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: Misc. No. 21-1230
This Document Relates to: All Actions	)	MDL No. 3014

BRIEF IN SUPPORT OF EMERGENCY MOTION OF DEFENDANT PHILIPS RS NORTH AMERICA LLC TO STAY OR AMEND PORTIONS OF PARAGRAPH 13 OF PRETRIAL ORDER #1 OR, IN THE ALTERNATIVE, FOR EMERGENCY HEARING FOR RELIEF WITH RESPECT TO FDA RECALL REMEDIATION

Defendant Philips RS North America LLC ("Respironics"), through its undersigned counsel, respectfully moves for immediate emergency relief regarding Paragraph 13 of Pretrial Order #1 (ECF No. 4, the "Order") governing preservation of evidence, but only to the extent Paragraph 13 (a) prohibits Respironics from continuing to rework and replace recalled devices as required by the U.S. Food and Drug Administration ("FDA") (the "FDA Recall Remediation"), and/or (b) precludes Plaintiffs or any other putative class members from submitting their recalled devices to Respironics for replacement or repair as part of the FDA Recall Remediation. Respironics is providing a copy of this emergency motion to the FDA.

A. The FDA Recall Remediation.

This MDL litigation arises from Respironics' June 14, 2021 recall of prescription medical devices, including CPAP, Bi-Level PAP and mechanical ventilator devices, which are regulated by the FDA in the United States. Throughout the recall and the development of the FDA Recall Remediation, Respironics has coordinated and continues to coordinate with the FDA. The FDA initially approved the Recall Remediation on August 16, 2021. The FDA Recall Remediation

requires Respironics to provide users of the recalled devices with new or remediated devices pursuant to certain defined timelines and protocols.

Pursuant to the Recall Remediation, the FDA is requiring Respironics to recall devices, remove the original PE-PUR sound abatement foam, and replace the devices with repaired or new devices containing FDA-approved replacement foam. In order to repair and replace the devices, it is necessary for Respironics to collect recalled devices and remediate those devices with FDA-approved replacement foam given the limited availably of new devices.

As of November 12, Respironics has received approximately 335,000 recalled devices from users. Respironics has returned approximately 115,000 reworked devices to users. Respironics currently is reworking about 2,500 devices per working day and is increasing capacity to enable it to rework up to 5,500 devices per day. Before this Court's Order on November 10, 2021, Respironics had anticipated that between November 12 and the initial case management conference set for December 15, it could have reworked approximately 56,500 devices.

B. The Order's Evidence Preservation Provisions Conflict With The FDA Recall Remediation and Ongoing Rework and Replacement of Recalled Devices.

The Court did not have this background before it entered the Order on November 10, 2021.[1] Paragraph 13 of the Order imposes broad obligations on the parties to preserve evidence that "may be relevant to this action." Order ¶ 13. In particular, Paragraph 13 provides that before any "tangible things" are "destroyed" or "altered," the parties must meet and confer "to resolve questions about whether the information should be preserved." *Id.* If the parties are

[1] By necessity and as is customary in an MDL, the Court entered this initial Order prior to any conference or hearing with the parties.

unable to agree,[2] "any party may apply to this court for clarification or relief from this order upon reasonable notice." *Id.*

Paragraph 13 imposes obligations on the parties that are in conflict with the FDA Recall Remediation. The preservation of evidence provision also arguably applies to absent class members, which could lead to users failing to submit their devices for replacement, and Respironics being unable to rework devices and provide replacements to users. Respironics therefore brings this motion for an immediate stay of the evidence preservation provision as it relates to the FDA-approved rework and replacement activities. Absent emergency relief, Respironics will have to cease or substantially limit its mitigation efforts in the United States until further order of this Court.

C. Respironics' Communications with Plaintiffs Regarding Device Preservation.

Long before the Court entered the Order, Respironics and a number of plaintiff groups have engaged in proactive discussions of evidence preservation issues and have made progress. On October 18, 2021, counsel for Respironics sent a letter to all Plaintiffs' counsel on the issue of device preservation. Ex. A., 10/18/21 Letter. The letter provided information about the FDA-approved rework and replacement process. Respironics also proposed to Plaintiffs' counsel an approach under which devices belonging to Plaintiffs and prospective plaintiffs would be preserved and not reworked, while permitting the FDA-approved rework and replacement process to proceed as to any other affected individuals. Respironics intends to continue to preserve the devices of Plaintiffs and prospective plaintiffs regardless of the relief Respironics seeks in this motion. Respironics ultimately hopes to present to the Court an agreed-upon order relating to

[2] Because of the emergency nature of this Motion, and because the Court has not yet appointed lead counsel or leadership for Plaintiffs, simultaneously with the filing of this Motion, Respironics is contacting counsel for Plaintiffs with whom Respironics has had prior discussions relating to evidence preservation in an effort to meet and confer.

evidence preservation, including how to protect the FDA Recall Remediation, but these discussions have not yet been concluded.

D. The Court Should Stay or Modify Paragraph 13 of the Order.

Good cause exists to stay or amend Paragraph 13 of the Order to permit Respironics to proceed with the FDA-approved rework of recalled devices. In its current form, however, the Order essentially prohibits Respironics from meeting the terms of the FDA Recall Remediation in the United States.[3] Respironics therefore respectfully requests an immediate stay of the preservation provisions, to the extent they prohibit Respironics from reworking recalled devices under the FDA-approved process, and to the extent they preclude Plaintiffs or any other putative class members from submitting their recalled devices to Respironics for replacement or repair. In the alternative, Respironics requests that the Court set an expedited hearing to further discuss this issue with the parties.

[3] Respironics is moving on an emergency basis because the initial hearing in the MDL will not occur for more than a month. As stated above, between now and then, Respironics anticipates that it would rework approximately 56,500 devices, if permitted to continue.

Dated: November 12, 2021

Respectfully submitted,

PHILIPS RS NORTH AMERICA LLC

By: /s/ *John P. Lavelle, Jr*

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EXHIBIT A

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October 18, 2021

VIA E-MAIL

Plaintiffs' Counsel of Record in MDL No. 3014

Re: In Re: Philips Recalled CPAP, Bi-Level PAP, and Mechanical Ventilator Products Liability Litigation - MDL No. 3014

Dear Counsel:

I write to you on behalf of defendants Philips RS North America LLC and Philips North America LLC ("Philips") with respect to preservation of devices in the possession of your clients.

Philips recently received authorization from the FDA for the rework of the recalled first-generation DreamStation devices, which consists of replacement of the PE-PUR sound abatement foam with a new material. In addition to this rework, the company has also started replacing certain affected first-generation DreamStation CPAP devices in the US with DreamStation 2 CPAP devices. As part of the rework of the affected first-generation DreamStation devices, Philips is providing replacement devices to consumers and requesting the return of their devices so that they can be reworked to provide replacement devices for other consumers in an expeditious manner. When devices are returned, Philips will instruct consumers to retain their SD cards. The preservation of SD cards and the data contained thereon will therefore be the responsibility of the individuals returning devices – not Philips.

The repair and replacement process outlined above is in keeping with the expectations of the FDA and the requirements that devices containing PE-PUR sound abatement foam be recalled and reworked to enable the provision of replacement devices to consumers.

Until a process is approved by the MDL Court, individuals who are named plaintiffs in litigation consolidated in the MDL will not be required by Philips to return their devices in order to receive a replacement device. Those individuals will be responsible for preservation of their SD cards and their devices including its PE-PUR foam.

Philips has implemented a process to identify devices returned to Philips by plaintiffs who have filed actions. If Philips identifies a device as returned by a plaintiff whom Philips knows has filed an action, Philips will not remediate that device and instead will place it into storage pending further discussions with leadership and liaison counsel on a device examination protocol.

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Philips is also willing to follow this same process for individuals who have retained counsel in anticipation of litigation provided that the following identifying information is provided: name and address of individual; name, model and serial number of device; date of acquisition and name of the provider (or DME) from whom they obtained the device.

We do not object to counsel communicating to their clients who have not filed suit that the individual may also choose to retain their device and still participate in the replacement program as long as counsel provides us with the identifying information specified above (name, address, serial number, etc.) and until such time as a different process is approved and ordered by the MDL Court.

Going forward, Philips intends to seek approval of a preservation and examination protocol from the MDL Court. As the MDL Court recognizes and appoints leadership and liaison counsel for plaintiffs, Philips and the formalized plaintiffs' counsel leadership team can meet and confer towards developing a protocol for remaining devices that can be submitted to the MDL Court for approval. By proceeding in this manner, a volume of devices will be preserved without impairing the ability of Philips to conduct rework consistent with the FDA's expectations and requirements.

Thank you for your anticipated cooperation.

Sincerely,

John P. Lavelle, Jr.

JPL/dms