https://www.nytimes.com/2022/11/15/health/cpap-philips-breathing-device-recall.html

Frustrations Grow Over Company's Response to Breathing Device Recalls

Lawsuits claim the company, Philips Respironics, knew of problems with its CPAP and other machines long before notifying customers of potential health risks.

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Tillie O'Kelley with her current CPAP machine her bedroom in Arcadia, La. She traces a decline in her health to a Philips CPAP she began using in 2014. Two years later, she was diagnosed with lung cancer.Rory Doyle for The New York Times

By 2015, Philips Respironics knew its breathing devices had a problem: Foam inside the CPAP machines, which help people with sleep apnea breathe at night, was breaking off into black flecks and blowing into the mouths and noses of users.

The company did nothing at the time. Years went by as complaints mounted, and the company made cursory efforts to examine the problem, according to an investigation conducted later by the Food and Drug Administration.

But it was not until April of last year, the company has claimed, that it realized the flaking foam contained potentially cancer-causing particles, setting off the largest and most disruptive medical device recall in more than a decade.

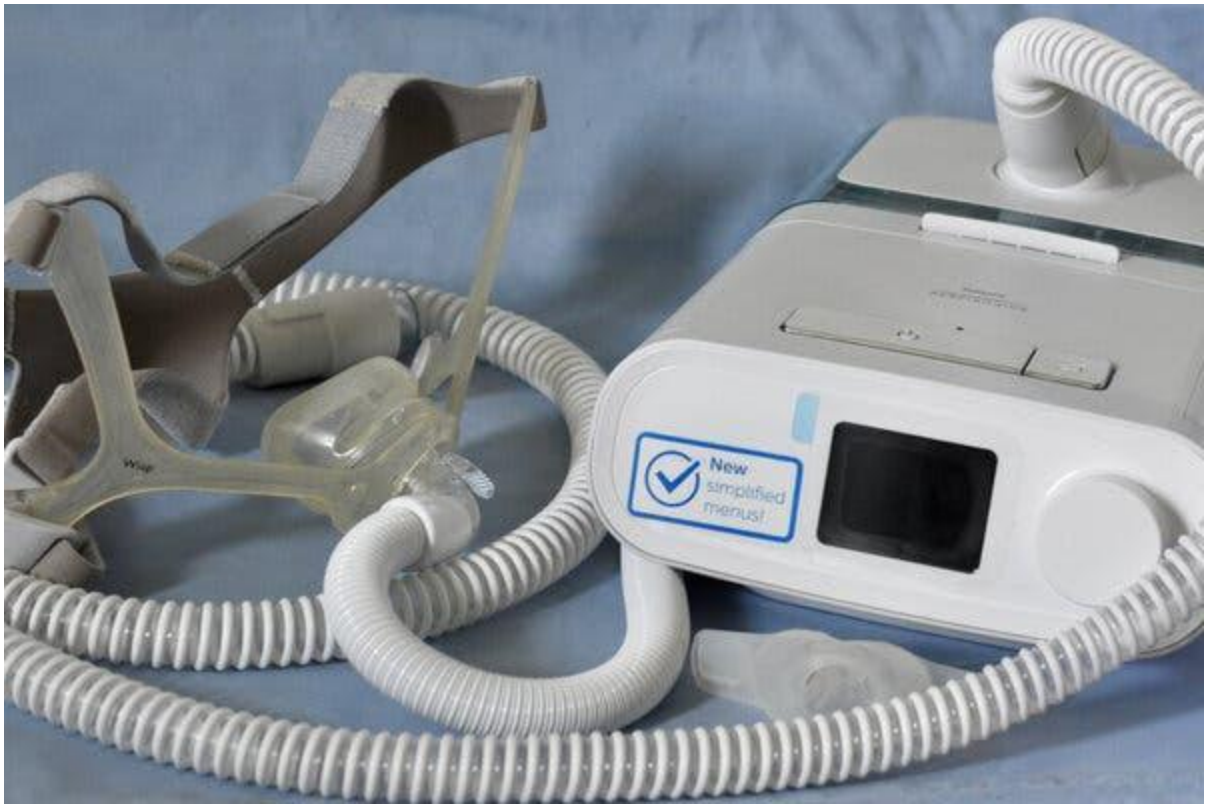
Nearly a year and a half after the recall that involved more than five million devices worldwide, millions of American have endured a long wait for a device. Many have been forced to find alternative methods to ensure they can breathe at night without becoming deprived of oxygen or risking a heart attack. Others have been outraged by unexpected illness, suspicious that a device meant to help them actually caused harm.

The U.S. Justice Department is now negotiating the terms of a consent decree with Philips, underscoring the deep concern about what the company knew — or should have known — before millions of people received devices that many believe caused devastating illnesses. A decree would likely require the company to document the steps it would take to prevent such a failure in the future.

Doug Shiffler, a retired tech executive in Utah, is one of hundreds of people suing the company. His wife began using the device in 2018, when there were no public warnings of possible problems with the machines, and developed a persistent cough.

By mid-2020, Joleen Shiffler was diagnosed with an aggressive lung cancer that baffled her doctors, although a direct link between her disease and the Philips device had not been established. Ms. Shiffler, 60, died within the year. “Why weren’t we informed that there was an issue?” Mr. Shiffler asked. If they had known, “I might be standing right beside Joleen instead of mourning her loss.”

It wasn’t until last year that the machines — about 15 million Philips breathing devices worldwide since 2009 — were found to cause potential “serious injury” or “permanent impairment.” The machines emitted chemicals with “toxic carcinogenic effects,” the company said, with two compounds registering levels above standard safety limits.



A Philips Dreamstation CPAP unit.Shutterstock

Philips now says it had assumed a “worst-case scenario” when it issued the initial warnings. A spokesman, Steve Klink, said a research review commissioned by the company did not find an association between its sleep apnea devices and cancer.

Fallout from the recall has been punishing for Philips: Its overall market value and stock have plummeted and the company recently announced thousands of layoffs as a result of those losses. The recall and others have exposed not only Philips’s poor record-keeping but the systemic, industrywide absence of a device tracking system that would allow companies to alert device users of significant problems.

Recalled devices include ventilators, BiPAP and CPAPs, or continuous positive airway pressure machines, which force open the airways of people who would otherwise stop breathing through the night. The recalled devices contain foam meant to dampen sound and vibrations that can also break down under hot and humid conditions.

As the recall unfolded, doctors said they were ill-equipped to balance the risks of the toxic chemicals against those of letting interrupted breathing go untreated, which can heighten the risk for cognitive decline, heart problems and

death. Device users have despaired over the difficulty of getting a replacement device or have bristled at deliveries of reconditioned models, which the company said account for about half of the replacements.

The wide-scale recall led to turmoil among consumers and within the company. Its chief executive at the time, Frans van Houten, stepped down, and the company's market value has plunged by about 70 percent. The company has also announced plans to lay off about 4,000 workers to offset losses.

Years after the first hints of a problem surfaced, the F.D.A. has now cast a critical eye on the company's safety and quality measures, tallying years of failures to address the foam problem and taking the unusual steps of ordering Philips to better communicate with device users.

"The F.D.A. shares the frustrations expressed by patients who are awaiting a resolution for this recall," Dr. Jeff Shuren, director of the F.D.A.'s device center, said in a statement. "We have employed rarely used regulatory tools to hold Philips accountable and we will continue to communicate with the firm to assure they take appropriate steps to correct the product."

Doug Shiffler of Ogden, Utah, at his wife's grave. He is one of hundreds of people suing Philips after his wife died of lung cancer with in a year of diagnosis.Kim Raff for The New York Times

The agency said it is conducting an in-depth review of complaints that have poured in since April of 2021, including more than 69,000 pertaining to cancer, difficulty breathing and chest pain. The complaints include 168 reports of death, although experts have said it can be difficult to determine whether the device caused any singular illness or death.

Fears about those symptoms and others have echoed within social media, where hundreds of people have aired concerns. "The way Philips was handling it was just, in my opinion, very, very poor and that made me angry," said Tom Wilson, a retired personal care product executive who runs a Facebook page about the device problems. "This is a big recall. And it's a dangerous recall."

Philips said it had produced four million replacement products, including two million that were shipped to the United States. Mr. Klink, the company spokesman, said that Philips had handled "limited complaints" related to foam degradation on a case-by-case basis in recent years. After the company's initial warning about the cancer risk, he said that some company tests found lower levels of chemical exposures and that reviews were continuing.

"At this stage, we can only apologize for the concern that has arisen, and we are working really hard to get to the bottom of the actual health risks," Mr. Klink said.

The F.D.A., however, has deemed the company's revised position "unpersuasive" after extensive document reviews and an inspection at Philips Respironics facility in Murrysville, Penn. (The parent company is based in the Netherlands.)

The agency review of company records showed that by 2015, the company had information from complaints, test reports and suppliers that the foam in the devices was degrading. Yet it "failed to adequately evaluate" the information or mitigate the problem, the F.D.A. noted.

In 2016, emails and test reports showed Philips learned that the foam could break down in as little as a year, F.D.A. records say. By 2018, a company engineer noted that the foam breakdown in a Philips ventilator was "not a good situation for" device users according to an email submitted in a lawsuit against Philips. The company launched — but quickly closed — a review of the matter that year, F.D.A. records showed.

In 2019, Philips “finally” began a formal internal investigation, according to F.D.A. records. Philips issued the recall in June 2021, a Class 1 designation reserved for the most serious defects that could result in death.

Doctors and device users were forced to react. Dr. Shannon Sullivan, a pulmonologist and sleep specialist at Stanford Medicine, developed recall guidelines for the American Association of Sleep Medicine. She said it was a difficult task given the uncertainty about the risk posed by unfamiliar compounds with names like “Dimethyl Diazine,” which the company said its devices emitted beyond a safe limit.

“That was a concern,” Dr. Sullivan said. “Can you really have a clinically sound risk-benefit analysis when some of the questions are unknown?”

Ms. O’Kelley showed an X-ray that revealed a nodule detected on her lower right lung.Rory Doyle for The New York Times

Philips performed additional testing, and in an internal December 2021 hazard assessment, concluded the device fumes presented a risk for moderate, rather than serious injury. The F.D.A. was not convinced, records show,

deeming the test methods flawed. The agency ordered the company to do more to communicate with users and proposed a second order — but has not issued it — to force the company to repair or replace devices or refund users.

Medical supply company operators, like Woody O'Neal of Birmingham, Ala., played a key role in notifying their customers about the recall. But he said uneven record-keeping practices in his industry had hobbled efforts to notify customers.

"It's kind of mind-blowing that this is still occurring," said Mr. O'Neal, a board member for the state's medical equipment trade association and owner of O'Neal Medical. "It's a real challenge for Philips to reach everybody because they don't know where all of these devices are."

Philips confirmed that it did not have a direct relationship to device users. It asked users to register their devices on the company website to communicate directly.

Joyce Baldassarre, 64, who lives outside of Philadelphia, did just that. She was diagnosed with sleep apnea about six years ago after a sleep study determined she stopped breathing dozens of times per hour.

Upon learning her CPAP machine was among those recalled, she decided to keep using it. "We don't wear this for funsies. It's certainly not attractive," Ms. Baldassarre said. "We wear it so we don't die in our sleep."

The device stopped working, though, leading to an agonizing wait for a new one. She struggled to keep her eyes from crossing in exhaustion while doing her data-entry job.

But once the anticipated replacement arrived in late September, she left it in the box. The notion of a refurbished device troubled her, as if she had been asked to use someone else's toothbrush.

"I'm afraid to open it," Ms. Baldassare said. "I really am. Everyone deserves a brand new machine."

Mr. Klink, of Philips, said the refurbished devices had been disinfected and the inner parts had been replaced. The company has said its effort to send devices to each user have also been hampered by supply chain challenges, including the global semiconductor chip shortage.

Mr. Shiffler of Utah held a photograph of his wife, Joleen, and their children. A member of the Church of Latter Day Saints, Mr. Shiffler said Joleen never drank alcohol or smoked before an aggressive lung cancer took hold. Kim Raff for The New York Times

For others, the wait is not for a device, but for answers. Even with ailments where a clear link can be established, like smoking and lung cancer, the illness can take years to manifest, Dr. Albert Rizzo, chief medical officer of the American Lung Association, said.

“I think it’s a wait-and-see of really looking at epidemiologic studies to see whether there’s a causal relationship based on patients who used the device and those who didn’t,” Dr. Rizzo said.

Adding a layer of complexity, Mr. Klink said foam with added flame retardant chemicals, a class that has separately been linked to cancer and reproductive harm, was only present in company ventilators, which comprise about 5 percent of the recalled devices. The company also issued an unrelated recall in September because of contaminated plastic giving off toxic chemicals in fewer than 400 breathing machines.

Mr. Shiffler, a member of the Church of Jesus Christ of Latter-day Saints, said his wife never drank alcohol or smoked before the aggressive lung cancer took hold. He viewed with derision a video of the former Philips chief executive, assuring device users about safety: He can strap Joleen’s device on at night for two years, Mr. Shiffler said, “and we’ll see how you do on a PET scan.”

The feeling of betrayal runs deep with Tillie O’Kelley, 76, as well. After her replacement device landed with a thump on her doorstep, she put it in a closet. She preferred to use a device from another company.

She traced a decline in her health to when she began to use a Philips CPAP in 2014. Before then, she was active, building on to her South Florida home, making stained glass and scuba diving in Cozumel, Mexico, where the water was so clear, she recalled, you could forget you were underwater.

By 2016, she was diagnosed with lung cancer; doctors removed the upper part of her left lung. Skin cancers, a thyroid mass and loss of feeling in her lower legs followed.

A plaintiff in one of many lawsuits against Philips, Ms. O’Kelley doesn’t expect to live long enough to understand why her health deteriorated so rapidly.

“If it’s just aging, then hallelujah. I got old badly,” Ms. O’Kelley said. “But if it wasn’t aging, then I’m really going to be pissed, and I’ll probably come back and haunt them.”