Philips issued the following statement in response to inquiries for this story:

"In 2021, Philips Respironics determined from user reports and initial testing that there are possible risks to users related to the polyester-based polyurethane (PE-PUR) sound abatement foam used in specific CPAP, BiPAP and mechanical ventilator devices. Following the issuance of the recall notification in June 2021, Philips Respironics initiated a global program to remediate the affected devices through replacement or repair.

"We regret the concern that the recall notification has caused for patients and care providers, and we deeply apologize for that. We understand how important these sleep therapy devices and ventilators are to patients and how they improve their lives every day and night. Resolving this for our patients has been, and remains, our highest priority.

"To date, we have produced approximately 99% of the new replacement devices and repair kits needed for patients under this recall. When we receive a new and complete patient registration today, we are generally able to provide a new device in about six weeks. We inform patients of this anticipated timeline and in many cases, are able to ship devices to patients more quickly.

"Patients with any remaining sleep therapy device currently in use that has not been remediated yet and not registered yet, are requested to register their product to facilitate the remediation of their devices.

"The remediation program is a mix of repaired and new devices. To be clear, with repaired devices the vital elements, such as the blower box and blower motor, are replaced with new parts.

"Over the past two years, together with five independent certified testing laboratories in the US and Europe, as well as other qualified third-party experts, and in consultation with regulators around the world, Philips Respironics has conducted a comprehensive test and research program on the PE-PUR foam to determine the prevalence of foam degradation, better assess and scope

the potential patient health risks related to possible emission of particulate matter from degraded foam and volatile organic compounds.

“The extensive data and results now available for sleep therapy devices are positive and reassuring. Results for the first-generation DreamStation, System One and DreamStation Go devices indicate that the occurrence of visible foam degradation is low and volatile organic compounds and particulate emissions related to foam degradation are within the applicable safety limit and are unlikely to cause appreciable harm to health in patients.

“Based on 13 independent epidemiological studies identified from a systematic literature review, no association has been established between use of Positive Airway Pressure (PAP) devices, including Philips Respironics PAP devices, and risk of cancer in patients with obstructive sleep apnea (OSA). Two rigorous independent studies showed no statistical difference in cancer risk between OSA patients who used Philips Respironics PAP devices versus other brands of PAP devices. Eleven other epidemiological studies provided little additional insight into this question, but their results generally suggested no excess risk of cancer associated with PAP use for OSA.”