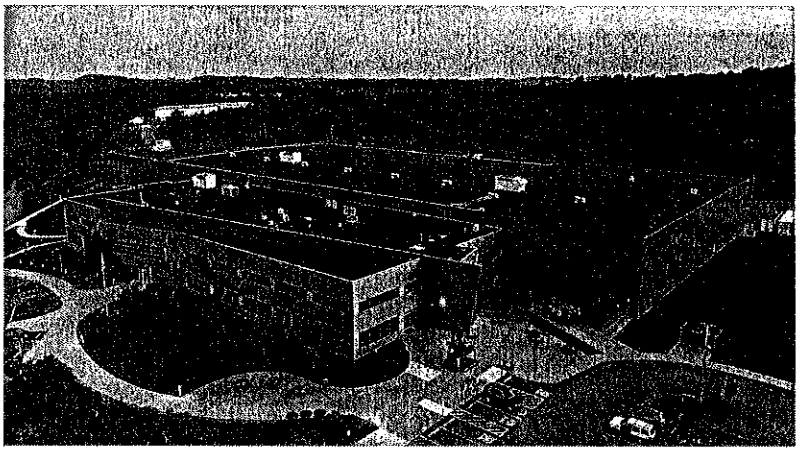

In wake of massive recall, SEC launches investigation into Philips Respironics

Feds to focus on whether global company properly alerted investors to breathing machine dangers

MICHAEL SALLAH, EVAN ROBINSON-JOHNSON AND MICHAEL KORSH
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As Philips Respironics settles costly legal battles over its defective breathing machines, the Securities and Exchange Commission has launched an investigation into the company's practices and whether it withheld critical information about the dangers of the devices before pulling them from the shelves in one of the largest recalls of its kind, the Post-Gazette has learned.

The SEC is seeking information about the inner workings of the company — including scientific tests of the flawed devices — and the steps it took to inform investors who stood to lose billions of dollars, according to multiple sources who spoke on the condition of anonymity.

Though the company agreed last month to pay more than $1 billion to settle lawsuits from patients who say they were sickened by the machines, the SEC inquiry is expected to focus on the impact on investors whose stock plummeted as the crisis in the company turned into a global health emergency.

The agency's investigation brings another wave of scrutiny to a company that has already faced hundreds of injury claims in federal court and allegations that Philips knew its popular sleep apnea devices posed serious risks, but continued to churn them out from two large factories outside Pittsburgh.

Just last month, Philips struck a consent decree with the Food and Drug Administration that requires the company to undergo regular inspections and a litany of safety checks, as well as halt the selling of its breathing machines until specific conditions are met.

David Chase, a Florida lawyer who once led investigations for the SEC, said his former agency will examine the responses of the company's leadership after it had discovered "a lurking, potential disaster."

"It comes down to what they knew and when did they know it. It's about disclosure," he said.

The SEC is empowered to bring civil actions that can lead to fines, sanctions and a host of other penalties that can have lasting impacts on corporations, including suspending a company's trading.

Mr. Chase, who now defends companies under SEC probes, said he expects the agency to investigate the roles of Philips' top leaders after discovering the CPAPs and ventilators were filled with an industrial foam capable of breaking down and releasing chemicals at dangerous levels into the masks of patients, including infants and the elderly.

The FDA said it received more than 560 reports of deaths associated with the machines, and an investigation last year by the Post-Gazette and ProPublica found at least 2,000 reports of cancer and hundreds of lung and kidney ailments.

The media organizations found the company withheld thousands of complaints about the crumbling foam in the years before the 2021 recall but failed to alert customers, investors or the federal government.

Sources said the SEC has issued subpoenas to multiple testing labs as part of an investigation into the company's discovery about the chemical emissions from the foam in devices that are designed to deliver clean air to patients, many who are already with compromised conditions.

Shayne Gad, a nationally recognized expert in toxicology in the Research Triangle of North Carolina, said his consulting firm received a subpoena "months ago" and turned over multiple test results on the foam to the SEC.

Mr. Gad, former president of the American College of Toxicology who reviewed tests of the devices dating back to 2021, said he found the foam could pose risks to patients and should not be sold.

Philips needed to "fix it and just do the right thing," he told the Post-Gazette in 2023. "That's why we were so strident."

The SEC said it would not comment "on the existence or nonexistence of a possible investigation," and declined to answer any questions.

In an email to the Post-Gazette, Philips did not respond to questions about the probe, but said in the years before the recall, complaints were examined on a case-by-case basis and when it became aware of the significance of the problem, "actions were taken leading to the voluntary recall notification in June of 2021, including the disclosure to shareholders of an associated provision in its Q1 2021 earnings announcement on April 26, 2021."

Internal Philips emails and text messages obtained by the Post-Gazette and ProPublica show a group of top company scientists were already meeting in 2018 to respond to complaints that the foam was degrading in its machines, three years before the flaw was reported to patients and investors.

By 2019, an internal study by the company showed the release of chemicals at excessive levels, according to court documents. One of the compounds: formaldehyde, which is found in fertilizers and glue and linked to some cancers.

Though it's nearly impossible to identify a causal link to specific cases of cancer, the foam in the 2019 study tested positive for genotoxicity, the ability of a chemical to spur cells to mutate and cause the disease.

After the announcement of the recall in 2021, the company's stock price plunged by nearly 80% — from a record high of $58 to a low of about $12 the next year — as Philips scrambled to send replacement machines to millions of users, records show.

"They are going to get records — video calls [with investors], public statements," said Mr. Chase, to determine if the company held back information that should have been disclosed. "I don't see how they can be accountable and truthful without disclosing it."

Philips initially said during the recall that the devices could cause "life-threatening" injuries or "permanent impairment," but has since walked back those findings, saying it does not appear the machines could lead to long-term harm. The FDA has challenged that assessment, saying the company's tests are not adequate.

The investigation by the SEC comes after shareholders filed a class-action case in federal court in New York in 2021 alleging Philips actively promoted the breathing machines at health fairs and in advertisements years after finding out they were defective.

The lawsuit points to an email exchange filed in federal court between a Philips engineer and one of the company's foam suppliers in 2018 that addresses the foam breaking down inside the machines and causing "a potential safety concern."

The Philips engineer noted that "[a]s you can imagine, this is not a good situation for our users," and added that he "flagged this message with high importance."

Citing an FDA inspection of the company's Murrysville facility just months after the 2021 recall was launched, the lawsuit says the problem with the foam was "discussed at several meetings attended by executives. Yet Philips continued to leave their potential harmful products in the marketplace — even touting them repeatedly during the pandemic."

The suit cites earnings calls dating back to 2016 when top executives, including former CEO Frans Van Houten, touted the company's success in respiratory care, while complaints were "pouring" into the company about degrading foam.

"Philips had been burying complaints for years — from its users, from the market at large and even from the FDA," the suit alleges.

In its response to the lawsuit, Philips, which has moved to dismiss the case, denied the allegations, stating the Dutch company's top executives did not know about the foam problems raised at Philips Respironics in Pittsburgh, one of its many U.S. subsidiaries, until shortly before the recall, "and promptly disclosed the issue to investors."

Though the SEC is conducting an inquiry into whether the company properly informed investors, it could be months before the federal agency decides whether to press forward with a government lawsuit, experts say.

Andrew Stoltmann, a Chicago securities attorney, said the agency will examine evidence on both sides, but when it comes to companies that make medical devices that impact peoples' lives, early disclosure is critical.

"This is stuff that gets directly into your lungs," he said. "You are going to get a little bit of time" before companies are required to tell investors, "but not a lot."

And if companies claim that they knew there was a problem, but didn't alert shareholders because they didn't know the extent of the dangers, "that's a really dangerous game for them to play."

The SEC has taken action against numerous medical device and drug companies and their top executives on a range of charges in recent years, including making false and misleading statements to investors.

Last year, the SEC accused the founder of a Florida company of promoting a stimulation device to reduce pain that turned out to be a plastic part with no medical value that was implanted in people and led to hundreds of injuries reported to the FDA, records show. The case has since been stayed while Laura Perryman, 55, awaits sentencing in June on criminal fraud charges filed in connection with the case by federal prosecutors.

Mr. Stoltmann said the revelation by the Post-Gazette and ProPublica last year that Philips kept secret more than 3,700 complaints about the faulty devices over the course of 11 years from the FDA -- despite a requirement to report the breakdowns in 30 days — presents hurdles for the global device maker to overcome with the SEC.

Though the company said more testing was required, Mr. Stoltmann said the "time period [for testing] is shortened" when complaints about devices begin to pile up, especially given "the severity of the complaints ... It should have been clear they had a problem."

Michael Sallah: msallah@post-gazette.com; @mikesallah7

Evan Robinson-Johnson: ejohnson@post-gazette.com; @sightsonwheels

Michael Korsh: mkorsh@post-gazette.com; @michael_korsh

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