Fast Facts About the Philips CPAP Recall

An estimated 54 million individuals in the United States between the ages of 30 and 70 have obstructive sleep apnea (OSA). OSA can affect men, women, and children. OSA leads to disruptions in breathing during sleep.

If left untreated, OSA is related to a number of potentially severe health problems—including high blood pressure, type 2 diabetes, heart disease, atrial fibrillation, pulmonary hypertension, stroke, and cognitive problems such as early onset dementia. Continuous positive airway pressure (CPAP) therapy is considered the gold standard for treatment.

The 2021 recall of Philips Respironics positive airway pressure devices affected 15 million devices globally, including more than 5 million in the U.S., according to the Philips Respironics website. Many patients and their doctors were unaware of the recall. Even among those who were aware, poor communication from Philips led to confusion about whether patients should continue using recalled devices, leading to treatment disruptions.

According to Philips Respironics, only 2.59 million of the affected U.S. devices have been remediated. Remediated patients include those who received a financial payment or whose devices were replaced with either a new or a repaired device.

There currently is no national registry of PAP devices. This makes it much harder for companies like Philips to contact patients in the event of a safety-related recall.

> They did, in my opinion, an extremely poor job communicating to not only consumers, but all the constituencies: the doctors, the DMEs. Frankly, nobody really knew what was going on, and everyone was upset. That, I think, was the biggest problem.
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> —Tom Wilson
> Philips CPAP Recall Support Group

Under the current system, doctors often do not know what kind of CPAP machine their patients use, so they can't notify patients of a recall. Requiring unique device identifiers (UDIs) to be logged into patients' electronic health records would make it possible for healthcare providers to alert patients to a recall.

The FDA protocol by which CPAP devices are approved—the 510k pathway—does not currently require rigorous clinical testing or testing of component parts like the foam that degraded in Philips devices and prompted the recall. Revising and strengthening the 510k clearance pathway's criteria could better protect patients.

The FDA has the authority to take a more active role in device recalls under 21 CFR 810, Medical Device Recall Authority. Philips recalled these devices voluntarily, but reports of adverse events and device malfunctions went unnoticed or unaddressed for extended periods.