IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

IN RE: PHILIPS RECALLED CPAP, BI-LEVEL PAP, AND MECHANICAL VENTILATOR PRODUCTS LITIGATION	Master Docket: No. 21-mc-1230-JFC
	MDL No. 3014
	(Oral Argument Requested)
This Document Relates to:	
Consolidated Third Amended Class Action Complaint for Economic Losses (ECF No. 785)	

MEMORANDUM OF LAW IN SUPPORT OF RESPIRONICS' AND THE PHILIPS DEFENDANTS' MOTION TO DISMISS UNDER RULE 12(b)(1) FOR LACK OF STANDING

John P. Lavelle, Jr. (PA54279)
john.lavelle@morganlewis.com
Lisa C. Dykstra (PA67271)
lisa.dykstra@morganlewis.com
MORGAN, LEWIS & BOCKIUS LLP
1701 Market Street
Philadelphia, PA 19103-2921

Wendy West Feinstein (PA86698)
wendy.feinstein@morganlewis.com
MORGAN, LEWIS & BOCKIUS LLP
One Oxford Center, 32nd Floor
Pittsburgh, PA 15219-6401

Counsel for Defendant Philips RS North America LLC

Michael H. Steinberg (CA143179)
steinbergm@sullcrom.com
SULLIVAN & CROMWELL LLP
1888 Century Park East
Los Angeles, CA 90067

Tracy Richelle High (NY3020096)
hight@sullcrom.com
William B. Monahan (NY4229027)
monahanw@sullcrom.com
SULLIVAN & CROMWELL LLP
125 Broad Street
New York, NY 10004

Counsel for Defendants Koninklijke Philips N.V., Philips North America LLC, Philips Holding USA, Inc., and Philips RS North America Holding Corporation

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Defendant Philips RS North America LLC ("Respironics") and Defendants Koninklijke Philips N.V., Philips North America LLC, Philips Holding USA, Inc., and Philips RS North America Holding Corporation (the "Philips Defendants") respectfully submit this memorandum in support of their motion to dismiss for lack of standing under Fed. R. Civ. P. 12(b)(1).

PRELIMINARY STATEMENT

Article III standing is not presumed. Yet, on their *third* attempt, Plaintiffs continue to fail to satisfy Article III's most basic requirements. None of the 112 Consumer Plaintiffs allege in the Third Amended Complaint (the "TAC") that their Continuous Positive Airway Pressure ("CPAP") or Bi-Level Positive Airway Pressure ("BiPAP") devices[1] malfunctioned, that the potential foam degradation issue that motivated Respironics' voluntary recall manifested in their devices, or that they experienced any actual problems with their individual devices at all. And any hypothetical risk of some injury manifesting in the future has been addressed by the Respironics recall. When a product—even a recalled product—performs as designed for some users, courts reject efforts to pair putative class actions alleging economic losses with individual tort claims brought by users who actually allege they experienced harm. That must be the result here as well.

This Motion presents the following jurisdictional issues: *First*, do the 112 Consumer Plaintiffs have Article III standing to assert claims when their only allegation is that they are due money because their devices were voluntarily recalled, and not because their product failed to perform or that they experienced any issues with their devices at all. The answer is no. Neither a recall by itself, nor an asserted but unmanifested defect, suffices to create a legal injury entitling

[1] Although the Respironics recall also involved certain ventilator devices, only the two hospital plaintiffs allege that they acquired ventilator devices. TAC ¶¶ 26-27.

Plaintiffs to recover *economic* damages. This is particularly so where, as here, Respironics has undertaken to repair or replace devices subject to the recall, as authorized by the FDA.

The same fundamental legal question applies to the ten Commercial Plaintiffs identified in the TAC,[2] as each fails to plead basic elements of Article III standing. For the two hospital plaintiffs, which used devices they purchased to treat multiple patients, there is no plausible claim that the mere purchase of the device—without more (such as an actual manifestation of the defect)—constitutes an economic loss. Nor can any injury alleged by the TPPs, or the even more attenuated MSP recovery entities, supply the basis for Article III standing for the same reasons, plus a host of intervening events and relationships that break any plausible causal chain.

Second, is there a Constitutional "case or controversy" for Plaintiffs to pursue a claim under the laws of the District of Columbia, Nebraska, North Dakota, South Dakota, Wyoming or any U.S. territory (other than Puerto Rico), where there are no Plaintiffs named in the TAC who allege they reside in these jurisdictions? And, relatedly, is there a "case of controversy" under Article III for Plaintiffs to seek relief for Respironics products no Plaintiff claims to have acquired? The answer to both questions also must be no.

ALLEGATIONS OF THE COMPLAINT

CPAP and BiPAP devices are prescribed to treat sleep apnea and other respiratory conditions by delivering pressurized air into a user's air pathway while they sleep. TAC ¶ 201. Respironics made the first commercially available CPAP device in 1985 and continued to manufacture and sell CPAP and BiPAP devices after its acquisition by Koninklijke Philips N.V.

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[2] The Commercial Plaintiffs consist of two hospitals, two third-party payors ("TPPs"), and six assignee recovery entities (collectively referred to as "MSP"), who allege that they acquired the right to seek claims on behalf of mostly unidentified TPP assignors. TAC ¶¶ 26-27, 136-50.

in 2008. TAC ¶ 206. Respironics' products are prescription medical devices that individuals can only acquire on the recommendation of a doctor. TAC ¶¶ 500, 582, TAC Ex. 47 at 1, 23.

On June 14, 2021, Respironics initiated a voluntary recall of certain of its devices "out of an abundance of caution." TAC ¶¶ 380-81. Shortly after the recall, the FDA notified patients to consult with their prescribing physicians to determine suitable treatment, which could include continued use of a recalled device.[3] Since the recall, Respironics has instituted a remediation program under which consumers can register to have their devices repaired or replaced—all at no cost to them. *E.g.*, TAC ¶ 415.

ARGUMENT

In this Circuit,[4] "[s]tanding consists of both a 'case or controversy' requirement stemming from Article III, Section 2 of the Constitution, and a subconstitutional 'prudential' element." *Pitt News v. Fisher*, 215 F.3d 354, 359 (3d Cir. 2000). Article III standing is the proper subject of a Rule 12(b)(1) motion. *See Potter v. Cozen O'Connor*, 46 F.4th 148, 153-57 (3d Cir. 2022). The absence of Article III standing requires dismissal. *See* Fed. R. Civ. P. 12(b)(1).

To survive a Rule 12(b)(1) challenge, a plaintiff must plead facts showing: "(i) that he suffered an injury in fact that is concrete, particularized, and actual or imminent; (ii) that the injury was likely caused by the defendant; and (iii) that the injury would likely be redressed by judicial relief." *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2203 (2021). Each named plaintiff bears the individual burden of pleading facts sufficient to support his, her or its standing. *See id.* at 2207-08; *DaimlerChrysler Corp.* v. *Cuno*, 547 U.S. 332, 342 n.3, 352 (2006) ("[T]he standing inquiry

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[3] *See* https://www.fda.gov/medical-devices/safety-communications/certain-philips-respironics-ventilators-bipap-and-cpap-machines-recalled-due-potential-health-risks.

[4] An MDL court sitting in this Circuit applies its own law, not the law of the transferor court, on questions of subject matter jurisdiction and standing. *See, e.g., In re Linerboard Antitrust Litig.*, No. Civ. A. 04-4001, 2005 WL 1625040, at *4 (E.D. Pa. July 11, 2005) (collecting cases).

requires careful judicial examination of a complaint's allegations to ascertain whether the particular plaintiff is entitled to an adjudication of the particular claims asserted.") (cleaned up); *Lewis v. Casey*, 518 U.S. 343, 358 n.6 (1996) ("[S]tanding is not dispensed in gross.").

Defendants may launch a standing challenge through either a facial or a factual attack. In a threshold facial attack, as here, the defendant "attacks the complaint on its face without contesting its alleged facts." *Hartig Drug Co.* v. *Senju Pharms. Co.*, 836 F.3d 261, 268 (3d Cir. 2016). This motion presents a facial attack given the total absence of any allegations in the TAC establishing that any Plaintiffs suffered a concrete and particularized economic injury. *See Spokeo, Inc.* v. *Robins*, 578 U.S. 330, 339-40 (2016).[5]

I. ALL OF THE PLAINTIFFS FAIL TO ALLEGE AN INJURY-IN-FACT.

A. None of the Plaintiffs Allege They Experienced Any Problem with Their Specific Devices.

In rote fashion, the TAC repeats substantially the same allegation for each Plaintiff: "[H]ad Plaintiff been aware of the Defect . . . Plaintiff would not have paid for the device." TAC ¶¶ 22-137. Yet, the TAC is devoid of ***any*** allegation that the potential issues that motivated the voluntary recall manifested in any Plaintiff's device. Nor does any Plaintiff allege that they registered to receive a repaired or replacement device from Respironics and that Respironics declined to provide them with one. These are meaningful omissions from the TAC, especially because Defendants raised precisely these same issues when Defendants moved to dismiss Plaintiffs' Second Amended Complaint.[6]

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[5] Thus far in this litigation, Plaintiffs have also refused to make their devices available for visual inspection by Defendants, effectively precluding Defendants from making a factual attack. Defendants reserve the right to raise a factual attack in the future.

[6] Defendants' Motion to Dismiss the Second Amended Complaint on 12(b)(1) grounds was ECF No. 721.

Plaintiffs again rely exclusively on the existence of the voluntary recall to allege injury. This invites error: it is well-settled that Plaintiffs cannot use the existence of a recall as a proxy to establish their own individual injury-in-fact in the "personal and unique way" required by the U.S. Supreme Court. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992); *see also, e.g.*, *In re McNeil Consumer Healthcare, Mktg. & Sales Pracs. Litig.*, No. MDL 2190, 2011 WL 2802854, at *14 (E.D. Pa. July 15, 2011) (dismissing plaintiffs' claims "in their entirety for lack of standing" where "[t]he mere purchase of Recalled Subject Products . . . cannot be sufficient to establish injury-in-fact"). "[T]he mere existence of a recall does not prove that any individual's [product] actually contained a nonconformity." *Burbank v. BMW of N. Am., LLC*, No. CV2101711KMESK, 2022 WL 833608, at *9 (D.N.J. Mar. 21, 2022). This is particularly the case where, as here, purchasers of a recalled product "are not in a monolithic category": the recall was motivated by the potential for an issue which may or may not manifest in any given device. *McNeil Consumer Healthcare*, 2011 WL 2802854, at *14; *see Heard v. FCA US LLC*, No. 18-912, 2020 WL 1285743, at *3 (N.D. Ala. Mar. 16, 2020) (A "recall notice, without more, does not give rise to a reasonable inference that [a product] was defective") (collecting cases); *Hughes v. Stryker Sales Corp.*, No. 08-0655, 2010 WL 1961051, at *4 (S.D. Ala. May 13, 2010) ("[P]laintiff does not explain how the mere fact of a product recall gives rise to a reasonable inference that the actual device implanted in [plaintiff] had a defect.").

Where, as here, economic injury is alleged to result from the purchase of a product, the Third Circuit has held that a plaintiff "must do more than simply characterize her purchases as economic injuries; she must allege facts that would permit a factfinder to determine that the economic benefit she received in purchasing her [products] was worth less than the economic benefit for which she bargained." *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales*

Pracs. & Liab. Litig., 903 F.3d 278, 293 (3d Cir. 2018) ("[I]njuries suffered by *others* do not permit us to conclude that [plaintiff] has *herself* suffered an injury in fact."). The weight of judicial authority nationwide confirms that where, as here, plaintiffs fail to allege that the particular product they purchased manifested a defect, they have not pled Article III standing. *See, e.g.*, *Damonie Earl et al. v. The Boeing Co. et al.*, No. 21-40720, 2022 WL 17088680, at *5 (5th Cir. Nov. 21, 2022) (holding that where "plaintiffs complain of a past risk of physical injury to which they were allegedly exposed because of" a defect in airplane design but "that risk never materialized, plaintiffs have suffered no injury in fact and lack Article III standing"); *Hadley v. Chrysler*, 624 F. App'x 374, 378 (6th Cir. 2015) (plaintiffs cannot simply conclude that "when there's a major safety defect, diminished value is commonsense"); *Wallace v. ConAgra Foods*, 747 F.3d 1025, 1030 (8th Cir. 2014) (plaintiff must do more than "allege that a product line contains a defect or that a product is at risk for manifesting this defect; rather, the plaintiffs must allege that their product *actually exhibited* the alleged defect").[7] This significant pleading deficiency applies to all Plaintiffs and requires dismissal.

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[7] *See also, e.g., Rivera v. Wyeth-Ayerst Lab'ys*, 283 F.3d 315, 319 (5th Cir. 2002) (plaintiffs never defined their economic injury as anything other than requesting their money back); *Briehl v. General Motors*, 172 F.3d 623, 628 (8th Cir. 1999) (where "a product performs satisfactorily and never exhibits an alleged defect, no cause of action lies"); *Johannessohn v. Polaris Indus.*, 9 F.4th 981, 988 (8th Cir. 2021) ("[P]laintiffs claiming economic injury do not have Article III standing in product defect cases unless they show a manifest defect."); *O'Neil v. Simplicity, Inc.*, 553 F. Supp. 2d 1110, 1116 (D. Minn. 2008), *aff'd*, 574 F.3d 501 (8th Cir. 2009) ("That the [product] has been recalled, therefore, does not ipso facto mean that the [product] has a manifest defect sufficient to permit [plaintiffs'] claims to proceed.") (collecting cases); *In re Polaris*, 364 F. Supp. 3d 976, 984 (D. Minn. 2019) (dismissing claims of those plaintiffs who did not experience vehicle issues, despite existence of a recall); *In re McNeil Consumer Healthcare*, 877 F. Supp. 2d 254, 271 (E.D. Pa. 2012) (dismissing claims for lack of standing where "[n]o plaintiff alleges facts" that would

B. Plaintiffs' Conclusory Allegations that the Devices Are "Worthless" Are Factually and Legally Insufficient to Establish Injury.

To avoid the natural conclusion that there has been no economic injury because the products performed as intended, Plaintiffs argue that their devices were "worthless" from the moment of purchase, effectively because they were subsequently recalled. This attempt to manufacture standing and end-run their pleading obligations fails in all respects.

First, because the TAC lacks ***any*** allegations that Plaintiffs' recalled devices manifested any defect or did not work for their intended purpose, the assertions that these recalled devices were "worthless" lack any plausible factual basis. *See, e.g.*, *McNeil Consumer Healthcare*, 2011 WL 2802854, at *14 ("[I]ndividuals who consume defective products cannot sue for economic damages unless the products failed to work as intended," because standing requires a plaintiff to "allege[] that her own product manifested [a] defect or that she had suffered [a] specific injury."); *Rivera v. Wyeth-Ayerst Lab'ys*, 283 F.3d 315, 320 (5th Cir. 2002) (no standing because the product worked as intended).[8]

Second, Respironics has undertaken a significant remediation program through which consumers can register to have their devices repaired or replaced—at no cost to them—plus receive

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show the product it failed to perform as intended); *Myers-Armstrong v. Actavis Totowa, LLC*, No. 08-04741, 2009 WL 1082026, at *4 (N.D. Cal. Apr. 22, 2009) (purchasing, without incident, medicine from "a plant whose quality-control had been compromised" does not give rise to injury); and *Williams v. Purdue Pharma*, 297 F. Supp. 2d 171, 176 (D.D.C. 2003) (plaintiffs failed to allege facts demonstrating that their product "failed to perform as advertised.").

[8] In fact, more than 15% of the Consumer Plaintiffs used their devices beyond their five-year useful life with no allegation of a manifested defect or any malfunctioning during that time. Accepting for purposes of this Motion that the useful life of the devices is the five years that Plaintiffs reference (TAC ¶ 410), at least twenty Plaintiffs plead they purchased their device five or more years before the Recall, including one acquiring his device "in or around 2007 or 2008" (TAC ¶ 97). TAC ¶¶ 32, 38, 40, 47-48, 55-56, 65, 68, 74, 85, 87, 97, 102-04, 111, 124-25, 128.

a new warranty for the repaired or replaced device.[9] The existence of the remediation program contravenes Plaintiffs' alleged economic loss, as set forth in more detail in Section II below. As a result, Plaintiffs' allegation that their devices are "worthless" is entirely implausible.

Third, although Plaintiffs contend that the recalled devices are "worthless" because they are "adulterated" or "misbranded" under applicable FDA regulations, *see* TAC ¶¶ 248-54, the prophylactic function of the recall under the Food, Drug & Cosmetic Act (the "FDCA") cannot give rise to a cognizable injury. *See Transunion*, 141 S. Ct. at 2206 ("[I]f the law of Article III did not require plaintiffs to demonstrate a 'concrete harm,' Congress could authorize virtually any citizen to bring a statutory damages suit against virtually any defendant who violated virtually any federal law."). Were Plaintiffs' position viable, any recall under the FDCA would require the manufacturer to reimburse all consumers for all sums paid for their devices (regardless of whether they manifested a defect), rather than repair the devices. That result is inconsistent with, *inter alia*, the FDCA, case law concerning recalls of products overseen by the FDA, and preemption jurisprudence. *See, e.g.*, *McNeil Consumer Healthcare*, 2011 WL 2802854, at *13 (rejecting claim that "mere purchase of the Recalled Subject Products, in and of itself, is sufficient to establish injury-in-fact"); Mem. of Law in Support of Respironics' Mot. to Dismiss Pursuant to Rule 12(b)(6), Section I.[10]

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[9] *See* TAC ¶¶ 17, 415; *see also* TAC Exs. 34-35 (providing links to an FAQ and to www.philips.com/SRC-update and www.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/en_US/philips-faqs-for-dme-hcp.pdf-us-2021-11-16.pdf ("All refurbished and new units come with a two-year warranty," and "[a]ll repaired units (RP Kit) come with a one-year warranty (parts are covered for one year and labor is covered for 90 days")).

[10] Plaintiffs' reliance on FDA regulations to allege injury reinforces the conclusion that their claims are preempted by federal law. *See* Mem. of Law in Support of Respironics' Mot. to Dismiss Pursuant to Rule 12(b)(6), Section I. This is particularly so because the FDCA expressly precludes private enforcement by parties like Plaintiffs. *See, e.g.*, 21 U.S.C. § 337(a).

C. The Commercial Plaintiffs Have Not Alleged Harm to Their Commercial Interests.

The claims of the Commercial Plaintiffs fail for these same reasons, and the additional reasons below.

1. *The Commercial Plaintiffs Do Not Allege Economic Harm.*

As the most basic of matters, the TAC does not allege facts plausibly demonstrating that the Commercial Plaintiffs *are worse off financially* because of anything Respironics did. The hospitals allege only that they paid for devices subject to the voluntary recall. TAC ¶¶ 26-27. The TPPs and related MSP assignee recovery entities allege only that they "paid for or reimbursed" or were otherwise "financially responsible" for recalled devices for their insureds. *Id.* ¶¶ 136-46. To support standing, the Commercial Plaintiffs rely on the repeated conclusory refrain that they suffered "an ascertainable loss of money or property," but never explain this purported loss or plead any facts in support of it. *See Cottregll v. Alcon Lab'ys*, No. CIV.A. 14-5859 FLW, 2015 WL 3889367, at *3 (D.N.J. June 24, 2015) ("[A] demand for damages, by itself, will not establish an injury-in-fact."); *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) ("Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.").

In fact, the TAC's unexplained allegations of a pecuniary loss are facially implausible. The hospitals do *not* allege they incurred additional expenses, could not provide any services, or lost any revenue due to the Respironics recall. The hospitals would have, in fact, obtained revenue as a result of the presence of ventilators and other devices, further rendering any allegation of economic loss implausible. The TPPs and related MSP recovery assignee entities similarly do not allege financial harm. Nor is it clear how they could. "TPPs are entities that pay or provide reimbursement for all or some of the cost" of a drug or medical device "for people whom they insure," *In re Restasis (Cyclosporine Ophthalmic Emulsion) Antitrust Litig.*, 335 F.R.D. 1, 10

(E.D.N.Y. 2020), funded by revenue from premiums paid by their insureds or plan sponsors. *See* TAC ¶ 136 n.18. Thus, the TAC's allegations amount to nothing more than that the TPPs met their obligations by providing the devices to their insureds, and that the devices the TPPs provided are being replaced. *See* TAC ¶¶ 136-37, 146-49.[11] Because no details are supplied to support any genuine economic harm, the TAC's conclusory allegations are insufficient.

2. *The TPPs Do Not Allege a Connection Between Their Alleged Injury and Any Wrongdoing by Defendants.*

In the Third Circuit, for an injury to be "fairly traceable" to defendant's conduct for purposes of Article III standing, plaintiff must plead a level of causation "akin to but-for causation, not proximate causation." *Adam v. Barone*, 41 F.4th 230, 235 (3d Cir. 2022). "But-for causation is established whenever an injury would not have occurred without the alleged action or event." *Id*. at 235 n.5 (citing *Univ. of Tex. S.W. Med. Ctr. v. Nassar*, 570 U.S. 338, 346-47 (2013)).

Here, the TPPs do not even attempt to allege but-for causation. They simply allege that they would not have paid or reimbursed for the devices, and that physicians "would not have prescribed" the devices, if they had been "aware of the Defect."[12] TAC ¶¶ 136-37, 146. The connection between Respironics and the TPPs' reimbursement for insureds is far too attenuated.

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[11] Ohio Carpenters alone among the TPPs alleges that because its beneficiaries "were not *immediately* provided by Philips with non-defective breathing devices, Ohio Carpenters also paid for replacement devices not manufactured by Philips." TAC ¶ 137 (emphasis added). Key facts are missing to show such purchases amount to a loss, such as whether Ohio Carpenters was obligated to make such payments (or chose voluntarily to do so), whether the insured user's device had manifested a defect, or whether the devices Ohio Carpenters replaced were beyond their useful life and therefore subject to replacement by Ohio Carpenters in the normal course of business in any event.

[12] The TAC also fails to address, or account for, the reality that the TPPs would have, pursuant to their obligations to beneficiaries, had to purchase a device for their beneficiaries and had to incur expenses for some form of device. *See, e.g.*, *In re Guidant Corp. Implantable Defibrillators Prod. Liab. Litig.*, 484 F. Supp. 2d 973, 982, 984 (D. Minn. 2007) (dismissing TPP claims in circumstances where there was "no allegation that the named TPP Plaintiffs had any role in selecting which devices a patient should receive.")

See, e.g., *United Food & Comm. Workers Cent. Penn. & Reg'l Health & Welfare Fund* v. *Amgen Inc.*, 400 F. App'x 255, 257 (9th Cir. 2010) (affirming dismissal of TPP claim because "the complaint proffered an attenuated causal chain…" separating the defendants' alleged fraud and TPPs' injuries); *Laborers Local 17 Health & Benefit Fund* v. *Philip Morris*, 191 F.3d 229, 244 (2d Cir. 1999) (rejecting TPPs standing as "the economic injuries alleged . . . [are] too remote as a matter of law for them to have standing").

In similar circumstances, federal courts have routinely held that any injury suffered by a TPP could not fairly be traced to the defendant's misconduct where the individual prescribing decisions of physicians were a key link in the causal chain. For instance, in *In re Guidant Corp. Implantable Defibrillators Prod. Liab. Litig.*, the court dismissed as "too speculative to establish a causal link" the TPP plaintiffs' claim that their injury flowed from "the independent choices of the doctors who recommend the devices to their patients and on the patients who decide to receive the devices, in lieu of other treatment options, if any." 484 F. Supp. 2d at 984.

3. *The TPPs Impermissibly Seek Duplicative or Derivative Recovery.*

That the TPP and recovery Plaintiffs lack standing to sue is further reinforced by the fact that they seek both duplicative recovery to that sought by the consumer Plaintiffs and that they seek to sue in a derivative manner, which they, as a matter of law lack the ability to do.

First, by claiming to sue on behalf of its or its assignors' insureds, who also directly seek recovery from Defendants, the TPP Plaintiffs and recovery entities seek to bring overlapping and duplicative claims for relief. The TAC makes plain that the TPP and recovery entities seek to recover the very same amounts that the individual consumer plaintiffs seek to recover. *See, e.g.*, TAC ¶ 137 (stating "Ohio Carpenters seeks full reimbursement of all out-of-pocket costs associated with paying or reimbursing for the Recalled Devices for itself **and its Beneficiaries**") (emphasis added); TAC ¶¶ 138, 140 (alleging the recovery entities right to pursue assigned claims

and that they were assigned the right to pursue recovery on behalf the assignor's "**Enrollees**") (emphasis added). If there is any injury and basis for recovery in this case—and there is not—both TPPs and their insureds cannot sue for the exact same alleged loss. *See SEIU v. Phillip Morris*, 249 F.3d 1068, 1073-74 (D.C. Cir. 2001) ("allowing [TPP] claims to proceed would create a risk of multiple recoveries and necessitate complicated rules for apportioning damages between" TPPs and their insureds).

Second, the TPP and recovery entity Plaintiffs face other standing problems. Some TPPs make a blanket allegation of a right to sue for their beneficiaries, ignoring the "settled rule" among federal courts that bars "direct suits by third parties seeking to recover the costs of medical care paid on behalf of individuals injured as a result of an alleged tortfeasor's conduct." *SEIU*, 249 F.3d at 1073; *see Perry v. Am. Tobacco*, 324 F.3d 845, 849 (6th Cir. 2003) (collecting cases). The TPPs' and recovery entities' claims, on their own terms, are *derivative* of their insureds' claims and are thereby a prohibited attempt to recover the expense of a medical device the TPP reimbursed. *See, e.g.*, *Seibels Bruce Grp., Inc. v. R.J. Reynolds Tobacco Co.*, No. C-99-0593 MHP, 1999 WL 760527, at *3 (N.D. Cal. Sept. 21, 1999) ("It is well established that insurers . . . may not bring direct claims based on the injuries of their claimants.") (citations omitted).

II. PLAINTIFFS DO NOT ALLEGE THAT THE RESPIRONICS REPAIR AND REPLACEMENT PROGRAM FAILED TO ADDRESS ANY HYPOTHETICAL ECONOMIC INJURY.

The TAC admits that Respironics has offered a *no-cost* repair and replacement program. *See, e.g.*, TAC ¶¶ 415, 418. Yet, no Plaintiff pleads that they registered for the program, let alone that they were denied a repaired or replacement device pursuant to it. The existence of the free repair and replacement program deprives Plaintiffs of standing to advance their claims. *See Johnson v. Guhl*, 357 F.3d 403, 412 (3d Cir. 2004) (plaintiffs did not have standing because they were offered a remedy); *Hadley v. Chrysler*, No. 13-cv-13665, 2014 WL 988962, at *5 (E.D. Mich.

Mar. 13, 2014), *aff'd*, 624 F. App'x 374 (6th Cir. 2015) (no standing where defendant promised to repair product free of charge); *In re McNeil Consumer Healthcare*, 877 F. Supp. 2d 254, 275 (E.D. Pa. 2012) (no standing for class of plaintiffs eligible for a refund who did not seek one because, absent any allegation of a denied or inadequate refund, there is "[n]o fact alleged by any of these plaintiffs [that] plausibly establishes that they suffered an injury").

Plaintiffs attempt to undermine the repair and replacement program by advancing the generalized and conclusory allegation that the program has been "slow." TAC ¶¶ 414-18. However, no Plaintiff even alleges they registered for the program, much less had to wait an unreasonable period of time to receive a repaired or replacement device. Rather, certain Plaintiffs merely allege that "because Plaintiff was not ***immediately*** provided by Philips with a non-defective breathing device, Plaintiff paid for a replacement device not manufactured by Philips." *E.g.*, TAC ¶ 23. Any individual Plaintiff's decision to buy a new device cannot give rise to an economic injury absent some facts—of which none are pled—to suggest an immediate replacement was necessary.[13]

III. PLAINTIFFS LACK STANDING TO ASSERT CLAIMS UNDER THE LAWS OF CERTAIN STATES AND TERRITORIES.

There are *no* named Plaintiffs who are citizens of, or who claim to have acquired their devices in, the District of Columbia, Nebraska, North Dakota, South Dakota, Wyoming or any U.S. territory other than Puerto Rico. *See* TAC ¶¶ 428-29, 477. Thus, no constitutional "case or controversy" exists, and accordingly, Counts 3, 4, 5, 6, 8, and 9 must be dismissed to the extent they are based on the laws of those states or territories, and Counts 21, 47, 48, 55, 62, and 72 must

[13] This is particularly the case for the more than 15% of the Consumer Plaintiffs who used their devices beyond their five-year useful life, with no allegation of a manifested defect or any malfunctioning during that time. *See* supra note 8.

be dismissed in their entirety. *See, e.g.*, *In re Packaged Ice Antitrust Litig.*, 779 F. Supp. 2d 642, 657 (E.D. Mich. 2011) (collecting cases); *In re Flash Memory Antitrust Litig.*, 643 F. Supp. 2d 1133, 1164 (N.D. Cal. 2009) ("Where . . . a representative plaintiff is lacking for a particular state, all claims based on that state's laws are subject to dismissal.").

IV. PLAINTIFFS LACK STANDING TO ASSERT CLAIMS FOR DEVICE MODELS THEY DID NOT PURCHASE.

Plaintiffs seek to bring a class action on behalf of consumers of each of the recalled products listed in Paragraph 6 of the TAC. TAC ¶¶ 5-6, 21, 428-29. But no named Plaintiff claims to have purchased, paid or reimbursed for, or otherwise acquired, an (1) E30; (2) DreamStation ASV; (3) DreamStation ST, AVAPS; (4) SystemOne ASV4; (5) C Series ASV, S/T, AVAPs; (6) Dorma 400, 500 CPAP; (7) REMStar SE Auto CPAP; (8) Trilogy 100 and 200; (9) Garbin Plus, Aeries, LifeVent; (10) A-Series BiPAP Hybrid A30; (11) A-Series BiPAP V30 Auto; (12) A-Series BiPAP A40; or (13) A-Series BiPAP A30.[14] All claims brought on behalf of any absent class member who purchased or otherwise acquired these thirteen types of devices should be dismissed for lack of standing. *See, e.g.*, *Snyder v. Green Roads*, 430 F. Supp. 3d 1297, 1303 (S.D. Fla. 2020) ("Plaintiffs do not have standing to assert claims based on the marketing of products that they did not purchase."); *Kisting v. Gregg Appliances*, 2016 WL 5875007, at *4 (E.D. Wis. Oct. 7, 2016) ("[A]n individual does not have standing to bring claims for products he did not purchase.").

[14] Further, some Plaintiffs do not even allege what device models they allegedly purchased or reimbursed for. *See* TAC ¶¶ 136, 137, 139, 141–45.

CONCLUSION

Defendants respectfully request that the Court dismiss the TAC in its entirety with prejudice.[15]

[15] Dismissal should be with prejudice. The TAC represents Plaintiffs' *third* attempt to plead their economic loss claims, and Plaintiffs should not be afforded a fourth bite at the apple, especially when Defendants raised these arguments in response to Plaintiffs' second attempt to plead standing. *See Mann* v. *Brenner*, 375 F. App'x 232, 240 n.9 (3d Cir. 2010) (affirming dismissal of second amended complaint with prejudice and denial of leave to amend because "allowing [plaintiff] a fourth bite at the apple would be futile").

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Respectfully submitted,

/s/ John P. Lavelle, Jr
John P. Lavelle, Jr. (PA54279)
john.lavelle@morganlewis.com
Lisa C. Dykstra (PA67271)
lisa.dykstra@morganlewis.com
MORGAN, LEWIS & BOCKIUS LLP
1701 Market Street
Philadelphia, PA 19103-2921
Tel: 215.963.5000

Wendy West Feinstein (PA86698)
wendy.feinstein@morganlewis.com
MORGAN, LEWIS & BOCKIUS LLP
One Oxford Center, 32nd Floor
Pittsburgh, PA 15219-6401
Tel: 412.560.3300

Counsel for Defendant Philips RS North America LLC

/s/ Michael H. Steinberg
Michael H. Steinberg (CA143179)
steinbergm@sullcrom.com
SULLIVAN & CROMWELL LLP
1888 Century Park East
Los Angeles, CA 90067
Tel: 310.712.6670

Tracy Richelle High
hight@sullcrom.com
William B. Monahan (NY4229027)
monahanw@sullcrom.com
SULLIVAN & CROMWELL LLP
125 Broad Street
New York, NY 10004
Tel: 212.558.4000

Counsel for Defendants Koninklijke Philips N.V., Philips North America LLC, Philips Holding USA, Inc., and Philips RS North America Holding Corporation

CERTIFICATE OF SERVICE

I hereby certify that on December 6, 2022, the foregoing document was electronically filed with the Clerk of the Court and served upon counsel of record through the Court's ECF system.

/s/ John P. Lavelle, Jr.
John P. Lavelle, Jr.