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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DON BAIN, JUDY GUTIERREZ, RONA KANEFF, MANUEL AMAYA, ROBERT MANDEVILLE, MARY TUSSING, STEVEN FILLMORE, JOHN COLEMAN, JOHNNY BISHOP, DIANA O'ROURKE, BERNARD BAUDOUIN, KIM HASTINGS, HENDERSON HARDY, ADAM LINDENBAUM, VANCE BRIGGS, STEVEN SPRINCZELES, BETH SLUDER, RICHARD COLEMAN, TERESA MCCLOY, DAVID FLEMING, DAVID RASMUSSEN, SALLY CALAHAN, MARTHA CLEMENTS, MICHAEL MOORE, individually and on behalf of all others similarly situated,

Plaintiffs,

v.

KONINKLIJKE PHILIPS N.V., PHILIPS NORTH AMERICA LLC, PHILIPS HOLDING USA, INC., AND PHILIPS RS NORTH AMERICA LLC d/b/a PHILIPS RESPIRONICS, INC.

Defendants.

Civil Action No.

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

Plaintiffs Judy Gutierrez, Rona Kaneff, Manuel Amaya, Robert Mandeville, Mary Tussing, Steven Fillmore, John Coleman, Johnny Bishop, Diana O'Rourke, Bernard Baudouin, Kim Hastings, Adam Lindenbaum, Vance Briggs, Steven Sprinczeles, Beth Sluder, Richard Coleman, Teresa McCloy, David Fleming, David Rasmussen, Sally Calahan, and Michael Moore (collectively, "Plaintiffs") bring this action on behalf of themselves and all others similarly situated against Defendants Koninklijke Philips N.V. ("Royal Philips"), Philips North America, LLC ("Philips NA"), Philips Holding USA, Inc. ("Philips Holding"), and Philips RS North America, LLC ("Philips RS") d/b/a Philips Respironics, Inc. ("Philips Respironics") (collectively, "Defendants" or "Philips") for the designing, manufacturing, marketing, distributing, and selling of hazardous and defective sleep and respiratory care devices (the "Hazardous Devices"). Plaintiffs seek both injunctive and monetary relief on behalf of the proposed Class. Plaintiffs make the following allegations pursuant to the investigation of their counsel and based upon information and belief, except as to the allegations specifically pertaining to themselves, which is based upon personal knowledge.

NATURE OF THE ACTION

A. Philips' Recall: A Choice Between A Risk Of Cancer Or A Lack Of Oxygen

1. On June 14, 2021, Philips announced a recall (the "Recall") of numerous of its CPAP and BiPAP machines and its ventilators (the "Hazardous Devices"), affecting more than 10.3 million units sold or distributed between 2009 and June 14, 2021. Philips stated that it was issuing the recall "due to two (2) issues related to the polyester-based polyurethan (PE-PUR) sound abatement foam used in Philips Continuous and Non-Continuous Ventilators: 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 "Defect").[1]

2. Philips warned that "[t]hese issues can result in serious injury which can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment."[2] Philips continued that "[t]o date, Philips Respironics has received several complaints regarding the presence of black debris / particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask). Philips also has received reports of headache, upper airway irritation, cough, chest pressure and sinus infection."[3]

3. Philips warned that "[t]he potential risks of particulate exposure include: Irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (e.g. kidney and liver) and toxic carcinogenic affects."[4] Philips also warned that "[t]he potential risks of chemical exposure due to off-gassing include: headache/dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, nausea/vomiting, toxic and carcinogenic effects."[5]

4. Philips proceeded to outline the affected models. These include the following models:[6]

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[1] Philips, "URGENT: Medical Device Recall: Philips Respironics Trilogy 100, Trilogy 200, Garbin Plus, Aeris, LifeVent, BiPAP V30, and BiPAP A30/A40 Series Device Models," (June 14, 2021), available at https://www.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/philips-recall-letter-2021-05-a-2021-06-a.pdf (last visited August 29, 2021). Philips also warned that "[t]he foam degradation may be exacerbated by use of unapproved cleaning methods, such as ozone . . . and off-gassing may occur during operation."

[2] *Id.*

[3] *Id.*

[4] *Id.*

[5] *Id.*

[6] For models suffering from the same Defect that have yet to be recalled, and for which there is limited information publicly available, Plaintiffs reserve the right to amend their complaint to reflect these additional models at the time of discovery.

All Devices manufactured before 26 April 2021, All serial numbers	
Continuous Ventilator, Minimum Ventilatory Support, Facility Use	E30 (Emergency Use Authorization)
Continuous Ventilator, Non-life Supporting	DreamStation ASV
	DreamStation ST, AVAPS
	SystemOne ASV4
	C-Series ASV
	C-Series S/T and AVAPS
	OmniLab Advanced+
Noncontinuous Ventilator	SystemOne (Q-Series)
	DreamStation
	DreamStation Go
	Dorma 400
	Dorma 500
	REMstar SE Auto

All Devices manufactured before 26 April 2021, All serial numbers	
Continuous Ventilator	Trilogy 100
	Trilogy 200
	Garbin Plus, Aeris, LifeVent
Continuous Ventilator, Minimum Ventilatory Support, Facility Use	A-Series BiPAP Hybrid A30 (not marketed in US)
	A-Series BiPAP V30 Auto
Continuous Ventilator, Non-life Supporting	A-Series BiPAP A40
	A-Series BiPAP A30

5. Philips then informed its users that "[t]o continue use of your device due to lack of alternatives, consult with your physician to determine if the benefit of continuing therapy with your device outweighs the risks identified in this letter."[7]

6. Leaving it to the user to decide between sleeping without oxygen on the one hand or continuing to use the Hazardous Devices and increasing the user's risk of cancer, on the other hand, Philips stated that "[a]s part of the registration process above, you will be provided information on the next steps to implement the permanent solution."[8]

7. However, as users have reported, consistent with Plaintiffs' experiences outlined below, Philips has yet to provide concrete information about next steps. Instead, users have

[7] *Id.*

[8] *Id.*

reported that Philips has ignored their calls and left them without information. For example, on June 16, 2021, one user reported to the Better Business Bureau that "I recently heard on local news that Philips CPAPs are being recalled . . . I called [Philips and] could not get a person, only websites. [I read that I should] file [a] complaint online which I did but how do I find out who/when will I get [my] replacement[?] I cannot sleep without the CPAP . . . I need help ASAP!!!" Although Philips received a report of this consumer's complaint consistent with the Better Business Bureau's practices, Philips has not responded.[9]

8. Worse, Philips has long known or should have known about the substantial and material risks involved with its Hazardous Devices. As Philips describes in its Recall Notice, patients who use the Hazardous Devices have complained about black particles in their machines for several years, and before the named Plaintiffs here purchased their products. Confirming this information, Philips stated that in 2020 *alone* it had received 486 foam-related complaints that would have informed them of the concerns posed by the PE-PUR foam.[10] Nonetheless, Philips intentionally chose to withhold information from the public until late April 2021 near the launch of its next generation of CPAP and BiPAP machines and ventilators.

9. Accordingly, Plaintiffs bring these claims against Philips individually and on behalf of a class of all others similarly situated users of the Hazardous Devices for (1) violation of California's Consumers Legal Remedies Act, Cal. Civ. Code § 1750, et seq.; (2) violation of California's Unfair Competition Law; (3) Breach of Implied Warranty under California's Song-

[9] Better Business Bureau, "How Complaints Are Handled" Online Complaint System, Available at https://www.bbb.org/consumer-complaints/file-a-complaint/get-started (last visited August 29, 2021) (nothing that "Everything you submit will be forwarded to the business within two business days. The business will be asked to respond within 14 days, and if a response is not received, a second request will be made.").

[10] Philips, "Sleep and Respiratory Care Update: Clinical Information," July 8, 2021, available at https://www.pediatrichomeservice.com/wp-content/uploads/2021/07/41109944.00-Global-Supplemental-Clinic-Information-document_070821_r5_002.pdf (last accessed August 29, 2021).

Beverly Act, Cal. Civ. Code § 1790, et seq.; (4) violation of Florida's Deceptive and Unfair Trade Practices Act, Fla. Stat. §§ 501.201, et seq.; (5) violation of Georgia's Fair Business Practices Act, Ga. Stat. Ann. §§ 10-1-390, et seq.; (6) violation of the Illinois Consumer Fraud Act, 815 Ill. Comp. Stat. 505/1, et seq.; (7) violation of Indiana's Deceptive Consumer Sales Act; (8) violation of Michigan's Consumer Protection Act, Mich. Comp. Law § 445.903, et seq.; (9) violation of New York's General Business Law, § 349; (10) violation of New York's General Business Law, § 350; (11) violation of North Carolina's Unfair and Deceptive Trade Practices Act, N.C. Gen. Stat. §§ 75-1.1, et seq.; (12) violation of Ohio's Consumer Sales Practices Act, Ohio Rev. Code Ann. §§ 1345.01, et seq.; (13) violation of Pennsylvania's Unfair Trade and Consumer Protection Law, 73, Pa. Cost. Stat. Ann. §§ 201-1, et seq.; (14) violation of Texas' Deceptive Trade Practices-Consumer Protection Act, Tex. Bus. & Com. Code §§ 17.01, et seq.; (15) Breach of Express Warranty; (16) Breach of Implied Warranty of Merchantability; (17) Fraudulent Misrepresentation; (18) Negligent Misrepresentation; (19) Fraudulent Concealment; (20) Unjust Enrichment; (21) Strict Liability—Failure to Instruct or to Warn; (22) Strict Liability – Design Defect; (23) Strict Liability –Manufacturing Defect; (24) Negligent Manufacturing Defect; (25) Negligent Failure to Warn or to Instruct; (26) Negligent Design Defect; (27) and Medical Monitoring.

JURISDICTION AND VENUE

10. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 as Plaintiff brings claims under federal statutes, warranting federal question jurisdiction. This Court has jurisdiction pursuant to 28 U.S.C. § 1367 over Plaintiffs' supplemental state law claims forming part of the same case or controversy as Plaintiffs' federal claims.

11. This Court also has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d)(2). The matter in controversy, exclusive of interests and costs, exceeds the sum or

value of $5,000,000 and is a class action in which there are more than 100 Class members, members of the Classes (as defined below) are citizens of states different from Defendants, and greater than two-thirds of the members of the Classes reside in states other than the states in which Defendants are citizens.

12. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391 because Defendant Philips NA—parent company of Philips RS and Philips Respironics, Inc.—resides in and is headquartered in this District, regularly transacts substantial business in this District, is subject to personal jurisdiction in this District, and therefore is deemed to be a citizen of this District. Venue is also proper in this judicial district as to Defendant Koninklijke Philips N.V. because, as a non-resident of the United States, Koninklijke Philips N.V. "may be sued in any judicial district." Additionally, Defendants have advertised in this district and have received substantial revenue and profits from their sale and/or leasing of the Hazardous Devices in this district; therefore, a substantial part of the events and/or omissions giving rise to the claims occurred, in part, within this district.

13. This Court has personal jurisdiction over Defendants because they have conducted substantial business in this District, and intentionally and purposefully placed the Hazardous Devices into the stream of commerce within Massachusetts and throughout the United States.

PARTIES

14. Plaintiff Don Bain is a citizen of Massachusetts residing in Tewksbury, Massachusetts. On or around 2018, Mr. Bain began using his Philips Dream Station to treat his sleep apnea. Prior to his Dream Station, Mr. Bain had a Philips SystemOne that he used from 2013 through 2018. Mr. Bain was prescribed the SystemOne and Dream Station to maintain a steady flow of oxygen into his nose and mouth as he sleeps. He has regularly used his

SystemOne and Dream Station each night for the past eight years. As a direct and proximate result of the use of these Hazardous Devices, Plaintiff Bain has inhaled and/or ingested degradation products from Defendant's PE-PUR Foam which has entered his lungs and bloodstream, and has resulted in an increased risk of illness, disease or disease process caused by his exposure. Plaintiff Bain would not have purchased this Hazardous Device if he had known it was defective, contained a carcinogenic byproduct, and would be subject to a recall for containing dangerous materials. Plaintiff Bain contacted Philips after learning of the Recall. Philips did not provide him with a plan or timeline for replacing his machine.

15. Plaintiff Judy Gutierrez is a citizen of California residing in Round Mountain, California. On or around 2014, Ms. Gutierrez began using her Philips SystemOne to treat her sleep apnea. Ms. Gutierrez was prescribed the Philips SystemOne to maintain a steady flow of oxygen into her nose and mouth as she sleeps. She has regularly used her SystemOne each night for the past seven years. As a direct and proximate result of the use of her SystemOne, Plaintiff Gutierrez has inhaled and/or ingested degradation products from Defendant's PE-PUR Foam which has entered her lungs and bloodstream, and has resulted in an increased risk of illness, disease or disease process caused by her exposure. Plaintiff Gutierrez would not have purchased this Hazardous Device if she had known it was defective, contained a carcinogenic byproduct, and would be subject to a recall for containing dangerous materials. Plaintiff Gutierrez contacted Philips after learning of the Recall. Philips did not provide her with a plan or timeline for replacing her machine.

16. Plaintiff Rona Kaneff is a citizen of California residing in Manteca, California. On or around 2017, Ms. Kaneff began using her Philips Dream Station to treat her sleep apnea. Ms. Kaneff was prescribed the Dream Station to maintain a steady flow of oxygen into her nose and mouth as she sleeps. She has regularly used her Dream Station each night for the past four

years. As a direct and proximate result of the use of her Dream Station, Plaintiff Kaneff has inhaled and/or ingested degradation products from Defendant's PE-PUR Foam which has entered her lungs and bloodstream, and has resulted in an increased risk of illness, disease or disease process caused by her exposure. Plaintiff Kaneff would not have purchased this Hazardous Device if she had known it was defective, contained a carcinogenic byproduct, and would be subject to a recall for containing dangerous materials. Plaintiff Kaneff contacted Philips after learning of the Recall. Philips did not provide her with a plan or timeline for replacing her machine.

17. Plaintiff Manuel Amaya is a citizen of California residing in San Pablo, California. On or around 2015, Mr. Amaya began using his Philips SystemOne to treat his sleep apnea. Mr. Amaya was prescribed the SystemOne to maintain a steady flow of oxygen into his nose and mouth as he sleeps. He has regularly used his SystemOne each night for the past six years. As a direct and proximate result of the use of his SystemOne, Plaintiff Amaya has inhaled and/or ingested degradation products from Defendant's PE-PUR Foam which has entered his lungs and bloodstream, and has resulted in an increased risk of illness, disease or disease process caused by his exposure. Plaintiff Amaya would not have purchased this Hazardous Device if he had known it was defective, contained a carcinogenic byproduct, and would be subject to a recall for containing dangerous materials. Plaintiff Amaya contacted Philips after learning of the Recall. Philips did not provide him with a plan or timeline for replacing his machine.

18. Plaintiff Robert Mandeville is a citizen of Florida residing in Palm Beach Gardens, Florida. On or around April 2018, Mr. Mandeville began using his Philips Dream Station to treat his sleep apnea. Mr. Mandeville was prescribed the Dream Station to maintain a steady flow of oxygen into his nose and mouth as he sleeps. He has regularly used his Dream Station each night for the past three-and-a-half years. As a direct and proximate result of the use

of his Dream Station, Plaintiff Mandeville has inhaled and/or ingested degradation products from Defendant's PE-PUR Foam which has entered his lungs and bloodstream, and has resulted in an increased risk of illness, disease or disease process caused by his exposure. Plaintiff Mandeville would not have purchased this Hazardous Device if he had known it was defective, contained a carcinogenic byproduct, and would be subject to a recall for containing dangerous materials. Plaintiff Mandeville contacted Philips after learning of the Recall. Philips did not provide him with a plan or timeline for replacing his machine. Because Mr. Mandeville requires his Dream Station when sleeping, he has incurred $1016.40 in out-of-pocket expenses to secure a temporary replacement.

19. Plaintiff Mary Tussing is a citizen of Florida residing in St. Petersburg, Florida. On or around 2017, Ms. Tussing began using her Philips Dream Station to treat her sleep apnea. Ms. Tussing was prescribed the Dream Station to maintain a steady flow of oxygen into her nose and mouth as she sleeps. She has regularly used her Dream Station each night for the past four years. As a direct and proximate result of the use of her Dream Station, Plaintiff Tussing has inhaled and/or ingested degradation products from Defendant's PE-PUR Foam which has entered her lungs and bloodstream, and has resulted in an increased risk of illness, disease or disease process caused by her exposure. Plaintiff Tussing would not have purchased this Hazardous Device if she had known it was defective, contained a carcinogenic byproduct, and would be subject to a recall for containing dangerous materials. Plaintiff Tussing contacted Philips after learning of the Recall. Philips did not provide her with a plan or timeline for replacing his machine.

20. Plaintiff Steven Fillmore is a citizen of Georgia residing in Ochlocknee, Georgia. On or around 2019, Mr. Fillmore began using his Philips Dream Station to treat his sleep apnea. Mr. Fillmore was prescribed the Dream Station to maintain a steady flow of oxygen into his nose

and mouth as he sleeps. He has regularly used his Dream Station each night for the past two years. As a direct and proximate result of the use of his Dream Station, Plaintiff Fillmore has inhaled and/or ingested degradation products from Defendant's PE-PUR Foam which has entered his lungs and bloodstream, and has resulted in an increased risk of illness, disease or disease process caused by his exposure. Plaintiff Fillmore would not have purchased this Hazardous Device if he had known it was defective, contained a carcinogenic byproduct, and would be subject to a recall for containing dangerous materials. Plaintiff Fillmore contacted Philips after learning of the Recall. Philips did not provide him with a plan or timeline for replacing his machine.

21. Plaintiff John Coleman is a citizen of Georgia residing in Augusta, Georgia. On or around January 2021, Mr. Coleman began using his Philips Dream Station to treat his sleep apnea. Mr. Coleman was prescribed the Dream Station to maintain a steady flow of oxygen into his nose and mouth as he sleeps. He has regularly used his Dream Station each night for the past nine months. As a direct and proximate result of the use of his Dream Station, Plaintiff Coleman has inhaled and/or ingested degradation products from Defendant's PE-PUR Foam which has entered his lungs and bloodstream, and has resulted in an increased risk of illness, disease or disease process caused by his exposure. Plaintiff Coleman would not have purchased this Hazardous Device if he had known it was defective, contained a carcinogenic byproduct, and would be subject to a recall for containing dangerous materials. Plaintiff Coleman contacted Philips after learning of the Recall. Philips did not provide him with a plan or timeline for replacing his machine.

22. Plaintiff Johnny Bishop is a citizen of Georgia residing in Dalton, Georgia. On or around 2020, Mr. Bishop began using his Philips Dream Station to treat his sleep apnea. Mr. Bishop was prescribed the Dream Station to maintain a steady flow of oxygen into his nose and

mouth as he sleeps. He has regularly used his Dream Station each night for the past year. As a direct and proximate result of the use of his Dream Station, Plaintiff Bishop has inhaled and/or ingested degradation products from Defendant's PE-PUR Foam which has entered his lungs and bloodstream, and has resulted in an increased risk of illness, disease or disease process caused by his exposure. Plaintiff Bishop would not have purchased this Hazardous Device if he had known it was defective, contained a carcinogenic byproduct, and would be subject to a recall for containing dangerous materials. Plaintiff Bishop contacted Philips after learning of the Recall. Philips did not provide him with a plan or timeline for replacing his machine.

23. Plaintiff Diana O'Rourke is a citizen of Indiana residing in Metamora, Indiana. On or around 2015, Ms. began using her Philips Dream Station to treat her sleep apnea. Ms. O'Rourke was prescribed the Philips Dream Station to maintain a steady flow of oxygen into her nose and mouth as she sleeps. She has regularly used her Dream Station each night for the past six years. As a direct and proximate result of the use of her Dream Station, Plaintiff O'Rourke has inhaled and/or ingested degradation products from Defendant's PE-PUR Foam which has entered her lungs and bloodstream, and has resulted in an increased risk of illness, disease or disease process caused by her exposure. Additionally, Ms. O'Rourke has developed severe congestion and shortness of breath that did not occur until she began using her Dream Station. Plaintiff O'Rourke would not have purchased this Hazardous Device if she had known it was defective, contained a carcinogenic byproduct, and would be subject to a recall for containing dangerous materials. Plaintiff O'Rourke contacted Philips after learning of the Recall. Philips did not provide her with a plan or timeline for replacing her machine.

24. Plaintiff Bernard Baudouin is a citizen of Illinois residing in Arlington Heights, Illinois. On or around 2019, Mr. Baudouin began using his Philips Dream Station to treat his sleep apnea. Mr. Baudouin was prescribed the Dream Station to maintain a steady flow of

oxygen into his nose and mouth as he sleeps. He has regularly used his Dream Station each night for the past two years. As a direct and proximate result of the use of his Dream Station, Plaintiff Baudouin has inhaled and/or ingested degradation products from Defendant's PE-PUR Foam which has entered his lungs and bloodstream, and has resulted in an increased risk of illness, disease or disease process caused by his exposure. Plaintiff Baudouin would not have purchased this Hazardous Device if he had known it was defective, contained a carcinogenic byproduct, and would be subject to a recall for containing dangerous materials. Plaintiff Baudouin contacted Philips after learning of the Recall. Philips did not provide him with a plan or timeline for replacing his machine. Because Mr. Baudouin requires his Dream Station when sleeping, he has incurred $500.00 in out-of-pocket expenses to secure a temporary replacement.

25. Plaintiff Kim Hastings is a citizen of Michigan residing in Union City, Michigan. On or around 2015, Mr. Hastings began using his Philips Trilogy 100 to deliver breaths to him because he is unable to breath in enough oxygen on his own to live. He has regularly used his Trilogy 100 every day for the past six-a-half years. As a direct and proximate result of the use of his Trilogy 100, Plaintiff Hastings has inhaled and/or ingested degradation products from Defendant's PE-PUR Foam which has entered his lungs and bloodstream, and has resulted in an increased risk of illness, disease or disease process caused by his exposure. Plaintiff Hastings would not have purchased this Hazardous Device if he had known it was defective, contained a carcinogenic byproduct, and would be subject to a recall for containing dangerous materials. Plaintiff Hastings contacted Philips after learning of the Recall. Philips did not provide him with a plan or timeline for replacing his machine.

26. Plaintiff Henderson Hardy is a citizen of New York residing in Hempstead, New York. On or around 2014, Mr. Hardy began using his Philips Dream Station to treat his sleep apnea. Mr. Hardy was prescribed the Dream Station to maintain a steady flow of oxygen into his

nose and mouth as he sleeps. He has regularly used his Dream Station each night for the past seven years. As a direct and proximate result of the use of his Dream Station, Plaintiff Hardy has inhaled and/or ingested degradation products from Defendant's PE-PUR Foam which has entered his lungs and bloodstream, and has resulted in an increased risk of illness, disease or disease process caused by his exposure. Plaintiff Hardy would not have purchased this Hazardous Device if he had known it was defective, contained a carcinogenic byproduct, and would be subject to a recall for containing dangerous materials. Plaintiff Hardy contacted Philips after learning of the Recall. Philips did not provide him with a plan or timeline for replacing his machine.

27. Plaintiff Adam Lindenbaum is a citizen of New York residing in Monticello, New York. On or around 2018, Mr. Lindenbaum began using his Philips Dream Station to treat his sleep apnea. Mr. Lindenbaum was prescribed the Dream Station to maintain a steady flow of oxygen into his nose and mouth as he sleeps. He has regularly used his Dream Station each night for the past three years. As a direct and proximate result of the use of his Dream Station, Plaintiff Lindenbaum has inhaled and/or ingested degradation products from Defendant's PE-PUR Foam which has entered his lungs and bloodstream, and has resulted in an increased risk of illness, disease or disease process caused by his exposure. Plaintiff Lindenbaum would not have purchased this Hazardous Device if he had known it was defective, contained a carcinogenic byproduct, and would be subject to a recall for containing dangerous materials. Plaintiff Lindenbaum contacted Philips after learning of the Recall. Philips did not provide him with a plan or timeline for replacing his machine.

28. Plaintiff Vance Briggs is a citizen of North Carolina residing in Burnsville, North Carolina. On or around 2014, Mr. Briggs began using his Philips Dream Station to treat his sleep apnea. Mr. Briggs was prescribed the Dream Station to maintain a steady flow of oxygen into

his nose and mouth as he sleeps. He has regularly used his Dream Station each night for the past seven years. As a direct and proximate result of the use of his Dream Station, Plaintiff Briggs has inhaled and/or ingested degradation products from Defendant's PE-PUR Foam which has entered his lungs and bloodstream, and has resulted in an increased risk of illness, disease or disease process caused by his exposure. Plaintiff Briggs would not have purchased this Hazardous Device if he had known it was defective, contained a carcinogenic byproduct, and would be subject to a recall for containing dangerous materials. Plaintiff Briggs contacted Philips after learning of the Recall. However, in light of wait times of over an hour, Plaintiff has not been able to establish contact with Philips to secure his replacement.

29. Plaintiff Steven Sprinczeles is a citizen of North Carolina residing in Sneads Ferry, North Carolina. On or around June 2021, Mr. Sprinczeles began using his Philips Dream Station to treat his sleep apnea. Mr. Sprinczeles was prescribed the Dream Station to maintain a steady flow of oxygen into his nose and mouth as he sleeps. He has regularly used his Dream Station each night for the past several months. As a direct and proximate result of the use of his Dream Station, Plaintiff Sprinczeles has inhaled and/or ingested degradation products from Defendant's PE-PUR Foam which has entered his lungs and bloodstream, and has resulted in an increased risk of illness, disease or disease process caused by his exposure. Plaintiff Sprinczeles would not have purchased this Hazardous Device if he had known it was defective, contained a carcinogenic byproduct, and would be subject to a recall for containing dangerous materials. Plaintiff Sprinczeles contacted Philips after learning of the Recall. Philips did not provide him with a plan or timeline for replacing his machine.

30. Plaintiff Beth Sluder is a citizen of North Carolina residing in Asheville, North Carolina. On or around 2009, Ms. Sluder began using her Philips Dream Station to treat her sleep apnea. Before that, Ms. Sluder used the previous model Dream Station beginning in 2004.

Ms. Sluder was prescribed the Dream Station to maintain a steady flow of oxygen into her nose and mouth as she sleeps. She has regularly used her Dream Stations each night for the past 17 years. As a direct and proximate result of the use of her Dream Station, Plaintiff Sluder has inhaled and/or ingested degradation products from Defendant's PE-PUR Foam which has entered her lungs and bloodstream, and has resulted in an increased risk of illness, disease or disease process caused by her exposure. Plaintiff Sluder has had three surgeries resulting from swelling in her throat, a known side effect of exposure to the PE-PUR Foam. Plaintiff Sluder would not have purchased this Hazardous Device if she had known it was defective, contained a carcinogenic byproduct, and would be subject to a recall for containing dangerous materials. Plaintiff Sluder contacted Philips after learning of the Recall. Philips did not provide her with a plan or timeline for replacing her machine.

31. Plaintiff Richard Coleman is a citizen of Ohio residing in Columbus, Ohio. On or around 2020, Mr. Coleman began using his Philips Dream Station to treat his sleep apnea. Mr. Coleman was prescribed the Dream Station to maintain a steady flow of oxygen into his nose and mouth as he sleeps. He regularly used his Dream Station each night for six months. As a direct and proximate result of the use of his Dream Station, Plaintiff Coleman has inhaled and/or ingested degradation products from Defendant's PE-PUR Foam which has entered his lungs and bloodstream, and has resulted in an increased risk of illness, disease or disease process caused by his exposure. Prior to using his Dream Station, Plaintiff Coleman did not experience issues with congestion. However, shortly after his use of the Hazardous Device, he began experiencing severe congestion. Plaintiff Coleman would not have purchased this Hazardous Device if he had known it was defective, contained a carcinogenic byproduct, and would be subject to a recall for containing dangerous materials. Plaintiff Coleman contacted Philips after learning of the Recall. Philips did not provide him with a plan or timeline for replacing his machine.

32. Plaintiff Teresa McCloy is a citizen of Ohio residing in Columbus, Ohio. On or around 2019, Ms. McCloy began using her Philips Dream Station to treat her sleep apnea. Ms. McCloy was prescribed the Dream Station to maintain a steady flow of oxygen into her nose and mouth as she sleeps. She has regularly used her Dream Station each night for the past two years. As a direct and proximate result of the use of her Dream Station, Plaintiff McCloy has inhaled and/or ingested degradation products from Defendant's PE-PUR Foam which has entered her lungs and bloodstream, and has resulted in an increased risk of illness, disease or disease process caused by her exposure. Plaintiff McCloy would not have purchased this Hazardous Device if she had known it was defective, contained a carcinogenic byproduct, and would be subject to a recall for containing dangerous materials. Plaintiff McCloy contacted Philips after learning of the Recall. Philips did not provide her with a plan or timeline for replacing her machine. She has tried contacting Philips on multiple occasions since submitting her information and Philips has not answered her calls.

33. Plaintiff David Fleming is a citizen of Pennsylvania residing in Lower Burrell, Pennsylvania. On or around 2015, Mr. Fleming began using his Philips Dream Station to treat his sleep apnea. Mr. Fleming was prescribed the Dream Station to maintain a steady flow of oxygen into his nose and mouth as he sleeps. He has regularly used his Dream Station each night for the past five-and-a-half years. As a direct and proximate result of the use of his Dream Station, Plaintiff Fleming has inhaled and/or ingested degradation products from Defendant's PE-PUR Foam which has entered his lungs and bloodstream, and has resulted in an increased risk of illness, disease or disease process caused by his exposure. Plaintiff Fleming would not have purchased this Hazardous Device if he had known it was defective, contained a carcinogenic byproduct, and would be subject to a recall for containing dangerous materials.

Plaintiff Fleming contacted Philips after learning of the Recall. Philips did not provide him with a plan or timeline for replacing his machine.

34. Plaintiff David Rasmussen is a citizen of Pennsylvania residing in Mechanicsburg, Pennsylvania. On or around 2020, Mr. Rasmussen began using his Philips Dream Station to treat his sleep apnea. Mr. Rasmussen was prescribed the Dream Station to maintain a steady flow of oxygen into his nose and mouth as he sleeps. He has regularly used his Dream Station each night for the past year. As a direct and proximate result of the use of his Dream Station, Plaintiff Rasmussen has inhaled and/or ingested degradation products from Defendant's PE-PUR Foam which has entered his lungs and bloodstream, and has resulted in an increased risk of illness, disease or disease process caused by his exposure. Plaintiff Rasmussen would not have purchased this Hazardous Device if he had known it was defective, contained a carcinogenic byproduct, and would be subject to a recall for containing dangerous materials. Plaintiff Rasmussen contacted Philips after learning of the Recall. Philips did not provide him with a plan or timeline for replacing his machine.

35. Plaintiff Sally Calahan is a citizen of Texas residing in Cleburne, Texas. On or around 2016, Ms. Calahan began using her Philips Dream Station to treat her sleep apnea. She has regularly used her Dream Stations each night for the past five years. As a direct and proximate result of the use of her Dream Station, Plaintiff Calahan has inhaled and/or ingested degradation products from Defendant's PE-PUR Foam which has entered her lungs and bloodstream, and has resulted in an increased risk of illness, disease or disease process caused by her exposure. Plaintiff Calahan has chronic sore throat and regularly wakes up with headaches, known side effects of exposure to the PE-PUR Foam. Plaintiff Calahan would not have purchased this Hazardous Device if she had known it was defective, contained a carcinogenic byproduct, and would be subject to a recall for containing dangerous materials. Plaintiff Calahan

contacted Philips after learning of the Recall. Philips did not provide her with a plan or timeline for replacing her machine.

36. Plaintiff Martha Clements is a citizen of Texas residing in Burleson, Texas. On or around 2019, Ms. Clement began using her Philips Dream Station to treat her sleep apnea. She has regularly used her Dream Stations each night for the past five years. As a direct and proximate result of the use of her Dream Station, Plaintiff Clements has inhaled and/or ingested degradation products from Defendant's PE-PUR Foam which has entered her lungs and bloodstream, and has resulted in an increased risk of illness, disease or disease process caused by her exposure. Plaintiff Clements would not have purchased this Hazardous Device if she had known it was defective, contained a carcinogenic byproduct, and would be subject to a recall for containing dangerous materials. Plaintiff Clements contacted Philips after learning of the Recall. Philips did not provide her with a plan or timeline for replacing her machine.

37. Plaintiff Michael Moore is a citizen of Texas residing in Sherman, Texas. On or around 2017, Mr. Moore began using his Philips Dream Station to treat his sleep apnea. Mr. Moore was prescribed the Dream Station to maintain a steady flow of oxygen into his nose and mouth as he sleeps. He has regularly used his Dream Station each night for the past four years. As a direct and proximate result of the use of his Dream Station, Plaintiff Moore has inhaled and/or ingested degradation products from Defendant's PE-PUR Foam which has entered his lungs and bloodstream, and has resulted in an increased risk of illness, disease or disease process caused by his exposure. Plaintiff Moore would not have purchased this Hazardous Device if he had known it was defective, contained a carcinogenic byproduct, and would be subject to a recall for containing dangerous materials. Plaintiff Moore contacted Philips after learning of the Recall. Philips did not provide him with a plan or timeline for replacing his machine.

38. None of the Plaintiffs listed above would have purchased the Hazardous Devices at issue here if Defendants had disclosed that they were unsafe to use for their ordinary and intended purposes.

39. Defendant Koninklijke Philips N.V. ("Royal Philips") is a public limited liability company established under the laws of the Netherlands, with its principal place of business in Amsterdam, the Netherlands.

40. Defendant Philips North America LLC ("Philips NA") is a Delaware corporation with its principal place of business in Cambridge, Massachusetts. Philips NA is a wholly-owned subsidiary of Royal Philips. Upon information and belief, Philips NA manages Royal Philips' lines of business, including Philips RS, in North America. The sole member of Philips NA is Philips Holding, a Delaware corporation with its principal place of business located in Cambridge, Massachusetts.

41. Defendant Philips Holding USA, Inc. ("Philips Holding") is a Delaware corporation with its principal place of business in Cambridge, Massachusetts. Philips Holding is a company that is the sole member of Defendant Philips NA.

42. Defendant Philips RS North America LLC ("Philips RS") is a Delaware corporation with its principal place of business located in Pittsburgh, Pennsylvania. Philips RS does business as Philips Respironics.

FACTUAL ALLEGATIONS

A. PHILIPS' HAZARDOUS DEVICES WERE MEANT TO SUPPORT LIFE

43. Philips' Hazardous Devices are designed and manufactured to help users breathe. Whether users suffer from sleep apnea or other such ailments impeding the proper free flow of

oxygen, users have turned to Philips for over 45 years because of its trusted reputation.[11] Before abusing that trust, Philips served as a pioneer in the field, introducing the first continuous positive airway pressure ("CPAP") machine in 1985 and later securing one of the first patents for bilevel positive airway pressure ("BiPAP"). More than a pioneer, Philips has long engineered technology relied upon by its users to make it through the night, when they might otherwise not.

44. Numerous of the devices treat obstructive sleep apnea, a potentially severe sleep disorder that manifests as follows: a person's breathing stops and starts repeatedly because air is unable to flow in and out of a person's nose or mouth.[12] According to the Mayo Clinic, there are two types of sleep apnea, including obstructive sleep apnea and central sleep apnea.[13] Obstructive sleep apnea occurs when the muscles in the back of the throat relax. When the muscles relax, the airway narrows or closes as a person breathes in. A person with this condition cannot get in enough air, which can lower the oxygen level in their blood. As a result, the brain senses the inability to breathe and briefly awakes the person from their sleep so that they can reopen their airway. Often times, a person under these conditions may snort, choke, or gasp. This pattern may repeat itself five to 30 times or more each hour, all night, impairing the person's ability to sleep. Central sleep apnea occurs when a person's brain fails to transmit signals to their breathing muscles. This leads a person to stop breathing for a period of time.

[11] AeroFlow Health, "About the Manufacturer: Philips Respironics," (Oct. 15, 2013), Available at https://cpapsupplies.com/blog/about-the-manufacturer-respironics#:~:text=Based%20in%20the%20Pittsburgh%2C%20PA,masks%20and%20Respironics%20was%20born (last accessed August 30, 2021).

[12] Mayo Clinic, "Sleep Apnea," Available at https://www.mayoclinic.org/diseases-conditions/sleep-apnea/symptoms-causes/syc-20377631 (last visited August 30, 2021).

[13] *Id.*

45. As described by Johns Hopkins, the consequences of sleep apnea can be severe.[14] According to one study, people with severe sleep apnea have three times the risk of dying due to any cause, than people without sleep apnea.[15] As demonstrated by certain notable deaths resulting from sleep apnea, such as that of Supreme Court Justice Antonin Scalia,[16] Star Wars', Kerry Fisher,[17] and The Sopranos', James Gandolfini, the risk of death when not using a prescribed CPAP or BiPAP is very real. In fact, according to one study published in the *American Journal of Respiratory and Critical Care Medicine*, users who stop operating their CPAP or Bi-PAP machines for a 14-day period, experience severe complications, including increase in heart rate and blood pressure and a deterioration in vascular function.[18]

46. One of the authors of that study, Malcolm Kohler, a senior consultant at the Sleep Disorders Center and Pulmonary Division of the University Hospital in Zurich, stated that the study's findings show that taking a break from the machine can lead to the return of symptoms within the first night. Such symptoms include, breathing cessation, gasping for air during sleep, awaking with severe headaches, difficulty staying asleep (insomnia), and excessive daytime sleepiness (hypersomnia).

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[14] John Hopkins Medicine, "The Dangers of Uncontrolled Sleep Apnea," *Health*, Available at https://www.hopkinsmedicine.org/health/wellness-and-prevention/the-dangers-of-uncontrolled-sleep-apnea (last visited August 30. 2021).

[15] American Academy of Sleep Medicine, "Study shows that people with sleep apnea have a high risk of death," (August 1, 2008), Available at https://aasm.org/study-shows-that-people-with-sleep-apnea-have-a-high-risk-of-death/ (last visited August 30, 2021).

[16] Ariana Eunjung Cha, "Did sleep apnea contribute to Justice Scalia's death? His unplugged breathing machine raises that question," The Washington Post (Feb. 24, 2016), Available at https://www.washingtonpost.com/news/to-your-health/wp/2016/02/24/scalia-may-have-forgotten-to-hook-himself-up-to-sleep-apnea-machine-why-that-can-be-dangerous/ (last visited August 30, 2021).

[17] American Sleep Apnea Association, "Yes, you can die from sleep apnea. Carrie Fisher did." Available at https://www.sleepapnea.org/carrie-fisher-yes-you-can-die-from-sleep-apnea/ (last visited August 30, 2021).

[18] Supra, note [Washington Post]

47. As a result of these risks, users, including Plaintiffs, turn to positive airway pressure delivery systems like the CPAP and BiPAP to deliver air pressure to users through a mask while that the user wears while sleeping. The positive airway pressure delivery system takes in room air, filters it, and pressurizes it to deliver therapy to keep the user's airway from collapsing during sleep. Positive airway pressure delivery systems, like the Hazardous Devices, also contain filters. The device's filter is deigned to clear elements from the environment, including dust, pet dander, smoke, and other potential allergens, from the air that is directed into the machine and ultimately inhaled and ingested into the user's lungs.[19]

B. RATHER THAN SUPPORT LIFE, PHILIPS' PE-PUR FOAM POSES A SIGNIFICANT HAZARD TO USERS

48. Philips designed and manufactured the Hazardous Devices with PE-PUR Foam for the purposes of sound abatement to improve noise insulation in the Devices. However, this Foam is defective for two reasons. First, it degrades into particles which may enter the Device's air pathway and becomes ingested or inhaled by the users. Second, the Foam off-gasses volatile organic compounds ("VOCs"). Both issues can result in serious injury that can be life-threatening and cause permanent impairment and require medical attention.

49. The PE-PUR Foam in the Hazardous Devices is defective due to its ability to degrade, exposing users to dangerous chemicals as the foam's particles enter the Hazardous Devices' air pathway. The disintegration of the PE-PUR Foam exposes a user to dangerous chemicals including Toluene Diamine ("TDA"), Toluene Diiscoyanate ("TDI") and Diethylene Gloycol ("DEG"). Exposure to these chemicals can be devastating to the user's respiratory system and other organs.

[19] Brandon Peters, MD, "How to Find and Change Air Filters on CPAP Machines," *Verywell Health* (July 23, 2020), Available at https://www.verywellhealth.com/how-to-change-filters-on-cpap-machines-3015044 (last accessed August 17, 2021).

50. Exposure to TDA may cause respiratory depression, a breathing disorder characterized by slow and ineffective breathing, as well as cause fatty degeneration of the liver, which can lead to liver failure.

51. Similarly, TDI, which is considered a "powerful irritant" to the respiratory system's mucous membranes, can cause inflammatory reactions and may lead to chemical bronchitis and respiratory tract. TDI also induces occupational asthma in workers exposed to polyurethan foam.

52. If DEG is inhaled or ingested by humans, it targets the renal and neurologic systems, and the kidney and nervous system, potentially leading to acute kidney failure and loss of motor function, visual and auditory functions as well as respiratory depression or coma as a result of exposure.

53. Moreover, potential risks of exposure to these chemicals may include irritation, headache, asthma, and toxic and carcinogenic effects. The irritation and airway inflammation may be especially prevalent in users with underlying lung diseases or reduced cardiopulmonary reserve. This heightened risk if of considerable concern as a substantial number of individuals suffer from the overlap syndrome involving both sleep apnea and COPD.

54. The PE-PUR Foam in the Hazardous Devices off-gases VOCs that are carcinogens and that can be inhaled or ingested by the users as the compounds penetrate the Device's air pathway.

55. Off-gassing is the airborne release of a chemical in vapor form. Off-gassing releases a smell, generally when the product is new, but numerous products or materials continue off-gassing even after the smell has disappeared.

56. Exposure to off-gassed VOCs can be devastating to a human's health, resulting in nose and respiratory irritation, damage to the liver, kidney, and central nervous system,

headaches, loss of coordination and nausea, and cancer. This risk is further compounded for users with underlying lung disease or reduced cardiopulmonary reserve who are at risk of adverse health consequences caused by exposure to VOCs.

57. As a result, the PE-PUR Foam used for sound abatement is dangerous and makes the Hazardous Devices defective.

C. PHILIPS KNEW OR SHOULD HAVE KNOWN ABOUT THE DEFECTIVE NATURE OF THE PE-PUR FOAM

58. Philips knew or should have known about the defective nature of the PE-PUR Foam and the Hazardous Devices. Using this knowledge, Philips fraudulently, intentionally, negligently, and/or recklessly omitted and concealed from Plaintiffs the risks inherent in the PE-PUR Foam.

59. Knowledge and information regarding the design and manufacture of the Hazardous Devices and the PE-PUR Foam and associated health risks were in the exclusive and superior possession of Philips, and was not provided to Plaintiffs, who could not have reasonably discovered the defective and dangerous nature of the Hazardous Devices through diligence. In light of industry standards, pre-production testing, consumer complaints, and Philips' own design and manufacturing updates, Philips was aware or should have been aware of the design and manufacturing defect in the Hazardous Devices, and the resulting harms to users' health.

60. First, the PE-PUR materials are not within industry standards. Beginning in 1993, PE-PUR was found unsuitable for use in the medical field because of rapid hydrolysis of the polyester soft segment. Instead, polyether polyurethanes replaced polyester-based polyurethane and have been used in medical devices for at least two decades.[20] Philips' competitor, ResMed,

[20] Pal Singh Chauhan, N. and Kumari Jangid, N. "Polyurethanes and Silicone Polyurethane Copolymers," Chapter in Encyclopedia of Biomedical Polymers and Polymeric Biomaterials (January, 2013), Available at

for example, uses polyether polyurethane, instead of polyester-based polyurethane, for its positive airway pressure delivery systems.[21] Therefore, based on the industry-accepted knowledge and practice, Philips knew or should have known that the PE-PUR Foam should not have been used in the Hazardous Devices, especially considering that humidifiers are often used with the Hazardous Devices as Philips informed its investors, high humidity can exasperate the degradation of the PE-PUR Foam and increase the risk of exposure to toxic material among users.

61. Second, Philips' regulatory compliance and testing would have demonstrated that the PE-PUR Foam is not safe. The Hazardous Devices were all approved for the market in accordance with the § 510(k) FDA Review Process. Philips submitted requests for PMA to the FDA stating that the Hazardous Devices were "substantially equivalent" to other similar medical devices in the market. Philips cited to its own predicate devices to support this assertion. Philips failed to inform the FDA, however, that PE-PUR Foam was included in the Hazardous Devices as a part of their modified design. Philips has also acknowledged in its April 26, 2021 report to investors that the Hazardous Devices were tested and stated that the tests revealed the risks and dangers of the PE-PUR Foam. Philips also acknowledged that humidity can exacerbate the risk to users. Accordingly, Philips either learned from its own testing or should have learned that the PE-PUR was dangerous to users.

62. Third, Philips knew or should have known as early as February 27, 2020, if not sooner, that certain cleaning methods for the Hazardous Devices could increase a user's risk of exposure to toxic chemicals. On that date, the FDA issued a Safety Communication concerning

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https://www.researchgate.net/publication/236144965_POLYURETHANES_AND_SILICONE_POLYURETHANE_COPOLYMERS (last accessed August 30, 2021).

[21] ResMed, "Information regarding Philips' Recall," Updated July 14, 2021, Available at https://www.resmed.com/en-us/other-manufacturer-recall-2021/#:~:text=ResMed%20devices%20use%20polyETHER%2Durethane,the%20device's%20in (last visited August 30, 2021).

the potential risks associated with the use of ozone and ultraviolet light products in the cleaning of positive airway pressure systems. The FDA stated that it received numerous reports from users experiencing "cough, difficulty breathing, nasal irritation, headaches, asthma attacks and other breathing complaints."[22] Recognizing this risk, Philips continued to sell the Hazardous Devices.

63. Fourth, Philips stated that it received 486 foam-related complaints in 2020 alone that would have informed them of the concern about the PE-PUR Foam.[23] These complaints are in addition to those submitted to the FDA and those posted on publicly accessible forums that Philips would have been aware of through its Online Reputational Management practices. Presumably Philips cares about its reputation and would have come across forums where consumers posted complaints about the Hazardous Devices.

64. For many years, and before Plaintiffs purchased their products, Defendants have consistently tracked complaints submitted to the FDA, the Consumer Product Safety Commission, and other sources where consumer complaints are either publicly available or are transmitted to manufacturers. From these sources, Defendants knew that its Hazardous Devices were experiencing unusually high levels of problems that ultimately led to the recall. The fact that so many customers made similar complaints indicates that the complaints were not the result of user error or anomalous incidents, but instead a systemic problem with the Hazardous Devices.

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[22] FDA, "Potential Risks Associated With The Use Of Ozone and Ultraviolet (UV) Light Products for Cleaning CPAP Machines and Accessories: FDA Safety Communication," Issued February 27, 2020, available at https://www.fda.gov/medical-devices/safety-communications/potential-risks-associated-use-ozone-and-ultraviolet-uv-light-products-cleaning-cpap-machines-and (last visited August 30, 2021).

[23] Philips, "Sleep and Respiratory Care Update: Clinic Information," July 8, 2021, Available at https://www.pediatrichomeservice.com/wp-content/uploads/2021/07/4110944.00-Global-Supplemental-Clinical-Information-document_070821_r5-002.pdf

65. Nonetheless, and despite this knowledge, Philips continued to advertise, market, distribute, and sale the Hazardous Devices.

D. PHILIPS HAS NOT REPLACED THE HAZARDOUS DEVICES AND HAS NO PLANS TO DO SO

66. Philips' recall does not provide patients with new CPAP, BiPAP, or ventilator devices. Instead, Philips suggests that users can purchase the next generation of its product. On June 14, 2021, Philips stated that "Philips is providing the relevant regulatory agencies with required information related to the launch and implementation of the projected correction. The company will replace the current sound abatement foam with a new material and has already begun preparation, which includes obtaining the relevant regulatory clearances. Philips aims to address all affected devices in scope of this correction as expeditiously as possible."

67. Philips continued that "As a part of the program, the first-generation Dream Station product families will be modified with a different sound abatement foam and shipped upon receipt of the required regulatory clearances. Philips' recently launched next-generation CPAP platform, Dream Station 2, is not affected by the issue. To support the program, Philips is increasing the production of its Dream Station 2 CPAP devices, that are available in the US and selected countries in Europe."

68. Therefore, Philips is not currently replacing the foam in the affected devices and may take a year or more to provide replacement foam.

69. At the same time, Philips intends to profit from the so-called recall by selling more of its next generation product. Philips intentionally timed the recall to coincide with the launch of the Dream Station 2.

70. Due to the design of the Hazardous Devices, it is prohibitively difficult for patients to remove or replace the PE-PUR foam themselves. There is also a general shortage of available replacement machines.

71. But as discussed, patients must use their machines every day, or else their symptoms—which can be severe, life-altering, and life-threatening—may return.

72. Consequently, the recall by Philips leaves patients without safe, free options. Patients may buy Philips' next generation product or a competitor's product, though at full price.

73. Worse, Philips has ignored users, including Plaintiffs, who have attempted to reach out for guidance in light of the scarce information. For example, one user reported to the Better Business Bureau on June 22, 2021, that: "My Dreamstation CPAP is affected by the recall, but there is no plan laid out to fix the issue, and I shouldn't have to be presented with the choices of either addressing my sleep apnea or possibly getting cancer from the device used to treat my sleep apnea. I'm filing a complaint so that Philips can send me an updated unit that is not affected by the recall. The 1-800 number that Philips has been putting out to the public is essentially useless, and not only have I been hung out on multiple times, the people there don't have any real answers." Although Philips received a report of this consumer's complaint, Philips has not responded.[24]

74. Another user reported to the Better Business Bureau on June 28, 2021, that: "My CPAP machine was recalled. I have experienced well over 100 times where I stop breathing while sleeping. I cannot live/sleep soundly without my machine. I would like Philips to replace my CPAP machine immediately." Although Philips received a report of this consumer's complaint, Philips has not responded.[25]

75. Another user reported to the Better Business Bureau on July 5, 2021, that: "Purchased about July 7, 2020. Cost approximately $410. I am required to have a CPAP for my health. I do not have one to use now that the company recalled the one they made [be]cause [it]

[24] *Id.*

[25] *Id.*

may cause possible illness because of materials inside the machine. I put in a complaint with the company approximately 4 weeks ago and have not heard back from them." Although Philips received a report of this consumer's complaint, Philips has not responded.[26]

76. Another user wrote to the Better Business Bureau on July 6, 2021, that: "I purchased on August 25, 2020 the Respironics Dream Station CPAP . . . 3 weeks ago I was notified of a recall of this unit . . . I was experiencing some of the health issues outlined in the recall so I have discontinued use. I need the machine to sleep and for the health benefits . . . I contacted them directly . . . I was on the phone for 2 hours and 35 minutes told my story numerous times and was assured I would be contacted the next week. It's now been over 3 weeks and I've heard nothing and I can't get back through to them on the phone." Although Philips received a report of this consumer's complaint, Philips has not responded.[27]

77. Another user wrote to the Better Business Bureau on July 12, 2021, that: "My Philips CPAP machine was recalled on June 14, 2021 and as of today, Monday July 12, 2021, I have not heard from Philips in regards to this situation. I have been calling Philips since I hear[d] the announcement on Channel 7 news on June 14th. They recalled my CPAP machine due to toxic foam (which Philips stated can cause cancer) . . . I haven't received a letter or email [of] what to do. They just advised us to stop using the machine. I cannot sleep without a CPAP machine. I needed to go out and purchase another machine (which my health insurance informed me that they will not pay for another machine). I can't afford paying for another machine ($699). I would like to be reimbursed for my new machine. Can someone please help me

[26] *Id.*

[27] *Id.*

resolve this situation[?]" Although Philips received a report of this consumer's complaint, Philips has not responded.[28]

78. Another user wrote to the Better Business Bureau on July 22, 2021, that: "I am a user of Philips Respironics CPAP machine . . . I read in the news about Philips CPAPs being recalled. I called Adapt Health, which is my durable medical goods supplier of my CPAP. They informed me that because the machine is patient-owned, I will have to deal with Philips directly regarding the CPAP recall. I registered on Philip's website . . . about four weeks ago. I received [a] confirmation number . . . at that moment. I received confirmation or any correspondence from Philips since that time. Although not life-sustaining, my CPAP is essential for my health. There is nothing on the [Philips] website that gives any sense of when our CPAPs will be repaired/replaced. The Philips agent I called would offer no timetable. I need to know what is being done to rectify this problem." Although Philips received a report of this consumer's complaint, Philips has not responded.[29]

79. Accordingly, not only has Philips peddled the Hazardous Devices, but has also bungled the Recall, leaving users with little alternative than to file this class action suit.

E. PLAINTIFFS AND CLASS MEMBERS HAVE ALREADY BEEN INJURED BY PAST SIGNIFICANT EXPOSURE TO PHILIPS' PE-PUR FOAM AND RESULTING PAST, PRESENT AND ONGOING INCREASED RISK OF DISEASE, REQUIRING THE EXPENDITURE OF THE COST OF MEDICALLY NECESSARY DIAGNOSTIC TESTING

80. Plaintiffs and Class Members have used the Recalled Breathing Machines during the time Philips admitted to the release of toxic chemicals found in the degraded polyester polyurethane foam.

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[28] *Id.*

[29] *Id.*

81. As a result of Philips' tortious design of the Hazardous Device, Plaintiffs and Class Members have in the past and continue to be significantly exposed to Philips hazardous chemicals by inhaling and/or ingesting them and absorbing them through their respiratory tract, where they are absorbed by skin and tissue, and enter into their bloodstreams.

82. Chemicals such as isocyanate, toluene diisocyanate, dimethyl diazine, phenol, 2,6-bis (1,1-dimethylethyl)-4-1-(1-methylpropyl) and other volatile organic compounds found in the PE-PUR Foam, or degradation of the foam, are proven hazardous substances, including but not limited to being carcinogenic.

83. As a proximate result of Philips' tortious conduct, Plaintiffs and Class Members have in the past and are presently at an increased risk of illness, disease, or disease process, including cancer, requiring them to incur, both presently and in the future, the cost of medically necessary diagnostic testing for the early detection of illness, disease process or disease related to hazardous properties of the toxins emitted from the Hazardous Devices.

84. Plaintiffs and Class Members have presently suffered injury proximately caused by Philips' tortious conduct. Plaintiffs have a legally protected interest in not being exposed to toxic chemical, such as Philips' toxic PE-PUR foam, and at levels that can result in an increased risk of illness, disease, or disease process. Plaintiffs and Class Members also have a legally protected interest in avoiding the present and future medical need for expensive diagnostic testing. The past and ongoing exposure to Philips' toxic PE-PUR foam and resulting past and ongoing increased risk of illness, disease or disease process associated with PE-PUR foam and its degradation, has caused the present and future need to incur the cost of medically necessary diagnostic testing for the early detection of disease as a result of Philips' advertisement and sale and Plaintiffs' and Class Members' use of the Hazardous Devices constituting an invasion of the legally protected interests of Plaintiffs and Class Members and injury to Plaintiffs and Class

Members. Plaintiff and Class Members would not have the present and future need to incur the cost of the diagnostic testing to determine the presence of illness, disease, or disease process, related to exposure of PE-PUR Foam but for the past and ongoing exposure they have suffered through the tortious conduct of Philips.

85. Monitoring procedures exist that make possible the early detection of the toxic and carcinogenic effects of the degradation products of the PE-PUR Foam used in Philips' Hazardous Devices. These monitoring procedures are different than for the unexposed populations, because the general unexposed population does not receive this testing as a routine matter of course, including because they are designed to detect diseases known to be associated with exposure to polyester-based polyurethane foam. The monitoring procedures will benefit Plaintiffs and Class Members since they will allow for the early detection of latent disease associated with exposure to toxic PE-PUR Foam. Catching cancer early often allow for more treatment options. Overall outlook depends on early diagnosis; the sooner a person is checked, the better the outcome will be.[30]

86. Medical monitoring is recognized as beneficial for early detection where there is an increased risk of disease from exposure to hazardous substances. The purpose of a medical monitoring program is early identification of latent or unrecognized illness, disease or disease process so that early treatment can be given to reduce the impacts of the toxic exposure. Medical monitoring is widely accepted as necessary and appropriate response to toxic exposure.

87. Plaintiffs and Class Members have the present need for diagnostic testing to diagnose properly the warning signs of the illness, disease, and/or disease process resulting from exposure to the toxins released by Philips' PE-PUR foam. Finding illness, disease and disease

[30] https://www.cancer.org/content/CRC/PDF/Public/8671.00.pdf (last accessed August 30, 2021).

processes early allows for more treatment options. If left to when the disease becomes obvious, Plaintiffs and Class Members will lose valuable treatment time. These monitoring procedures are different from what would normally be recommended in the absence of exposure to the degradation products of Philips' PE-PUR Foam. Plaintiffs and Class Members present need to incur the cost of diagnostic testing is reasonably medically necessary as a direct and proximate result of Philips' conduct due to the Plaintiffs' and Class Members' past and ongoing exposure to the degradation products of Philips' PE-PUR Foam.

88. Plaintiffs and the Class are currently in need of costly diagnostic testing. Specifically, they need monitoring procedures that are reasonably necessary to enable Plaintiffs and Class Members to obtain early detection and diagnosis of illness, disease and disease process, including abnormalities indicative of cancer, made medically necessary as the proximate result of Philips' tortious conduct described herein.

89. Plaintiffs and Class Members seek as damages the costs of such diagnostic testing for the early detection of illness, disease, and disease process, and to allow for early treatment beneficial to Plaintiffs and Class Members, or in the alternative, the award of the reasonable and necessary costs of the establishment of a court-supervised program of diagnostic testing through injunctive relief.

90. Plaintiffs and Class Members also seek all other available and necessary relief in connection with this claim.

TOLLING OF THE STATUTE OF LIMITATIONS

91. Any applicable statute of limitations has been tolled by the deceptive conduct alleged herein. Through no fault or lack of diligence, Plaintiffs and Class members were deceived regarding the Hazardous Devices and could not reasonably discover the latent nature of the defect.

92. Plaintiffs and Class Members could not reasonably discover Philips' deception with respect to the Hazardous Devices prior to experiencing a failure and/or being informed of the reason for the failure. Within the time period of any applicable statute of limitations, Plaintiffs and Class Members could not have discovered through the exercise of reasonable diligence that Philips was concealing the Defect.

93. Plaintiffs and Class Members did not discover and did not know of any facts that would have caused a reasonable person to suspect that Philips was concealing a latent defect and/or that the Hazardous Devices contained a defect in the use of the PE-PUR Foam. As alleged herein, the existence of the Defect and safety risk were material to the Plaintiffs and Class Members at all relevant times.

94. At all times, Philips is and was under a continuous duty to disclose to Plaintiffs and Class Members the true standard, quality, and grade of the Hazardous Devices at issue and to disclose the Defect and potential health and safety risks associated with the Hazardous Devices.

95. Philips knowingly, actively, and affirmatively concealed the facts alleged herein, including the Defect. Plaintiffs and Class Members reasonably relied on Philips' knowing, active, and affirmative concealment.

96. For these reasons, all applicable statute of limitations have been tolled based on the discovery rule and Philips' fraudulent concealment and Philips is estopped from relying on any statutes of limitations in defense of this action.

CLASS ALLEGATIONS

97. Plaintiffs bring this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of themselves and the classes. This action satisfies requires set forth in Rule 23(a) and Rule 23(b).

98. Plaintiffs bring this action individually and on behalf of the following classes:

Nationwide Class: All persons in the United States who purchased a Hazardous Device for personal use. Excluded from the Nationwide Class are Philips, their legal representatives, assigns, and successors and any entity in which Philips has a controlling interest. Also excluded is the judge to whom this case is assigned and any member of the judge's immediate family and judicial staff.

California Subclass: All individuals and entities in the State of California who purchased a Hazardous Device for personal use. Excluded from the California Subclass are Philips, their legal representatives, assigns, and successors and any entity in which Philips has a controlling interest. Also excluded is the judge to whom this case is assigned and any member of the judge's immediate family and judicial staff.

Florida Subclass: All individuals and entities in the State of Florida who purchased a Hazardous Device for personal use. Excluded from the Florida Subclass are Philips, their legal representatives, assigns, and successors and any entity in which Philips has a controlling interest. Also excluded is the judge to whom this case is assigned and any member of the judge's immediate family and judicial staff.

Georgia Subclass: All individuals and entities in the State of Georgia who purchased a Hazardous Device for personal use. Excluded from the Georgia Subclass are Philips, their legal representatives, assigns, and successors and any entity in which Philips has a controlling interest. Also excluded is the judge to whom this case is assigned and any member of the judge's immediate family and judicial staff.

Indiana Subclass: All individuals and entities in the State of Indiana who purchased a Hazardous Device for personal use. Excluded from the Indiana Subclass are Philips, their legal representatives, assigns, and successors and any entity in which Philips has a controlling interest. Also excluded is the judge to whom this case is assigned and any member of the judge's immediate family and judicial staff.

Illinois Subclass: All individuals and entities in the State of Illinois who purchased a Hazardous Device for personal use. Excluded from the Illinois Subclass are Philips, their legal representatives, assigns, and successors and any entity in which Philips has a controlling interest. Also excluded is the judge to whom this case is assigned and any member of the judge's immediate family and judicial staff.

Massachusetts Subclass: All individuals and entities in the State of Massachusetts who purchased a Hazardous Device for personal use. Excluded from the Massachusetts Subclass are Philips, their legal representatives, assigns, and successors and any entity in which Philips has a controlling interest. Also excluded is the judge to whom this case is assigned and any member of the judge's immediate family and judicial staff.

Michigan Subclass: All individuals and entities in the State of Michigan who purchased a Hazardous Device for personal use. Excluded from the Michigan Subclass are Philips, their legal representatives, assigns, and successors and any entity in which Philips has a

controlling interest. Also excluded is the judge to whom this case is assigned and any member of the judge's immediate family and judicial staff.

New York Subclass: All individuals and entities in the State of New York who purchased a Hazardous Device for personal use. Excluded from the New York Subclass are Philips, their legal representatives, assigns, and successors and any entity in which Philips has a controlling interest. Also excluded is the judge to whom this case is assigned and any member of the judge's immediate family and judicial staff.

North Carolina Subclass: All individuals and entities in the State of North Carolina who purchased a Hazardous Device for personal use. Excluded from the North Carolina Subclass are Philips, their legal representatives, assigns, and successors and any entity in which Philips has a controlling interest. Also excluded is the judge to whom this case is assigned and any member of the judge's immediate family and judicial staff.

Ohio Subclass: All individuals and entities in the State of Ohio who purchased a Hazardous Device for personal use. Excluded from the Ohio Subclass are Philips, their legal representatives, assigns, and successors and any entity in which Philips has a controlling interest. Also excluded is the judge to whom this case is assigned and any member of the judge's immediate family and judicial staff.

Pennsylvania Subclass: All individuals and entities in the State of Pennsylvania who purchased a Hazardous Device for personal use. Excluded from the Pennsylvania Subclass are Philips, their legal representatives, assigns, and successors and any entity in which Philips has a controlling interest. Also excluded is the judge to whom this case is assigned and any member of the judge's immediate family and judicial staff.

Texas Subclass: All individuals and entities in the State of Texas who purchased a Hazardous Device for personal use. Excluded from the Texas Subclass are Philips, their legal representatives, assigns, and successors and any entity in which Philips has a controlling interest. Also excluded is the judge to whom this case is assigned and any member of the judge's immediate family and judicial staff.

Claims for personal injury are specifically excluded from the Classes.

99. Subject to additional information obtained through discovery, the foregoing class definitions may be modified or narrowed by an amended complaint, or at class certification, including through the use of multi-state subclasses to account for material differences in state law, if any.

100. Numerosity: Although the actual size of the Classes is unknown, Plaintiffs are informed and believe that the proposed Nationwide Class is comprised of at least millions of individuals, and that there are millions of customers nationwide who purchased the Hazardous

Devices, making joinder impractical. The proposed Subclasses consist of at least tens of thousands of individuals who purchased a Hazardous Device. The disposition of the claims of these Class Members in a single class action will provide substantial benefits to all parties and to the Court.

101. Commonality: There exist questions of law and fact common to all Class Members. These include, but are not limited to, the following:

(a) Whether Philips was negligent in manufacturing and selling the Hazardous Devices;

(b) Whether Philips failed to warn consumers regarding the risks of the Hazardous Devices;

(c) Whether Philips failed to warn consumers regarding the risks of the Hazardous Devices;

(d) Whether Philips' practices constitute unfair or deceptive acts or practices under state consumer protection statutes;

(e) Whether Philips breached their express warranties to Plaintiffs and the Classes;

(f) Whether Philips breached their implied warranties to Plaintiffs and the Classes;

(g) Whether the chemical in or emitted from the polyester-based polyurethane foam is a proven hazardous substance;

(h) Whether Plaintiffs and Class Members have been significantly exposed to Philips' polyester-based polyurethane foam;

(i) Whether Plaintiffs and Class Members are at an increased risk of illness, disease, or disease process because of their exposure to Philips' toxic polyester-based polyurethane foam;

(j) Whether early detection of illness, disease or disease process will provide benefits to Plaintiffs and Members of the Class;

(k) The appropriate nature of class-wide equitable relief;

(l) Whether Philips was unjustly enriched by the sale of the Hazardous Devices;

(m) Whether Philips should be ordered to disgorge, for the benefit of Class Members, all or part of their ill-gotten profits received from the sale of the Hazardous Devices; and

102. Typicality: The claims of the representative Plaintiffs are typical of the claims of Class Members, in that the representative Plaintiffs, like all Class Members, purchased the Hazardous Devices. The representative Plaintiffs, like all Class Members, has suffered a common injury: they paid for a defective product that they would not have purchased had they known the truth about it. The factual basis of Philips' misconduct is common to all class members.

103. Adequacy: Plaintiffs will fairly and adequately represent and protect the interests of the Class. Plaintiffs have retained counsel with substantial experience in prosecuting consumer class actions, including actions involving defective consumer products, failure to disclose material information regarding product safety and violation of consumer protection statutes. Plaintiffs and their counsel are committed to vigorously prosecuting this action on behalf of the Classes and have the financial resources to do so. Neither Plaintiffs nor their counsel have any interests adverse to those of the Classes.

104. Predominance of Common Questions: Common questions of law and fact predominate over any questions involving individualized analysis. Fundamentally, there are no material questions of fact or law that are not common to the Class Members. The performance of the Hazardous Devices relative to their represented qualities is a common question, as if Philips' knowledge regarding the Hazardous Devices' performance and Philips' uniform omission to Class Members of these material facts. Common questions of law include whether Philips' conduct violates consumer protection statutes and other laws, and Class Members' entitlement to damages and remedies.

105. Superiority: Plaintiffs and Class Members have suffered and will continue to suffer harm and damages as a result of Philips' unlawful and wrongful conduct. A class action is superior to other available methods for the fair and efficient adjudication of the subject controversy. Most Class Members likely would find the cost of litigating their individual claims to be prohibitive and will have no effective remedy at law. Thus, absent a class action, Class Members will continue to incur damages and Philips' misconduct will proceed without remedy. Class treatment of common questions of law and fact is also superior to multiple individual actions or piecemeal litigation in that it conserves resources of the courts and the litigants and promotes consistency and efficiency of adjudication. There is no impediment to the management of this action because of the virtual identicalness of the questions of law and fact common to all Class Members.

106. Injunctive Relief: Philips, through its uniform conduct, acted or refused to act on grounds generally applicable to the Class as a whole, making injunctive relief appropriate to the Class as a whole. Plaintiffs seek class-wide injunctive relief on grounds consistent with the standards articulated in Rule 23(b)(@) that establish final injunctive relief as an appropriate class-wide remedy, in that Philips continues to provide half-truths and misleading information

about the Hazardous Devices and continues to omit material facts regarding the Hazardous Devices. The injuries suffered by Plaintiffs and the Classes area result of Philips' actions and are ongoing.

CAUSES OF ACTION

COUNT I
(California's Consumers Legal Remedies Act, Cal. Civil Code § 1750, *et seq* ("CLRA"))

107. Plaintiffs incorporate by reference and realleges each and every allegation contained above, as though fully set forth herein.

108. Plaintiffs residing in California bring this claim against each Defendant. They bring this claim individually and on behalf of a subclass consisting of California residents.

109. Civil Code § 1770(a)(5) prohibits "[r]epresenting that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities which they do not have or that a person has a sponsorship, approval, status, affiliation, or connection which he or she does not have." Civil Code § 1770(a)(7) prohibits "[r]epresenting that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another." Civil Code § 1770(a)(9) prohibits "advertising goods or services with intent not to sell them as advertised."

110. Defendants violated Civil Code § 1770(a)(5), (a)(7) and (a)(9) by holding out the Hazardous Devices as fit for use as CPAP machines, when in fact the products were defective, dangerous, and useless.

111. The defect at issue here involves a critical safety-related component of the Affected Products, and it was unsafe to operate the Affected Products.

112. Defendant had exclusive knowledge of the defect, which was not known to Plaintiffs or class members.

113. Defendant made partial representations to Plaintiffs and class members, while suppressing the safety defect. Specifically, by displaying the product and describing its features, the product packaging and Defendant's website implied that the product was suitable for use as a CPAP machine, without disclosing that the Affected Products had a critical safety-related defect that could result in harm to users.

114. Plaintiffs and class members have suffered harm as a result of these violations of the CLRA because they have incurred charges and/or paid monies for the Affected Products that they otherwise would not have incurred or paid.

115. Plaintiffs and the Subclass members seek restitution, the payment of costs and attorneys' fees, and any other relief deemed appropriate and proper by the Court. Plaintiffs reserve their right to seek damages under the CLRA on completion of statutory notice under Civil Code §1782(a).

COUNT II
(Violations of California's Unfair Competition Law ("UCL"))

116. Plaintiffs incorporate by reference and realleges each and every allegation contained above, as though fully set forth herein.

117. Plaintiffs residing in California bring this claim against each Defendant. They bring this claim individually and on behalf of a subclass consisting of California residents.

118. By committing the acts and practices alleged herein, Defendants violated California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code §§ 17200-17210, by engaging in unlawful, fraudulent, and unfair conduct.

119. Defendants violated the UCL's proscription against engaging in unlawful conduct as a result of its violations of the common law and of CLRA, Cal. Civ. Code § 1770(a)(5) and (a)(7) as alleged above.

120. As more fully described above, Defendants' misleading marketing, advertising, packaging, and labeling of the Hazardous Devices is likely to deceive reasonable consumers.

121. Defendants' acts and practices described above also violate the UCL's proscription against engaging in unfair conduct.

122. Plaintiffs and the other California Subclass members suffered a substantial injury by virtue of buying the Affected Products that they would not have purchased absent Defendants' unlawful, fraudulent, and unfair marketing, advertising, packaging, and omission about the defective nature of the Hazardous Devices, or by virtue of paying an excessive premium price for the unlawfully, fraudulently, and unfairly marketed, advertised, packaged, and labeled product.

123. There is no benefit to consumers or competition from deceptively marketing and omitting material facts about the defective nature of the Products.

124. Plaintiffs and the other California Subclass members had no way of reasonably knowing that the Hazardous Devices they purchased were not as marketed, advertised, packaged, or labeled. Thus, they could not have reasonably avoided the injury each of them suffered.

125. The gravity of the consequences of Defendants' conduct as described above outweighs any justification, motive, or reason therefore, particularly considering the available legal alternatives which exist in the marketplace, and such conduct is immoral, unethical, unscrupulous, offends established public policy, or is substantially injurious to Plaintiffs and the other members of the California Subclass.

126. Pursuant to California Business and Professional Code § 17203, Plaintiffs and the California Subclass seek an order of this Court that includes, but is not limited to, an order requiring Defendant to: (a) provide restitution to Plaintiffs and the other California Subclass

members; (b) disgorge all revenues obtained as a result of violations of the UCL; (c) pay Plaintiffs' and the California Subclass' attorney's fees and costs.

COUNT III
(Breach of Implied Warranty Under the Song-Beverly Act, Cal. Civ. Code § 1790 *et seq*.)

127. Plaintiffs incorporate by reference and realleges each and every allegation contained above, as though fully set forth herein.

128. Plaintiffs residing in California bring this claim against each Defendant. They bring this claim individually and on behalf of a subclass consisting of California residents.

129. Under the Song-Beverly Consumer Warranty Act, Cal. Civ. Code § 1790, et seq., every sale of consumer goods in this State is accompanied by both a manufacturer's and retail seller's implied warranty that the goods are merchantable, as defined in that Act.

130. The Hazardous Devices at issue here are "consumer goods" within the meaning of Cal. Civ. Code § 1791(a).

131. Plaintiffs and the Class members who purchased one or more of the Hazardous Devices are "retail buyers" within the meaning of Cal. Civ. Code § 1791.

132. Defendants are in the business of manufacturing, assembling, producing and/or selling the Hazardous Devices to retail buyers, and therefore are a "manufacturer" and "seller" within the meaning of Cal. Civ. Code § 1791.

133. Defendants impliedly warranted to buyers that the Hazardous Devices were merchantable in that they would: (a) pass without objection in the trade or industry under the contract description, and (b) were fit for the ordinary purposes for which the Products are used. In order for a consumer good to be "merchantable" under the Act, it must satisfy both of these elements. Defendants breached these implied warranties because the Products were unsafe and defective. Therefore, the Hazardous Devices would not pass without objection in the trade or industry and were not fit for the ordinary purpose for which they are used.

134. Plaintiffs and Class members purchased the Hazardous Devices in reliance upon Defendants' skill and judgment in properly packaging and labeling the Products.

135. The Hazardous Devices were not altered by Plaintiffs or Class members.

136. The Hazardous Devices were defective at the time of sale when they left the exclusive control of Defendants. The defect described in this complaint was latent in the product and not discoverable at the time of sale.

137. Defendant knew that the Hazardous Devices would be purchased and used without additional testing by Plaintiffs and Class members.

138. Any purported disclaimers in connection with an express warranty are legally insufficient to bar this claim. First, under section 1792.3 of the Song–Beverly Act, implied warranties of merchantability and fitness may only be waived when the sale of consumer goods is made on an "as is" or "with all faults" basis. The Hazardous Devices were not sold on an "as is" or "with all faults" basis, and the disclaimer made no mention of the sale being "as is" or "with all faults." Second, a disclaimer of implied warranties is effective only if it is "conspicuous" and made available to the consumer prior to the sale of the product. Any purported disclaimers were not conspicuous.

139. As a direct and proximate cause of Defendants' violation of the Song-Beverly Act, Plaintiffs and Class members have been injured and harmed because they would not have purchased the Hazardous Devices if they knew the truth about the products, namely, that they were unfit for their intended purpose.

COUNT IV
(Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. §§ 501.201 *et seq.*)

140. Plaintiffs incorporate by reference and realleges each and every allegation contained above, as though fully set forth herein.

141. Plaintiffs residing in Florida bring this claim against each Defendant. They bring this claim individually and on behalf of a subclass consisting of Florida residents.

142. Plaintiffs and class members are "consumers" under Fla. Stat. § 501.203(7), the Hazardous Devices are "goods" within the meaning of FDUTPA, and the transactions at issue constitute "trade or commerce" as defined by FDUTPA.

143. The Florida Deceptive and Unfair Trade Practices Act ("FDUTPA"), Fla. Stat. § 501.204. provides that "[u]nfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful."

144. For the reasons alleged above, Defendants violated and continue to violate FDUTPA by engaging in the herein described unconscionable, deceptive, unfair acts or practices proscribed by Fla. Stat. § 501.201, et seq.

145. Defendants' acts and practices, including its material omissions, described herein, were likely to, and did in fact, deceive and mislead members of the public, including consumers acting reasonably under the circumstances, to their detriment.

146. At all times mentioned herein, Defendants engaged in trade or commerce in Florida, as defined by Fla. Stat. § 501.203(8), in that they advertised, offered for sale, sold or distributed goods or services in Florida and/or engaged in trade or commerce directly or indirectly affecting the people of Florida.

147. Defendants repeatedly advertised, both on the labels for the Hazardous Devices, on its websites, and through a national advertising campaign, among other items, that the Hazardous Devices were and are safe for use by individuals when in fact they were not safe for use in their ordinary and intended purpose.

148. Defendants' representations and omissions were material because they were likely to deceive reasonable consumers to induce them to the Hazardous Devices without being aware that using the Hazardous Devices could cause adverse health effects.

149. As a direct and proximate result of Defendants' unfair and deceptive acts or practices, Plaintiffs and class members suffered damages by purchasing the Hazardous Devices because they would not have purchased the Hazardous Devices had they known the truth, and they received a product that was worthless because it was unsafe to use for its ordinary and intended purpose.

150. Defendants' deceptive trade practices caused injury in fact and actual damages to Plaintiffs and class members in the form of the loss or diminishment of value of the Hazardous Devices, which allowed Defendant to profit at the expense of Plaintiffs and class members. The injuries were to legally protected interests. The gravity of the harm of Defendats' actions is significant and there is no corresponding benefit to consumers of such conduct.

151. Plaintiffs and class members seek relief for the injuries they have suffered as a result of Defendants' unfair and deceptive acts and practices, as provided by Fla. Stat. § 501.211 and applicable law.

COUNT V
(Violations of Georgia Fair Business Practices Act, Ga. Stat. Ann. §§ 10-1-390, et seq.)

152. Plaintiffs incorporate by reference and realleges each and every allegation contained above, as though fully set forth herein.

153. Plaintiffs residing in Georgia bring this claim against each Defendant. They bring this claim individually and on behalf of a subclass consisting of Georgia residents.

154. The Georgia Fair Business Practices Act, Ga. Stat. Ann. § 10-1-393, states that, "[u]nfair or deceptive acts or practices in the conduct of consumer transactions and consumer acts or practices in trade or commerce are declared unlawful."

155. By the conduct described in detail above and incorporated herein, Defendants engaged in unfair and deceptive trade practices.

156. Defendants' omissions regarding the Hazardous Devices, described above, are material facts that a reasonable person would have considered in deciding whether or not to purchase (or to pay the same price for) the Hazardous Devices.

157. Defendants intended for Plaintiffs and the other class members to rely on Defendants' omissions regarding Hazardous Devices.

158. Plaintiffs and the other class members justifiably acted or relied to their detriment upon Defendants' omissions of fact concerning the above-described dangers of using the Hazardous Devices, as evidenced by Plaintiffs' and the other class members' purchases of the Hazardous Devices.

159. Had Defendants disclosed all material information regarding the Hazardous Devices to Plaintiffs and the other class members, Plaintiffs and the other class members would not have purchased the Hazardous Devices or would have paid less for them.

160. Defendants' omissions deceived Plaintiffs, and those same business practices have deceived or are likely to deceive members of the consuming public and the other members of the class.

161. In addition to being deceptive, Defendants' business practices were unfair because Defendants knowingly sold Plaintiff and the other Class members Hazardous Devices that are essentially unusable for the purposes for which they were sold. The injuries to Plaintiff and the other class members are substantial and greatly outweigh any alleged countervailing benefit to Plaintiffs and the other class members or to competition under all of the circumstances. Moreover, in light of Defendants' exclusive knowledge of the dangers of using the Hazardous

Devices, the injury is not one that Plaintiffs or the other class members could have reasonably avoided.

162. As a direct and proximate result of Defendants' unfair and deceptive trade practices, Plaintiffs and the other class members have suffered ascertainable loss and actual damages. Plaintiffs and the other class members who purchased the Hazardous Devices would not have purchased them, or, alternatively, would have paid less for them had the truth about the Hazardous Devices been disclosed.

163. Plaintiffs and the other class members seek actual damages, attorneys' fees and costs, and all other relief allowed under Ga. Stat. Ann. § 10-1-399.

COUNT VI
(Illinois Consumer Fraud Act, 815 Ill. Comp. Stat. 505/1, *et seq*.)

164. Plaintiffs incorporate by reference and realleges each and every allegation contained above, as though fully set forth herein.

165. Plaintiffs residing in Illinois bring this claim against each Defendant. They bring this claim individually and on behalf of a subclass consisting of Illinois residents.

166. Plaintiffs and class members are "consumers," as defined by ILCS 505/1(e). 127. Each Defendant is a "person" as defined by 815 ILCS 505/1(c). 128. The Hazardous Devices are "merchandise" as defined by 815 ILCS 505/1(b). 129.

167. The Illinois Consumer Fraud and Deceptive Business Practices Act ("ILCS") prohibits "unfair or deceptive acts or practices, including but not limited to the use or employment of any deception, fraud, false pretense, false promise, misrepresentation or the concealment, suppression or omission of any material fact, with intent that others rely upon the concealment, suppression or omission of such material fact . . . in the conduct of trade or commerce . . . whether any person has in fact been misled, deceived or damaged thereby." 815 ILCS 505/2. 130.

168. Defendants engaged in trade or commerce in Illinois as defined by ILCS 815 ILCS 505/1(f), in that they advertised, offered for sale, sold or distributed goods or services in Illinois and/or engaged in trade or commerce directly or indirectly affecting the people of Illinois. 131.

169. Defendants represented that the Hazardous Devices were and are safe for use by individuals when in fact they contain an unsafe material, which could cause a Hazardous Device user to suffer adverse health effects from use of the Hazardous Devices.

170. Defendants' representations and omissions were material because they were likely to deceive reasonable consumers to induce them to buy the Hazardous Devices without being aware that they were unsafe to use for their intended purpose.

171. As a direct and proximate result of Philips' unfair and deceptive acts or practices, Plaintiffs and class members suffered damages by purchasing the Hazardous Devices because they would not have purchased them had they known the truth, and they received a product that was worthless because it is unsafe to use for its intended purpose.

172. Defendants' deceptive trade practices caused injury in fact and actual damages to Plaintiffs and class members in the form of the loss or diminishment of value of the Hazardous Devices, which allowed Defendants to profit at the expense of Plaintiffs and class members.

173. The gravity of the harm of Defendants' actions is significant and there is no corresponding benefit to consumers of such conduct.

174. Plaintiffs and class members seek all available relief under the Illinois Consumer Fraud Act.

COUNT VII
(Indiana Deceptive Consumer Sales Act)

175. Plaintiffs incorporate by reference and realleges each and every allegation contained above, as though fully set forth herein.

176. Plaintiffs residing in Indiana bring this claim against each Defendant. They bring this claim individually and on behalf of a subclass consisting of Indiana residents.

177. Each Defendant is a "person" as defined by Ind. Code §24-5-0.5-2(a)(2).

178. Each Defendant is a "supplier" as defined by Ind. Code §24-5-0.5-2(a)(3).

179. Sales of the Hazardous Devices are "consumer transactions" as that term is defined at Ind. Code §24-5-0.5-2(a)(1).

180. Defendants engaged in unfair and deceptive acts in violation of the Indiana Deceptive Consumer Sales Act, Ind. Code §§24-5-0.5-0.1, et seq., by the practices described above, and by knowingly and intentionally concealing the true nature of the Hazardous Devices from Plaintiffs and class members.

181. These acts and practices violate Indiana Deceptive Consumer Sales Act, Ind. Code §24-5-0.5-3(b)((1)-(2).

182. Defendants' unfair or deceptive acts or practices occurred repeatedly in their trade or business and were capable of deceiving the purchasing public.

183. Defendants knew that the Hazardous Devices were dangerous and not fit for their intended purpose, making them susceptible to failure for their essential purpose, and that they would become useless and worthless as a result of reasonable and foreseeable use by consumers.

184. Defendants owed a duty to Plaintiffs and class members to disclose that the Hazardous Devices were dangerous because: (1) Defendants were in a superior position to know the true state of facts about the defect within the Hazardous Devices; (2) Plaintiffs and class members could not reasonably have been expected to learn or discover that the Hazardous Devices were dangerous and inconsistent with the advertisements and representations about the Hazardous Devices; (3) Defendants knew that Plaintiffs and class members could not reasonably have been expected to learn or discover the presence of or dangers posed by the Hazardous

Devices; and (4) Defendants actively concealed and failed to disclose the presence of and dangers posed by the Hazardous Devices.

185. Defendants intentionally and knowingly concealed material facts concerning the dangers of the Hazardous Devices.

186. The facts that Defendants concealed are material in that a reasonable consumer would have considered them to be important in deciding whether to purchase the Hazardous Devices. Had Plaintiffs and class members known of the presence of and dangers posed by the Hazardous Devices, they would not have purchased the Hazardous Devices or would have paid less for them.

187. Defendants' violations were willful and were done as part of a scheme, artifice, or device with intent to defraud or mislead, and therefore are incurable deceptive acts or omissions under the Indiana Deceptive Consumer Sales Act.

188. The Indiana Deceptive Consumer Sales Act provides that "[a] person relying upon an uncured or incurable deceptive act may bring an action for the damages actually suffered as a consumer as a result of the deceptive act or five hundred dollars ($500), whichever is greater. The court may increase damages for a willful deceptive act in an amount that does not exceed the greater of: (1) three (3) times the actual damages of the consumer suffering the loss; or (2) one thousand dollars ($1,000)." Ind. Code §24-5-0.5-4(a). 147.

189. The Indiana Deceptive Consumer Sales Act provides that "[a]ny person who is entitled to bring an action under subsection (a) on the person's own behalf against a supplier for damages for a deceptive act may bring a class action against such supplier on behalf of any class of persons of which that person is a member . . . ." Ind. Code §24-5-0.5-4(b).

190. Plaintiffs' and class members' injuries were proximately caused by Defendants' fraudulent and deceptive business practices.

191. Plaintiffs and class members seek all available relief under the Indiana Deceptive Consumer Sales Act.

COUNT VIII
(Michigan Consumer Protection Act, Mich. Comp. Laws § 445.903 *et seq.*)

192. Plaintiffs incorporate by reference and realleges each and every allegation contained above, as though fully set forth herein.

193. Plaintiffs residing in Michigan bring this claim against each Defendant. They bring this claim individually and on behalf of a subclass consisting of Michigan residents.

194. Class Members were "person[s]" within the meaning of the Mich. Comp. Laws § 445.902(1)(d).

205. At all relevant times hereto, each Defendant was a "person" engaged in "trade or commerce" within the meaning of the Mich. Comp. Laws § 445.902(1)(d) and (g).

206. The Michigan Consumer Protection Act ("Michigan CPA") prohibits "[u]nfair, unconscionable, or deceptive methods, acts, or practices in the conduct of trade or commerce.…" Mich. Comp. Laws § 445.903(1). Defendants engaged in unfair, unconscionable, or deceptive methods, acts or practices prohibited by the Michigan CPA, including: "(c) Representing that goods or services have… characteristics… that they do not have.…;" "(e) Representing that goods or services are of a particular standard… if they are of another;" "(s) Failing to reveal a material fact, the omission of which tends to mislead or deceive the consumer, and which fact could not reasonably be known by the consumer;" "(bb) Making a representation of fact or statement of fact material to the transaction such that a person reasonably believes the represented or suggested state of affairs to be other than it actually is;" and "(cc) Failing to reveal facts that are material to the transaction in light of representations of fact made in a positive manner." Mich. Comp. Laws § 445.903(1). By failing to disclose and actively concealing that

the Hazardous Devices were unsafe to use for their ordinary and intended purpose, Defendants participated in unfair, deceptive, and unconscionable acts that violated the Michigan CPA.

207. In the course of their business, Defendants willfully failed to disclose and actively concealed the dangerous nature of the Hazardous Devices and otherwise engaged in activities with a tendency or capacity to deceive. Defendants also engaged in unlawful trade practices by employing deception, deceptive acts or practices, fraud, misrepresentation or concealment, suppression or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale of Hazardous Devices. Defendants are directly liable for engaging in unfair and deceptive acts or practices in the conduct of trade or commerce in violation of the Michigan CPA.

208. As alleged above, Defendants knew of the defective and unsafe nature of the Hazardous Devices.

209. Plaintiffs and class members were deceived by Defendants' omissions into believing the Hazardous Devices were safe. The true information could not have reasonably been known by the consumer.

210. Defendants knew or should have known that their conduct violated the Michigan CPA.

211. Defendants engaged in a deceptive trade practice when it failed to disclose material information concerning the Hazardous Devices which it knew at the time of the sale. Defendants deliberately withheld information that the Hazardous Devices were unsafe to ensure that consumers would purchase Hazardous Devices.

212. Defendants owed the Class an independent duty, based on its respective knowledge, to disclose the defective nature of Hazardous Devices, because Defendants: (1) possessed exclusive knowledge of the defect rendering Hazardous Devices inherently more

dangerous and unreliable than similar products; (2) intentionally concealed the danger of the Hazardous Devices through their deceptive marketing; (3) and/or made incomplete representations about the safety and reliability of Hazardous Devices while purposefully withholding material facts from Plaintiffs and class members that contradicted these representations.

213. Defendants' unfair or deceptive acts or practices were likely to deceive reasonable consumers, about the true safety and reliability of Hazardous Devices. Defendants intentionally and knowingly misrepresented material facts regarding the Hazardous Devices with an intent to mislead the Class.

214. The dangerous and defective nature of the Hazardous Devices was material to the Plaintiffs and class members. Had Plaintiffs and class members known that their Hazardous Devices were unsafe to use, they would either not have purchased their Hazardous Devices, or would have paid less for them than they did.

215. Plaintiffs and class members suffered ascertainable loss caused by Defendants' failure to disclose material information. The Class overpaid for their Hazardous Devices and did not receive the benefit of their bargain.

216. Plaintiffs and class members have been damaged by Defendants' concealment and non-disclosure of the fact that the Hazardous Devices are unsafe to use for their ordinary and intended purpose.

217. Plaintiffs and class members continue to be at risk of irreparable injury as a result of Defendants' and omissions, and these violations present a continuing risk to Plaintiffs and class members.

218. The unlawful acts and practices complained of herein affect the public interest.

219. As a direct and proximate result of Defendants' violations, Plaintiffs and class members have suffered injury-in-fact and/or actual damage.

220. Plaintiffs and the class seeks injunctive relief to enjoin Defendants from continuing their unfair and deceptive acts; monetary relief against Defendants measured as the greater of (a) actual damages in an amount to be determined at trial and (b) statutory damages in the amount of $250 for each Plaintiff and class member; reasonable attorneys' fees; declaratory relief in the nature of a judicial determination of whether each Company's conduct violated the Michigan Statute, the just total amount of penalties to be assessed against each thereunder, and the formula and procedure for fair and equitable allocation of statutory penalties among the Michigan Class; and any other just and proper relief available under Mich. Comp. Laws § 445.911.

221. Plaintiffs and class members also seek punitive damages against Defendants because they carried out despicable conduct with willful and conscious disregard of the rights and safety of others. Defendants intentionally and willfully misrepresented the safety and reliability of the Hazardous Devices, deceived Plaintiffs and class members, and concealed material facts that only it knew, all to avoid the expense and public relations nightmare of correcting flaws in the Hazardous Devices. Defendants' unlawful conduct constitutes malice, oppression, and fraud warranting punitive damages.

COUNT IX
(New York GBL § 349)

195. Plaintiffs incorporate by reference and realleges each and every allegation contained above, as though fully set forth herein

196. Plaintiffs residing in New York bring this claim against each Defendant. They bring this claim individually and on behalf of a subclass consisting of New York residents.

197. Defendants used deception, fraud, false pretenses, and omissions of material fact in connection with its failure to disclose to Plaintiffs and class members that the Hazardous Devices were dangerous and did not conform to the products' labels, packaging, advertising, and statements. This conduct was unfair, deceptive, and misleading in violation of GBL §349.

198. The defect in the Hazardous Devices pertained to the devices' central functionality, and made the Hazardous Devices unsafe to use for their normal and intended operation. Defendants' failure to disclose the risks of using the Hazardous Devices were material facts, and Defendants were obligated to disclose these material facts to Plaintiffs and class members. A reasonable consumer attaches importance to such material facts and are induced to act thereon in making purchasing decisions.

199. Plaintiffs and class members were misled by Defendants' failure to disclose material facts that the Affected Products were unsafe to use for their ordinary and intended purpose.

200. At all relevant times, Defendants had exclusive knowledge that the Hazardous Devices could cause users to suffer adverse health effects which do not conform to the products' labels, packaging, advertising, and statements.

201. Defendants further knew or reasonably should have known that there was no disclosure on the Hazardous Devices' packaging that the products contained dangerous materials that were at risk of causing users of the Hazardous Devices to suffer from adverse health effects.

202. At all relevant times, Defendants knew or reasonably should have known that Plaintiffs and class members relied on the foregoing omissions and will continue to be deceived and harmed by Defendants' conduct.

203. The foregoing deceptive acts and practices were directed at Plaintiffs and class members.

204. Plaintiffs and class members have been injured as a direct and proximate result of Defendants' violations described above as they would not have purchased the Hazardous Devices at all had they known about the risk of suffering adverse health effects as a result using the Hazardous Devices.

205. As a result of Defendants' unlawful action, Plaintiffs and class members seek to enjoin Defendants' deceptive and unlawful acts and practices described herein to recover actual damages, fifty dollars or both, whichever is greater, as well as treble damages, reasonable attorneys' fees, and all other remedies this Court deems proper.

COUNT X
(New York GBL § 350)

206. Plaintiffs incorporate by reference and realleges each and every allegation contained above, as though fully set forth herein.

207. Plaintiffs residing in New York bring this claim against each Defendant. They bring this claim individually and on behalf of a subclass consisting of New York residents.

208. Defendants violated GBL §350 by engaging in false and misleading advertising that failed to disclose to Plaintiffs and class members that the Hazardous Devices were dangerous and did not conform to the products' labels, packaging, advertising, and statements.

209. The defect in the Hazardous Devices pertained to the devices' central functionality and made the Hazardous Devices unsafe to use for their normal and intended operation. Defendants' failure to disclose the risks of using the Hazardous Devices were material facts, and Defendants were obligated to disclose these material facts to Plaintiffs and class members. A reasonable consumer attaches importance to such material facts and are induced to act thereon in making purchasing decisions.

210. Plaintiffs and class members were misled by Defendants' failure to disclose material facts that the Affected Products were unsafe to use for their ordinary and intended purpose.

211. At all relevant times, Defendants had exclusive knowledge that the Hazardous Devices could cause users to suffer adverse health effects which do not conform to the products' labels, packaging, advertising, and statements.

212. Defendants further knew or reasonably should have known that there was no disclosure on the Hazardous Devices' packaging that the products contained dangerous materials that were at risk of causing users of the Hazardous Devices to suffer from adverse health effects.

213. At all relevant times, Defendants knew or reasonably should have known that Plaintiffs and class members relied on the foregoing omissions and will continue to be deceived and harmed by Defendants' conduct.

214. The foregoing deceptive acts and practices were directed at Plaintiffs and class members.

215. Plaintiffs and class members have been injured as a direct and proximate result of Defendants' violations described above as they would not have purchased the Hazardous Devices at all had they known about the risk of suffering adverse health effects as a result using the Hazardous Devices.

216. As a result of Defendants' unlawful action, Plaintiffs and class members seek to enjoin Defendants' deceptive and unlawful acts and practices described herein to recover actual damages, five hundred dollars or both, whichever is greater, as well as treble damages, reasonable attorneys' fees, and all other remedies this Court deems proper.

COUNT XI
(North Carolina Unfair and Deceptive Trade Practices Act,
N.C. Gen. Stat. §§ 75-1.1, et *seq.*)

217. Plaintiffs incorporate by reference and realleges each and every allegation contained above, as though fully set forth herein.

218. Plaintiffs residing in North Carolina bring this claim against each Defendant. They bring this claim individually and on behalf of a subclass consisting of North Carolina residents.

219. Defendants engaged in unlawful, unfair, and deceptive trade practices in violation of the North Carolina Unfair and Deceptive Trade Practices Act by advertising, selling, and warranting the defective Hazardous Devices.

220. Defendants knew that the Hazardous Devices were dangerous and not suitable for their ordinary and intended purpose.

221. In advertising, selling, and warranting the Hazardous Devices, Defendants omitted material facts concerning dangers of using the Hazardous Devices. Defendants failed to give Plaintiffs and the other class members sufficient notice or warning regarding this defect.

222. Defendants intended that Plaintiffs and the other class members rely upon Defendants' omissions when purchasing the Hazardous Devices.

223. Plaintiffs and the other class members were deceived by Defendants' concealment of the defect.

224. Defendants' conduct was in commerce and affected commerce.

225. As a direct and proximate result of these unfair, willful, unconscionable, and deceptive commercial practices, Plaintiffs and the other class members have been damaged and seek to recover actual and treble damages, as well as attorneys' fees and costs, and all other relief allowed under N.C. Gen. Stat §§ 75-16 and 75-16.1.

COUNT XII
(Ohio Consumer Sales Practices Act, Ohio Rev. Code Ann. §§ 1345.01, *et seq*.)

226. Plaintiffs incorporate by reference and realleges each and every allegation contained above, as though fully set forth herein.

227. Plaintiffs residing in Ohio bring this claim against each Defendant. They bring this claim individually and on behalf of a subclass consisting of Ohio residents.

228. Defendants, Plaintiff, and the other Class members are "persons" within the meaning of Ohio Rev. Code Ann. § 145.01(B).

229. Defendant is a "supplier" as defined by Ohio Rev. Code Ann. § 1345.01(c).

230. Plaintiffs and the other Class members are "consumers" as that term is defined in Ohio Rev. Code Ann. § 1345.01(D), and their purchase and lease of the Hazardous Devices are "consumer transactions" within the meaning of Ohio Rev. Code Ann. § 1345.01(A).

231. Ohio Rev. Code Ann. § 1345.02 prohibits unfair or deceptive acts or practices in connection with consumer transactions.

232. In the course of Defendants' business, Defendants violated the Ohio Consumer Sales Practices Act ("CSPA") by selling Hazardous Devices, which are unsafe to use for their ordinary and intended purpose.

233. Further, as a result of placing a defective product into the stream of commerce, Defendants breached their implied warranty in tort, which is an unfair and deceptive act, as defined in Ohio Rev. Code Ann. § 1345.09(B).

234. Defendant also committed unfair and deceptive acts in violation of the Ohio CSPA by knowingly placing into the stream of commerce the Hazardous Devices.

235. Defendants committed an unfair and deceptive act by knowingly concealing the dangerous defect associated with the Hazardous Devices and failing to inform Plaintiffs and the other Class members of this defect.

236. Defendants' unfair or deceptive acts or practices were likely to, and did, in fact, deceive consumers, including Plaintiff and the other Class members, into believing the Hazardous Devices were safe and suitable for their ordinary and intended purposes.

237. Plaintiff and the other Class members suffered ascertainable loss and actual damages as a direct result of Defendants' concealment of and failure to disclose that the Hazardous Devices were unsafe. Plaintiff and the other Class members who purchased Hazardous Devices would not have done so, or would have paid significantly less, if the true nature of the Hazardous Devices had been disclosed.

238. Plaintiffs and the other Class members seek compensatory damages, injunctive/equitable relief, and attorneys' fees pursuant to Ohio Rev. Code Ann. § 1345.09.

COUNT XIII
(Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73, Pa. Cons. Stat. Ann. §§ 201-1, *et seq*.)

239. Plaintiffs incorporate by reference and realleges each and every allegation contained above, as though fully set forth herein.

240. All Plaintiffs bring this claim against each Defendant, individually and on behalf of a nationwide class. Alternatively, each Plaintiff residing in Pennsylvania brings this claim against each Defendant on behalf of themselves and a subclass consisting of Pennsylvania residents.

241. At all times mentioned herein, Defendants engaged in "trade" or "commerce" in Pennsylvania, as defined by 73 Pa. Cons. Stat. Ann. §201-2(3), in that they advertised, offered for sale, and sold goods, property, or services primarily for personal, family, or household purposes, and advertised, solicited, offered for sale, and sold "services," "property," "article[s]," "commodit[ies]," or "thing[s] of value" in Pennsylvania.

242. Pennsylvania's Unfair Trade Practices and Consumer Protection Law ("UTCPL"), 73 Pa. Cons. Stat. Ann. §201-3 provides that "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce . . . are hereby declared unlawful."

243. For the reasons discussed herein, Defendants violated and continues to violate the UTCPL by engaging in the herein described unconscionable, deceptive, unfair acts or practices proscribed by UTCPL §§201-1, et seq. Defendants' acts and practices, including their material omissions, described herein, were likely to, and did in fact, deceive and mislead members of the public, including consumers acting reasonably under the circumstances, to their detriment.

244. Defendants repeatedly advertised on the labels and packing for the Hazardous Devices, on their websites, and through national advertising campaigns, among other items, that the Hazardous Devices were safe and fit for human use.

245. Defendants failed to disclose the material information that the Hazardous Devices were unsafe and unfit for human use.

246. Defendants' representations and omissions were material because they were likely to deceive reasonable consumers to induce them to buy the Hazardous Devices without being aware that they were unsafe and unfit for human use. As a direct and proximate result of Defendants' unfair and deceptive acts or practices, Plaintiffs and members of the Class suffered damages by purchasing Hazardous Devices because they would not have purchased them had they known the truth, and they received a product that was worthless because it was unsafe to use for its intended and ordinary purpose.

247. Defendants' deceptive trade practices caused injury in fact and actual damages to Plaintiffs and members of the Class in the form of the loss or diminishment of value of the

Hazardous Devices that Plaintiffs and Class Members purchased, which allowed Defendants to profit at the expense of Plaintiffs and Class Members.

248. The injuries to Plaintiffs and members of the Class were to legally protected interests.

249. The gravity of the harm of Defendants' actions is significant and there is no corresponding benefit to consumers of such conduct.

250. Plaintiffs and Class Members seek relief for the injuries they have suffered as a result of Defendants' unfair and deceptive acts and practices, as provided by 73 Pa. Cons. Stat. Ann. §201-9.2 and applicable law.

COUNT XIV
(Texas Deceptive Trade Practices-Consumer Protection Act,
Tex. Bus. & Com. Code §§ 17.01, *et seq.*)

251. Plaintiffs incorporate by reference and realleges each and every allegation contained above, as though fully set forth herein.

252. Plaintiffs residing in Texas bring this claim against each Defendant. They bring this claim individually and on behalf of a subclass consisting of Texas residents.

213. The Texas Deceptive Trade Practices—Consumer Protection Act ("TDTPA") states that it is unlawful to commit "[f]alse, misleading, or deceptive acts or practices in the conduct of any trade or commerce." Tex. Bus. & Com. Code § 17.46.

214. By the conduct described in detail above and incorporated herein, Defendants engaged in false, misleading and deceptive trade practices.

215. Defendants' omission concerning the dangerous defects in the Hazardous Devices, described above, are material facts that a reasonable person would have considered in deciding whether or not to purchase (or to pay the same price for) the Hazardous Devices.

216. Defendants intended for Plaintiff and the other Class members to rely on Defendants' omissions regarding the dangerous defects in the Hazardous Devices.

217. Plaintiff and the other Class members justifiably acted or relied to their detriment upon Defendants' omissions of fact concerning the above-described dangerous defects in the Hazardous Devices, as evidenced by Plaintiff and the other Class members' purchases of the Hazardous Devices.

218. Had Defendant disclosed all material information regarding the Hazardous Devices to Plaintiff and the other Class members, Plaintiff and the other Class members would not have purchased or leased Hazardous Devices or would have paid less for them.

219. Defendants' omissions deceived Plaintiffs, and those same business practices have deceived or are likely to deceive members of the consuming public and the other members of the Class.

220. In addition to being deceptive, the business practices of Defendants were unfair because Defendants knowingly sold Plaintiff and the other Class members Hazardous Devices that are essentially unusable for the purposes for which they were sold. The injuries to Plaintiff and the other Class members are substantial and greatly outweigh any alleged countervailing benefit to Plaintiff and the other Class members or to competition under all of the circumstances. Moreover, in light of Defendants' exclusive knowledge of the danger of using the Hazardous Devices, the injury is not one that Plaintiff or the other Class members could have reasonably avoided.

221. As a direct and proximate result of Defendants' unfair and deceptive trade practices, Plaintiff sand the other Class members have suffered ascertainable loss and actual damages.

222. Plaintiff and the other Class members seek all available relief under the TDTPA.

COUNT XV
(Breach of Express Warranty Against Defendants)

253. Plaintiffs incorporate by reference and realleges each and every allegation contained above, as though fully set forth herein.

254. Each Plaintiff brings this claim against each Defendant under the laws of the state where that Plaintiff lives. They each bring this claim individually and on behalf of a subclass that corresponds with the state in which each Plaintiff lives. Each Plaintiff also reserves his or her right to represent a multistate class that includes states with comparable applicable laws.

255. Defendants marketed and sold the Hazardous Devices into the stream of commerce with the intent that the Hazardous Devices would be purchased by Plaintiffs and the Class.

256. In connection with the purchase, rental, or lease of each one of its Hazardous Devices, Defendants provide an express warranty that the devices "shall be free from defects of workmanship and materials and will perform in accordance with the product specifications for a period of two (2) years from the date of sale […] to the dealer." The express warranty further provides that Defendants will "repair or replace" the product if it "fails to perform in accordance with the product specifications."

257. As a manufacturer of medical devices, Defendants were required to provide this warranty to purchasers of the Hazardous Devices.

258. Defendants' warranties formed the basis of the bargain that was reached when Plaintiffs and the Class purchased their Hazardous Devices equipped with the PE-PUR Foam.

259. Plaintiffs and the Class experienced defects within the warranty period as the PE-PUR Foam was installed in the Hazardous Devices prior to purchase by Plaintiffs and the Class. Despite the existence of a warranty, Defendants failed to inform Plaintiffs and the Class that the

Hazardous Devices contained defective workmanship and materials, and failed to fix the Hazardous Devices free of charge.

260. Defendants breached the express warranty promising to repair and correct a defect of workmanship and materials, and has been unable to repair or adjust the materials and workmanship defects of the Hazardous Devices.

261. Affording Defendants a reasonable opportunity to cure their breach of the written warranty would be unnecessary and futile here.

262. Furthermore, the limited warranty promising to repair and/or correct a defect of workmanship and materials fails in its essential purpose because the contractual remedy is insufficient to make Plaintiffs and the Class whole, and because Defendants have failed and/or have refused to adequately provide the promised remedies within a reasonable time.

263. Accordingly, recovery by Plaintiffs and the other proposed members of the Class is not limited to the limited warranty promising to repair and/or correct a defect, and Plaintiffs, individually and on behalf of the other proposed members of the Class, seeks all remedies as allowed by law.

264. Also, as alleged in more detail herein, at the time Defendants warranted and sold the Hazardous Devices, they knew that the Hazardous Devices did not conform to Defendants' warranties and were inherently defective, and Defendants wrongfully and fraudulently concealed material facts regarding their Hazardous Devices. Plaintiffs and the other members of the Class were therefore induced to purchase the Hazardous Devices under false and/or fraudulent pretenses.

265. Moreover, many of the injuries flowing from the Devices cannot be resolved through the limited remedy of repairs or replacements, as many incidental and consequential damages have already been suffered due to Defendants' fraudulent conduct as alleged herein.

Due to Defendants' failure and/or continued failure to provide such limited remedy within a reasonable time, any limitation on the Plaintiffs' and the Class' remedies would be insufficient to make Plaintiffs and the Class whole.

266. Defendants were provided notice of these issues by numerous complaints filed against them, including those submitted to FDA and the instant complaint, within a reasonable amount of time after the defect was discovered.

267. As a direct and proximate result of Defendants' breach of express warranty, Plaintiffs and the Class have sustained damages.

268. Plaintiffs and the Class seek actual damages, injunctive and declaratory relief, attorneys' fees, costs, and any other just and proper relief available thereunder for Defendants' failure to deliver goods conforming to their express warranties and resulting breach.

COUNT XVI
(Breach of Implied Warranty of Merchantability Against Defendants)

269. Plaintiffs incorporate by reference and realleges each and every allegation contained above, as though fully set forth herein.

270. Each Plaintiff brings this claim against each Defendant under the laws of the state where that Plaintiff lives. They each bring this claim individually and on behalf of a subclass that corresponds with the state in which each Plaintiff lives. Each Plaintiff also reserves his or her right to represent a multistate class that includes states with comparable applicable laws.

271. Defendants are and were at all relevant times merchants engaging in the sale of goods to Plaintiffs and the Class.

272. There was a sale of goods from Defendants to Plaintiffs and the Class.

273. A warranty that the Hazardous Devices were in merchantable condition is implied by law in the instant transactions. These devices, when sold and at all times thereafter, were not in merchantable condition and are not fit for the ordinary purpose for which such devices are

used. Specifically, the Hazardous Devices are inherently defective in their workmanship and materials in that they contained PE-PUR Foam.

274. Defendants were provided notice of these issues by complaints lodged by consumers with the FDA—which medical device manufacturers like Defendants routinely monitor—before or within a reasonable amount of time after the allegations of the Hazardous Devices defects became public.

275. As a direct and proximate result of Defendants' breach of the implied warranty of merchantability, Plaintiffs and the Class have sustained damages.

276. Plaintiffs and the Class seek actual damages, injunctive and declaratory relief, attorneys' fees, costs, and any other just and proper relief available under the laws.

COUNT XVII
(Fraudulent Misrepresentation Against Defendants)

277. Plaintiffs incorporate by reference and realleges each and every allegation contained above, as though fully set forth herein.

278. Each Plaintiff brings this claim against each Defendant under the laws of the state where that Plaintiff lives. They each bring this claim individually and on behalf of a subclass that corresponds with the state in which each Plaintiff lives. Each Plaintiff also reserves his or her right to represent a multistate class that includes states with comparable applicable laws.

279. Defendants falsely represented to Plaintiffs and the Class that the Hazardous Devices were safe for human use.

280. Defendants intentionally, knowingly, and recklessly made these misrepresentations to induce Plaintiffs and the Class to purchase the Hazardous Devices.

281. Defendants knew or should have known that their representations about the Hazardous Devices were false in that the Hazardous Devices contained PE-PUR Foam and were thus at risk of causing adverse health effects to Affected Users which does not conform to the

products' labels, packaging, advertising, and statements. Defendants knowingly allowed their packaging, labels, advertisements, promotional materials, and websites to intentionally mislead consumers, such as Plaintiffs and the Class.

282. Plaintiffs and the Class did in fact rely on these misrepresentations and purchased the Hazardous Devices to their detriment. Given the deceptive manner in which Defendants advertised, marketed, detailed, represented and otherwise promoted the Hazardous Devices, Plaintiff's and the Class' reliance on Defendants' misrepresentations was justifiable.

283. As a direct and proximate result of Defendants' conduct, Plaintiffs and the Class have suffered actual damages in that they purchased the Hazardous Devices that were worth less than the price they paid and that they would not have purchased at all had they known of the health risks, including cancer, associated with the use of the Hazardous Devices that do not conform to the Hazardous Devices' labels, packaging, advertising, and statements.

284. Plaintiffs and the Class seek actual damages, injunctive and declaratory relief, attorneys' fees, costs, and any other just and proper relief available under the laws.

COUNT XVIII
(Negligent Misrepresentation Against Defendants)

285. Plaintiffs incorporate by reference and realleges each and every allegation contained above, as though fully set forth herein.

286. Each Plaintiff brings this claim against each Defendant under the laws of the state where that Plaintiff lives. They each bring this claim individually and on behalf of a subclass that corresponds with the state in which each Plaintiff lives. Each Plaintiff also reserves his or her right to represent a multistate class that includes states with comparable applicable laws.

287. Defendants had a duty to Plaintiffs and the Class to exercise reasonable and ordinary care in the developing, testing, manufacture, marketing, detailing, distribution, and sale of the Hazardous Devices.

288. Defendants breached their duty to Plaintiffs and the Class by developing, testing, manufacturing, advertising, marketing, detailing, distributing, and selling products to Plaintiffs and the Class that did not have the qualities, characteristics, and suitability for use as advertised by Defendants and by failing to promptly remove the Hazardous Devices from the marketplace or take other appropriate remedial action upon becoming aware of the health risks of the Hazardous Devices.

289. Defendants knew or should have known that the qualities and characteristics of the Hazardous Devices were not as advertised, marketed, detailed, or otherwise represented or suitable for their intended use and were otherwise not as warranted and represented by Defendants. Specifically, Defendants knew or should have known that: (1) the use of Hazardous Devices was accompanied by risk of adverse health effects that do not conform to the packaging and labeling; (2) the Hazardous Devices were adulterated, or at risk of being adulterated, by the PE-PUR Foam; and (3) the Hazardous Devices were otherwise not as warranted and represented by Defendants.

290. As a direct and proximate result of Defendants' conduct, Plaintiffs and the Class have suffered actual damages in that they purchased Hazardous Devices that were worth less than the price they paid and that they would not have purchased at all had they known they contained PE-PUR Foam that could cause users of the Hazardous Devices to suffer adverse health effects that do not conform to the products' labels, packaging, advertising, and statements.

291. Plaintiffs and the Class seek actual damages, injunctive and declaratory relief, attorneys' fees, costs, and any other just and proper relief available.

COUNT XIX
(Fraudulent Concealment Against Defendants)

292. Plaintiffs incorporate by reference and realleges each and every allegation contained above, as though fully set forth herein.

293. Each Plaintiff brings this claim against each Defendant under the laws of the state where that Plaintiff lives. They each bring this claim individually and on behalf of a subclass that corresponds with the state in which each Plaintiff lives. Each Plaintiff also reserves his or her right to represent a multistate class that includes states with comparable applicable laws.

294. Defendants concealed from and failed to disclose to Plaintiffs and the Class that use of the Hazardous Devices is accompanied by a risk of adverse health effects that do not conform to the products' labels, packaging, advertising, and statements, or acted with reckless disregard for the truth, and denied Plaintiffs and the other Class members information that is highly relevant to their purchasing decision.

295. Defendants further affirmatively concealed from Plaintiffs in advertising, marketing, detailing and other forms of communication, including standard and uniform material provided with each Affected Device, that the Hazardous Devices they were selling had no defects, and would perform and operate properly when driven in normal usage.

296. Defendants knew at the time they actively concealed this information that this information was material.

297. The Devices purchased or leased or rented by Plaintiffs and the Class were, in fact, defective, unsafe, and unreliable because the Hazardous Devices contained PE-PUR Foam, as alleged herein.

298. Defendants owed Plaintiffs a duty to disclose the true safety, performance, and reliability of the Hazardous Devices, and the Defendants' devaluing of safety and performance, because Plaintiffs and the Class relied on Defendants' material representations that the Hazardous Devices they were purchasing were safe and free from defects.

299. Defendants were under a duty to disclose to Plaintiffs and the Class the true safety, quality, characteristics, fitness for use, and suitability of the Hazardous Devices because:

(1) Defendants were in a superior position to know the true state of facts about their Hazardous Devices; (2) Defendants were in a superior position to know the risks associated with the use of, characteristics of, and suitability of the Hazardous Devices for use by individuals; and (3) Defendants knew that Plaintiffs and the Class could not reasonably have been expected to learn or discover that Hazardous Devices were misrepresented in the packaging, labels, advertising, and websites prior to purchasing Hazardous Devices.

300. The aforementioned concealment was material because if it had been disclosed, reasonable consumers like Plaintiffs and the Class would not have bought Hazardous Devices, or would not have bought those Hazardous Devices at the prices they paid.

301. Plaintiffs and the Class justifiably relied on Defendants' reputation – along with Defendants' failure to disclose the faulty and defective nature of the PE-PUR Foam – in purchasing Defendants' Hazardous Devices.

302. Plaintiffs and the Class and Class justifiably relied on Defendants' omissions to their detriment. The detriment is evidence from the true quality, characteristics, and risk associated with the use of Hazardous Devices, which is inferior when compared to how Hazardous Devices are advertised and represented by Defendants.

303. As a result of their reliance, Plaintiffs and the other Class members have been injured in an amount to be proven at trial, including, but not limited to, their lost benefit of the bargain and overpayment at the time of purchase and/or the diminished value of their Hazardous Devices.

304. Defendants' conduct was knowing, intentional, with malice, demonstrated a complete lack of care, and was in reckless disregard for the rights of Plaintiffs and the other Class members. Plaintiffs and the Class members are therefore entitled to an award of punitive damages.

305. As a direct and proximate result of Defendants conduct, Plaintiffs and the Class suffered actual damages in that they purchased Hazardous Devices that were worth less than the price they paid and that they would not have purchased at all had they known of the health risks associated with the use of the Hazardous Devices which do not conform to the Hazardous Devices' labels, packaging, advertising, and statements.

306. Plaintiffs and the Class seek actual damages, injunctive and declaratory relief, attorneys' fees, costs, and any other just and proper relief available under the laws.

COUNT XX
(Unjust Enrichment Against Defendants)

307. Plaintiffs incorporate by reference and realleges each and every allegation contained above, as though fully set forth herein.

308. Each Plaintiff brings this claim against each Defendant under the laws of the state where that Plaintiff lives. They each bring this claim individually and on behalf of a subclass that corresponds with the state in which each Plaintiff lives. Each Plaintiff also reserves his or her right to represent a multistate class that includes states with comparable applicable laws.

309. To the extent required by law, this cause of action is alleged in the alternative to legal claims, as permitted under Fed. R. Civ. P. 8.

310. Plaintiffs and Class members conferred benefits on Defendant by purchasing the Affected Products.

311. Defendants were unjustly enriched in retaining the revenues derived from Plaintiffs and Class members' purchases of the Affected Products. Retention of those moneys under these circumstances is unjust and inequitable because Defendants failed to disclose that the Affected Products were unfit for their intended purpose. These omissions caused injuries to Plaintiffs and Class members because they would not have purchased the Products if the true facts were known.

312. Retention of those moneys also is unjust and inequitable because, as alleged above, Defendants commenced an ineffective recall that resulted in few returns, and generally no refunds, thereby protecting profits Defendants collected from selling the defective products.

313. Because Defendants' retention of the non-gratuitous benefits conferred on them by Plaintiffs and Class members is unjust and inequitable, Defendants must pay restitution to Plaintiffs and Class members for its unjust enrichment, as ordered by the Court.

COUNT XXI
(Strict Liability-Failure to Instruct or to Warn Against Defendants)

314. Plaintiffs incorporate by reference and realleges each and every allegation contained above, as though fully set forth herein.

315. Each Plaintiff brings this claim against each Defendant under the laws of the state where that Plaintiff lives. They each bring this claim individually and on behalf of a subclass that corresponds with the state in which each Plaintiff lives. Each Plaintiff also reserves his or her right to represent a multistate class that includes states with comparable applicable laws.

316. Defendants had a duty to instruct and/or to warn Plaintiffs and the Class regarding the defect and Dangers associated with the Hazardous Devices.

317. Defendants failed to provide adequate instructions and/or warnings regarding the risks of the PE-PUR Foam.

318. Defendants had information regarding the true risks but failed to instruct and/or to warn Plaintiff, the Class, their DME retailers, and their physicians to strengthen their instructions or warnings.

319. Despite Defendants' obligation to unilaterally strengthen the instructions or warnings, Defendants instead chose to actively conceal this knowledge.

320. Plaintiffs and Class members would not have purchased, chosen, and/or paid for all or part of the Hazardous Devices if they knew of the PE-PUR Foam and risks of purchasing the product.

321. This defect proximately caused Plaintiffs and the Class members' injuries which include economic injuries.

322. Based on the foregoing, Plaintiffs and the Class seek all damages permitted by law in an amount to be proven at trial.

COUNT XXII
(Strict Liability-Design Defect Against Defendants)

323. Plaintiffs incorporate by reference and realleges each and every allegation contained above, as though fully set forth herein.

324. Each Plaintiff brings this claim against each Defendant under the laws of the state where that Plaintiff lives. They each bring this claim individually and on behalf of a subclass that corresponds with the state in which each Plaintiff lives. Each Plaintiff also reserves his or her right to represent a multistate class that includes states with comparable applicable laws.

325. The design of the Hazardous Devices, including, but not limited to, design and use of the PE-PUR Foam and the placement of the PE-PUR Foam within the Hazardous Devices, was defective and unreasonably dangerous, causing degradation and inhalation and ingestion of the PE-PUR Foam, and causing Affected Users to risk experiencing headaches, irritation, inflammation, respiratory issues, and exposure to materials with toxic and carcinogenic effects.

326. The design of the Hazardous Devices and the PE-PUR Foam rendered the Devices not reasonably fit, suitable, or safe for their intended purpose, and rendered the Hazardous Devices of de minimis value.

327. The dangers of the Hazardous Devices outweighed the benefits and rendered the products unreasonably dangerous.

328. Safer, alternative devices from other manufacturers were available that did not suffer from the defect as set forth herein and that did not have an unreasonable risk of harm as with the Hazardous Devices and their PE-PUR Foam. Indeed, there are other CPAP and other machines that do not use a similarly PE-PUR Foam that is subject to degradation, inhalation, and ingestion.

329. The risk benefit profile of the Hazardous Devices was unreasonable, and the products should have had stronger and clearer warnings and/or instructions or should not have been sold in the market.

330. The Hazardous Devices did not perform as an ordinary consumer would expect. Based on the foregoing, Plaintiffs and the Class seek all damages permitted by law in an amount to be proven at trial.

COUNT XXIII
(Strict Liability-Manufacturing Defect Against Defendants)

331. Plaintiffs incorporate by reference and realleges each and every allegation contained above, as though fully set forth herein.

332. Each Plaintiff brings this claim against each Defendant under the laws of the state where that Plaintiff lives. They each bring this claim individually and on behalf of a subclass that corresponds with the state in which each Plaintiff lives. Each Plaintiff also reserves his or her right to represent a multistate class that includes states with comparable applicable laws.

333. At all times herein mentioned, Defendants were involved in researching, designing, developing, manufacturing, testing, selling and/or distributing the Hazardous Devices, which are defective and unreasonably dangerous.

334. The Hazardous Devices were expected to and did reach Plaintiffs without a substantial change in its condition.

335. The finished Hazardous Devices deviated, in terms of construction and production, from the specifications or planned output in a manner that made it unreasonably dangerous.

336. At all relevant times, the Hazardous Devices were defectively and improperly manufactured and designed by Defendants in that Defendants continued to supply consumers with the Hazardous Devices despite having full knowledge that the devices posed substantial and avoidable bodily injury, including cancer.

337. The foreseeable risks of the Hazardous Devices were known or should have been known by Defendants and could been avoided by Defendants.

338. The foreseeable risks of the Hazardous Devices were known or should have been known by Defendants and could been avoided by Defendants.

339. At all relevant times, the subject device was defectively manufactured by Defendants in that it is more dangerous than what an ordinary consumer would expect when used in an intended and reasonably foreseeable manner.

340. At all relevant times, Defendants actively deceived Affected Users that their use of the Hazardous Devices posed safety risks that far outweighed any benefits.

341. Furthermore, the Hazardous Devices were defectively manufactured in that their PE-PUR Foam component can degrade into dangerous toxic particles that enter the devices' air pathway and can off-gas certain chemicals. These characteristics cause, among other conditions, cancer. Plaintiffs and other similarly situated consumers were unknowingly subjected to receiving different doses of toxins, carcinogens, and other deleterious components and contaminants when using the devices.

342. As a direct and proximate result of the defective manufacture of the Hazardous Devices, Plaintiffs and the Class suffered and will continue to suffer damages for which they are

entitled to recovery, including but not limited to compensatory damages, consequential damages, interest, costs, and attorneys' fees.

COUNT XXV
(Negligent Manufacturing Defect Against Defendants)

343. Plaintiffs incorporate by reference and realleges each and every allegation contained above, as though fully set forth herein.

344. Each Plaintiff brings this claim against each Defendant under the laws of the state where that Plaintiff lives. They each bring this claim individually and on behalf of a subclass that corresponds with the state in which each Plaintiff lives. Each Plaintiff also reserves his or her right to represent a multistate class that includes states with comparable applicable laws.

345. Defendants negligently manufactured the Hazardous Devices. Defendants owed Plaintiffs and the Class a duty to manufacture the Hazardous Devices in a reasonable manner. The manufacture of the Hazardous Devices, including but not limited to the inclusion and placement of the PE-PUR Foam within the Hazardous Devices, was defective and unreasonably dangerous, causing degradation and inhalation and ingestion of the foam by Affected Users, and causing headaches, irritation, inflammation, respiratory issues, and exposure to materials with toxic and carcinogenic effects among Affected Users.

346. The manufacture of the Hazardous Devices to contain PE-PUR Foam rendered the Hazardous Devices not reasonably fit, suitable, or safe for their intended purpose.

347. The dangers of the Hazardous Devices outweighed the benefits and rendered the products unreasonable dangerous. Indeed, there are CPAP and other machines, including Defendants' other devices that do not use a similarly toxic foam that is subject to degradation, inhalation and ingestion.

348. Safer, alternative devices from other manufacturers were available that did not have an unreasonable risk of harm as with the Hazardous Devices and their PE-PUR Foam.

349. The risk benefit profile of the Hazardous Devices was unreasonable, and the products should have had stronger and clearer warnings and/or instructions or should not have been sold in the market.

350. The Hazardous Devices did not perform as an ordinary consumer would expect.

351. Plaintiffs and the Class suffered damages in an amount to be determined at trial.

COUNT XXVI
(Negligent Failure to Warn or to Instruct Against Defendants)

352. Plaintiffs incorporate by reference and realleges each and every allegation contained above, as though fully set forth herein.

353. Each Plaintiff brings this claim against each Defendant under the laws of the state where that Plaintiff lives. They each bring this claim individually and on behalf of a subclass that corresponds with the state in which each Plaintiff lives. Each Plaintiff also reserves his or her right to represent a multistate class that includes states with comparable applicable laws.

354. Defendants had a duty to instruct or to warn Plaintiffs and the Class regarding the defect and true risks associated with the Hazardous Devices.

355. Defendants failed to provide adequate instructions and/or warnings regarding the risks of the PE-PUR Foam in the Hazardous Devices.

356. Defendants had information regarding the true risks but failed to instruct and/or to warn Plaintiff, Class, their DME retailers, and their physicians to strengthen their warnings and/or instructions.

357. Despite Defendants' obligation to unilaterally strengthen the instructions and/or warnings, Defendants instead chose to actively conceal this knowledge.

358. Plaintiffs and the Class would not have purchased, chosen, and/or paid for all or part of the Hazardous Devices if they knew of the PE-PUR Foam and risks of purchasing the product.

359. This defect proximately caused injuries to the Plaintiffs and the Class which include economic injuries.

360. Plaintiffs and the Class suffered damages in an amount to be determined at trial.

COUNT XXVII
(Negligent Design Defect Against Defendants)

361. Plaintiffs incorporate by reference and realleges each and every allegation contained above, as though fully set forth herein.

362. Each Plaintiff brings this claim against each Defendant under the laws of the state where that Plaintiff lives. They each bring this claim individually and on behalf of a subclass that corresponds with the state in which each Plaintiff lives. Each Plaintiff also reserves his or her right to represent a multistate class that includes states with comparable applicable laws.

363. Defendants negligently designed the Hazardous Devices. Defendants owed Plaintiffs and the Class a duty to design the Hazardous Devices in a reasonable manner. The design of the Hazardous Devices, including but not limited to the design and placement of the PE-PUR Foam within the Devices, was defective and unreasonably dangerous, causing degradation and inhalation and ingestion of the foam by Affected Users, and causing headaches, irritation, inflammation, respiratory issues, and exposure to materials with toxic and carcinogenic effects among Affected Users.

364. The design of the Hazardous Devices to include the PE-PUR Foam rendered the products not reasonably fit, suitable, or safe for their intended purpose.

365. The dangers of the Hazardous Devices outweighed the benefits and rendered the products unreasonable dangerous.

366. Safer, alternative devices from other manufacturers were available that did not have an unreasonable risk of harm as with the Hazardous Devices and their PE-PUR Foam.

Indeed, there are CPAP and other machines that do not use a similarly toxic foam that is subject to degradation, inhalation and ingestion.

367. The risk benefit profile of the Hazardous Devices was unreasonable, and the products should have had stronger and clearer warnings and/or instructions or should not have been sold in the market.

368. The Hazardous Devices did not perform as an ordinary consumer would expect.

369. Plaintiffs and the Class suffered damages in an amount to be determined at trial.

PRAYER FOR RELIEF

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

a. An order declaring this action to be a proper class action, appointing Plaintiffs and their counsel to represent the Class, and requiring Defendants to bear the costs of class notice;

b. An order temporarily and permanently enjoining Defendants from continuing the unlawful, deceptive, fraudulent, and unfair business practices alleged in this Complaint;

c. Appropriate injunctive relief;

d. Equitable relief in the form of buyback of the Hazardous Devices;

e. Costs, restitution, damages, including statutory, penalties, and disgorgement in an amount to be determined at trial;

f. An order requiring Defendants to pay both pre- and post-judgment interest on any amounts awarded;

g. An award of costs and attorneys' fees; and

h. Such other or further relief as may be appropriate.

JURY TRIAL DEMANDED

Plaintiff demands a trial by jury on all claims so triable.

Dated: August 31, 2021

Respectfully submitted,

MAZOW & MCCULLOUGH, P.C.

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