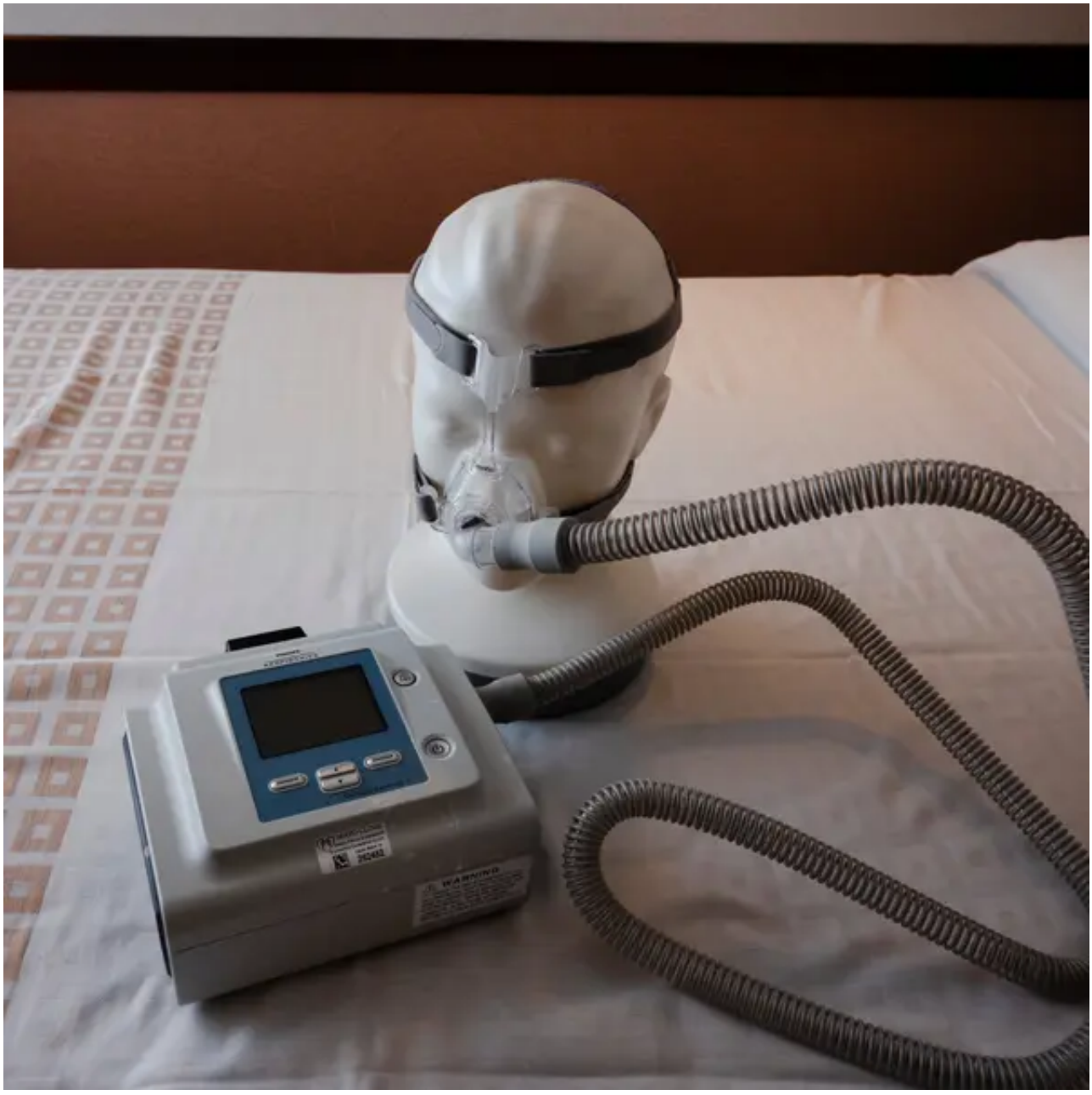
Philips Suspends U.S. Sales of Breathing Machines After Recall

Under a settlement with regulators, the company must revamp some operations before resuming sales of its CPAP and ventilator devices in the United States.

Jan. 29, 2024



A Philips Respironics CPAP machine. Roughly five million breathing devices were in circulation at the time of the

recall.Andrea Ellen Reed for The New York Times

Philips Respironics announced on Monday that it would halt sales of all of its breathing machines in the United States after reaching a settlement with the Food and Drug Administration over continuing problems with the devices.

Millions of the company's ventilators and CPAP machines, used to ease breathing at night, were recalled after reports that they blew bits of foam and potentially toxic gases into consumers' airways.

Under the settlement, Philips said it would have to meet a list of standards in a "multiyear" plan before it could resume business in the United States. The company said further details would be disclosed when the agreement was finalized in court. But it added that it would continue to repair existing devices and provide service for people using them.

The company initially began the recall of millions of devices in June 2021 and paused sales of new sleep therapy machines to the United States, according to Steve Klink, a spokesman for Philips. At the time, the company and the F.D.A. cited the potential for serious injury or permanent impairment from the potentially cancer-causing chemicals emitted from the devices.

The company has since released results of additional testing, saying the devices were "not expected to result in appreciable harm to health in patients," and it said it was continuing to conduct tests. The F.D.A. has pushed back on some of the company's updated claims, and at one point called them "unpersuasive." Philips has also faced continuing scrutiny and undertaken more recalls in its attempts to upgrade the devices.

Dr. Jeff Shuren, director of the F.D.A.'s device division, said the agency could not comment until the agreement was finalized and filed with the court.

The initial recall affected about 15 million breathing machines produced since 2006, though roughly five million were still in circulation in mid-2021.

With replacements not immediately available, the recall caused confusion and upset for many doctors and patients. Many struggled to weigh the risk of continuing to use a faulty device against the peril of sleeping with impaired breathing.

Millions of people suffer from sleep apnea, or interrupted breathing, which is associated with elevated rates of strokes, heart attacks and possible cognitive decline. Recalled machines included CPAP, or continuous positive airway pressure, machines; BiPap devices; and ventilators.

Philips, which is based in Amsterdam, disclosed that it had reached an agreement, or a consent decree, that was brokered with the U.S. Justice Department and the F.D.A., along with the announcement of its fourth-quarter earnings. The company said it wrote down about 363 million euros related to the cost of completing the settlement requirements. Its stock, which trades in the United States, was down about 7 percent Monday morning.

The company said it would continue to sell its products in other countries.

Thousands of patients have since sued Philips, claiming that the machines led to a wide range of respiratory and other ailments, including allegations of deaths from lung cancer. In September, the company reached a $479 million settlement with plaintiffs that was meant to cover the financial losses related to repairing or replacing the machines. Litigation over illnesses and medical costs is still pending.

Christina Jewett covers the Food and Drug Administration. She is an award-winning investigative journalist and has a strong interest in how the work of the F.D.A. affects the people who use regulated products. More about Christina Jewett

A version of this article appears in print on Jan. 30, 2024, Section B, Page 3 of the New York edition with the headline: Philips Suspends U.S. Sales of