Company that made millions of defective sleep apnea machines ordered to overhaul manufacturing

April 10 2024, by Matthew Perrone

Jeffrey Reed, who experienced persistent sinus infections and two bouts of pneumonia while using a Philips CPAP machine, poses with the device at his home, Oct. 20, 2022, in Marysville, Ohio. The company responsible for a global recall of sleep apnea machines will be barred from resuming production at U.S. facilities until it meets a number of safety requirements under a long-awaited settlement announced Tuesday, April 9, 2024 by federal officials. Credit: AP

Photo/Jay LaPrete, file

The company responsible for a global recall of sleep apnea machines will be barred from resuming production at U.S. facilities until it meets a number of safety requirements, under a long-awaited settlement announced Tuesday by federal officials.

Philips will be required to overhaul its manufacturing and quality control systems and hire independent experts to vet the changes, according to a court order announced by the U.S. Department of Justice. The company must also continue to replace, repair or provide refunds to all U.S. customers who got the defective devices, the department said.

The action is a major step toward resolving one of the biggest medical device recalls in history, which has dragged on for nearly three years.

Most of the devices recalled are continuous positive airway pressure, or CPAP, machines. They force air through a mask to keep mouth and nasal passageways open during sleep. Left untreated, sleep apnea can lead to dangerous drowsiness and increased risk of heart attack.

Philips has recalled more than 5 million of the machines since 2021 because their internal foam can break down over time, leading users to inhale tiny particles and fumes while they sleep. Efforts to repair or replace the machines have been plagued by delays that have frustrated regulators and patients in the U.S. and other countries.

Lawyers for the federal government alleged that the company failed to comply with good manufacturing practices needed to ensure device safety. The company did not admit to the allegations, according to the court filing.

"This office, the FDA and our partner agencies are committed to holding manufacturers accountable when they violate the law and put the public at risk," U.S. Attorney Eric Olshan said in a statement.

Under the legal agreement, Philips must hire independent auditors to create a plan for fixing its manufacturing problems and for monitoring problems with the sleep devices. The plan must then be approved by the Food and Drug Administration. The experts must also certify that new foam selected by the company meets FDA safety standards.

Jeffrey Reed, of Marysville, Ohio, experienced persistent sinus infections and two bouts of pneumonia during the seven years he used a Philips machine.

"I worry about my long-term health," Reed said. "I used this machine for years and no matter what money I might get out of this, what's going to happen?"

Reed received a newer Philips device after returning his old machine, but he doesn't like to use it, preferring a competitor's device.

"I don't trust the company," Reed said. "I don't want to use it."

Reed is one of more than 750 people who have filed personal injury lawsuits against the company over the devices. Those cases have been consolidated in a federal court in Pennsylvania.

Similar lawsuits are pending in Canada, Australia, Israel and Chile, according to the company.

The Dutch manufacturer announced in January it had reached a tentative agreement with the FDA and the Department of Justice. But U.S. regulators wouldn't confirm the deal at the time because it had not yet

been reviewed by a federal judge.

A company spokesman said Tuesday the agreement provides "a roadmap of defined actions, milestones, and deliverables to meet relevant regulatory requirements," in an emailed statement. He noted that Philips will still be able to export some machines for sale outside the U.S.

The FDA's website warns patients that the risks of ingesting the sound-dampening foam could include headache, asthma, allergic reactions and more serious problems.

An FDA inspection of Philips' Pennsylvania offices in the fall of 2021 uncovered a spate of red flags, including emails suggesting the company was warned of the problem with its foam six years before the recall.

Between 2016 and early 2021, FDA found 14 instances where Philips was made aware of the issue or was analyzing the problem. "No further design change, corrective action or field correction was conducted," the FDA inspectors repeatedly noted.

In 2022, the FDA took the rare step of ordering Philips to step up its outreach to customers about the recall including "clearer information about the health risks of its products." At the time, the agency estimated only about half the people in the U.S. with affected machines knew they had been recalled.

Customers trying to obtain refunds or new or refurbished devices from the company have reported long delays.

Citation: Company that made millions of defective sleep apnea machines ordered to overhaul