WILENTZ
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Philips CPAP Lawsuits

Results achieved in prior matters are not meant to be a guarantee of success as the facts and legal circumstances vary from matter to matter.

While we no longer handle Philips CPAP cases, we continue to advocate for clients in related areas. Visit our Defective Drugs and Device Injuries page to view all of the current cases we are handling.

There are millions of patients around the world that rely on Philips breathing machines as a treatment for sleep apnea and for assisted breathing. However, in response to complaints of serious health issues reported by users, Phillips announced a recall in April 2021 of certain models of its Continuous Positive Airway Pressure (CPAP) and Bi-Level Positive Airway Pressure (BiLevel PAP) sleep machines, including several models from its flagship "DreamStation" product line as well as certain of its mechanical ventilator devices. On June 30, 2021, the U.S. Food & Drug Administration issued this safety warning to patients and healthcare providers concerning the potential health dangers associated with the foam used in the manufacture of these Philips sleep machines and ventilators.

What is PE-PUR foam and Why is it Potentially Dangerous?

Many of the machines that Philips recalled were manufactured using polyester-based polyurethane (PE-PUR) sound abatement foam to reduce sound and vibration in these affected devices. Over time, or from certain cleaning methods used, the foam may break down and potentially enter the device's air pathway tube, causing its user to inhale or swallow PE-PUR foam. Inhalation of this foam has been associated with lung, liver and kidney damage and diseases, and, increased risk of certain cancers and pulmonary fibrosis. Phillips also warns that PE-PUR foam may off-gas certain chemicals during operation. Because Philips has used PE-PUR sound abatement foam in many of its products over the years, there are potentially millions of users that may have been exposed to this degraded foam, which has been associated with these risks and injuries, as well as less serious effects such as headaches, inflammation, respiratory difficulties, nausea and vomiting.

Serious Health Risks Linked to PE-PUR Foam Exposure

On April 26, 2021, Philips issued a recall notification for the specific machines that are manufactured with PE-PUR, sold by its Respironics subsidiary. This comes after Philips spent an extended period of time analyzing the potential risks of the sound abatement foam in its products. Risks are reportedly related to the degradation of the sound abatement foam in specific products. For individuals who live in areas with high heat and high humidity, there is a potential risk of foam degradation based on weather conditions. Further, certain cleaning methods may also lead to degradation of the foam, among other reasons.

Philips acknowledged in its recall letter that the company received a number of complaints about the presence of black debris and particles within the airpath circuit ("extending from the device outlet, humidifier, tubing, and mask"). When the foam degrades, it can enter the air pathway of the device. When this occurs, an individual utilizing the machine may unwittingly inhale or ingest the degraded material. Additionally, the foam may release chemical vapors into the user, which may lead to certain health issues. In its recall letter, Philips stated that the company received reports of "headache, upper airway irritation, cough, chest pressure and sinus infection," while also acknowledging that there are other potential risks of particulate exposure.

The health risks related to exposure to the degraded PE-PUR foam include:
- respiratory issues
- irritation
- headaches
- inflammation
- toxic and carcinogenic effects, including issues with organs, including kidney, liver and lungs

The health risks related to exposure to chemical vapors include:
- hypersensitivity
- irritation
- nausea
- vomiting
- headaches
- toxic and carcinogenic effects, including issues with organs

Which Philips Sleep Machines and Ventilator Models Have Been Recalled?

According to the recall announcement issued by Philips, these CPAP and BiLevel PAP Devices (Manufactured Between 2009 and April 26, 2021) are impacted:

- E30 (Emergency Use Authorization)
- DreamStation ASV
- DreamStation ST, AVAPS
- SystemOne ASV4
- C-Series ASV
- C-Series S/T
- AVAPS
- OmniLab Advanced+
- SystemOne (Q-Series)
- DreamStation
- DreamStation Go
- Dorma 400
- Dorma 500
- REMstar SE Auto

Ventilators

- Trilogy 100
- Trilogy 200
- Garbin Plus, Aeris, LifeVent
- A-Series BiPAP Hybrid A30
- A-Series BiPAP V30
- A-Series BiPAP A40
- A-Series BiPAP A30

Instructions for Patients Using Recalled Philips Sleep Machines and Ventilators

This FDA notice[1] issued on June 30, 2021 (updated September 10, 2021) instructs users of the recalled models of BiPap and CPAP machines to stop using the device and use another similar device not included in the recall, or to continue using the affected device upon instruction by their physician, using alternative sleep apnea treatments, and/or initiating long term therapies.

In its recall letter, Phillips recommends users of the affected ventilator machines not stop their current therapy until they speak with their physician. If you have been prescribed one of the recalled devices and have not already done so, consult your physician for guidance and follow her/his advice.

The U.S. Food & Drug Administration has published an FAQ for Philips Respironics CPAP, BiPAP, and Ventilators related to the recall.[2]

Philips Machines and Ventilators Lawsuits - What is Being Done?

A class action lawsuit filed in Massachusetts, *Shelton v. Koninklijke Philips N.V., et al.*, No. 1:21-cv-11076 (D. Mass.), alleges that Philips knew about the significant health risks associated with use of these affected machines prior to the recall. Additionally, it is also alleged that patients who utilized the affected devices have actually complained to Philips about black particles for a number of years. Yet despite this evidence, Philips did not warn about the hazards until late April 2021, and did not recall the impacted machines until June. Philips is also being accused of timing the recall to go alongside its launch of new CPAP products. As a result of all of these allegations, the attorneys at Wilentz are determined to hold Philips accountable for injury caused by users' exposure to toxic and carcinogenic degraded PU-PUR foam.

On October 8th, 2021, The Judicial Panel on Multidistrict Litigation ordered all federal actions to be consolidated in the Western District of Pennsylvania. MDL No. 3014 − IN RE: PHILIPS RECALLED CPAP, BI−LEVEL PAP, AND MECHANICAL VENTILATOR PRODUCTS LIABILITY LITIGATION, with the consent of that court, will be assigned to the Honorable Joy Flowers Conti for coordinated or consolidated pretrial proceedings.