SPRING ED GUIDE
EVOLVING EDUCATION
32-PAGE SPECIAL SECTION INSIDE

DUKES ADVANCE TO A-10 TOURNAMENT FINAL
SPORTS, B-1

SHOPPING SAVINGS INSIDE

Special Report on Youth Sports
A look at the challenges faced and rewards reaped by children in athletics. **Health & Wellness, H-1**

Sunday

PA. NEWSPAPER OF THE YEAR
Winner of the Keystone Media Award in 2020, 2022 and 2023 for top performing newsroom among Pennsylvania's largest news organizations
KEYSTONE MEDIA AWARDS 1st PLACE

Pittsburgh Post-Gazette

ONE OF AMERICA'S GREAT NEWSPAPERS

$5.00 | 237 YEARS OF SERVICE | SUNDAY, MARCH 17, 2024 | VOL. 97, NO. 229, 3/17/24 | FINAL

SENATE RACE TURNS PROXY BATTLE

Presidential campaign themes engulf Casey-McCormick contest

By Benjamin Kail
Pittsburgh Post-Gazette

WASHINGTON — While Democratic U.S. Sen. Bob Casey and Republican challenger David McCormick have highlighted their own careers and positions as their pivotal race heats up, the candidates and their political parties have spent almost as much time trying to link each other to the unpopular figures atop the tickets: President Joe Biden and former President Donald Trump.

Mr. Casey's team is trying to connect Mr. McCormick to Mr. Trump on such issues as abortion, taxes and election denial that it says are out of touch with most Keystone State

SEE **SENATE**, PAGE A-7

Election 2024

INSIDE
Israel, antisemitism continue to be flashpoints in Pa.'s U.S. Senate race. **Page A-3**

Associated Press photos
U.S. Sen. Bob Casey is in a fight for his seat with Republican David McCormick, right. Presidential politics are playing a role in the race.

PG INVESTIGATION

Different Pa. maker of medical devices faces scrutiny over foam use

A familiar breathing machine concern

By Michael D. Sallah, Evan Robinson-Johnson and Michael Korsh
Pittsburgh Post-Gazette

Months after Philips Respironics launched a massive recall of its breathing machines fitted with an industrial foam capable of spewing dangerous particles and fumes into the lungs of patients, another device maker just 60 miles away fired off a letter to customers that it was abruptly dropping its popular machines.

Drive DeVilbiss Healthcare said the news was "unfortunate short notice," but it would no longer be making its sleep apnea devices after delivering them to customers for decades from its sprawling facility in Somerset, Pa.

The company's CEO blamed a shortage of parts driven by the pandemic and hurdles in obtaining electronic chips as among the reasons for ending the sales of what was once a DeVilbiss signature device.

But what was not disclosed in the letter was that the DeVilbiss machines were filled with the same type of foam as the Philips devices — a material that can degrade and release volatile organic compounds, including formaldehyde, into the noses and mouths of users.

SEE **DEVILBISS**, PAGE A-6

Sebastian Foltz/Post-Gazette photos

Irish eyes are smilin'

City of Pittsburgh Firefighter Michael Ceoffe, above, shakes hands with longtime friend Devin Faloon, of Lawrenceville, on Saturday during the St. Patrick's Day Parade, Downtown. At left, Mike Zdinak, 45, of Ross, cheers for first responders marching in the parade.
Story, Page C-1

STEELERS ACQUIRE QB JUSTIN FIELDS
Trade with Bears brings in backup for Russell Wilson.
Sports, Page B-1

Local pizza-makers are ready to spin dough on world stage

By Hal B. Klein
Pittsburgh Post-Gazette

Matt Hickey struts to the center of the upstairs room at Caliente Pizza & Drafthouse's Aspinwall location following the conclusion of the local chain's weekly managerial meeting. The gathered crowd whoops as the top-hatted commissary manager, dressed in the green-and-glitter of an end-of-the-rainbow leprechaun, begins to swing to the introductory chords of Dropkick Murphys' "I'm Shipping Up to Boston."

As the thumping song builds momentum, Mr. Hickey, like a flair bartender from the "Cocktail" era, spins two soft-green, pizza-shaped dough rounds into the air. His teammates burst

SEE **PIZZA**, PAGE A-4

Hal B. Klein/Post-Gazette
Iron Born Pizza's Pete Tolman, left, and Sara Boyer following a mid-March Pizza Expo practice with friend and fellow competitor Eddie Stalewski.

JARED COHON | 1947 – 2024

Helped thrust CMU into global spotlight as president

By Maddie Aiken
Pittsburgh Post-Gazette

Jared Cohon, the former president of Carnegie Mellon University who helped thrust the elite institution into the global spotlight, has died. He was 76.

Mr. Cohon became CMU's eighth president in 1997. He remained in that role until 2013, when he stepped down and began teaching civil and

SEE **COHON**, PAGE A-8

Jared Cohon

6 08136 26303 2

Benjamin B. Braun/Post-Gazette photos

The Drive DeVilbiss Healthcare facility in Somerset. DeVilbiss has defended its attention to safety standards, saying the company used the polyester foam in its DV5 machines, also known as the IntelliPAP, but has not detected any "safety or performance issues."

Safety concerns over breathing machines at another Pa. medical device maker

DEVILBISS, FROM A-1

Though the global company had posted a statement just two weeks after the Philips recall in 2021 that its DV5 devices were packed with the polyester-based polyurethane foam, it did not launch a recall or take steps to remove the material because the company said it did not find the same problems.

Over the next two years, the Food and Drug Administration would receive complaints about black debris turning up in the DeVilbiss devices while customers took to social media to post alarms about potential health risks and contamination in their machines, but the agency has yet to issue a public alert even as the machines are used by patients across the country.

"A public notification is years overdue," said Dr. Robert Steinbrook, director of Public Citizen's Health Research Group and an adjunct professor at the Yale School of Medicine. "It's a public health issue. [The FDA] should have considered a recall and a notification to consumers."

In the wake of the Philips recall, which the FDA classified as the most severe because the devices could lead to serious injury and death, the foam was singled out as the reason for what became a global health crisis.

'To my horror'

Since DeVilbiss halted the production of its machines — churned out for years at a factory near the Pennsylvania Turnpike — several complaints forwarded to the FDA about the DV5 models describe black particles, tar, and flecks of black foam inside machines that are only supposed to deliver clean air.

In one complaint in 2022, a device user described waking up "with a nose full of black snow" and another machine user last year detailed "black debris in my CPAP" and foam that "had turned into a black sticky tar-like substance."

"To my horror," wrote another in 2023, the foam particles are breaking up "and shedding is all over the fan motor and the chamber."

In emailed responses to the Post-Gazette, DeVilbiss defended its attention to safety standards, saying the company used the polyester foam in its DV5 machines, also known as the IntelliPAP, but has not detected any "safety or performance issues."

In all, the company said it made about 665,137 of the machines since 2007 in five different models to treat sleep apnea, a chronic disorder that causes breathing to stop and start during the night.

After learning about the Philips recall in 2021, DeVilbiss said it commissioned a risk assessment of its devices that was measured against the latest regulatory standards and found "the devices were safe for patient exposure."

But the details of those assessments — including the testing methodology used by the company — have not been released to the public, despite warnings by scientists and industry experts that the foam should not be used in breathing devices.

Tests of the material in the Philips machines reviewed by the Post-Gazette and ProPublica and carried out by three independent labs in 2021 found the foam emitted chemicals at levels that exceed safety thresholds established by multiple organizations. Among them: formaldehyde, a compound used in plywood and fertilizer that has been tied to respiratory ailments and some cancers.

"You need to remove the foam," said an engineer familiar with those tests and who spoke on the condition of anonymity because the person still works in the industry.

"You have a component that's known to degrade. It's fundamental chemistry. You can't change the way chemistry works. The potential harm outweighs the probability that it's safe."

Both DeVilbiss and the FDA said that because of the different interior design of the DV5 device and the location of the foam in the machines, the risks are not the same as the Philips machines.

"The PE-PUR foam exposure and the potential for particulate matter entering the airway is much greater for the Philips' devices," said Carly Pflaum, an FDA spokeswoman.

She said there's currently "no evidence of a safety signal" that suggests the devices "present a significant risk" to users.

However, experts who reviewed photos and documents of the DV5 on behalf of the Post-Gazette said the foam sits directly on top of the blower as well as below and around it and there's an air intake hole surrounded by the material which is positioned in front of the air path.

Duty to inform

At least two of the complaints filed with the FDA indicate the particles reached the hose and mask of users, and other patients shared their concerns on social media, pointing to the same problem. "The reports I see do not look good," said Madris Kinard, a former FDA analyst who founded a company in York, Pa., that tracks the agency's data.

Internal correspondence obtained by the Post-Gazette between the FDA and DeVilbiss shows the federal agency itself raised concerns earlier this year about the material in a DeVilbiss oxygen concentrator machine, warning the company in an email that "polyester-based polyurethanes have been shown to degrade over time releasing volatile organic compounds and particulate matter which can be a safety concern for patients."

Safety advocates say the FDA had a duty to tell the public about the foam so that DeVilbiss customers could make their own decisions about whether to keep using the machines.

The federal agency's talks with the company, which once boasted in ads to have the quietest CPAPs on the market, comes as scientists debate the hazards of a material that has been widely used in shoes, furniture and other products, but is known to degrade under heat and moisture and pose serious risks to those who breathe from the machines for hours each night.

An investigation by the Post-Gazette and ProPublica last year found that Philips received thousands of complaints about the foam degrading inside its devices dating to 2011, but failed to turn over the reports to the FDA as required by law until after the company launched a recall in June 2021.

Over the next two years, people using Philips devices reported symptoms that included vomiting, dizziness and headaches, as well as newly diagnosed cancers of the throat, sinuses, lungs and esophagus. Though it's nearly impossible to identify a causal link to specific cases of cancer, records show the foam used by Philips has tested positive multiple times for genotoxicity, the ability of a chemical to spur cells to mutate and cause the disease.

DeVilbiss, a global company with its headquarters in Port Washington, N.Y., said it has not received reports of injuries or deaths associated with the foam and that tests of the DV5 have not shown positive results for genotoxicity.

But medical experts interviewed by the Post-Gazette and ProPublica said that like cigarettes and asbestos, the long-term impact of the foam can take years to assess and that some people who have experienced health issues may not know the cause of their illness was from a CPAP, a machine regularly at their bedside.

In the aftermath of the Philips recall, the FDA said it launched a review of other companies that may be using the foam and in the case of DeVilbiss, the complaints about degraded foam were filed by people who were using the machine beyond the product's five-year service life.

"The FDA continues to strongly encourage consumers to follow the required labeling of their medical devices," said Ms. Pflaum.

But the veteran engineer who reviewed the same complaints about the DeVilbiss CPAPs said there is no way for the agency to know when the foam began breaking down — the first year or a decade later. "It's not like on the first day of the 6th year it starts to degrade," the engineer said. "That flies in the face of established precedents."

When Philips pulled its devices off the shelves in 2021 after discovering the foam was breaking down and potentially endangering the health of millions of users, DeVilbiss moved quickly to distance itself from the crisis.

The company posted an online notice June 29, 2021, saying that it used the same type of foam inside its DV5 models, and that it would continue to monitor reports about the machines, but there did not appear to be any problems.

Two months later, on Aug. 25, 2021, the company sent a letter to customers and announced it would no longer be making sleep apnea devices after 35 years in the business.

Those devices included the company's next generation DV6 machines, which were unveiled in 2016 with a different foam not known to break down.

In the letter, CEO Derek Lampert said the company, which once controlled about 7% of the nation's sleep apnea market, would continue to honor the warranties on the machines and keep selling parts, including filters and tubing, "to support continued usage of the CPAPs by users."

The letter was dated on the same day the FDA finished an inspection of the Somerset facility, where regulators turned up a slew of deficiencies, including poor management and review of complaints about the company's devices, most notably its oxygen concentrators.

In early 2022, DeVilbiss sold its sleep apnea operations to 3B Medical, now called React Health, for $2.25 million plus future royalties, according to a sales agreement, but continues to investigate all complaints and potential problems that could put patients at risk.

Drive DeVilbiss is an offshoot of a 135-year-old company known as DeVilbiss Manufacturing, founded by an Ohio physician in the 1880s who developed an atomizer that sprayed medicine into the throats of patients suffering from colds.

The company launched its first oxygen concentrator in 1977 and its first CPAP in 1989 – just four years after Respironics rolled out its CPAP – expanding its distribution to more than 80 countries. Devilbiss was acquired by wheelchair maker Drive Medical in 2015.

'A flurry of bits'

In the aftermath of the company's decision to stop making the CPAPs, users of the machines turned to social media websites, including Reddit and YouTube, to press for more information about the potential risks.

"The machine blows out very small pieces of black, disintegrating foam," one user wrote on a sleep apnea support board in 2022. "When I try to clean it up, it leaves black, tar-like smears."

Another noted that he woke up "with nostrils full of flecks of black foam." When he removed the hose from the machine and turned it back on, "a flurry of bits of foam shot out, about four tablespoons of the stuff."

Nick Dunn, a sleep apnea technician in Australia with over 130,000 YouTube subscribers, has released numerous videos since the Philips recall warning of what he said were potential hazards from the foam breakdown.

In one segment last year, Mr. Dunn showed how Devilbiss machines are filled with polyester foam and shared a video from a customer who found the material had badly broken down inside the machine. "Like grease, so sticky," the customer said.

In a public report to the FDA in 2023, Devilbiss said it stepped up the monitoring of complaints after the Philips recall and did "additional confirmatory testing," though details of those tests have not been made public.

The Therapeutic Goods Administration, Australia's FDA equivalent, launched its own inquiry in 2021 of the health issues surrounding all respiratory devices sold in the country, and has asked DeVilbiss to provide "evidence to support the long-term safety of the foam materials." The TGA identified several DeVilbiss models with polyester foam and said it is still reviewing the company's safety information.

When DeVilbiss revealed it was using the same foam, the company said there are different chemical and mechanical variations of the material and it had been monitoring its complaints as well as sales, service and repair data and did not detect any health risks.

But several experts interviewed by the Post-Gazette said material that's known to degrade — especially foam capable of emitting chemicals into the chambers — creates its own hazards when placed inside breathing devices. Many patients using CPAPs are already suffering from chronic illnesses, including heart conditions, pulmonary disease and other ailments, making them even more vulnerable.

A medical researcher who has written extensively about the Philips health crisis said a broader review of all breathing devices fitted with foam should take place in the U.S.

"FDA should've convened an advisory committee to consider the issues raised by Philips about the broader category," said Kushal Kadakia, a public health researcher at Harvard Medical School. "The big issue with medical device recalls is that we focus so much on individual actors and not enough on whether the safety signal we are seeing could affect an entire class of products."

For years, CPAP makers have inserted different kinds of foam in their devices to quiet the humming, vibrating machines that disturbed patients and their partners as they slept.

The largest Philips competitor, ResMed, said it used different foams in its machines, including silicone, which has not been found to break down like the polyester polyurethane.

As early as 2014, the FDA co-hosted a meeting with medical device companies in Herndon, Va., where they discussed the potential dangers of materials packed inside ventilators and releasing volatile organic compounds in the machines.

Michael Twery, former director of sleep disorders research at the National Institutes of Health, said most people won't link acute symptoms like coughing or dizziness to use of a potentially damaged device unless they are warned about the problem.

"It's kind of like living in a house with lead paint," he said. "It's not like you can feel it."

Michael Sallah: msallah@post-gazette.com; @msallah7; Even Robinson-Johnson: ejohnson@post-gazette.com; Michael Korsh: mkorsh@post-gazette.com; @michael_korsh

Foam breakdown in Drive DeVilbiss Healthcare CPAPs

The medical device maker, which runs a large facility in Somerset, acknowledged it was using the same kind of foam as Philips in its breathing machines — a material capable of breaking down and emitting hazardous particles into the masks of patients. Though DeVilbiss, which stopped making the devices in 2021, said it did not detect the same problems, some complaints filed with the FDA and posted on social media, report similar issues as the Philips devices: black debris, tar-like substance, other contamination in the devices.

COMPLAINTS FILED WITH FDA

Nov. 22, 2022

Description

I NOTICED BLACK DEBRIS IN MY CPAP (CONTINUOUS POSITIVE AIRWAY PRESSURE) HOSE. I TOOK THE MACHINE APART AND FOUND A HOLE WAS TORN APART NEAR THE CIRCULATION PUMP. THE CPAP WAS A DEVILBISS INTELLIRAP OR DV51D. THE FOAM INSULATION HAD TURNED INTO A BLACK STICKY TAR LIKE SUBSTANCE. FDA SAFETY REPORT ID (B)(4).,I NOTICED BLACK DEBRIS IN MY CPAP (CONTINUOUS POSITIVE AIRWAY PRESSURE) HOSE. I TOOK THE MACHINE APART AND FOUND A HOLE WAS TORN APART NEAR THE CIRCULATION PUMP. THE CPAP WAS A DEVILBISS INTELLIRAP OR DV51D. THE FOAM INSULATION HAD TURNED INTO A BLACK STICKY TAR LIKE SUBSTANCE. FDA SAFETY REPORT ID (B)(4).

Other Elements

June 27, 2023

Description

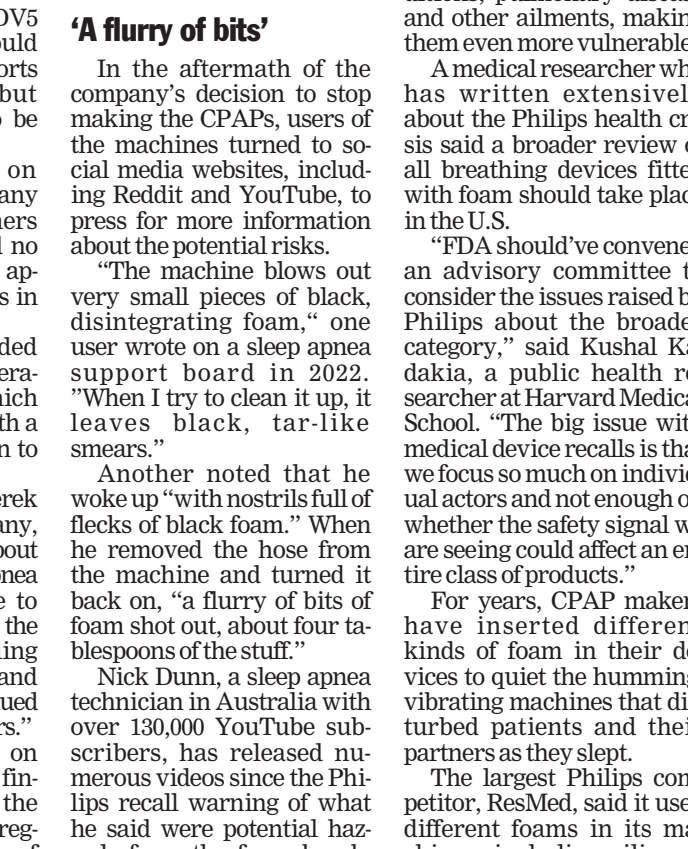
ADDITIONAL INFORMATION RECEIVED FROM REPORTER ON JUNE 27TH 2023 FOR REPORT NUMBER MW5118808.,I AM A CPAP USER. I HAVE BOUGHT A DEVILBISS DV54D ONLINE FROM THE US. I AM A MALAYSIAN RESIDENT. DUE TO THE PHILIPS RECALL ON THE FOAM ISSUES. I HAVE OPENED MY CPAP MACHINE UP AND TO MY HORROR, THE FOAM FOR THE DEVILBISS HAVE DEGRADED AND THE FOAM PARTICLES AND SHEDDING IS ALL OVER THE FAN MOTOR AND THE CHAMBER. I HAVE NO RELATED SYMPTOMS BUT WORRY OF THE LONG TERMS RISK FOR BREATHING IN THIS FOAM MATERIAL. NO TEST PERFORMED. ONLY OPENED UP AND PERFORMED VISUAL INSPECTION OF THE SOUND ABATEMENT FOAM.

Other Elements

FOAM NEAR THE AIR FLOW

Though Drive DeVilbiss said the design and mechanics of its DV5 series CPAPs are different than the recalled Philips machines, this photo shows the close proximity of the polyester-based polyurethane foam — known to break down under heat and moisture — to the airpath of devices that are only supposed to deliver clean air.

Photo courtesy of CPAP Reviews



Source: U.S. Food and Drug Administration Manufacturer and User Facility Device Experience database

James Hilston/Post-Gazette

Since Drive DeVilbiss Healthcare halted production of its CPAP machines — churned out for years at a factory near the Pennsylvania Turnpike — several complaints forwarded to the FDA about DV5 models describe black particles and tar inside machines that are supposed to deliver clean air.