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Sunday

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Inside the raging battle at Philips

PG EXCLUSIVE:
A trove of newly obtained documents shows internal fights and resignations over firm's handling of dangerous breathing devices

By Michael D. Sallah and Michael Korsh
Pittsburgh Post-Gazette

Shortly after arriving as medical director at Philips Respironics four years ago, Hisham Elzayat faced an internal crisis that threatened one of the world's largest makers of breathing machines.

The longtime heart surgeon had pored over a spate of complaints about the company's best-selling devices, which were filled with an industrial foam capable of breaking down into tiny particles and fumes.

When inhaled, the toxic material could move through the nose and sinus cavity and into the lungs, a stealth intruder that threatened incalculable harm.

After meeting with a top Philips biosafety engineer who also expressed concerns, the 46-year-old doctor said he had seen enough.

In June 2020, he pushed to stop all shipping of the devices from the company's factories near Pittsburgh and pressed to meet with one of the company's most powerful executives to take on what he called an unfolding emergency.

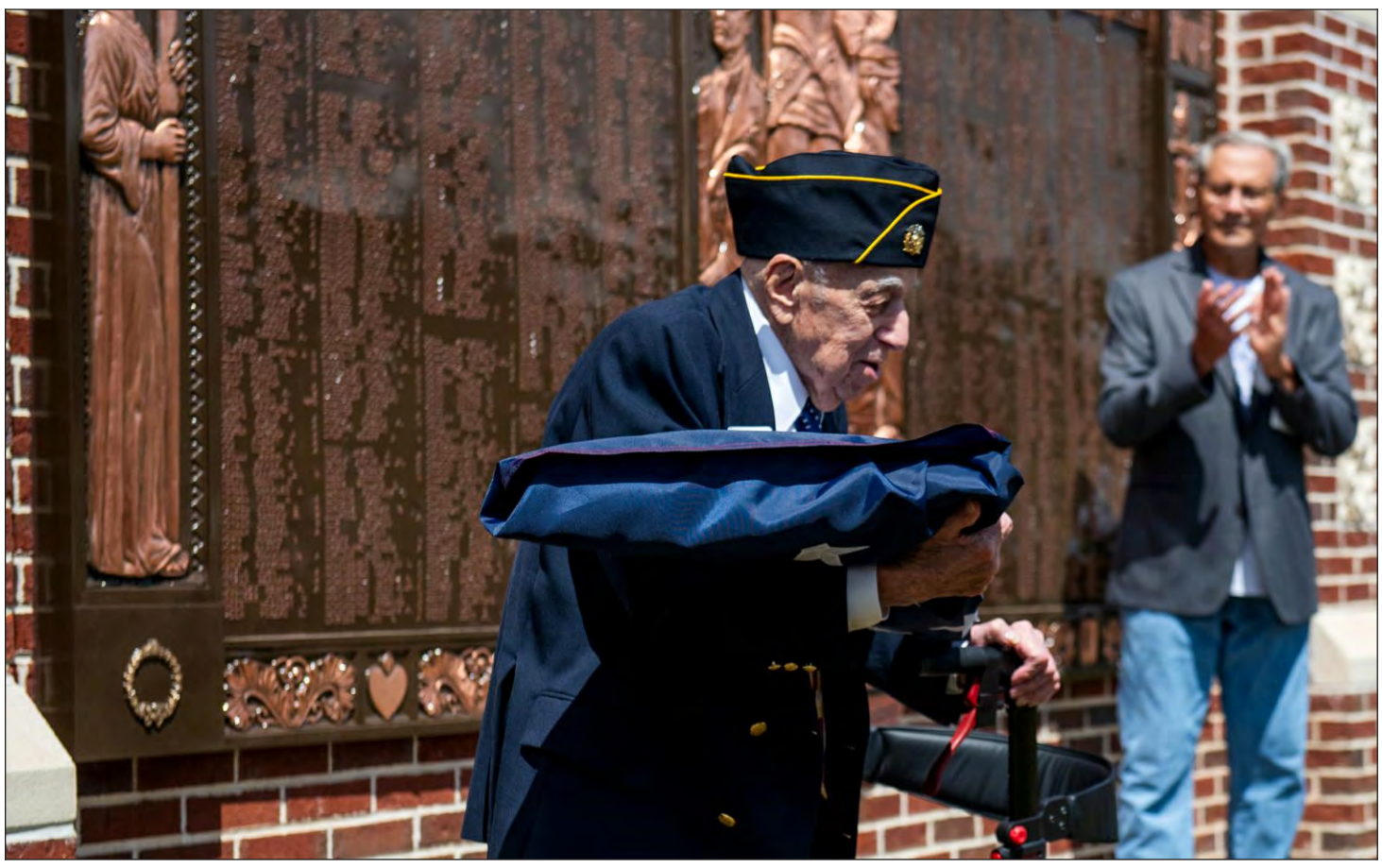
"I have made my safety concerns known," he recalled in an internal complaint.

But the company turned down his request to halt the deliveries and instead ratcheted up

SEE **PHILIPS**, PAGE A-6

MORE INSIDE
Excerpts of internal memos that illustrate the battle from within Royal Philips. **Pages A-6 & A-7**

WWII MONUMENT REDEDICATED



Esteban Marenco/Post-Gazette

World War II veteran Howard Pfeifer, 100, holds an American flag given to him during Saturday's unveiling of a newly restored memorial at St. John Vianney Cemetery in Carrick. The memorial by sculptor Frank Vittor includes the names of 1,017 St. George Church parishioners who served in World War II, including 35 who were killed in the war. It previously was located in front of St. George Church in Allentown. Vittor's work originally was dedicated in May 1947. **Story, Page C-1**

Record student loan debt frustrates young Pa. voters

By Maddie Aiken and Megan Tomasic
Pittsburgh Post-Gazette

Student loan cancellation plans were an "extremely important issue" when Gerard Dorvè-Lewis was deciding how to vote in the November presidential election.

A Ph.D. student studying higher education at the University of Pittsburgh, Mr. Dorvè-Lewis has already amassed $40,000 in federal student loan debt.

He said he was "extremely disappointed" when the U.S. Supreme Court last year struck down President Joe Biden's student loan cancellation plan that would have wiped out more than $400 billion in total debt. He was one of nearly 1.8 million Pennsylvanians who would have been affected.

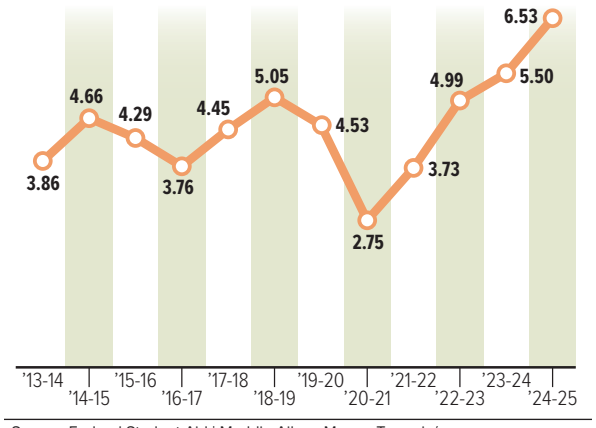
Now, the 31-year-old feels like Mr. Biden's efforts since the ruling are "lesser than what was originally promised." Even though the situation has left the Lawrenceville resident frustrated, he plans to vote for the Democrat in November.

But change is necessary, he said.

SEE **VOTERS**, PAGE A-10

Interest rates on subsidized federal loans, 2013-24

During the 2024-25 school year, federal student loans will carry 6.53% interest rates for undergraduate students — the highest rate in more than a decade.



Source: Federal Student Aid | Maddie Aiken, Megan Tomasic/ Post-Gazette (research); James Hilston/Post-Gazette (graphic)

Election 2024

BIDEN'S WALL OF SUPPORT SHOWS SIGNS OF CRACKING

His visit to Pa. on Sunday aims to reassure party base

By Matt Viser and Shane Harris
The Washington Post

President Joe Biden, in both words and actions on Friday, made clear that he has little intention of quickly or quietly leaving the presidential race, issuing a blunt warning that if leading Democratic donors and elected officials want to alter his thinking, they are going to have to wage a protracted and public battle.

By Saturday, that battle showed signs of intensifying.

Rep. Angie Craig, D-Minn., who is in a competitive race and among the more endangered Democrats, on Saturday morning called on Mr. Biden to drop out of the race, saying "there is only a small window left to make sure we have a candidate best equipped to make the case and win."

"Given what I saw and heard from the President during last week's debate in Atlanta, coupled with the lack of a forceful

SEE **BIDEN**, PAGE A-11

MORE INSIDE
- Should Biden quit? Democrats weigh potential rewards and steep risks. **Page A-5**
- As Trump dominated the docket, a divided Supreme Court moved inexorably to the right. **Page A-13**

Pa. energy costs rising — but why?

By Anya Litvak
Pittsburgh Post-Gazette

Pennsylvania produces so much natural gas that it trails only Texas, and so much electricity — more than half of which comes from natural gas power plants — that it's the chief exporter of electrons to other states on the regional grid. But the gravy doesn't flow down to consumers in proportion to those rankings, at least not through the pocketbook.

According to data collected by the Energy Information Administration, the Keystone State is the 13th most expensive for the cost of electricity to residential consumers, and it ranks 23rd among states for natural gas prices.

SEE **ENERGY**, PAGE A-8

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Internal fights and resignations over dangerous breathing machines

PHILIPS, FROM A-1

sales of its CPAPs and ventilators during the throes of the pandemic while Philips took in hundreds of millions of dollars.

Dr. Elzayat's internal battle to pull the machines off the shelves is detailed in hundreds of pages of company emails, text messages and reports that have been turned over to federal prosecutors as part of a criminal investigation of the leadership of the company, according to sources with direct knowledge of the probe.

The confidential documents, which have been obtained by the Post-Gazette, show for the first time the surgeon was among nearly a dozen Philips engineers and others who pushed the company to warn patients about the dangers of the foam before Philips removed millions of the devices from the market during a recall in June 2021 and to later stop the company from downplaying the risks.

Though Dr. Elzayat stayed on, several employees resigned over the safety threats.

"This is getting uglier every day," he wrote to a testing lab shortly after the recall.

The records show that several Philips scientists raised concerns over the company's efforts to search for test results that they said would be more favorable as hundreds of complaints about the defective machines poured into the company.

Failed safety tests

The Justice Department declined to comment on the probe, but experts interviewed by the Post-Gazette say the internal correspondence could provide key information for investigators in assessing when top leaders learned of the deficiencies and whether they concealed the dangers.

"The government's focus will be on the executives who had the authority to stop the train," said Ryan Stumphauzen, a former Florida federal prosecutor who once led health care fraud investigations.

The new records show that as far back as 2008 — far earlier than the company has disclosed — the foam in the devices failed safety tests. The material received the lowest possible score for cytotoxicity, the ability of a chemical to destroy cells and increase the risk of organ damage.

The debates over patient protections became so intense that a panel of managers sent a memo to Philips regulatory leaders two months after the recall, questioning what they called the company's "aggression, relentlessness and disdain" for the health warnings raised by the team, the records show.

"The customer and patients are very seldom put first," wrote regulatory specialist Eliza Shearer.

A Post-Gazette and ProPublica investigation last year found that Philips withheld thousands of reports about the foam breaking down in the devices for years, despite a federal law that requires device makers to report the breakdowns in 30 days.

Since the recall, the Food and Drug Administration has received more than 560 reports of deaths associated with the devices, and the Post-Gazette has found at least 5,500 cases of cancer reported to the agency.

Though Philips agreed in April to a consent decree with the FDA to undergo regular inspections and other safety checks, the company announced last month that it would end manufacturing at the two factories near Pittsburgh in 2025 and move those operations to a third-party company outside the state.

Even while Philips was dominating the sleep apnea market, the newly obtained records show the devices repeatedly failed emissions testing for volatile organic compounds including formaldehyde, a known carcinogen, dating to January 2019.

The records also shed new light on differences that took place within Philips over testing methods and whether the company's actions would tip off federal regulators.

When one of the outside labs hired by Philips tried to reduce the formaldehyde readings in the foam in 2021, a senior Philips manager sent a warning to a colleague.

Philips officials "basically want to manipulate the data to make it look favorable," said Bill Moret, a longtime test engineer, who added in a message to another coworker: "This whole thing is a joke."

In 2019, a confidential report by Philips summarized the test failings — showing alarming levels of formaldehyde released from the foam — and detailed grim concerns about the company's most popular devices.

"The severity of harm is crucial with respect [to children]," the report said.

In an emailed response last week, Philips said that "patient safety and quality are Philips' highest priorities" and that the foam used in the recalled sleep apnea machines has undergone extensive testing from Philips using "five independent, certified testing laboratories and third-party experts" since the June 2021 recall, and that the company and its outside experts have found the material "is not expected to result in appreciable harm to health in patients."

Fighting erupts

Philips would not comment on the records obtained by the Post-Gazette, saying the material is subject to a confidentiality agreement reached in federal court in Pittsburgh, where the company was sued by hundreds of patients who say they were injured by the defective devices.

Philips agreed to pay $1 billion earlier this year to settle the claims, which alleged the company concealed the dangers of the breathing machines while waging aggressive marketing campaigns to sell them.

Despite Philips' claims the devices do not cause harm, the FDA has said the company's tests are not adequate, and the federal agency has continued to maintain that the recall is the most serious, reserved for device defects that can cause injuries or death.

Neither Mr. Moret nor Ms. Shearer, both of whom no longer are with the company, responded to interview requests.

By the time Dr. Elzayat joined the company as a medical director in March 2020, Philips had received more than 475 complaints about foam breaking down in the machines in the prior five years, the newly obtained records show.

A cardiothoracic surgeon and former research fellow at the Emory University School of Medicine, Dr. Elzayat was asked to join a select group within the company known as Project Uno, which was launched years earlier to deal with the problem, he wrote in an internal complaint. After reading the 2019 report and reviewing patient complaints that had been shared with group members, he said he grew alarmed.

Calling the foam a "major risk" to patient safety, Dr. Elzayat wrote that he "escalated the issue to the management level."

By June 23, he took the rare step of pushing to halt shipments of the devices until more tests could be carried out and requested a meeting with John Frank, then vice president and general manager of the sleep and respiratory care unit in Pittsburgh, according to an email. But his request to shut down the deliveries was turned down.

"Every time I suggested or demanded that something gets fixed, the answer was always, 'Do you know how many devices [are] out there?' " he wrote in the complaint. He said he met briefly with Mr. Frank to talk about safety matters, but no further sessions were held.

Over the next year, Dr. Elzayat and others were locked in a fight with company leaders to press for protections for patients and to determine whether the devices — millions across the country and beyond — should be pulled from the market.

Dr. Elzayat did not respond to repeated interview requests. Mr. Frank, who left the company in 2022, did not respond to requests for an interview. David Ferguson, who took over the top job in 2021 and left the company earlier this year, could not be reached.

Benjamin B. Braun/Post-Gazette

Internal fights broke out among safety experts and company leaders at Philips in 2020 over the dangers of the company's bestselling breathing machines and the length of time it took for the company to pull the devices from the shelves, according to newly obtained company records. "This is getting uglier every day," a Philips medical director emailed a colleague.

2008 test showed foam used in Philips breathing devices was cytotoxic

Below are excerpts from a June 13, 2008, cytotoxicity test of the foam used inside the CPAP breathing machines.

TOXiKON
Leaders in Life Science and Technology

TOXIKON FINAL GLP REPORT: 08-2417-G1

L929 MEM ELUTION TEST – ISO

Test article
Polymer Technologies Foam PAFS4-BU

Author
Franck Grall, Pharm.D., Ph.D.

Final Report Date
June 13, 2008

Performing Laboratory
Toxikon Corporation, 15 Wiggins Ave., Bedford, MA 01730

Sponsor
Respironics, Incorporated, 365 Plum Industrial Court, Pittsburgh, PA 15239

STUDY SUMMARY

Severe biological reactivity (Grade 4) was observed in the L929 mammalian cells at 48 hours post exposure to the test article extract. The observed cellular response obtained from the positive control article extract (Grade 4) and negative control extract (Grade 0) confirmed the suitability of the test system. **Based on the criteria of the protocol, the test article, Polymer Technologies Foam PAFS4-BU, is considered cytotoxic** and does not meet the requirements of the Elution Test, ISO 10993–5 guidelines.

Highlighted, bold emphasis added. Recreated from original documents

Source: Internal Philips records — James Hilston/Post-Gazette

Philips doctor: Company failed to respond to safety concerns

Excerpts from a Aug. 2, 2021, internal ethics complaint filed by Philips Respironics medical director Hisham Elzayat, who said he was excluded from key meetings to discuss safety.

Reporter Information

Reporter anonymous: No

Reporter first name: Hisham

Reporter last name: Elzayat

Please identify the person(s) engaged in this behavior:
David Ferguson - SRC/HRC Business Leader
Gary Lotz

Did complainant observe this personnally or is it based on rumors?
Yes

Please identify the primary applicable Philips organization:
CC - SRC

Where did it happen? Insite

When did it happen (indicated last time it has happened)?
Throughout the last year

How long has it been going on? 6-12 months

Has this incident been reported to management? Yes

If reported to management, who was it reported to?
Jan Kimpen - CMO
David Ferguson - SRC business leader
Peter Ziese - medical innovation

Details:
I have worked on the critical issues associated with Project UNO – our ventilators and continuous positive airway pressure machines — for several months. From the first time I reviewed both the toxicology and volatile organic compound ("VOC") reports, I expressed my concern for patient safety. I have expressed my views that the Health Hazard Evaluations ("HHEs") should take into account all identified risks associated with potential patient safety impact.

Unfortunately, after expressing my initial concerns, opinions, and clinical assessment on this topic, I was excluded from several key meetings. I have expressed significant concern for patient safety to directly to Gary Lotz, who was the head of Clinical and Medical Affairs for SRC at that time and ultimately accountable to ensure my expert physician opinion would always be considered by the entire team, in addition to many others.

Unfortunately, my opinion was not considered regarding patient safety; however, I was in fact excluded from key meetings, including those with John Frank, the head of Ambulatory Monitoring and Diagnostic Services.

Highlighted, bold emphasis added. Recreated from original documents

Source: Internal Philips records — James Hilston/Post-Gazette

'These go in patients'

After long and contentious meetings, Dr. Elzayat and 11 others moved forward in November 2020 to carry out hazardous health evaluations of the DreamStation sleep apnea device and Trilogy ventilators, which could be used by children and pregnant women, the group noted.

By the time the studies were finished in April 2021, the team found the chemicals emitted in the machines presented "unacceptable" risks to patients that could cause "life-threatening" injuries and "permanent impairment." Among the compounds: diethylene glycol, which is used in antifreeze and brake fluid.

In May, Philips medical affairs supervisor Drilon Saliu said that the presence of phenol, a compound that can cause kidney or liver damage with severe exposure, was alarming. "These are not widgets — these go in PATIENTS," he wrote in a Teams chat.

The evaluations and push by team members prompted Philips to launch a recall, the largest of its kind, on June 14, 2021. Up to 15 million devices would be impacted.

Within two months, Philips' shareholders filed a lawsuit in New York alleging the company concealed the dangers from investors while hundreds of lawsuits were filed in federal court in Pittsburgh, accusing the company of selling devices that led to injuries, including cancer and organ failure.

Despite the company's acknowledgment of the risks, Philips embarked on a course that would soon surprise safety engineers and lead to fights within the company.

While multiple tests showed excessive levels of formaldehyde and phenol, Philips turned to at least two other independent labs in 2021 after the recall was launched to get other opinions, prompting scientists within the company to question why Philips was searching for new tests.

One of the labs had found in 2019 that the foam emitted excessive levels of formaldehyde, but had now changed its analysis methods, records and interviews show.

Heated discussions took place when one faction in the company pushed for tests using thresholds that would ensure the readings would be acceptable, records show.

"It was obvious he was trying to pass the device by any method that would work," wrote Philips engineer James Horne after a company supervisor in August 2021 pushed for more positive results.

'Babies are using our products'

That same month, the sleep and respiratory regulatory managers sent a 10-page memo to a company leadership team providing the complaints of at least a dozen employees, including some who resigned over the safety of the breathing machines and other devices.

Many of the workers claimed the business interests of Phillips were taking precedence over the health of patients, records show.

In the case of Holly Cotter, a regulatory engineer who resigned from Philips in July 2021 and was considered "a key contributor" to Project Uno, "she was very upset about how long it took the business [interests] to react to the seriousness of the health issue that arose from the project designs," the memo said.

"Holly said the ultimate reason she quit is that she felt that the business did not care for the end users and that babies are using our products."

Ms. Shearer, the compliance specialist, said she was upset over what she called the company's push for growth over protections. "I

SEE **PHILIPS**, PAGE A-7

Andrew Harnik/Associated Press

Key internal documents — including text messages, emails and reports — have been turned over to the U.S. Justice Department as part of a criminal investigation into Philips and the role of its top executives in handling the health crisis surrounding its breathing machines.

Documents reveal employees' anger over safety breakdowns

PHILIPS, FROM A-6

have witnessed the prioritization of more — more revenue, more market share, more cost savings — to the detriment of our customers and more specifically patients' safety and well being," she wrote.

Disputes erupted within the company over the science itself — the methods of testing the chemicals released from material in machines that are strapped to peoples' mouths and noses for hours at a time.

At one point, a manager from a lab hired by Philips said his group was able to "bring the formaldehyde levels down" in the foam by coming up with an average reading from test scores taken throughout the day, a method that masked the risks.

But the manager warned in an email that "this particular data set would raise some flags in the regulatory review."

By October 2021, Philips had brought in a consultant who claimed the phenol found in the foam was not as harmful as previously determined, citing a 2010 Canadian study that set a higher threshold for risk, according to emails.

In response, Dr. Elzayat sent an email to the Pittsburgh leadership team and pointed out that the consultant failed to take into account a subsequent Canadian study that came out two months later that rejected the earlier assessment, saying the thresholds did pose critical risks.

He later said in an internal complaint the Philips managers never responded to his message, and that he was already being shut out of meetings and assigned to a new supervisor. "I had been alienated and neutralized," he wrote.

Just six months after announcing the recall, company engineers exchanged emails saying the company — after turning to two additional labs — was getting test results that showed the foam was not as dangerous as previously reported, records show.

On Dec. 23, Philips released a statement that the company had used "certified testing laboratories" and third-party experts to show the foam would not likely cause long-term harm and that previous findings relied on a "limited data set and toxicological risk assessment."

At the same time, complaints were bombarding the company — thousands since the recall — from patients and others who reported black particles, tar, dust and other debris in devices that were only supposed to deliver clean air, records show.

Some of the patients said they were hospitalized for vomiting, fainting, kidney failure and a host of respiratory illnesses.

Submitted photo

Dr. Hisham Elzayat, the Philips medical director who helped lead the battle to remove the machines from the market.

USA.philips.com

David Ferguson was among the top leaders at Philips Respironics during the tumultuous 2021 recall of millions of the company's breathing machines.

By the end of 2021, scientists expressed concerns that patients waiting for new devices during the recall would continue to use their old machines in light of the company's claims the foam no longer posed severe risks.

One of the labs hired by Philips in Pennsylvania refused to change its results in 2021 that showed multiple failings for chemical compounds.

One of the lab's biggest concerns, records show, is that while individual chemicals in the foam can pass and fail according to various recognized thresholds, the foam ultimately tested positive for genotoxicity — the ability of a chemical to cause cells to mutate, a process that can lead to cancer.

"No one wants to own the foam is bad," Matthew Heidecker, a lab executive, emailed a Philips engineer.

More safety issues

Emails show the lab took its tests and other evaluations in 2021 to Shayne Gad, a nationally recognized expert on toxicology and former president of the American College of Toxicology.

In one of his evaluations, Mr. Gad, who has written numerous scholarly papers on medical device safety, said the phenol emitted from the foam was genotoxic, one of the most serious failings, and that other tests that passed the foam failed to accurately assess the risks.

In addition to Mr. Gad, the FDA stepped forward and challenged the company's findings in 2022, saying the tests by Philips to recast the risks were not adequate.

The FDA found that "the recalled devices present an unreasonable risk of substantial harm to the public health," the report said.

Philips said it would continue to perform tests on the machines while it embarked on a plan to replace the problem foam with a new silicone material in the replacement devices.

But that material, too, raised safety concerns among Philips' scientists.

Tests by independent labs hired by Philips found the new foam used by the company — material fitted in the millions of replacement machines — was also emitting hazardous chemicals, including formaldehyde.

One of the devices was the DreamStation 2, a newly released sleep apnea machine that was promoted as one of the company's primary replacements. The FDA noted in a report that the machine failed emissions testing because it produced "compounds of concern" and that pediatric patients who use the devices could be especially vulnerable.

"This is all so sad," wrote Katie Feurer, a Philips engineer, in a Teams message to Mr. Saliu, the head of medical affairs, in September 2021. "I wish it were different."

Mr. Saliu, who is no longer with the company, said Philips had not been transparent with his team about the tests on the new foam. "This behavior must stop," he wrote to Ms. Feurer. "Patients count on Philips with their health and well being and the foam MUST be safe — quality must be ensured, period. Patient safety is what matters above ALL other things."

Ms. Feurer responded: "I am with you 1000000%," and later added in the same exchange: "I find it very strange that there are 10 devices sent to three different test houses [labs] — this is not normal and look like fishing for results that we like."

Mr. Saliu responded: "Yes, exactly and that is NOT normal."

In a recent statement, Philips said the material had been "extensively tested by multiple, independent certified laboratories in accordance with the applicable regulatory standards, and no safety issues have been identified."

"The repaired and new replacement devices with the silicone sound abatement foam are safe," the company said in a 2023 response to the Post-Gazette.

Internally, the company's tests drew criticism from several scientists. In one case, Dr. Sujata Bhatia, a bioengineer and physician, said she was alarmed after she reviewed some of the test results of the silicone in 2022.

"This is not a typo. The volatile organic compound is 6.25 times the threshold for safe exposure," she texted an independent lab. Ms. Feurer, Mr. Saliu and Dr. Bhatia did not respond to interview requests.

In its own statement to the Post-Gazette, the FDA said more tests are needed on the foam before determining if the devices pose "risks to patients," and that people should continue to use the machines in lieu of going without a device as the tests continue.

Prosecutors bear down

Medical experts interviewed by the Post-Gazette say the internal fights over the foams and the complaints filed by employees underscore just how serious the differences were between factions of the company while millions of people were still using the machines.

"The whole regulatory process [fell] apart," said Kushal Kadakia, a public health researcher at Harvard Medical School who has written about the recall.

Beyond the staff members who pushed for reforms, Mr. Kadakia said the FDA should have stepped in sooner to ensure the safety concerns were addressed. The agency did not take any action until the recall in 2021. "Why is this happening to medical devices as opposed to drugs?" he said. "Because there is so little [regulation] of medical devices."

The FDA said that it responded as soon as it learned of the dangers, nearly two months before the machines were removed from the market. But the Post-Gazette and ProPublica found that the agency received hundreds of complaints about the devices starting in 2011 about the foam breaking down in the chambers. Some reports singled out "contamination," a red flag that experts say should have prompted an inquiry.

"Where was the oversight?" said Dr. Rita Redberg, a cardiologist at the University of California San Francisco who researches medical device safety. "There were reports from the company to the FDA about problems with the devices dating back to 2011."

John Cogan Jr., a former attorney for the U.S. Department of Health and Human Services, said prosecutors in the federal probe will more than likely scrutinize the role of company leaders in the crisis and the decisions they made when faced with the hundreds of complaints that came into Philips before the recall.

"They are going to look at the individuals," said Mr. Cogan, a University of Connecticut law professor and an expert in health care law. "It's high profile. It's a lot of money. The damage is severe."

He said he was alarmed by the records that now show "there were a significant number of people pushing back in the company" for stronger safety measures. "And then the company goes out to look for new data. You have to imagine how that looks to a jury."

Dr. Elzayat said that he was ultimately stripped of his duties as medical director after he refused to sign an updated health evaluation in late 2021 that said the foam was no longer unsafe, records show. "I have been excluded from all meetings and communications," he wrote in 2022.

Others have left the company, including Mr. Moret, who did not respond to interview requests.

Mr. Kadakia said the emergence of the records provides a rare glimpse into the role of employees who challenged their own company during a health crisis. "It's an example of people who were willing to resign their own jobs. In medicine, the first rule is to do no harm. To me, they abided by that rule."

Now, it's up to federal investigators to examine the roles of people in the company who were making key decisions and to see "if they were intentionally holding back information," he said. "It's really a story about transparency — who had access to information and when."

For company scientists pressing for patient protections, the dangers of the foam were known for years. "What's there is literally there," wrote Mr. Moret in a text to an outside lab just months before the recall. "And no matter what you do, it's not going to go away."

Michael D. Sallah: msallah@post-gazette.com; @mikesallah7; Michael Korsh; mkorsh@post-gazette.com; @michael_korsh

Memo detailing internal turmoil at Philips

In August 2021, a Philips regulatory management team sent a memo to company regulatory leaders, saying that concerns within the team has led to some resignations and harsh criticism about company's approach to safety.

MEMO

To: Connected Care Regulatory Leadership

Date: 05 August, 2021

Subject: Examples of Risk, Non-Compliance, and Ethics issues at SRC

From: SRC/HRC Regulatory Management Team

This memo's purpose is to illustrate the corporate culture at SRC, particularly as it relates to issues resulting in unmitigated risk, noncompliance to internal procedures or external statutes/regulations/standards/certifications, and compromised ethics. Several interrelated and independent situations from both the Sleep and Respiratory Care (SRC) and Hospital Respiratory Care (HRC) business units are detailed throughout the body of this memo with evidence provided where available as a referenced attachment.

Date(s) of Event: July 14, 2021

Individual/roles involved: Holly Cotter, Regulatory Engineer

Summary of Event: Holly submitted her resignation on 7/2/21. She was a key contributor to the UNO project as a Regulatory Engineer. In my discussions with her upon her resignation, she was very upset about how long it took the business to react to the seriousness of the health issue that arose from the product designs.

Date(s) of Event: July 30, 2021

Individual/roles involved: Eliza Shearer, Senior Reg Engineer

Summary of Event: She resigned in July 2021, citing her strong ethical and moral code as being a reason she could not continue her employment at SRC. Please see the attachment (Exit Perspective(s) In the attachment below she cites an accessory not manufactured by Philips

Highlighted emphases added. Recreated from original documents

Source: Internal Philips records James Hilston/Post-Gazette

Gene J. Puskar/Associated Press

Within two months of a massive recall in 2021, Philips shareholders filed a lawsuit in New York alleging the company concealed the dangers from investors while hundreds of lawsuits were filed in federal court in Pittsburgh.