceuticals and a subscription-based website that provides information about pharmaceuticals) were not in direct competition with each other, but the allegations that the defendant misstated the price of the plaintiff's product, which could affect the plaintiff's sales, were sufficient to state a claim under the Lanham Act).

One treatise has explained:

> ***Unfair Competition and Trademark Infringement by a Non-Competitor: Archaic and Modern Law Compared***. In the early history of the common law creation of a tort of "unfair competition," relief was usually accorded for both trademark infringement and false advertising only if the parties were in direct competition with each other….As to trademark infringement, case law in the early 20th Century began to reject the earlier precedent that required direct competition….This new view that a trademark could be infringed by a non-competitor gradually grew until by the late twentieth century, it was clear that a strong mark could infringed by unauthorized use on non-competitive goods or services so long as there was a likelihood of confusion over sponsorship, affiliation, or connection.
>
> ***A Challenge to False Advertising Brought by a Non-Competitor***. A similar expansion and growth occurred in unfair competition by false advertising but at a later date. Under the common law, only a competitor (and one with a monopoly position in the genuine product) had standing to sue for false advertising….But passage of Lanham Act § 43(a) in 1946 opened a new chapter and several courts permitted a non-competitor to have standing to sue for false advertising…. However, some courts (such as the Ninth Circuit) denied standing to a non-competitor. The Ninth Circuit read the Lanham Act Congressional intent language about protecting "unfair competition"…in a literal and constrained way so as to require that the plaintiff alleging false advertising must be in a direct competitive relationship with defendant….The Supreme Court in the 2014 *Lexmark* decision read that Congressional statement of purpose directly contrary to the way the Ninth Circuit did, observing that "unfair competition" is not to be read literally to require competition….Thus, the High Court in *Lexmark* rejected the direct competition test of false advertising standing championed by the Ninth Circuit.

§ 1:8. What is unfair competition?, 1 McCarthy on Trademarks and Unfair Competition § 1:8 (5th ed.) (footnotes omitted).

Based upon the foregoing, Lanham Act suits are not limited to competitors; rather, a plaintiff may sue a defendant pursuant to the Lanham Act if: (1) the plaintiff suffered an injury to a commercial interest in sales or business reputation; and (2) the injury to a commercial interest in sales or business reputation was proximately caused by the defendant's false advertisement. See e.g., Asociacion de Laboratorios Clinicos, Inc. v. Med. Card Sys., Inc., Civ. A. No. 15-1099, 2015 WL 13548474 (D.P.R. Jul. 24, 2015).

Despite the Philips defendants' arguments to the contrary in this case, see ECF No 313 at 9 n.4 (arguing Lexmark "did not hold that reputational claims could be brought under the Lanham Act where no competitor relationship existed…[r]ather, it relaxed the direct competitor requirement to allow indirect competitors to bring suit against each other"), the court in Asociacion explained that a Lanham-Act plaintiff need not show that it is even an *indirect* competitor of the defendant to have standing to sue under the act if it is able to establish the two requirements set forth in Lexmark. The court in Asociasion explained:

> Defendants next claim that, though Lexmark established that *direct* competition is not required, it remains necessary under the Act that the parties be at least *indirect* competitors. **This proffered distinction is both unsupported and unworkable.** Defendants cite only to a pre-Lexmark case stating, consistent with pre-Lexmark conceptions of standing, that § 43(a) is intended "to protect commercial interests that have been harmed by a competitor's false advertising." Suntree Techs., Inc. v. Ecosense Int'l, Inc., 693 F.3d 1338, 1348 (11th Cir. 2012) (quoting Nat. Answers, Inc. v. SmithKline Beecham Corp., 529 F.3d 1325, 1330 (11th Cir. 2008)).

Asociacion, 2015 WL 13548474, at *11 (emphasis added).

As discussed above, the Philips defendants argue that SoClean's Lanham Act claim should be dismissed because SoClean did not and cannot allege that it is a competitor or an indirect competitor with any of the Philips defendants, which is a requirement to sue under Lanham Act. The Philips defendants' argument misses the mark. Under Lexmark, and according to the authority cited above, to pass muster at the pleading stage, SoClean needs to set forth factual allegations to show plausibly the elements of a Lanham Act claim and that (1) it suffered commercial injury; and (2) the injury was proximately caused by the Philips defendants' violations of the Lanham Act. SoClean alleged plausibly that it suffered commercial injury proximately caused by the Philips defendants' false statements about the cause of the recall and ozone. According to the allegations in the second amended complaint, van Houten and the

Philips defendants made at least eight false statements that ozone in products used to clean CPAP machines was to blame for the Philips' product recall to shift blame for the recall from the Philips defendants to SoClean:

1. **2021 Q1 Quarterly Report by KPNV:** *"Philips" identified possible risks associated with the sound abatement foam used in certain of Philips' sleep and respiratory care devices currently in use, i.e., the foam may degrade under certain circumstances, including use of unapproved cleaning methods, such as ozone, and certain environmental conditions involving high humidity and temperature;*

2. **2021 Q1 Earnings Call statements by van Houten, KPNV's CEO:** *van Houten stated that ozone in fact has an impact on the foam used in the machine, which makes it degrade*;

3. **2021 Q2 Earnings Call statements by van Houten, KPNV's CEO:** *van Houten answered a question about whether "Philips" had any data about ozone and foam degradation and said "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";*

4. **June 14, 2021 Recall Notice by Respironics:** *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;*

5. **Q&A by KPNV on its website:** *KPNV* recommended that "customers and patients halt use of ozone-related cleaning products . . . ." and asserted that degradation was caused by ozone. KPNV stated: "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."

6. **July 2021 update by KPNV:** "Philips is recommending that customers and patients do not use ozone-related cleaning products."

7. ***June 28, 2022 Press Release****: KPNV and Philips NA issued to healthcare providers, patients, and other stakeholders identical press releases with an update on the foam testing and research program, which provided a quote from van Houten: "Results to date also indicate that ozone cleaning significantly exacerbates foam degradation." The press release also provided:* "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." *and*

8. **July 12-14, 2021, MedTrade West TradeShow Philips statements to distributors:** 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. 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.

SoClean alleged that as a result of the foregoing eight statements (or eight sets of statements):[16]

> 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.

(ECF No. 211 ¶ 27.)

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[16] The Philips defendants in their motion to dismiss and related submissions make specific arguments about the eight statements (or sets of statements) set forth above. To the extent SoClean set forth factual allegations in the second amended complaint sufficient to show plausibly that the Philips defendants made *other* actionable statements, the Philips defendants waived any dismissal argument with respect to those statements because they did not raise the arguments in the motion to dismiss or related briefing. The court in Vay v. Huston, No. CV 14-769, 2016 WL 1408116, at *8 (W.D. Pa. Apr. 11, 2016), explained:

> [L]egal arguments not raised and relief that is not specifically sought in the initial motion are generally deemed waived. See e.g., Sproull, 2010 WL 339858, at *3 ("[T]he reply brief generally cannot be used to expand the issues presented for adjudication beyond those raised in the moving papers."); Rivers v. Nat'l Ass'n of Letter Carriers, No. 15–3070 (SRC), 2016 WL 389983, at *2 (D.N.J. Feb. 1, 2016) (citing Anspach v. City of Philadelphia, 503 F.3d 256, 259 (3d Cir. 2007)) ("New arguments in the reply brief are waived."); E.E.O.C. v. Aldi, Inc., No. CIV.A. 06–01210, 2008 WL 859249, at *5 (W.D. Pa. Mar. 28, 2008) ("Because Aldi conceded this element in its opening brief and only challenges it in its reply brief, the Court finds that Aldi waived any challenge to the second prong for purposes of summary judgment.").

Id. The court's consideration of the parties' arguments in this case, therefore, is limited to the eight sets of statements set forth above.

Based upon the foregoing, SoClean set forth factual allegations sufficient to show plausibly that it suffered commercial injury, i.e., loss of sales and damage to its reputation. SoClean also set forth factual allegations sufficient to show plausibly that its commercial injury was caused by van Houten and the Philips defendants' statements that ozone cleaners were to blame for the foam degradation at issue in the product recall. Under those circumstances, SoClean was not required to allege that it is a competitor—direct or indirect—with defendants to sue under the Lanham Act. The motion to dismiss will be denied with respect to this issue, i.e., whether SoClean set forth factual allegations sufficient to show plausibly that it is within the "zone of interests" protected by the Lanham Act.[17]

b. Whether SoClean has a lawful interest to be protected by the Lanham Act

The Philips defendants argue that SoClean is not within the zone of interests protected by the Lanham Act because the only commerce protected by the Lanham Act is *lawful* commerce. According to the Philips defendants, SoClean illegally marketed its devices at issue in this case, and, therefore, SoClean falls outside the Lanham Act's zone of interests. (ECF No. 276 at 15-16.) SoClean argues that it is not required to plead affirmatively that it engaged in lawful commerce

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[17] SoClean also alleges that it competes with defendants in two ways: (1) SoClean sells an ozone cleaner for household items that competes directly with a Philips-branded UV light sanitizer for household items; and (2) KPNV owns intellectual property directed to technologies for cleaning and sanitizing sleep and respiratory equipment that compete with ozone, including patents for disinfecting CPAP and other respiratory equipment using vaporized hydrogen peroxide and UV light. (ECF No. 299 at 8-9.) The Philips defendants argue that they expressly warned against the use of UV light cleaning devices on CPAP and BiPAP equipment, and, therefore, SoClean cannot show the UV light box was in competition with the SoClean devices at issue in this case. (ECF No. 313 at 10.) Second, the Philips defendants argue "[t]here is no suggestion that Defendants currently sell, intend to sell, let alone are in the midst of launching, any competing PAP cleaner, not least because ozone cleaning products are not lawfully marketed for cleaning PAPs per the FDA's explicit statements." (ECF No. 313 at 10 n.6.)

Having determined that SoClean is not required to show that it actually competed—directly or indirectly—with the Philips defendants to state a Lanham Act claim, this court need not consider whether SoClean showed plausibly that it competed with any of the defendants.

when it sold its products. SoClean cites decisions in which "courts have held that the sellers of 'unapproved' drug products…may bring Lanham Act false advertising suits." (ECF No. 299 at 11.) In any event, SoClean argues that it "affirmatively alleges it lawfully markets the SoClean devices[,]" e.g., it registered its devices with the FDA, operated with the FDA's knowledge and under the FDA's supervision, and the FDA never found the devices were illegally marketed or ordered SoClean to stop selling the devices. (Id. at 4.)

The Philips defendants are correct that the Court in Lexmark recognized that "the zone-of-interests test…is an element of the cause of action under the statute…[and] like any other element of a cause of action…must be adequately alleged at the pleading stage in order for the case to proceed." Lexmark, 572 U.S. 118, 134 n.6. At this stage, and without deciding whether "lawful commerce" is an element of a false advertising claim under the Lanham Act, however, the court notes that SoClean set forth factual allegations sufficient to show that it marketed and sold SoClean 2 with the knowledge of the FDA. SoClean in the second amended complaint alleges:

- SoClean interacted extensively with the FDA since it launched the SoClean 2 device in 2014 and consistently maintained its establishment registration and device listing with the FDA (id. ¶ 59);

- from January 29, 2018 to February 1, 2018, the FDA conducted a thorough inspection of SoClean's manufacturing facility and did not issue any Form 483 observations following the inspection or any concerns about the marketing or distribution of SoClean's products (id. ¶ 60);

- in 2018, SoClean representatives worked collaboratively and openly with federal officials and law enforcement regarding the importation of counterfeit and knock-off filter cartridges (id. ¶ 61);

- the FDA told SoClean that its "devices appear to use ozone and are intended to disinfect and sanitize mask and other accessories for Continuous Positive Airway Pressure (CPAP) therapy devices," "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, and requested copies of all current product labeling, including operating instructions and promotional material, and 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 (id. ¶ 62);

- SoClean responded to the FDA and explained how it had been operating under the good-faith belief that the company's product was a Class I medical device, revised the company's website and labeling to address the FDA's comments, and removed claims pertaining to the cleaning, sanitizing, or disinfection of CPAP machines (id. ¶ 63);

- in or around March 2020, the FDA told SoClean that its device "may be more appropriately regulated as a Class II medical device under CFR 880.6992 Medical Device Disinfector," and "may be appropriate for classification through the De Novo pathway" (id. ¶ 64);

- on June 17, 2020, SoClean submitted a presubmission to FDA for the latest version of the device, i.e., the SoClean 3, which included a description of the SoClean 3 device, an overview of the anticipated product development plan for SoClean 3, several test plans describing testing intended to evaluate the safety and efficacy characteristics of SoClean 3, and a number of questions for the FDA's consideration (id. ¶ 65);

- 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, and on August 17, 2020, a teleconference between the FDA and SoClean took place during which SoClean and the FDA discussed the FDA's feedback (id. ¶ 66);

- on March 1, 2021, SoClean met with the FDA to ask additional questions and receive clarification about SoClean's submission for regulatory approval, and the FDA told SoClean that "a lot of progress has been made" and was "on an appropriate path" (id. ¶ 67);

- pursuant to the FDA's guidance, SoClean submitted a de novo application for regulatory approval, and on or about April 1, 2022, the FDA formally accepted SoClean's submission, which is currently under review (id. ¶ 68);

- SoClean has been fully transparent with and has followed the guidance of the FDA (id. ¶ 69);

- 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 (id. ¶ 69);

- SoClean continues to sell its products under the guidance of the FDA (id.);

- the FDA is not currently investigating and has not requested testing about what effect, if any, ozone has on polyester-based polyurethane foam (id. ¶ 70); and

- SoClean legally markets its ozone cleaner products with the knowledge of the FDA and without a requirement for premarket authorization (id. ¶ 71).

The Philips defendants argue, however, that based upon documents that are integral to the second amended complaint,[18] SoClean illegally marketed and sold the SoClean 2, which was an adulterated product. (ECF No. 276 at 11 n.2.) For example, Exhibit C to the Philips defendant's Rule 12(b)(6) motion to dismiss is a letter from the FDA to SoClean and in pertinent part provides:

> It has come to our attention that you may be marketing the SC1200 SoClean 2 CPAP Sanitizing Machine; SC1600 SoClean ProLab CPAP Sanitizing Machine; and SoClean 2 Go CPAP Sanitizing machine, which meet the definition of a device as that term is defined in section 201(h) of the Federal Food Drug and Cosmetic Act (FD&C Act), in a manner that potentially violates the FD&C Act.
>
> Specifically, we have conducted a review of our files, and have been unable to identify any Food and Drug Administration (FDA) clearance or approval number for the SC1200 SoClean 2 CPAP Sanitizing Machine; SC1600 SoClean ProLab CPAP Sanitizing Machine; or SoClean 2 Go CPAP Sanitizing machine as currently marketed on https://www.soclean.com/ as well as other direct-to-consumer venues.

(ECF No. 259-1 at 2.)

[18] At the Rule 12(b)(6) stage, a court may use only the complaint, exhibits attached to the complaint, matters of public record and undisputedly authentic documents if the complainant's claims are based upon these documents. Mayer v. Belichick, 605 F.3d 223, 230 (3d Cir. 2010); Pension Benefit Guar. Corp. v. White Consol. Indus., Inc., 998 F.2d 1192, 1196 (3d Cir. 1993). A court may also consider "any matters incorporated by reference or integral to the claim, items subject to judicial notice, matters of public record, orders, [and] items appearing in the record of the case." Buck v. Hampton Twp. Sch. Dist., 452 F.3d 256, 260 (3d Cir. 2006). If other matters are presented and not excluded by the court, the motion must be treated as one for summary judgment. FED. R. CIV. P. 12(d). This court need not decide whether the documents relied upon by the Philips defendants are properly before this court in resolving the Rule 12(b)(6) motion to dismiss. Even if the court considered those documents, it would deny the motion to dismiss. The law applicable to this dispute has not been fully briefed, and, on the present record, the court cannot determine the legal implications of the FDA's conduct in this case. The court requires additional information, e.g., FDA experts, to determine whether SoClean legally marketed the SoClean 2 and is, therefore, within the zone of interests of the Lanham Act.

The Philips defendants also attached to their Rule 12(b)(6) motion Exhibit L, which shows that the FDA knew that—as of about March 21, 2021—SoClean continued to market the SoClean 2 and would continue to market the SoClean 2 until September 15, 2021. (ECF No. 259-4.) Exhibit L is an email from John J. Smith ("Smith"), a legal representative of SoClean, to, among other persons, Liqun Zhao of the FDA. In the email, Smith provides summary minutes of a call that took place between FDA representatives and SoClean representatives about the SoClean 2. (Id.) The summary minutes, which SoClean believed "accurately reflect[ed] the discussion among the participants," in pertinent part provide:

> SoClean acknowledges FDA position concerning the company's PAP accessory products and, in light of that position, is providing the following plan:
>
> > • SoClean appreciates and understands FDA's current position and expectations, and will continue to work interactively with the agency to meet those expectations.
> >
> > • In response to FDA's expectations to submit a premarket submission for each device that is currently marketed within six months of the Friday, March 19 teleconference, SoClean makes the following commitments:
> >
> > > o Submit a de novo request for the SoClean3 device on or before September 15, 2021. As FDA is aware, this device has been the focus of several Q-Sub submissions under Q201292.
> > >
> > > o Discontinue the marketing and distribution of the SoClean2 device on or before September 15, 2021.

(Id. at 3.)

Here, at the Rule 12(b)(6) stage, the court must deny without prejudice the motion with respect to whether SoClean set forth factual allegations sufficient to show plausibly that it had a legally protected interest in marketing the SoClean 2. The law applicable to this dispute has not been fully briefed. On the present record, the court cannot determine the legal implications of the FDA's conduct in this case. The court requires additional information, e.g., FDA experts, to

determine whether SoClean legally marketed the SoClean 2 and is, therefore, within the zone of interests of the Lanham Act. For example, Exhibit L plausibly shows that even if the FDA raised issues with the SoClean 2, the FDA knew SoClean was marketing the SoClean 2 and would continue to do so until at least September 15, 2021. At this stage, however, the briefing is insufficient for the court to determine whether the FDA's knowledge that SoClean would continue to market SoClean 2 meant that SoClean had a legally protected interest in marketing the SoClean 2 during the relevant timeframe. This court appointed an FDA expert and will appoint a second FDA expert to develop the record with respect to how the FDA's conduct impacts the law applicable to these issues. Based upon the foregoing, the motion to dismiss will be denied without prejudice with respect to the Philips defendants' argument that SoClean failed to set forth factual allegations sufficient to show plausibly that it engaged in lawful commerce.[19] There needs to be a fully developed record about the legal or illegal marketing of the SoClean 2 before this issue can be resolved.

4. Whether SoClean plausibly alleged that defendants made a statement about its devices in "commercial advertising or promotion"

Section 1125(a)(1)(B) of the Lanham Act prohibits misrepresentations only in "'commercial advertising or promotion.'" Parker, 242 F. App'x 839.

> Courts use the Gordon & Breach test to determine whether a statement at issue is "commercial advertising or promotion" under the Act….In Gordon & Breach Sci. Publishers v. Am. Inst. of Physics, the court defined "commercial advertising or promotion" as "(1) commercial speech; (2) by a defendant in commercial competition with the plaintiff; (3) for the purpose of influencing consumers to buy

[19] Indeed, this court at the hearing on the supplemental submissions with respect to the Rule 12(b)(1) motion to dismiss explained that there was not a sufficient record for the court to understand the FDA's conduct in this case, which at times appeared to be contradictory, to make a finding about whether SoClean has standing under Article III of the United States Constitution to pursue this case against the Philips defendants. (Hearing Transcript ("H.T.") 6/15/2023 (ECF No. 413) at 27-28.) The court determined the Rule 12(b)(1) motion was premature, it would appoint an FDA expert, and permit the parties to raise the issue on a fully developed record.

> the defendants goods or services ... [and] (4) must be disseminated sufficiently to the relevant purchasing public to constitute 'advertising' or 'promotion' within that industry."

Incarcerated Ent., LLC v. CNBC LLC, 331 F. Supp. 3d 352, 358 (D. Del. 2018).

In determining whether a communication is commercial speech, one district court has explained:

> Commercial speech is "broadly defined expression related to the economic interests of the speaker and its audience, generally in the form of a commercial advertisement for the sale of goods and services."…Following United States Supreme Court guidance, our court of appeals outlined a three factor test to determine whether speech is commercial:…"(1) is the speech an advertisement; (2) does the speech refer to a specific product or service; and (3) does the speaker have an economic motivation for the speech."…Satisfaction of all three characteristics provides "strong support" for concluding the speech is commercial….**In sum, the "commercial speech doctrine rests heavily on 'the common sense distinction between speech proposing a commercial transaction ... and other varieties of speech**.' "

Id. at 359 (emphasis added).[20] Speech that "proposes a commercial transaction" "possesses certain hallmarks, including pertinent price and product information." GeigTech E. Bay LLC v. Lutron Elecs. Co., No. 18 CIV. 5290 (CM), 2019 WL 1768965, at *10 (S.D.N.Y. Apr. 4, 2019). Even if the speaker is "motivated by…[its] own economic interests," it is not necessarily commercial speech if it "otherwise lack[s]…the usual trappings of commercial speech." Id.

[20] These three factors were discussed by the Supreme Court of the United States in Bolger v. Youngs Drug Products Corp., 463 U.S. 60, 66 (1983), to determine whether a communication is commercial speech and are considered by courts to determine whether a communication is commercial speech. See e.g., Handsome Brook Farm, LLC v. Humane Farm Animal Care, Inc., 700 F. App'x 251, 257 (4th Cir. 2017) (explaining the Supreme Court identified these three factors as "qualities of commercial speech"); SKF USA, Inc. v. U.S. Customs & Border Prot., 556 F.3d 1337, 1371 (Fed. Cir. 2009); see also § 31:141. Levels of constitutional protection—Distinguishing commercial speech from other speech, 6 McCarthy on Trademarks and Unfair Competition § 31:141 (5th ed.).

Here, as discussed above, there are eight statements (or sets of statements) at issue.[21] Each of those statements (or set of statements) will be addressed below to determine whether SoClean set forth factual allegations sufficient to show plausibly that the relevant statement is commercial speech, and, thus, could be considered commercial advertising or promotion for purposes of the Lanham Act.

i. Quarterly reports and earning calls

With respect to **the quarterly reports and earning calls (statements 1-3)**, courts hold that those kinds of communications—without allegations that defendants intended to influence the consumers and the communication was disseminated to the consumers—do not constitute commercial speech. For example, in Allergan, Inc. v. Merz Pharms., LLC, No. SACV 11-446 AG (EX), 2011 WL 13323246, at *2 (C.D. Cal. Nov. 14, 2011), the court held that "corporate earnings calls do not qualify as commercial speech intended to influence consumers[;]" rather, "'[s]tatements made during an earnings conference call primarily to influence investors that may have an incidental effect of promoting goods to customers are not within the reach of the Lanham Act.'" Id. (quoting Tercia, Inc. v. Insmed Inc., 2006 WL 1626930, at *18 (June 9, 2006)). The court in Allergan specifically noted that the plaintiff did not set forth any factual allegations in the complaint to show plausibly that the earning calls were made to influence consumers. Id.

Similarly, in Genus Lifesciences Inc. v. Lannett Co., Inc., 378 F. Supp. 3d 823, 834 (N.D. Cal. 2019) ("Genus I"), the court held that the plaintiff failed to set forth plausible Lanham-Act claims because it did not set forth factual allegations sufficient to show plausibly that statements made during investor earnings calls and in securities filings were commercial speech. The court

[21] See discussion supra pp. 43-44.

explained that the plaintiff did not set forth any "specific allegations that…[the statements] were made for the purpose of influencing customers or were disseminated sufficiently to the relevant purchasing public." Genus Lifesciences Inc. v. Lannett Co., Inc., No. 18-CV-07603-WHO, 2019 WL 4168958, at *4 (N.D. Cal. Sept. 3, 2019) (Genus II). The court in Genus I did acknowledge, however, that statements in earnings calls or securities filings may be considered commercial speech, but the plaintiff must set forth factual allegations to show plausibly that the statements were made "for the purpose of influencing the customers…to buy…[the product], or were disseminated sufficiently to the relevant purchasing public…to constitute "advertising" or "promotion" within the…[relevant] industry." Genus I, 378 F.Supp.3d at 835-36.

In Sigma Dynamics, Inc. v. E. Piphany, Inc., No. C 04-0569 MJJ, 2004 WL 2648370, at *3 (N.D. Cal. June 25, 2004), the court—at the motion to dismiss stage—considered communications made by the defendant in various different situations: press releases, on earnings conference calls, in annual reports and on the defendant's website. Id. The court summarily found that the statements made in the press releases and on the website were commercial speech because they "are generally available to the public." Id. The court did note, however, that more proof may be required at a later stage in the litigation for the court to make a merits determination about whether the evidence was sufficient to find the statements on the website and in the press releases were actually commercial speech. Id. With respect to the earnings calls and annual reports, the court explained:

> Plaintiff's Lanham Act claim should be dismissed with respect to four other categories of statements. First, Defendant argues that the statements to investors during earnings conference calls are not actionable under the Lanham Act because the statements were made for the purpose of reporting Defendant's financial condition and not for the purpose of influencing consumers to purchase Defendant's software. *See* Com pl. ¶¶ 20-24. Plaintiff alleges that Defendant advertises its products through earnings conference calls with investors (Compl.¶ 14) and argued at the hearing that potential customers can listen in on the conference calls.

> However, the complaint contains no allegations that consumers do attend the conference calls. More importantly, the complaint contains no allegations regarding the purpose of the calls, let alone that the purpose of the investor calls was to influence customers to buy Defendant's goods or services. Statements made during an earnings conference call primarily to influence investors that may have an incidental effect of promoting goods to customers are not within the reach of the Lanham Act. See Rice, 330 F.3d at 1181 (holding that representations constitute commercial advertising for purposes of the Lanham Act if, inter alia, the representation is "for the purpose of influencing consumers to buy defendant's goods or services.").

Id.

Here, the factual allegations in the second amended complaint are not sufficient to show plausibly that the earnings calls and quarterly report were advertising or promotional; rather, the factual allegations in the second amended complaint show plausibly that the earnings calls and quarterly report primarily served their typical function, i.e., to influence investors. The comments about ozone, SoClean, and the DreamStation were made during the normal course of the earnings calls and in the quarterly report and may have had an incidental effect of promoting goods, i.e., to deflect blame for the recall and promote Philips' goodwill so that the consumers would continue to purchase Philips' devices (the DreamStation 2); indeed, SoClean alleges that defendants engaged in a "coordinated public relations campaign to deflect blame, avoid accountability, and mitigate reputational damage" with respect to the recall and that SoClean was the target of that "smear campaign." (ECF No. 211 ¶¶ 7, 12.) There are no allegations, however, that the earnings calls or quarterly report were made primarily to advertise or promote defendants' products.

Additionally, the factual allegations in the second amended complaint do not show plausibly that the communications in the earnings calls and quarterly report were sufficiently disseminated to be considered advertising or commercial speech. One district court has explained:

> publication of information does not become "advertising" until it reaches an audience of sufficient size. Until that point, it is not "advertising" and it fruitless to discuss whether it has a deceptive effect.

Gen. Steel Domestic Sales, LLC v. Chumley, 129 F. Supp. 3d 1158, 1175 (D. Colo. 2015). There are no factual allegations that any consumers listened to the earnings calls or read the quarterly report. Sigma, 2004 WL 2648370, at *3 ("Plaintiff alleges that Defendant advertises its products through earnings conference calls with investors (Compl.¶ 14) and argued at the hearing that potential customers can listen in on the conference calls. However, the complaint contains no allegations that consumers do attend the conference calls."). Based upon the foregoing, the motion to dismiss the Lanham Act claim to the extent it is based upon the alleged "false advertising" that took place during the earnings calls and in the quarterly report will be granted.

ii. Recall notice

With respect to the **recall notice (statement 4)**, at least one court has held that a recall notice is not commercial speech. The court in Eli Lilly & Co. v. Roussel Corp., 23 F. Supp. 2d 460, 480 (D.N.J. 1998), explained:

> The announcement of the withdrawal of Opos' AADA and the recall notice do not constitute commercial advertising or promotion because they are not designed to influence customers to purchase defendant's goods. See Gordon & Breach, 859 F.Supp. at 1536. On the contrary, they are intended to inform consumers that the goods will no longer be available for sale. Furthermore, the recall notices complied with the FDA regulations. The notices announced that all shipments of bulk cefaclor into the United States would temporarily cease. The notices informed purchasers that further distribution of unprocessed lots of cefaclor should cease immediately. See 21 C.F.R. § 7.49(c). Furthermore, the recall notices did not contain any promotional materials or statements to detract from the recall message. See id.

Id. Here, SoClean alleges the following with respect to the recall notice:

> The recall notification issued by Royal Philips and Philips RS ("Recall Notice")…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."
>
> …
>
> 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.
>
> …
>
> 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.
>
> …
>
> 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.
>
> …
>
> Royal Philips and Philips NA published the Recall Notice and the accompanying press releases on their respective public websites.

(ECF No. 211 ¶¶ 98-107.) Based upon the foregoing allegations, the recall notice was not an advertisement; rather, it was a recall notice with respect to the FDA recall of the Philips defendants' products. The recall notice refers to specific products, but not to influence anyone to

buy the products; rather, like in Eli Lily, the products are mentioned because the Philips defendants had to inform the consumers about the recall of the products. Businesses like the Philips defendants surely have an economic motivation whenever they speak. The motivation here, however, was not to encourage anyone to buy their products. To the extent the Philips defendants' comments in the recall notice were written as part of the alleged smear campaign against SoClean, any effect of promoting defendants' products (by deflecting blame to SoClean to promote the Philips defendants' goodwill) was incidental to the primary purpose of the recall notice, which was to inform consumers about the recall. Based upon the foregoing consideration of the Bolger factors, and in consideration of Eli Lily, SoClean failed to set forth factual allegations sufficient to show plausibly that the recall notice was commercial speech. The motion to dismiss will be granted with respect to the Lanham Act claim based upon the recall notice.

iii. Frequently asked questions

The analysis of the three factors used to determine whether a communication is commercial speech is similar for the **"Frequently Asked Questions" ("FAQs") (statement 5)** posted on KPNV's website. SoClean's allegations with respect to the FAQs are, as follows:

> 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. (ECF No. 212 ¶ 127.)
>
> On four separate occasions, Royal Philips recommended that "customers and patients halt use of ozone-related cleaning products . . . ." (Id.¶ 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." (Id. ¶ 129.)
>
> 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." (Id. ¶ 130.) Royal Philips directed customers to the FDA's Safety Communication about ozone leakage and UV light, which was unrelated to the product recall. (Id.)
>
> 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." Royal Philips identified products that were unaffected by the recall, including the DreamStation 2. (Id. ¶ 131.)
>
> 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." (Id. ¶ 132.) 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." (Id. ¶ 132.)

With respect to the Bolger factors, the FAQs—although accessible on KPNV's website—were not an advertisement. The FAQs mention specific products manufactured by defendants and ozone cleaners generally, but do not do so for the purpose of selling those goods; rather, KPNV must refer to its products to field questions about the recall of its products. Lastly, every time the Philips defendants speak, it is likely for an economic gain. The purpose of the FAQs, however, was not to influence anyone to make a purchase; rather, viewed in the light most favorable to SoClean, KPNV had to provide consumers information about the recall and an incidental effect of that communication may have been to promote its goodwill and deflect blame for the recall. Based upon the foregoing, SoClean failed to set forth factual allegations sufficient to show plausibly that the FAQs on its website were commercial speech. The motion to dismiss will be granted to the extent the Lanham Act claim is based upon the Philips defendants' alleged statements in the FAQs.

iv. July 8, 2021 update

With respect to the **July 8, 2021 update (statement 6)**, SoClean alleges that "[o]n July 8, 2021,..[KPNV] published an update to physicians and health care providers…on its public website." (EF No. 211 ¶ 117.) The update provides, in part:

> **Supplemental clinical information for physicians and providers for specific CPAP, Bi-Level PAP, and mechanical ventilator devices**
>
> On June 14, 2021, Philips issued a recall notification for the US only/field safety notice for the rest of the world for specific sleep and respiratory care devices due to two issues related to the polyester-based polyurethane (PE-PUR) sound abatement foam used in certain Philips continuous and non-continuous ventilators: 1) the PE-PUR foam may degrade into particulates which may enter the device's air pathway and be ingested or inhaled by the user, and 2) the PE-PUR foam may emit certain chemicals.

(ECF No. 274 at 2.) The purpose of the July 2021 update was to provide physicians information about "the health risks related to the two identified PE-PUR sound abatement foam issues[,]" i.e., foam degradation and "Chemical emissions from the PE-PUR foam." (Id.) The July 2021 update provided, in part:

> The information in this document is based on the test data and information available to date and considers a reasonable worst-case scenario. Further testing, that is ongoing, will help Philips better estimate the reasonable worst-case probability of the health risks related to the two identified PE-PUR sound abatement foam issues.

(Id. at 5.) The July 2021 update provides two references to ozone and does not explicitly reference SoClean. Under the heading "Foam degradation," the July 2021 update provides, among other things, that "[t]he foam degradation may be accelerated by environmental conditions of high temperatures and humidity. Unauthorized cleaning methods such as ozone cleaning may exacerbate potential degradation…." (Id. at 2.) A note at the end of the July 2021 update provides: "Philips is recommending that customers and patients do not use ozone-related cleaning products." (Id. at 6.)

With respect to whether the July 2021 update is commercial speech, the July 2021 update is not an advertisement. It is an informational document directed to physicians to provide updated information about the recall of defendants' devices. Its purpose was to provide information about the "worst-case scenario health risks" and not to sell any products to the physicians. To the extent the document promotes defendants' goodwill, and, thus, would make the physicians more likely to prescribe their patients defendants' devices in the future, that effect is incidental to the primary purpose of the document, which was to inform the physicians about the "worst-case scenario" health risks associated with the foam degradation and chemical emissions from the foam. The speech refers to the Trilogy devices and defendants' C-PAP and Bi-PAP devices that were subject to the recall. The speech does not refer to the Philips defendants' other devices, e.g., the DreamStation 2. The Philips defendants needed to refer to their products to inform the physicians about the health risks. As discussed above, the Philips defendants always have an economic motivation for speech, but, in this situation, the overwhelming motivation was to inform the physicians about the "worst-case scenario" health risks because of the foam degradation and chemical emissions. Based upon the foregoing analysis, SoClean did not set forth factual allegations sufficient to show plausibly that the July 2021 update to physicians was advertisement, promotion, or commercial speech and the motion to dismiss the Lanham Act claim will be granted with respect to this issue.

v. June 28, 2022 press release

With respect to the **June 28, 2022 Press Release (statement 7)**, SoClean alleges:

> 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."

(ECF No. 211 ¶¶ 164-80 (emphasis added).)

"[I]n some circumstances, a press release may constitute an advertisement." SCO Grp., Inc. v. Novell, Inc., 692 F. Supp. 2d 1287, 1295 (D. Utah 2010). A press release may be considered commercial speech if it is an advertisement for a product, refers to a specific product, and has an economic motivation. Star-Brite Distrib., Inc. v. Kop-Coat, Inc., No. 09-60812-CIV, 2010 WL 750353, at *3 (S.D. Fla. Mar. 4, 2010).[22] Consideration of those factors with respect to

[22] The court in Star-Brite Distributing explained the press release in that case constituted commercial speech:

> Although the press release does not contain all of the characteristics of core commercial speech, it nonetheless promotes ethanol fuel additives in general and attacks Star–Brite's competitor's product. Star–Brite is a counter-defendant in competition with the counter-plaintiff and the press release is intended to influence consumers to buy StarTron rather than VEGA. Kop–Coat sufficiently alleges that the press release was placed in marine industry and online trade publication websites, constituting sufficient dissemination to the retailers who purchase the products.

the June 28, 2022, press release shows that SoClean did not set forth factual allegations sufficient to show plausibly that the press release was commercial speech.

First, the press release was not an advertisement, i.e., "a message with a clear, promotional purpose." Keel v. Axelrod, 148 F.Supp.3d 411, 423 (E.D. Pa. Dec. 1, 2015). It did not "promote any competing product…[or] explicitly propose a commercial transaction." Golo, LLC v. Highya, LLC, 310 F.Supp.3d 499, 504 (E.D. Pa. 2018). The Philips defendants in the press release inform the reader about the Philips defendants' updated testing on the recalled DreamStation devices.

Second—based upon the allegations of the second amended complaint—the only products referred to by name in the press release are the recalled DreamStation devices. The Philips defendants could not sell those devices because of the recall. As discussed above, generally recall notices are not commercial speech because, among other reasons, their purpose is to inform about the recall and advise consumers that the recalled goods are no longer available for sale. Here, the purpose of the press release was to provide consumers with an update about the recalled devices and testing.

Third, as discussed above, the Philips defendants generally have an economic motive when they speak because they are for-profit businesses. To the extent the press release was—in any part—intended to place blame on ozone products for the recall and to promote the good will of the Philips defendants, the economic benefit flowing from that purpose was incidental to the purpose of informing consumers about the updated testing with respect to the recall.

On balance, there are insufficient allegations in the second amended complaint to show that the press release was commercial speech. The press release did not propose a commercial

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Star-Brite Distrib, 2010 WL 750353 at *3.

transaction, it only referred to recalled products by name, and any economic benefit was incidental to the purpose of the press release, which was to inform readers about the Philips defendants updated testing. This is not a case in which the press release compared two products, touted one product as superior to another, or promoted the defendant's product. See e.g.,, Mimedx Grp., Inc. v. Osiris Therapeutics, Inc., Civ. A. No. 16-3645, 2017 WL 3129799, at *6-8 (S.D.N.Y. July 21, 2017) (finding statements in a press release at issue were commercial speech because "[t]hey touted the benefits of Defendant's product over Plaintiff's competing product and…[were] principally directed to a consumer audience, not a scientific one"); ZS Assocs., Inc. v. Synygy, Inc., Civ. A. No. 10-4274, 2011 WL 2038513, at *7 (E.D. Pa. May 23, 2011) ("The press release at issue here describes the services that Synygy provides and discusses the value that they provide to Synygy's clients. The release is intended not only to set forth Synygy's legal claims but also to persuade potential clients to choose Synygy over ZS."). The motion to dismiss will, therefore, be granted with respect to SoClean's Lanham Act claim based upon the June 28, 2022 press release.

vi. Statements to its distributors

With respect to Philips RS' **statements to its distributors (statement 8)** (allegedly made at the direction of the other Philips defendants) during the MedTrade West tradeshow from July 12-14, 2021, the Philips defendants assert three arguments: (1) SoClean improperly uses "on information and belief" pleading; (2) SoClean's pleadings do not satisfy the heightened pleading standards for claims of fraud set forth in Federal Rule of Civil Procedure 9(b); and (c) SoClean's allegations do not show plausibly that the allegedly false statements were sufficiently disseminated to constitute commercial advertising or promotion. Each of those arguments will be addressed below.

a. Information and belief and heightened pleading

SoClean's allegations with respect to Philips RS' alleged false statements made in July 2021 during the MedTrade West tradeshow are as follows:

> On July 12-14, 2021, MedTrade West, the largest home medical equipment trade show and conference in the United States, took place in Phoenix, Arizona. The largest distributors and resellers of both Philips RS and SoClean products were in attendance. MedTrade conferences typically have over 500,000 attendees from around the globe. (Id. ¶ 133.) Philips RS cancelled its public booth on the floor of the conference during the MedTrade West conference in July 2021; instead, 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, to the suite. (Id. ¶ 134.) 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. 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. 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. (Id. ¶ 135.)
>
> 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. 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. (Id. ¶ 136.)
>
> Resellers and distributors have cited Defendants' false and misleading statements about ozone cleaners as the reason for not placing orders with SoClean. (Id. ¶ 137.) Sales to distributors and resellers once accounted for the majority of SoClean's sales and revenue. (Id.) 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." (Id. ¶ 138.) 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. (Id. ¶ 139.) 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. (Id. ¶ 140.)

The Philips defendants argue that "SoClean…improperly uses the 'on information and belief' preface for *all* of the alleged distributor statements at MedTrade West." (ECF No. 276 at 23. According to the Philips defendants, if the statements made at MedTrade West were commercial speech, those statements cannot be peculiarly within their control. The Philips defendants rely upon the following excerpt from an unpublished opinion by the Court of Appeals for the Third Circuit in support of that argument:

> Clondalkin's second argument—insinuating that the Federal Rules of Civil Procedure do not permit facts pleaded upon information and belief to serve as the sole basis for relief—is plainly incorrect. This Court has explained that pleading upon information and belief is permissible "[w]here it can be shown that the requisite factual information is peculiarly within the defendant's knowledge or control"—so long as there are no "*boilerplate and conclusory allegations* " and "*[p]laintiffs ... accompany their legal theory with factual allegations that make their theoretically viable claim plausible.*" In re Rockefeller Ctr. Props., Inc. Sec. Litig., 311 F.3d 198, 216 (3d Cir.2002) (quoting In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1418 (3d Cir.1997)). In fact, this Court has explained that "[s]everal Courts of Appeals accept allegations 'on information and belief' when the facts at issue are peculiarly within the defendant's possession." Lincoln Benefit Life Co. v. AEI Life, LLC, 800 F.3d 99, 107 n. 31 (3d Cir.2015) (citing Carolina Cas. Ins. Co. v. Team Equip., Inc., 741 F.3d 1082, 1087 (9th Cir.2014); Pirelli Armstrong Tire Corp. Retiree Med. Benefits Tr. v. Walgreen Co., 631 F.3d 436, 442–43 (7th Cir.2011); Med. Assur. Co. v. Hellman, 610 F.3d 371 (7th Cir.2010); Arista Records, LLC v. Doe 3, 604 F.3d 110, 120 (2d Cir.2010)).2

McDermott v. Clondalkin Grp., Inc., 649 F. App'x 263, 267–68 (3d Cir. 2016). In McDermott, the court of appeals also recognized:

> The Second Circuit has accepted allegations on information and belief "where the belief is based on factual information that makes the inference of culpability plausible[.]" Arista, 604 F.3d at 120 (citing Iqbal, 556 U.S. at 678, 129 S.Ct. 1937). The Seventh Circuit is even more lenient, permitting allegations upon information and belief "so long as (1) the facts constituting the [allegation] are not accessible to the plaintiff and (2) the plaintiff provides 'the grounds for his suspicions.' " *Pirelli,* 631 F.3d at 443 (citation omitted).

Id. at 268 n.2.

A leading treatise has recognized that pleading on information and belief is acceptable:

> Although there is no express authorization in the federal rules for pleading on information and belief, allegations in this form have been held to be permissible,…even after the Twombly…and Iqbal…decisions….In part, recognition of this type of pleading is based on the fact that indirect support for it can be drawn from two sources within the rules. Federal Rule of Civil Procedure 11 provides that all pleadings be signed by the party, if he is unrepresented, or by an attorney of record, and specifies various means for enforcing the requirement of pleading in good faith….Moreover, the attorney's signature indicates that he or she has prepared the pleading on the basis of "the best of the person's knowledge, information, and belief."…Those words seem to be an implicit recognition of pleading on information and belief, although it should be stressed that under Rule 11 the attorney's information and belief must have been "formed after an inquiry reasonable under the circumstances."
>
> Further support pleading based on information and belief is found in the provision in Federal Rule of Civil Procedure 8(b)(5) permitting a pleader to state that he is "lacks knowledge or information sufficient to form a belief about the truth of an allegation."…The close relationship between the right to claim a lack of information and the right to assert something on the basis of information and belief seems to justify permitting both types of allegations. It is also worth noting that generally the codes permitted pleading on this basis, although the common law forbade it as being inconsistent with the quest for certainty in the pleadings….There is no evidence that the federal rules were intended to depart from the code practice.
>
> Beyond the technical question of authority, permitting allegations on information and belief is a practical necessity….How else can a pleader avoid the appearance of perjury when he is without direct personal knowledge regarding one or more of the allegations necessary to his claim and therefore must plead on a less certain footing? Pleading on information and belief is a desirable and essential expedient when matters that are necessary to complete the statement of a claim are not within the knowledge of the plaintiff but he has sufficient data to justify interposing an allegation on the subject….Similarly, a corporation may find pleading on information and belief a useful form of allegation when its information has been received from subordinate employees within the firm….The same is true whenever the pleader must rely on information furnished by others. However, pleading on information and belief is not an appropriate form of pleading if the matter is within the personal knowledge of the pleader or "presumptively" within his knowledge, unless he rebuts that presumption. Thus, matters of public record or

> matters generally known in the community should not be alleged on information and belief inasmuch as everyone is held to be conversant with them. Conversely, since Rule 11 requires that allegations be based on a "reasonable" inquiry, care must be exercised in terms of the pleader having a solid basis for pleading on information and belief.
>
> Some cases suggest that when allegations are made on the basis of information and belief, the facts on which the pleader's belief is founded also should be alleged….Such supporting allegations seem to be unnecessary and inconsistent with the philosophy of the federal pleading rules, except when the stricter pleading requirements of Federal Rule of Civil Procedure 9, which relate to such matters as fraud and special damages, are involved or the matter pleaded in some way casts aspersions on the defendant's moral character. Similarly, as is discussed at length in another section, the Private Securities Litigation Reform Act mandates a heightened pleading requirement for allegations on information and belief in securities cases.

5 A. BENJAMIN SPENCER, FEDERAL PRACTICE AND PROCEDURE, Statement of the Claim—Pleading on Information and Belief § 1224 (4th ed.) (footnotes omitted).

The Philips defendants argue that, according to SoClean, Philips RS' allegedly false statements at MedTrade West were fraudulent, and, therefore, the court should apply the Rule 9(b) heightened pleading standard to those allegations in the second amended complaint. (ECF No. 276 at 23.) The Philips defendants concede, however, that the issue has not been definitively decided by the Third Circuit Court of Appeals. (Id.) SoClean argues that many district courts within the Third Circuit have declined to apply the Rule 9(b) standard to Lanham Act claims, and, in any event, SoClean set forth factual allegations sufficient to satisfy the Rule 9(b) heightened pleading standard.

As the above-quoted treatise has recognized, generally claims that are subject to the Rule 9(b) pleading cannot be plead based upon "information and belief," unless there are supporting allegations. The treatise also provides:

> Allegations of the circumstances of a fraud based on information and belief, which are commonplace and often a necessity in many litigation contexts, usually do not satisfy the particularity requirement of Rule 9(b), unless accompanied by a statement of the facts upon which the pleader's belief is founded or by allegations that the necessary information lies within the defendant's control….Thus, Rule 9(b)'s fraud pleading requirement should not be understood to require absolute particularity as to matters peculiarly within the opposing party's knowledge that the pleader is not privy to at the time of the pleading and that can only be developed through discovery….For example, when the pleader is asserting that third persons have been defrauded, the pleader may lack sufficient information to be able to detail the claim at the outset of the action and less particularity should be required.

§ 1298 Pleading Fraud With Particularity—Extent of Requirement, 5A Fed. Prac. & Proc. Civ. § 1298 (4th ed.). Thus, "when the pleader is asserting that third persons have been defrauded, the pleader may lack sufficient information to be able to detail the claim at the outset of the action and less particularity should be required." Id.

This court need not decide whether the Third Circuit Court of Appeals would apply the Rule 9(b) heightened pleading standards to SoClean's Lanham Act false advertising claim because—even if the heightened pleading standards apply to SoClean's claims[23]—the Rule 9(b)

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[23] One treatise has explained: "A complaint for false advertising need not be pleaded with particularity,…although there is emerging case law to the contrary." 1 CHARLES E. MCKENNEY AND GEORGE F. LONG III, FEDERAL UNFAIR COMPETITION: LANHAM ACT 43A, Right to prohibit false advertising § 6:3 (footnotes omitted).

The Third Circuit Court of Appeals has not ruled on the issue and the district courts within the Third Circuit are not in agreement. Some courts hold the Rule 9(b) heightened pleading standard applies to Lanham Act claims, specifically false advertising claims. Some courts hold that the Rule 9(b) heightened pleading standards do not apply to Lanham Act claims. Some courts recognize an "intermediate" standard between Rule 9(b) and Rule 8, i.e., Iqbal/Twombly.

One district court explained:

> The traditional pleading standard under Rule 8 of the Federal Rules of Civil Procedure requires that parties plead only a "short and plain statement of the claim." However, Rule 9(b) states: "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Generally speaking,

"Rule 9(b) serves to give defendants notice of the claims against them, provide[ ] an increased measure of protection for their reputations, and reduce[ ] the number of frivolous suits brought solely to extract settlements." In re Suprema Specialties, Inc. Sec. Litig., 438 F.3d 256, 270 (3d Cir.2006) (alterations in original) (quoting In Re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1418 (3d Cir.1997)). Defendants urge the court to adopt a so-called "intermediate" approach recognized by some lower courts in the context of certain Lanham Act claims. First articulated in Max Daetwyler Corp. v. Input Graphics, Inc., 608 F.Supp. 1549 (E.D.Pa.1985), this approach strikes a balance between outright application or rejection of Rule 9(b) and sets a heightened pleading standard for false advertising claims under the Lanham Act. Specifically, our sister court held that the complaint

> need not satisfy all of the pleading requirements which have been imposed under Rule 9. But the policies which underlie Rule 9's requirement that the nature of an alleged misrepresentation be pleaded with specificity are equally applicable to the type of misrepresentation claims presented in plaintiffs' Lanham Act claim. In litigation in which one party is charged with making false statements, it is important that the party charged be provided with sufficiently detailed allegations regarding the nature of the alleged falsehoods to allow him to make a proper defense.

Id. at 1556….Max Daetwyler was decided over 25 years ago, prior to the sweeping changes of the Supreme Court's decisions in Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007) and Ashcroft v. Iqbal, 556 U.S. 662, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009). See Wellness Publ. v. Barefoot, 2008 U.S. Dist. LEXIS 1514, 2008 WL 108889 (D.N.J.2008); EVCO Tech. & Dev. v. Buck Knives, Inc., 2006 U.S. Dist LEXIS 68549, 2006 WL 2773421 (E.D.Pa.2006); H.H. Fluorescent Parts, Inc. v. DM Technology & Energy Inc., 2005 U.S. Dist. LEXIS 26699 (E.D.Pa.2005); Gallup, Inc. v. Talentpoint, Inc., 2001 U.S. Dist. LEXIS 18560, 2001 WL 1450592 (E.D.Pa.2001). The Third Circuit has noted that, as a result of Twombly and Iqbal jurisprudence, "pleading standards have seemingly shifted from simple notice pleading to a more heightened form of pleading, requiring a plaintiff to plead more than the possibility of relief to survive a motion to dismiss." Fowler v. UPMC Shadyside, 578 F.3d 203, 210 (3d Cir.2009). Thus, some courts have conjectured that the intermediate pleading requirements imposed for some Lanham Act claims may very well be identical to the pleading requirements that all claims must now meet. See, e.g., Mycone Dental Supply Co. v. Creative Nail Design, Inc., 2012 U.S. Dist. LEXIS 116924 at * *12–13 (D.N.J.2012).

heightened pleading standards would be satisfied because this case is analogous to cases in which the plaintiff asserts that a defendant defrauded third parties, and, therefore, "absolute particularity" need not be shown. Liu v. Chau, No. 1:20-CV-006369, 2022 WL 409709, at *3 (E.D.N.Y. Feb. 10, 2022).

SoClean alleges that Philips RS at the direction of the other Philips defendants made a false representation to third parties, i.e., the resellers and distributors. According to SoClean, the Philips defendants rented space at a hotel and made false representations to the distributors and resellers. As described above, "when the pleader [(SoClean)] is asserting that third persons [(the distributors and resellers)] have been defrauded, the pleader may lack sufficient information to be able to detail the claim at the outset of the action and less particularity should be required." Id. This is not a case in which SoClean was present when the allegedly false statements were made or the false statements were generally broadcast to the public. Under those circumstances, even if the heightened pleading standards applied to Lanham Act false advertising claims generally, the court would not require absolute particularity under Rule 9(b) and would accept pleading based upon information and belief.

Here, based upon information and belief, SoClean pleaded facts about the allegedly false statements with particularity, i.e., with sufficient allegations for the Philips defendants to know what the false statements were, to whom they were made (the invitees to the suite rented by Philips RS), and when and where the statements were made. The court will deny the motion to dismiss to the extent defendants argue that the claims based upon the MedTrade West allegations in the second amended complaint should be dismissed because: (1) SoClean pleaded "on information

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UHS of Delaware, Inc. v. United Health Servs., Inc., No. 1:12-CV-00485, 2013 WL 1308303, at *3 (M.D. Pa. Mar. 28, 2013).

and belief[;]" and (2) the Rule 9(b) heightened pleading standards apply to the Lanham Act false advertising claims.

b. Commercial advertising or promotion

The Philips defendants also argue that their statements to the distributors were not made in "commercial advertising or promotion" because they were "oral statements disseminated to a small group of people." (ECF No. 276 at 25.) The Philips defendants are correct that "purely private" communications cannot be "commercial advertising or promotion." Advanced Fluid Sys. v. Huber, 28 F.Supp.3d 306, 334 (M.D. Pa. 2014); Gordon & Breach Sci. Publishers S.A. v. Am. Inst. of Physics, 859 F. Supp. 1521, 1535 (S.D.N.Y. 1994), holding modified by Fashion Boutique of Short Hills, Inc. v. Fendi USA, Inc., 314 F.3d 48 (2d Cir. 2002). The analysis whether a communication is "purely private, however, is not simple. Whether a communication is "purely private," and, therefore, cannot be "commercial advertising or promotion" is a matter of degree based upon specific facts of a case, including facts about the pertinent industry.

Courts have recognized that the extent of dissemination of the speech plays an important role in determining whether it is commercial speech. For example, in American Needle & Novelty, Inc. v. Drew Pearson Marketing, Inc., 820 F.Supp. 1072, 1077–78 (N.D.Ill.1993), the court found that in the "licensed headwear industry," "a single letter privately addressed to a non-consuming licensor did not rise to the requisite level;" rather, the single letter was an "isolated individualized written statement" and not commercial speech. Similarly in Advanced Fluid Sys., Inc. v. Huber, 28 F. Supp. 3d 306, 334 (M.D. Pa. 2014), aff'd, 958 F.3d 168 (3d Cir. 2020), the court recognized that "the singular and private communication between" the defendant and a third party did not constitute commercial advertising or promotion, and, therefore, was not commercial speech.

In contrast, in National Artists Management Co. v. Weaving, 769 F.Supp. 1224, 1232 (S.D.N.Y.1991), the telephone calls made by the former president of a theatrical booking company and her husband regarding their reasons for leaving the company sufficed as commercial speech in the "theatre-booking industry" because services are promoted "'by word-of-mouth and information is spread through a network of telephone contacts with producers, promoters, and presenters.'" Gordon, 858 F.Supp. at 1535 (quoting Nat'l Artists, 769 F.Supp. at 1235).

When faced with similar arguments with respect to the Philips defendants' Rule 12(b)(6) motion to dismiss the first amended complaint, this court on the record at the motion hearing explained, among other things, that there were insufficient allegations with respect to how the business is conducted, the size of MedTrade West, how many distributors there are in the market, and how many distributors the Philips defendants spoke to about SoClean at the hotel. (H.T. 8/30/2022 (ECF No. 56) at 87-90.)

The court in American Needle explained that "public dissemination of false information to retailers at a trade show would most likely constitute 'commercial advertising and promotion[.]'" American Needle, 820 F.Supp. at 1078. In Seven-Up Co. v. Coca-Cola Co., 86 F.3d 1379, 1385 (5th Cir. 1996), the court explained that a relevant factor is the "specifics of the industry," including how many potential buyers are in a given industry. The court explained:

> Where the potential purchasers in the market are relatively limited in number, even a single promotional presentation to an individual purchaser may be enough to trigger the protections of the Act. In Mobius Management Sys., Inc. v. Fourth Dimension Software, Inc., 880 F.Supp. 1005 (S.D.N.Y.1994), the court held that a single letter from a computer software manufacturer to a potential customer could constitute "commercial advertising or promotion" within the meaning of the Lanham Act. The court explicitly recognized the requirement that "only promotional representations that are directed at the *purchasing public* can be reached by § 43(a)." Id. at 1020 (emphasis added). Nevertheless, the court

> concluded that this promotion had been disseminated sufficiently to the relevant purchasing public, which was "quite small."…Id. at 1020–21. The court went on to suggest, "Moreover, in this case the true relevant purchasing public consisted solely" of the one potential customer, whose impending purchase of a competitor's product spurred the defendant to write the false and misleading letter comparing the two products, in a "last-ditch effort to torpedo" the purchase. Id. at 1021….The court reasoned that "to label this behavior as anything but 'commercial advertising or promotion' would defeat the broad remedial purposes of the Lanham Act." Id.

Seven-Up Co. v. Coca-Cola Co., 86 F.3d 1379, 1386 (5th Cir. 1996) (footnotes omitted).

In Seven-Up, the defendant gave a very developed presentation to 11 of the 74 relevant customers at a tradeshow. Applying the foregoing rationale to the facts off the case before it, the court in Seven-Up explained:

> Drawing on these cases, we conclude that Coca–Cola's presentation, "The Future Belongs to Sprite," falls within the meaning of "commercial advertising or promotion" under § 43(a) of the Lanham Act….Coca–Cola's use of part or all of the presentation materials during negotiations with representatives of the eleven "cross-franchise" bottlers does not constitute merely isolated, individual statements of opinion by a single sales representative to a single customer. The presentation materials in this case were specifically developed and designed by Coca–Cola to target these independent bottlers and convince them, based on comparative sales statistics, to switch from 7UP to Sprite. The promotional presentation that was finally developed, "The Future Belongs to Sprite," comprised as it was of various types of documents, including visual aids such as charts, graphs, and overhead projections, may only have been shown in its entirety to two bottlers. Nevertheless, this presentation, even if used only in part, is a far cry from the individualized comments held by some courts to fall outside the meaning of commercial advertising or promotion under the Act.
>
> The product Coca–Cola was promoting by means of "The Future Belongs to Sprite" was the Sprite concentrate, which the independent bottlers would combine with carbonated water and a sweetener to create the final soft drink product for sale to the general public. At the time "The Future Belongs to Sprite" was created, the seventy-four "cross-franchise" bottlers targeted by the Coca–Cola presentation were the only relevant potential "consumers" or "purchasing public" for this intermediate product. Coca–Cola presented part or all of "The Future Belongs to Sprite" to representatives of eleven of these "cross-franchise" bottlers. Based on these facts, we find that the Coca–Cola presentation was specifically intended to influence consumers to buy its product, and we also find that the presentation was disseminated sufficiently to the relevant purchasing public to constitute "advertising" or "promotion" within the soft drink industry….

> Accordingly, we conclude that Seven–Up has properly stated a claim under § 43(a) of the Lanham Act. This conclusion is consistent with the pro-competitive and broad remedial goals of the Lanham Act.

Id.

As set forth above, SoClean alleges in the second amended complaint that:

- MedTrade West was the largest home medical equipment trade show and conference in the United States; indeed, "MedTrade conferences typically have over 500,000 attendees from around the globe" (ECF No. 211 ¶ 133);

- the largest distributors and resellers of both Philips RS and SoClean products were in attendance (id.);

- Philips RS invited disrtibutors and sellers of medical device equipment that service both Philips RS and SoClean to a private suite (id. ¶ 134);

- 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, i.e., "SoClean was the problem," and that SoClean was to blame for the product recall one month earlier (id. ¶ 135);

- 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 (id. ¶ 135);

- resellers and distributors have cited the Philips defendants' false and misleading statements about ozone cleaners as the reason for not placing orders with SoClean (id. ¶ 137)

- sales to distributors and resellers once accounted for the majority of SoClean's sales and revenue (id.) and

- 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 (id. ¶ 140.)

The foregoing allegations and the reasonable inferences drawn from those allegations are sufficient to show plausibly that the allegedly false statements made by Philips RS at the direction of the other Philips defendants to the distributors and resellers of devices manufactured by Philips

RS and SoClean were disseminated to a sufficient number of SoClean's distributors and resellers during the tradeshow held on July 12-14, 2021, so that by the end of July 2021, all but one of SoClean's top distributors and resellers stopped placing orders with SoClean. In other words, the allegedly false statements made by Philips RS at the direction of the other Philips defendants were disseminated sufficiently to the relevant purchasing public, i.e., the distributors and resellers, to constitute advertising or promotion of Philips RS within the medical device equipment industry. Based upon the foregoing, the motion to dismiss should be denied to the extent SoClean's Lanham Act claim is based upon the allegedly false statements made by Philips RS at the direction of the other Philips defendants to the resellers and distributors in July 2021.

5. Whether SoClean set forth factual allegations to show plausibly that defendants' statements were false or misleading

The Philips defendants—citing to the portion of their briefing with respect to the state-law defamation claims (which cites New Hampshire law)—argue that SoClean did not set forth factual allegations sufficient to show plausibly that any of defendants' statements were false or misleading. (ECF No. 276 at 26.) The Philips defendants explain:

> The gist of Defendants' statements—that consumers' devices are being recalled because the foam may degrade, both on account of high heat humidity as well as ozone, and that while customers still have their devices, they should not use ozone cleaners because they are unapproved, potentially harmful, and might harm their CPAP devices—is substantially true and grounded in FDA proclamations. ***This is what the FDA has said, continues to say, and has even rebuked Respironics for not saying enough.***

Id. at 37. The Philips defendants argue that SoClean's allegations that they misled the FDA about ozone's exacerbation of foam degradation should be disregarded because the FDA was investigating SoClean and issued its public Safety Communication warning against the use of ozone cleaners more than a year before the recall at issue in this case, which was more than a year before the Philips defendants could have allegedly influenced or misled the FDA. (Id.) The Philips

defendants argue that these allegations do not satisfy the Rule 8 or Rule 9 pleading standards. (Id. at 37-38.)

The Philips defendants also argue that the following statements it allegedly made do not constitute false or misleading statements because they are non-actionable *opinions*:

- "Customers and patients should halt use of ozone-related cleaning products" (ECF No. 211 ¶ 128);
- Ozone is an "aggressive cleaning method" (id. ¶ 109); and
- "SoClean was the problem" (id. ¶ 135).

(Id. at 38.)

In response, SoClean argues:

> SoClean has plausibly alleged that the challenged statements deceived its resellers, distributors, customers, and others into falsely believing ozone cleaners, including SoClean's devices, were responsible for foam degradation in Defendants' recalled devices. Indeed, the FDA itself felt the need to correct the record and issued a statement that 'the unreasonable risk associated with [Defendants'] 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." SAC ¶ 163. SoClean has therefore plausibly alleged the falsity of Defendants' statements blaming ozone for their product recall.

(ECF No. 299 at 17.)

One district court has explained:

> False or misleading statements support a cause of action under the Lanham Act if they are "either (1) literally false or (2) literally true or ambiguous, but has the tendency to deceive consumers." Groupe SEB USA, Inc. v. Euro-Pro Operating LLC, 774 F.3d 192, 198 (3d Cir. 2014) (internal quotations omitted) (citing Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharm. Co., 290 F.3d 578, 586 (3d Cir. 2002)).

Newborn Bros. Co. v. Albion Eng'g Co., 481 F. Supp. 3d 312, 347 (D.N.J. 2020).

As discussed above, based upon the allegations in the second amended complaint, the only alleged statement by the Philips defendants that was sufficiently pleaded to support a

Lanham Act claim as commercial advertising or promotion is the statement made by Philips RS at the direction of the other Philips defendants to the resellers and distributors during the MedTrade West tradeshow that SoClean was to blame for the recall. This opinion, therefore, will consider only whether SoClean set forth factual allegations sufficient to show plausibly that statement is false.

The Philips defendants' belief that SoClean or ozone was to blame for the product recall is set forth in KPNV's June 2021 Recall Notice, which provided: "The foam degradation [in Philips' machines] maybe 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" (ECF No. 5 ¶ 6.) There are two assertions of fact here: (1) the foam degradation may be exacerbated by use of ozone cleaning methods; and (2) off-gassing gassing may occur during operation of the ozone cleaning methods.

SoClean set forth the following allegations to show that the Philips defendants' statements that the foam degradation may be exacerbated by the use of ozone cleaners and off-gassing may occur during operation of the ozone cleaning methods were false:

> 8. The recall notification issued by Royal Philips and Philips RS ("Recall Notice") 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."
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> …
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> 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."

…

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.

…

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.

…

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.

…

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.
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> …
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> 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.

(ECF No. 211.)

The foregoing allegations show plausibly that the recall was caused by the Philips defendants' choice of foam and had nothing to do with the ozone cleaners. To the extent the Philips RS—at the direction of the other Philips defendants—implicated ozone cleaners as a reason for the foam degradation, and, thus, blamed SoClean for the recall, SoClean's allegations show plausibly that the recall was not based upon ozone cleaners and, therefore, Philips RS' statement to the resellers and distributors was—at the very least—misleading.

The foregoing allegations show plausibly that the Philips defendants' statement that off-gassing may occur during use of *ozone cleaners* is false. SoClean's allegations in the second amended complaint show plausibly that the off-gassing concerns in the recall were due to the "production process of the foam." (ECF No. 211 ¶ 118.) Any statement by the Philips defendants in the Recall Notice or to the distributors and resellers that off-gassing may occur during the operation of the ozone cleaners was—at least—misleading about the real reason the products were recalled with respect to off-gassing. To the extent the Philips defendants' statement about ozone

cleaners and off-gassing sent a message that off-gassing by ozone cleaners was the reason for the recall, SoClean showed plausibly that statement was at least misleading, if not false.

Based upon the foregoing, SoClean satisfied its burden at this stage to show plausibly that the statement made by Philps RS—at the direction of the other Philips defendants—to the resellers and distributors blaming SoClean for the recall was misleading or false. The motion to dismiss, therefore, will be denied to the extent SoClean asserts a Lanham Act claim against the Philips defendants based upon Philips RS' statement to the resellers and distributors that SoClean was to blame for the product recall.

B. New Hampshire Consumer Protection Act Claim

The Philips defendants argue that because SoClean's claim for violation of New Hampshire's consumer protection law is based upon the same alleged misrepresentations as the Lanham Act claim, the court should apply the Rule 9(b) heightened pleading standards to those claims. The Philips defendants also argue that SoClean did not set forth factual allegations to plausibly show that: (1) defendants' statements were made in "trade or commerce;" (2) defendants' conduct occurred in New Hampshire; or (3) defendants uttered an actionable representation of fact. Each of those arguments will be addressed below.

1. New Hampshire Consumer Protection Law generally

The New Hampshire Consumer Protection Law ("NHCPA") provides, in pertinent part:

> It shall be unlawful for any person to use any unfair method of competition or any unfair or deceptive act or practice in the conduct of any trade or commerce within this state. Such unfair method of competition or unfair or deceptive act or practice shall include, but is not limited to, the following….Disparaging the goods, services, or business of another by false or misleading representation of fact….

N.H. Rev. Stat. Ann. § 358-A:2(VIII). A plaintiff asserting a claim under the NHCPA must prove: "1) the defendant is a person; 2) the defendant used an unfair method of competition or a

deceptive act or practice; and 3) the act occurred in trade or commerce." Milford Lumber Co. v. RCB Realty, Inc., 780 A.2d 1259, 1263 (2001). The plaintiff must also prove that the unfair competition occurred within New Hampshire. Wilcox Indus. Corp. v. Hansen, 870 F. Supp. 2d 296, 305 (D.N.H. 2012).

2. Whether Rule 9(b) heightened pleading standards apply

The Philips defendants argue that because SoClean's claims arising under the NHCPA sound in fraud, i.e., the Philips defendants allegedly made misrepresentations about SoClean, the court should apply the Rule 9(b) heightened pleading standards to SoClean's claim arising under the NHCPA.

Federal district courts within New Hampshire have held that the Rule 9(b) heightened pleading standards apply to claims arising under the NHCPA when the claims sound in fraud. Micronics Filtration Holdings, Inc. v. Miller, No. 18-CV-303-JL, 2018 WL 4845749, at *1 (D.N.H. Oct. 4, 2018). When the fraud is directed at a third party, like in this case, the heightened pleading standards do not require absolute particularity and are not as demanding as defendants suggest. See Leonard v. Abbott Lab'ys, Inc., No. 10-CV-4676, 2012 WL 764199, at *20 (E.D.N.Y. Mar. 5, 2012) (holding that Rule 8 pleading standards applied to a NHCPA claim because unlike a claim for fraud, the NHCPA did not include the elements of reliance or scienter); see discussion supra pp.66-73 with respect to pleading third-party fraud in a Lanham Act claim. The court, therefore, will permit information and belief factual allegations.

3. Whether the Philips defendants' statements were made in trade or commerce

The NHCPA defines "trade or commerce" as follows:

> II. "Trade" and "commerce" shall include the advertising, offering for sale, sale, or distribution of any services and any property, tangible or intangible, real, personal or mixed, and any other article, commodity, or thing of value wherever situate, and

> shall include any trade or commerce directly or indirectly affecting the people of this state.

N.H. Rev. Stat. Ann. § 358-A:1. The New Hampshire Supreme Court has explained that to determine whether the consumer protection laws apply to a transaction, i.e., whether the transaction is personal or business, the court must consider: "the activity involved, the nature of the transaction, and the parties to determine whether a transaction is a personal or business transaction." Hughes v. DiSalvo, 729 A.2d 422, 424 (N.H. 1999). The court in Hughes explained: "Remedies under the Consumer Protection Act are 'not available where the transaction is strictly private in nature, and is in no way undertaken in the ordinary course of a trade or business.' " Id. (quoting Lantner v. Carson, 373 N.E.2d 973, 975 (N.H. 1978)). The distinction noted by the Supreme Court of New Hampshire in Hughes, however, was not whether a business performed a certain kind of transaction on a day-to-day basis; rather, the distinction noted was whether the transaction was a strictly private transaction or was a business transaction.

Here, the factual allegations of the second amended complaint plausibly show that the Philips defendants were engaged in trade or commerce for financial profit because they were in the business of selling the CPAP and BiPAP machines and used distributors and resellers to make those sales.[24] SoClean plausibly alleged that that Philips RS at the direction of the other Philips defendants told the resellers and distributors at the MedTrade West tradeshow in July 2021 that SoClean was responsible for the recall to deflect blame from the Philips defendants and their products and to maintain goodwill with the resellers and distributors so that they would

[24] The parties in their briefing did not address whether SoClean set forth factual allegations to state a plausible claim for relief under the NHCPA with respect to each of the allegedly disparaging remarks made by the Philips defendants about SoClean. Because the allegations with respect to Philips RS' alleged comments made during the MedTrade West tradeshow have the most promise, those allegations are considered to determine whether SoClean set forth factual allegations sufficient to state a plausible claim for relief under the NHCPA.

continue to purchase defendants' products. Based upon the foregoing, SoClean plausibly alleged that the Philips defendants were engaged in trade or commerce when Philips RS—at the direction of the other Philips defendants—allegedly told the resellers and distributors that SoClean was to blame for the product recall.

The Philips defendants, however, argue that all their conduct alleged in this case was part of the recall, which could not have constituted trade or commerce. As discussed above, however, SoClean plausibly alleged that SoClean was not to blame for the recall, and, therefore, Philips RS' alleged statements to the resellers and distributors at the MedTrade West tradeshow in July 2021 that SoClean was the reason for the recall fell outside the scope of the recall and were part of the Philips defendants engaging in trade or commerce to sell their products. Based upon the foregoing, SoClean set forth factual allegations to show plausibly that the Philips defendants were engaged in trade or commerce when Philips RS—at the direction of the other Philips defendants—told the resellers and distributors at the MedTrade West tradeshow in July 2021 that SoClean was responsible for the recall.

4. Whether the Philips defendants' conduct occurred in New Hampshire

The New Hampshire Supreme Court has not addressed "whether conduct in trade or commerce must occur in New Hampshire to be actionable under the [NHCPA]." Michael J. Kenison, A Practical Guide to Understanding RSA 358A in New Hampshire § 10.3.1 (1st ed. 2014). One treatise has explained:

> The New Hampshire Supreme Court has not directly addressed whether conduct in trade or commerce must occur in New Hampshire to be actionable under the CPA. Arguably, room for interpretation exists between the broad language of N.H. Rev. Stat. Ann. § 358-A:1, II, which describes trade and commerce as "wherever situate" and "*directly or indirectly* affecting people in this state," and N.H. Rev. Stat. Ann. § 358-A:2, which says "...trade or commerce *within* this state." (emphasis added). The federal district court for the District of New Hampshire has concluded that the

> offending conduct must actually occur in New Hampshire to be actionable under the CPA.

Id. For example, in Pacamor Bearings, Inc. v. Minebea Co., 918 F. Supp. 491, 504 (D.N.H. 1996), the court held that the "within this state" language from the NHCPA requires the defendant's violative conduct to take place within New Hampshire's borders to be actionable. The court in Pacamor Bearings, Inc. v. Minebea Co., 918 F. Supp. 491, 504 (D.N.H. 1996), adopted that rationale and explained: "It is the 'offending conduct' that must occur within the state—the "unfair method of competition or any unfair or deceptive act or practice" in trade or commerce—not the actual sale."

SoCleans cites LaChance v. U.S. Smokeless Tobacco Co., 931 A.2d 571 (N.H. 2007), in support of its argument that: "The New Hampshire Supreme Court has explained that a pleading sufficiently states a claim under the NHCPA if the 'allegations encompass conduct which was part of trade or commerce that had direct or indirect effects on the people of [New Hampshire]." Id. At 578. As the Philips defendants point out, however, LaChance is not directly on point. The Supreme Court of New Hampshire in LaChance considered whether indirect purchasers may file a lawsuit under the NHCPA. The court held that indirect purchasers could file suit and found support in the NHCPA's law definition of "trade or commerce." The court explained:

> Another aspect of the CPA's language also supports the conclusion that indirect purchasers may bring suit. RSA 358–A:2 makes it unlawful to "use any unfair method of competition or any unfair or deceptive act or practice in the conduct of any trade or commerce within this state." RSA 358–A:1, II (Supp.2006), defines "[t]rade" and "commerce" to "include any trade or commerce *directly or indirectly* affecting the people of this state." (Emphasis added.) Citing Blewett v. Abbott Laboratories, 86 Wash.App. 782, 938 P.2d 842, 846 (1997), *rev. denied,* 133 Wash.2d 1029, 950 P.2d 475 (1998), the defendants contend that the phrase "directly or indirectly" has no bearing on who may bring suit and instead defines the types of business conduct regulated. Even if we adopt the defendants' position, it cannot be denied that the plaintiffs' allegations encompass conduct which was

> part of trade or commerce that had direct or indirect effects on the people of this state. Thus, if nothing else, "directly or indirectly" is further evidence of the broad sweep the legislature intended for the CPA. Similarly, in Ciardi, the Massachusetts Supreme Judicial Court noted that Massachusetts' consumer protection statute "regulates trade and commerce 'directly or *indirectly* affecting the people of this commonwealth,' " Ciardi, 762 N.E.2d at 308. It then concluded that although indirect purchasers are barred from bringing suit under the state antitrust act, they are not barred from bringing consumer protection claims.

LaChance, 931 A.2d at 578. The court in LaChance did not directly address whether the offending conduct must take place within New Hampshire to be actionable under the NHCPA.

SoClean cites In re Chocolate Confectionary Antitrust Litig., 749 F. Supp. 2d 224, 235 (M.D. Pa. 2010), for the proposition that "[t]o ascertain whether this prerequisite has been satisfied, the court must focus upon the 'offending conduct' itself rather than the locus of actual sales or the site of product manufacture." SoClean also cites to In re Niaspan Antitrust Litig., 42 F. Supp. 3d 735, 761 (E.D. Pa. 2014), in which the court cited to LaChance for the proposition that the NHCPA shall be construed broadly and held that factual allegations that plausibly show the defendant had a nationwide scheme to defraud are sufficient to show that the offending conduct took place within the state.

The Philips defendants argue that SoClean "has not adequately pleaded that defendants' alleged statements were received in New Hampshire." (ECF No. 276 at 28.) The Philips defendants are correct that SoClean did not set forth factual allegations to show plausibly that defendants' misrepresentations to the distributors and resellers at the MedTrade West tradeshow were made in New Hampshire; rather, SoClean alleges that the tradeshow took place in Arizona. SoClean, however, set forth factual allegations to show plausibly that the MedTrade West tradeshow was the largest medical device tradeshow in the United States, the largest distributors

and resellers of Philips RS and SoClean products were in attendance, and the Philips defendants engaged in a nationwide scheme to place blame on SoClean for the recall. SoClean alleges:

> 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.
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> …
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> 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."
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> 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.

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.

…

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.
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> …
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> 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.
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> …
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> 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.
>
> …
>
> 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.

(ECF No. 211.)

Based upon the foregoing, and the allegations that the MedTrade West tradeshow was the largest tradeshow for medical devices in the United States and the largest distributors and resellers of both Philips RS and SoClean products were in attendance, a reasonable inference is created by the factual allegations in the second amended complaint that Philips defendants had a nationwide campaign to place the blame for the recall onto SoClean and attempted to do so via statements to the resellers and distributors during the MedTrade West tradeshow. At least one court has held that—at the motion to dismiss stage—allegations that the defendants had a nationwide scheme to defraud are sufficient to show plausibly that the offending conduct took place within the state under the NHCPA. In re Niaspan Antitrust Litig., 42 F. Supp. 3d 735, 761 (E.D. Pa. 2014) ("Given that the statute is broadly worded, and in the absence of detailed briefing on this issue, the Court finds this line of cases persuasive on the record before it. The

Court therefore denies defendants' Motion to Dismiss the end-payor plaintiffs' NHCPA claim."). Based upon the foregoing, the factual allegations in the second amended complaint show plausibly that the Philips defendants were engaged in a nationwide campaign to place blame on SoClean for the recall. At the motion to dismiss stage, those allegations are sufficient to show plausibly the "within the state" requirement of the NHCPA is satisfied.

5. Whether defendants made an actionable representation of fact

The Philips defendants argue that—for the same reasons asserted with respect to the claim asserted under the Lanham Act—SoClean did not set forth factual allegations to show plausibly that defendants disparaged SoClean's goods by any false or misleading representation of fact. (ECF No. 276 at 29.) SoClean argues that it set forth factual allegations sufficient to plausibly show there exists actionable misrepresentations of fact under the NHCPA, i.e., "the SAC allege that Defendants lied to the public and mislead the FDA about the existence of data purporting to show that ozone accelerated foam degradation." (ECF No. 299 at 20.)

For the same reasons as set forth above, SoClean set forth factual allegations sufficient to show plausibly that Philips RS—at the direction of the other Philips defendants—made a misrepresentation of fact when it communicated to the resellers and distributors at the MedTrade West tradeshow that SoClean and ozone were responsible for the product recall. For the reasons discussed above, the motion to dismiss will be denied with respect to the NHCPA claim.

C. New Hampshire Tortious Interference Claim

1. Whether SoClean mislabeled claim III

In the second amended complaint, SoClean titles its third claim "Tortious Interference with Advantageous and Prospective Business Relationships." (ECF No. 211 at 56.) The Philips defendants argue that New Hampshire law applies to this case because SoClean is domiciled in

New Hampshire, and, New Hampshire does not recognize a tort entitled "tortious interference with advantageous and prospective business relationships." (ECF No. 276 at 29.) SoClean clarifies that claim III is a claim for (1) tortious interference with existing (advantageous) contractual relationships; and (2) tortious interference with prospective contractual relationships, both of which are recognized under New Hampshire law. SoClean also asserts that it does not concede New Hampshire law applies to the torts asserted in claim III and addresses claim III under New Hampshire law only to show that defendants did not satisfy their burden to show they are entitled to dismissal of the claim, even under New Hampshire law.

New Hampshire recognizes the torts of (1) intentional interference with existing contractual relations; and (2) intentional interference with prospective contractual relations. One district court has explained:

> "To establish liability for tortious interference with contractual relations, a plaintiff must show that: (1) the plaintiff had an economic relationship with a third party; (2) the defendant knew of this relationship; (3) the defendant intentionally and improperly interfered with this relationship; and (4) the plaintiff was damaged by such interference." City of Keene v. Cleaveland, —— N.H. ——, 118 A.3d 253, 259 (N.H. 2015) (internal quotation marks omitted). To be actionable, the interference must be improper, meaning motivated by an improper purpose. Nat'l Emp't Serv. Corp. v. Olsten Staffing Serv., Inc., 145 N.H. 158, 162 (2000); accord City of Keene, 118 A.3d at 259 ("Whether the alleged conduct is improper requires an inquiry into the mental and moral character of the defendant's conduct.) (internal quotation marks omitted). To be wrongful, interference must "surpass[ ] the permissible bounds of rough-and-tumble business competition." Cook & Companyinsurance Servs., Inc. v. Volunteer Firemen's Ins. Servs., Inc., 2015 WL 5458279, at *2 (D. Mass. Sept. 17, 2015).
>
> A claim for tortious interference with a prospective contractual relationship requires proof that the defendant "induced or otherwise purposely caused a third person not to enter into or continue a business relation with another and thereby caused harm to the other." Sarah's Hat Boxes, L.L.C. v. Patch Me Up, L.L.C., 2013 WL 1563557, at *13 (D.N.H. Apr. 12, 2013) (internal quotation marks omitted). The interference also must be improper. Alternative Sys. Concepts, Inc. v.

> Synopsys, Inc., 229 F. Supp. 2d 70, 74 (D.N.H. 2002). "[C]ertain types of conduct such as fraud or threats of physical violence ordinarily will be sufficient to support a claim for interference with a prospective contractual relationship, but the use of ordinary means of persuasion or the exertion of limited economic pressure will not, by itself, be sufficient." Wilcox Indus. Corp. v. Hansen, 870 F. Supp. 2d 296, 307 (D.N.H. 2012).

Moulton v. Bane, No. 14-CV-265-JD, 2015 WL 7274061, at *12 (D.N.H. Nov. 16, 2015).

Another district court explained:

> A claim for intentional interference with prospective contractual relations exists under New Hampshire law when "[o]ne who, without a privilege to do so, induces or otherwise purposely causes a third person not to ... enter into or continue a business relation with another" and thereby causes harm to the other. Synopsys, 229 F.Supp.2d at 73–74 (quoting Baker, 121 N.H. at 644, 433 A.2d 1271). To prevail on such a claim, Wilcox must show that: "(1) [it] had an economic relationship with a third party; (2) the defendant[s] knew of this relationship; (3) the defendant[s] intentionally and improperly interfered with this relationship; and (4) [Wilcox] was damaged by such interference." M & D Cycles, Inc. v. Am. Honda Motor Co., Inc., 208 F.Supp.2d 115, 119 (D.N.H.2002) *aff'd,* 70 Fed.Appx. 592 (1st Cir.2003). The asserted economic relationship must "give rise to a reasonable expectation of economic advantage." Preyer v. Dartmouth Coll., 968 F.Supp. 20, 26 (D.N.H.1997) (quoting Heritage Home Health, Inc. v. Capital Region Health Care Corp., Civ. No. 95–558–JD, 1996 WL 655793, at *4 (D.N.H. Oct. 1, 1996)).

Wilcox Indus. Corp. v. Hansen, 870 F. Supp. 2d 296, 306–07 (D.N.H. 2012).

As SoClean argues, "it is not unusual" for a plaintiff to plead these claims together. (ECF No. 299 at 21.) For example, in Moulton, the plaintiff labeled the pertinent claim "tortious interference" and the court—at the motion for summary judgment stage—analyzed whether material issues of fact existed with respect to claims for (1) tortious interference with existing contractual relations, and (2) tortious interference with prospective contractual relations.

This court will, therefore, consider claim III in the second amended complaint as two separate claims: (1) tortious interference with existing contractual relations; and (2) tortious interference with prospective contractual relations. The motion to dismiss with respect to this

issue will be denied to the extent the Philips defendants invite the court to elevate substance over form. The court in CNX Gas Co. v. Lloyd's of London, 410 F. Supp. 3d 746, 752 (W.D. Pa. 2019), explained:

> [T]he spirit behind the Rules Enabling Act of 1934…[is] to simplify federal pleading and prioritize substance over form. Pub. L. 73-415, 48 Stat. 1064 (codified as amended at 28 U.S.C. § 2072). That spirit is not only a historical force, but a contemporary one, one that compels federal courts to cast aside petty formalism in favor of a "forgiving spirit" towards technical lapses in complaint drafting. *See* Paul D. Carrington, *"Substance" and "Procedure" in the Rules Enabling Act*, 1989 DUKE L. J. 281, 307; *see also* WRIGHT & MILLER, 5 FED. PRAC. & PROC. CIV. § 1286 (3d ed. Aug. 2019).

Id. at 752–53; see 5 A. Benjamin Spencer, Federal Practice & Procedure § 1286 (4th ed.) ("A pleading will be judged by the quality of its substance rather than according to its form or label…and, if possible, it will be construed to give effect to all its allegations."). Arguably, the Philips defendants understood the claims SoClean attempted to assert because they address the substance of those claims in their opening brief. (ECF No. 276 at 30.) Whether SoClean set forth factual allegations to state plausible claims for tortious interference with existing or contractual relations will be discussed below.

2. Whether SoClean set forth factual allegations to state a plausible claim for tortious interference with existing contractual relationships

With respect to the first element of the tort, i.e., the plaintiff had an economic relationship with a third party, SoClean in the second amended complaint alleges that it has "business, economic, and contractual relationships with customers, including third-party distributors, resellers, and DMEs that purchase SoClean's ozone cleaners[, and] SoClean has entered into written contracts with distributors, resellers, and DMEs." (ECF No. 211 ¶ 240.) SoClean alleges that its products were sold via resellers and distributors. A reasonable inference, therefore, arises that SoClean had an economic and contractual relationship with those resellers and distributors.

With respect to the second element, i.e., whether the defendant knew of this relationship, SoClean in the second amended complaint alleges that defendants knew about SoClean's "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." (ECF No. 211 ¶ 241.) SoClean also alleges that defendants cancelled their booth at the MedTrade West tradeshow, secured a hotel suite, invited multiple select partners, including distributors and sellers of medical device equipment that service both Philips RS and SoClean, and spoke with them about SoClean; indeed, SoClean alleges that defendants spoke directly to SoClean's distributors and resellers during the MedTrade West conference. (Id. ¶ 135.) A reasonable inference may be drawn from those allegations that defendants were aware that SoClean had an economic relationship with those distributors and resellers and that is why defendants invited those entities to the hotel suite and informed them about SoClean's alleged role in the recall.

With respect to the third element, i.e., whether the defendant intentionally and improperly interfered with this relationship, SoClean in the second amended complaint alleges that defendants made the alleged misrepresentations to SoClean's resellers and distributors with "with an improper motive and means to preserve Defendants' sales and reputation and to prevent SoClean from continuing its existing business and contractual relationships." (ECF No. 211 ¶ 246.)

With respect to the fourth element, i.e., whether the plaintiff was damaged by such interference, SoClean set forth factual allegations sufficient to show plausibly that it suffered damages as a result of the misrepresentations made by defendants to SoClean's resellers and distributors during the MedTrade West tradeshow. SoClean alleges:

> 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.

(ECF No. 211 ¶ 137.)

Based upon the foregoing, SoClean set forth factual allegations in the second amended complaint to state plausible claims for tortious interference with existing contractual relations under New Hampshire law. The motion to dismiss will be denied with respect to this issue.

3. Whether SoClean set forth factual allegations to state plausible claims for tortious interference with *prospective* contractual relationships

SoClean also set forth factual allegations to show plausibly that the Philips defendants intentionally interfered with their prospective contractual relationships. Along with the foregoing elements, which are the same for both torts, SoClean also alleged that some of the distributors and resellers informed SoClean that they would not place future orders with SoClean because of the alleged misrepresentations made by the Philips defendants. Under those circumstances, SoClean set forth factual allegations to state a plausible claim for tortious interference with prospective contractual relationship. The motion to dismiss will be denied with respect to SoClean's claim III, i.e., tortious interference with existing and prospective contractual relationships.

D. New Hampshire Defamation Claim

One district court has explained:

> Under New Hampshire law, in order to survive a motion to dismiss, the plaintiff "must have alleged facts that would show that the defendants failed to exercise reasonable care in publishing a false and defamatory statement of fact about the plaintiff[ ] to a third party." Automated Transactions, LLC v. Am. Bankers Ass'n, 172 N.H. 528, 216 A.3d 71, 77 (2019) (quotation and brackets omitted) (emphases added); see also Pierson v. Hubbard, 147 N.H. 760, 763, 802 A.2d 1162 (2002); Indep. Mechanical Contractors v. Gordon T. Burke & Sons, 138 N.H. 110, 118, 635 A.2d 487 (1993).

Martin v. Mooney, 448 F. Supp. 3d 72, 84 (D.N.H. 2020).

1. Whether defendants' statements were of and concerning SoClean

It does not appear that courts of New Hampshire have closely considered the element of a defamation claim that the allegedly defamatory statements must be "of and concerning" or "about" the plaintiff. The Restatement (Second) of Torts provides:

> **A defamatory communication is made concerning the person to whom its recipient correctly, or mistakenly but reasonably, understands that it was intended to refer.**

Restatement (Second) of Torts § 564 (1977). The concept that the defamatory statement must be reasonably understood to be about the plaintiff finds support in the Supreme Court of New Hampshire's consideration of other elements of a defamation claim. For example, in Gascard v. Hall, 293 A.3d 472 (N.H. Oct. 20, 2022), the Supreme Court of New Hampshire explained that "'an opinion is ... actionable for defamation when the opinion may reasonably be understood to imply the existence of defamatory fact as the basis for the opinion.'" Id. at 476 (quoting Boyle v. Dwyer, 216 A.3d 89 (N.H. 2019)). The Supreme Court of New Hampshire has also cited to the Restatement (Second) of Torts when considering other elements of a claim for defamation. See e.g., Pierson v. Hubbard, 802 A.2d 1162, 1165 (2002) (citing Restatement (Second) of Torts § 558 (1997), which sets forth the elements of a claim for defamation)). Based upon the foregoing, the court will consider whether SoClean set forth factual allegations to show plausibly that the Philips defendants' allegedly defamatory statements could reasonably be understood by their recipients to be about SoClean.

The Philips defendants argue that their allegedly defamatory statements concerned a class of products and how those products affected the Respironics line of CPAP products, and, therefore, were not "of and concerning" SoClean. (ECF No. 276 at 32.) According to the Philips defendants, the defamation claim is a "re-labeled" trade libel claim, and New Hampshire does

not recognize a cause of action for trade libel. (Id. at 32.) SoClean argues that "defamation claims focused on statements regarding plaintiff products and businesses are routinely accepted," and the allegations of the second amended complaint show that the Philips defendants referred directly to SoClean in some of its statements and, in any event, SoClean is synonymous with "ozone cleaners," and, therefore, industry commentators and SoClean's customers understood defendant's communications to refer to SoClean and SoClean products. (ECF No. 299 at 26-27.)

SoClean is correct that the well-pled allegations in the second amended complaint show plausibly that Philips RS' alleged statements to the resellers and distributors at MedTrade West tradeshow specifically referred to SoClean. Under those circumstances, the allegations in the second amended complaint are sufficient to show plausibly that this element is met.

With respect to defendants' other statements about ozone cleaners generally, the factual allegations are sufficient to show plausibly that the recipients of those statements understood that defendants were referring to SoClean; indeed, SoClean alleges:

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

(ECF No. 211.) The foregoing allegations and the reasonable inferences drawn from the factual allegations contained in them show plausibly that SoClean was the market leader in ozone cleaners and accounted for the vast majority of sales of those products, and that distributors, resellers, and customers reasonably understood that when defendants referred to "ozone cleaners," they were referring to SoClean's products.

The Philips defendants argue, however, that SoClean's claim is a claim for trade libel, which is not recognized in New Hampshire, and not a claim for defamation. As SoClean argues, however, at least one district court applying New Hampshire law found that a plaintiff could maintain a claim of defamation based the defendant's false statements of fact about the plaintiff and its product to third parties, including potential customers. Lilly Software Assocs., Inc. v. Blue Ridge Designs, Inc., No. CIV. 00-93-JD, 2001 WL 531205, at *2 (D.N.H. Apr. 20, 2001). Importantly, in Lilly, the plaintiff alleged that the defendant's statements injured its reputation. Similarly here, SoClean alleges that defendants made statements about SoClean itself ("SoClean is the problem") and SoClean's product, i.e., ozone cleaner, and, as a result:

> 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.

(ECF No. 211 ¶ 27.) That SoClean alleges harm to its reputation is important. One treatise has explained:

> Defamation is part of this chapter because a defamation cause of action exists when false and disparaging statements are made about a natural person's business

> character or about a business itself. In many states, if a negative statement concerns the honesty or general business conduct of a firm or of an agent of the firm, a possible claim sounds in defamation. In contrast, if a statement concerns the quality of a firm's products or the firm's ownership rights in a tangible or intangible asset, the appropriate cause of action is some form of business disparagement (also known as injurious falsehood).

3 LOUIS ALTMAN, MALLA POLLACK, CALLMANN ON UNFAIR COMPETITION, TRADEMARKS AND MONOPOLIES, Overview of defamation § 11:4 (4th ed.) (citing inter alia Ira Green, Inc. v. Military Sales & Service Co., 775 F.3d 12 (1st Cir. 2014) (deciding that under Rhode Island law, a false statement concerning the quality of goods is actionable as disparagement but is not actionable as defamation per se unless made under circumstances and in a manner that implies that the manufacturer or vendor is dishonest, fraudulent or incompetent). In other words, "[d]efamation of a corporation injures the reputation of the corporation[, while] product disparagement injures the reputation of its products." Dairy Stores, Inc. v. Sentinel Pub. Co., Inc., 516 A.2d 220 (N.J. 1986).

Because the Philips defendants allegedly directly referred to SoClean "as the problem" and SoClean alleged that the Philips defendants' conduct caused injury to SoClean's reputation and goodwill, the court—at this stage—will deny the motion to dismiss with respect to the Philips defendants' argument that SoClean failed to state a plausible claim for defamation because its claim is a claim for trade libel, which is not recognized under New Hampshire law. The Philips defendants may raise this argument, if warranted by facts adduced during discovery, at the motion for summary judgment stage of the proceedings.

2. Whether SoClean is a public figure and set forth factual allegations sufficient to show plausibly that defendants acted with actual malice

The Supreme Court of New Hampshire has explained:

> "In an effort to strike a balance between First Amendment freedoms and state defamation laws, [we] accord[ ] ... significance to the [public or private] status of each individual plaintiff. Under the taxonomy developed by the [United States] Supreme Court, private plaintiffs can succeed in defamation actions on a state-set standard of proof (typically, negligence), whereas the Constitution imposes a higher hurdle for public figures and requires them to prove actual malice."

Thomas v. Tel. Publ'g Co., 929 A.2d 993, 1016 (N.H. 2007) (quoting Pendleton v. City of Haverhill, 156 F.3d 57, 66 (1st Cir.1998)). "Actual malice" is "a subjective awareness of the falsity or probable falsity of a statement." Id. at 1008. "[A]ctual malice is concerned with the publisher's attitude toward the truth…." Id.

"Determining whether an individual is a public or private figure presents a threshold question of law,…which is 'grist for the court's—not the jury's—mill.'" Id. (quoting Pendleton, 156 F.3d at 67). The court in Thomas explained:

> The United States Supreme Court has created two subclassifications of public figures: (1) persons who are public figures for all purposes; and (2) so-called limited-purpose public figures who are public figures for particular public controversies. Gertz, 418 U.S. at 351, 94 S.Ct. 2997. With respect to the first group, "an individual may achieve such pervasive fame or notoriety that he becomes a public figure for all purposes and in all contexts." Id. When determining that an individual is this type of public figure, courts should
>
> > not lightly assume that a citizen's participation in community and professional affairs rendered him a public figure for all purposes. Absent clear evidence of general fame or notoriety in the community, and pervasive involvement in the affairs of society, an individual should not be deemed a public personality for all aspects of his life.
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> Id. at 352, 94 S.Ct. 2997.
>
> …
>
> As to the second group, individuals may become limited-purpose public figures when they "have thrust themselves to the forefront of particular public controversies in order to influence the resolution of the issues involved." Gertz, 418 U.S. at 345, 94 S.Ct. 2997. Then, they "become[ ] a public figure for a limited range of issues." Id. at 351, 94 S.Ct. 2997. Courts make the limited-purpose public figure determination "by looking to the nature and extent of an individual's participation

in the particular controversy giving rise to the defamation." Id. at 352, 94 S.Ct. 2997.

Finally, we must draw a distinction between these public figures and private citizens.

> Even if the foregoing generalities do not obtain in every instance, the communications media are entitled to act on the assumption that public officials and public figures have voluntarily exposed themselves to increased risk of injury from defamatory falsehood concerning them. No such assumption is justified with respect to a private individual. He has not accepted public office or assumed an influential role in ordering society. He has relinquished no part of his interest in the protection of his own good name, and consequently he has a more compelling call on the courts for redress of injury inflicted by defamatory falsehood. Thus, private individuals are not only more vulnerable to injury than public officials and public figures; they are also more deserving of recovery.

Id. at 345, 94 S.Ct. 2997 (quotations and citation omitted). Accordingly, private plaintiffs need not establish actual malice to recover actual damages. See Pendleton, 156 F.3d at 66.

Id. at 1017. With respect to whether a plaintiff is a limited purpose public figure, *which is a question of law*, the Supreme Court of New Hampshire has explained:

> "[I]ndividuals may become limited-purpose public figures when they have thrust themselves to the forefront of particular public controversies in order to influence the resolution of the issues involved." Thomas, 155 N.H. at 341, 929 A.2d 993 (quotation omitted). "Then, they become [ ] public figure[s] for a limited range of issues." Id. (quotation and brackets omitted). "Courts make the limited-purpose public figure determination by looking to the nature and extent of an individual's participation in the particular controversy giving rise to the defamation." Id. (quotation omitted).

Lassonde v. Stanton, 956 A.2d 332, 341 (N.H. 2008). The first step of the inquiry is to define the controversy for which the plaintiff may be a public figure. One district court has recognized: "Defining public controversy has proven difficult for courts." Amor v. Conover, No. 5:21-CV-

05574-JMG, 2022 WL 7127657, at *3 (E.D. Pa. Oct. 12, 2022).[25] The Supreme Court of New Hampshire explained:

> "As the first step in [the limited-purpose public figure] inquiry, the court must isolate the public controversy" in question. Waldbaum v. Fairchild Publications, Inc., 627 F.2d 1287, 1296 (D.C.Cir.), cert. denied, 449 U.S. 898, 101 S.Ct. 266, 66 L.Ed.2d 128 (1980); see Thomas, 155 N.H. at 341, 929 A.2d 993; Hatfill v. New York Times Co., 532 F.3d 312, 322 (4th Cir.2008); Copp v. Paxton, 45 Cal.App.4th 829, 52 Cal.Rptr.2d 831, 844 (1996). "Identification of the implicated public controversy is not a mere formality," Norris v. Bangor Pub. Co., 53 F.Supp.2d 495, 503 (D.Me.1999), because the scope of the controversy in which the plaintiff involves himself defines the bounds of his public presence, OAO Alfa Bank v. Center for Public Integrity, 387 F.Supp.2d 20, 42–43 (D.D.C.2005).
>
> "A public controversy is not simply a matter of interest to the public; it must be a real dispute, the outcome of which affects the general public or some segment of it in an appreciable way." Waldbaum, 627 F.2d at 1296; see Norris, 53 F.Supp.2d at 503 (the implications of a public controversy will affect the public and not merely the litigants).
>
> > The [United States] Supreme Court has made clear that essentially private concerns or disagreements do not become public controversies simply because they attract attention. Rather, a public controversy is a dispute that in fact has received public attention

[25] The court in Amor explained:

> While the Third Circuit has not explicitly defined what constitutes a public controversy, it has found that "a public controversy must be a real dispute, the outcome of which affects the general public or some segment of it ... [t]o be 'public,' the dispute must affect more than its immediate participants." Marcone v. Penthouse Int'l Magazine for Men, 754 F.2d 1072, 1083 (3d Cir. 1985) (citing Waldbaum v. Fairchild Publications, Inc., 627 F.2d 1287, 1296 (D.C. Cir. 1980)). See, e.g., id. (holding that allegedly defamatory statements concerning large scale drug trafficking, "one of the most troubling issues of our time, surely falls within the ambit of public controversy."); Avins v. White, 627 F.2d 637, 648 (3d Cir. 1980) (holding that allegedly defamatory comments regarding law school dean's behavior during accreditation process concerned a public controversy because the law school's accreditation efforts "affected the general public or some segment of it in an appreciable way") (quoting Waldbaum, 627 F.2d at 1296).

Amor v. Conover, No. 5:21-CV-05574-JMG, 2022 WL 7127657, at *3 (E.D. Pa. Oct. 12, 2022).

> because its ramifications will be felt by persons who are not direct participants.
>
> Waldbaum, 627 F.2d at 1296 (citation omitted); *cf.* Time, Inc. v. Firestone, 424 U.S. 448, 454–55, 96 S.Ct. 958, 47 L.Ed.2d 154 (1976) (divorce of extremely wealthy individuals not a public controversy despite interest of some portion of public in such marital difficulties); Hatfill, 532 F.3d at 323–24 (threat from bioterrorism and the nation's readiness to handle that threat a public controversy); Tavoulareas v. Piro, 817 F.2d 762, 773–74 (D.C.Cir.) (public controversy existed concerning manner in which United States oil industry responded to the rise of OPEC and energy crisis of 1970s), *cert. denied,* 484 U.S. 870, 108 S.Ct. 200, 98 L.Ed.2d 151 (1987); Thomas, 155 N.H. at 342, 929 A.2d 993 (string of burglaries, even of a large number of homes, not a public controversy; only those whose homes had been burgled truly affected). "If the issue was being debated publicly and if it had foreseeable and substantial ramifications for non-participants, it was a public controversy." Waldbaum, 627 F.2d at 1297.

Lassonde v. Stanton, 956 A.2d 332, 340 (N.H. 2008).

Once the court defines the public controversy, it must assess whether the plaintiff "'thrust [itself]…to the forefront of [the] particular public controvers[y] in order to influence the resolution of the issues involved.'" Currier v. Town of Gilmanton, No. 18-CV-1204-LM, 2022 WL 3359156, at *11 (D.N.H. Aug. 15, 2022), reconsideration denied, No. 18-CV-1204-LM, 2022 WL 11961748 (D.N.H. Oct. 20, 2022) (quoting Thomas v. Tel. Publ'g Co., 155 N.H. 314, 341, 929 A.2d 993, 1017 (2007), as modified on denial of reconsideration (Aug. 29, 2007)). Some courts also consider whether the controversy preexisted the alleged defamatory statements at issue. See e.g., Little v. Breland, 93 F.3d 755, 757 (11th Cir. 1996) ("The public controversy must have preexisted the alleged defamation.").

The Philips defendants argue that the relevant controversy in this case is "the safety issues surrounding the use of ozone." (ECF No. 276 at 33 (citing Quantum Elecs. Corp. v. Consumers Union, 811 F. Supp. 753, 764 (D.R. I. 1995).) SoClean argues in response that the controversy in this case is "whether SoClean's products caused or accelerated the degradation of sound abatement

foam in Philips CPAP machines, thereby making Defendants' products unsafe and rendering SoClean responsible for the recall." (ECF No. 299 at 27-28.) SoClean argues *that* controversy did not exist until defendants began to blame SoClean and ozone cleaners for the foam degradation. (Id.)

At the motion to dismiss stage of the litigation, the court will defer the decision about the relevant controversy because if SoClean's devices were legally marketed and safe (as SoClean alleges) and the Philips defendants provided the FDA erroneous information about ozone's role in the foam degradation, then the controversy would not be about the safety of SoClean's ozone-generating devices. As discussed above and at the hearing with respect to the supplemental briefing on the Rule 12(b)(1) motion to dismiss, the court is without sufficient information to determine whether SoClean legally marketed the SoClean 2, e.g., an FDA expert opinion.

3. Whether the statements were substantially true or protected expressions of opinion

One district court has explained:

> To be "true," a statement only needs to be "substantially true," which does not require that every detail in the statement be accurate. Boyle v. Dwyer, 172 N.H. 548, 554, 216 A.3d 89 (2019). Rather, a statement is "substantially true" if the substance or "gist or sting" of the statement is justified. Id. Although the substantial truth of a statement is normally one of fact for the jury, a court may decide the issue as a matter of law when the "underlying facts as to the gist or sting" are undisputed. Id.
>
> In addition, the First Amendment to the United States Constitution imposes certain restraints on state defamation law, including that only statements that present or imply the existence of facts that can be proven true or false can be actionable as defamation. Gray v. St. Martin's Press, Inc., 221 F.3d 243, 247 (1st Cir. 2000); see also Thomas v. Tel. Publ'g Co., 155 N.H. 314, 338, 929 A.2d 993 (2007). That said, an opinion statement may still be actionable when it implies the existence of undisclosed factual statements that are themselves defamatory. Gray, 221 F.3d at 248. The determination of whether a statement relates to a verifiable

> fact or a subjective opinion is one ordinarily decided by judges as a matter of law. Id.; Thomas, 155 N.H. at 338, 929 A.2d 993.

Currier v. Town of Gilmanton, No. 18-CV-1204-LM, 2022 WL 11961748, at *3 (D.N.H. Oct. 20, 2022).

The Philips defendants argue that the "gist" of their alleged statements is substantially true, i.e., "that consumers' devices are being recalled because the foam may degrade, both on account of high heat and humidity as well as ozone, and that while customers still have their devices they should not use ozone cleaners because they are unapproved, potentially harmful, and might harm their CPAP devices." (ECF No. 276 at 37.) According to the Philips defendants, "[t]his is what the FDA has said, continues to say, and has even rebuked Respironics for not saying enough." (Id.) The Philips defendants argue that SoClean did not set forth factual allegations sufficient to satisfy the Rule 9 heightened pleading standards with respect to their allegations that the Philips defendants mislead the FDA about the foam degradation. (Id. at 37-38.) The Philips defendants also argue the following statements alleged in the second amended complaint are non-actionable opinions: "customers and patients should halt use of ozone-related cleaning products;" ozone is "an aggressive cleaning method;" and "SoClean was the problem." (Id. at 38.)

SoClean argues that the Philips defendants' arguments about the truth of their alleged statements are an attempt "to recast…[their] communications as voicing vague general concerns regarding ozone cleaner safety, rather than what they were really doing: scapegoating SoClean and its products for the dangerous conditions and user injuries for which Defendants bear sole responsibility." (ECF No. 299 at 29.) SoClean argues that it set forth factual allegations sufficient to show plausibly that "the FDA's tentative statements regarding a possibility that ozone use affected foam degradation came from Defendants' misstatements to the FDA on or about April 23, 2021." (Id.) SoClean argues that the "opinions" pointed out by the Philips defendants were

"reasonably understood to imply the existence of defamatory fact as the basis for the opinions, and, therefore, they are actionable. (Id. at 29-30.) Lastly, SoClean argues that to the extent Rule 9(b) applies, that standard is met where the factual information is within the Philips defendants' knowledge or control, and SoClean set forth factual allegations sufficient to plausibly show the general time frame and substance of the allegedly fraudulent statements. (Id. at 30 n.12.)

As discussed above, SoClean set forth factual allegations sufficient to show plausibly that the Philips defendants' statements blaming SoClean for the recall because ozone exacerbated the degradation of the foam and caused chemical emissions from the foam were false. Although the Philips defendants' alleged statement that SoClean was the problem with respect to the foam degradation and recall may be classified as the Philips defendants' opinion, the statement implies defamatory facts about SoClean and its products that SoClean has plausibly alleged are not true, i.e., SoClean's products exacerbated the foam degradation and cause chemical emissions from the foam. Hall, 293 A.3d at 476.

The Philips defendants also argue that Rule 9(b) applies to the defamation claim. As explained above, however, SoClean alleges that the Philips defendants made the defamatory statements at MedTrade West tradeshow to third parties, i.e., the resellers and distributors. Under those circumstances, to the extent the Rule 9(b) heightened pleading standards apply, absolute particularity is not required because the information is within the control of defendants and those third parties. See discussion supra p.84. Based upon the foregoing, the motion to dismiss with respect to the claim for defamation to the extent it is based upon the allegations that defendants told the resellers and distributors at the MedTrade West tradeshow that SoClean was the problem will be denied.

VI. Conclusion

The Rule 12(b)(6) motion to dismiss will be granted with respect to SoClean's Lanham Act claim based upon alleged statements made by the Philips defendants in quarterly reports, on earnings calls, in the recall notice, in a Q&A posted on one of the Philips defendants' websites, an update dated July 2021, and a press release issued on June 28, 2022. The court will deny the motion without prejudice with respect to whether SoClean was illegally marketing the SoClean 2 until there is a developed record about the import of the FDA's conduct with respect to the SoClean 2 device. The motion to dismiss will be denied in all other respects.

An appropriate order will be entered.

BY THE COURT,

Dated: November 17, 2023

/s/ JOY FLOWERS CONTI
Joy Flowers Conti
Senior United States District Court Judge