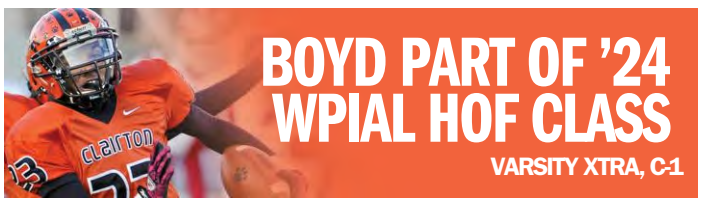

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GAO WILL INVESTIGATE FDA HANDLING OF RECALLS

WITH EVERY BREATH

Congressional watchdog will launch inquiry into agency's oversight of medical device recalls, including Philips' CPAPs

By Jonathan D. Salant
Pittsburgh Post-Gazette
Haajrah Gilani, Phillip Powell and Juliana Ventura
Medill Investigative Lab

WASHINGTON — Congressional investigators are launching an inquiry into the Food and Drug Administration's oversight of medical device recalls for the first time in years following reports that the agency failed to issue warnings about breathing machines capable of sending hazardous particles and fumes into the lungs of patients.


Blumenthal


Durbin

U.S. Sens. Dick Durbin, D-Ill., and Richard Blumenthal, D-Conn., urged the Government Accountability Office to investigate, citing reports by ProPublica and the Pittsburgh Post-Gazette that detailed the role of the FDA in an ongoing health crisis that has threatened millions of people in the United States and around the world.

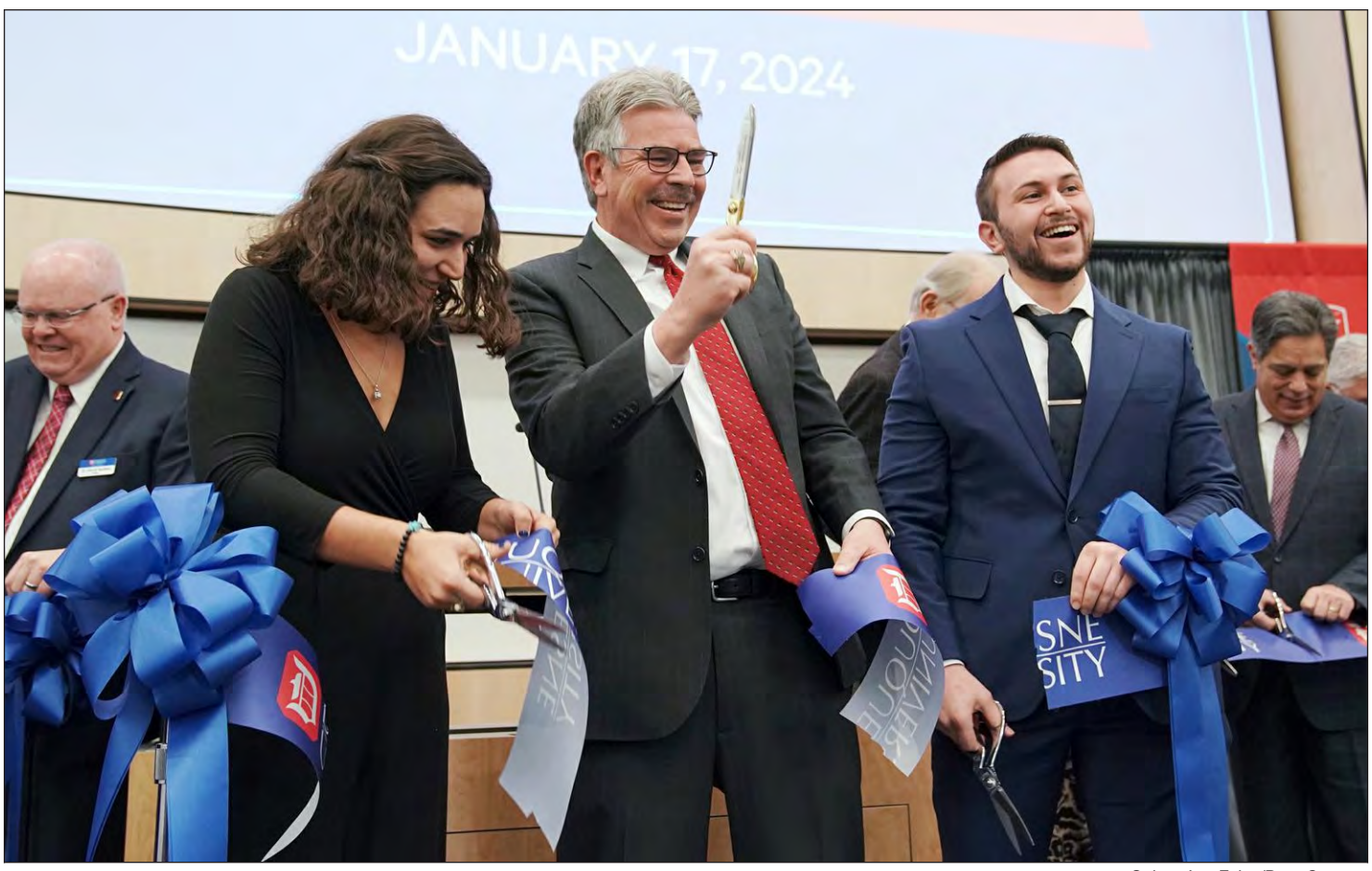
The news organizations revealed that the agency had received hundreds of complaints about breathing machines manufactured by Philips Respironics long before the company announced a massive recall in 2021, but took no action to alert patients or doctors.

Philips withheld thousands of additional complaints over the course of 11 years while customers who relied on the machines to breathe reported respiratory problems, kidney and liver conditions, and cancer, the news organizations found.

"It's clear from the Philips case that information about patient harm was known for years and not properly shared or addressed," Mr. Durbin, who chairs the Senate Judiciary Committee, said in a statement. "We must ensure there is

SEE **INQUIRY**, PAGE A-7

A CENTURY IN THE MAKING



Sebastian Foltz/Post-Gazette

Dr. John Kauffman, dean of Duquesne University's College of Medicine, far left, joins university President Ken Gormley, center, and future medical students Rose Trimpey-Warhaftig and Jacob Dimenbort at the official opening of the university's College of Osteopathic Medicine. The inaugural class of 85 students will begin their studies at the Uptown center in August.

A NEW DAY AT DUQUESNE

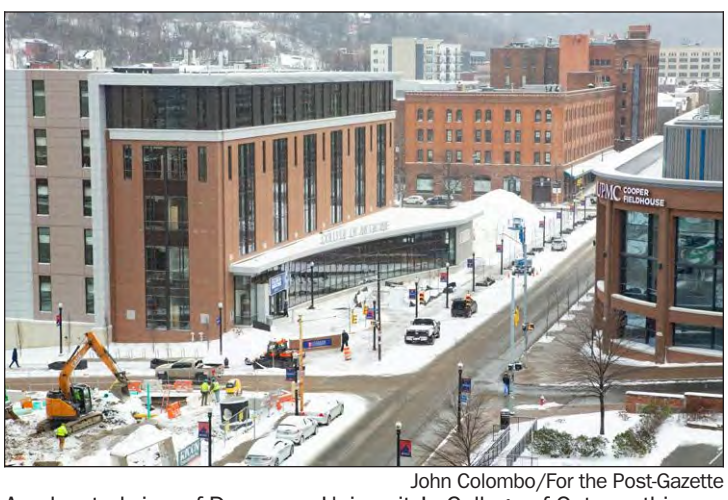
University opens medical school with a focus on region's high-need areas

By Anya Sostek
Pittsburgh Post-Gazette

In 1910, Duquesne University — then called Pittsburgh Catholic College — was looking to expand by adding a law school and a medical school. The law school started the following year, but the medical school couldn't get enough community support, due to the belief that one existing medical school in Pittsburgh was sufficient.

More than a century later, amid a nationwide shortage in primary care doctors, Duquesne is getting its medical school. Duquesne's College of Medicine has officially opened, with a focus on training primary care physicians who will practice in high-need areas in the region.

A ribbon-cutting ceremony Wednesday morning at the new building on Forbes Avenue began with a procession by university leadership from Old Main, the oldest building on Duquesne's campus.


John Colombo/For the Post-Gazette

An elevated view of Duquesne University's College of Osteopathic Medicine, at the corner of Forbes Avenue and Magee Street.

"For Duquesne, it's been the biggest undertaking we've done in 100 years," Provost David Dausey said. "It's more than just building a new building — it's creating an entire community infrastructure to support these students, who will go on to support the community."

Pennsylvania has a predicted shortage of 1,000 primary care physicians by 2030, according to the Hospital and Healthcare Association of Pennsylvania, and

SEE **DUQUESNE**, PAGE A-6

CONGRESSIONAL CONCERNS

Answers sought on care at VA

Local health system receives lowest ratings

By Benjamin Kail
Pittsburgh Post-Gazette

WASHINGTON — Democratic members of Pennsylvania's congressional delegation are pressing the Veterans Affairs Pittsburgh Healthcare System to address staffing, communication and other challenges they say are impacting the quality of care for almost 85,000 veterans.

U.S. Sens. Bob Casey and John Fetterman, and Reps. Chris

SEE **CARE**, PAGE A-2

Hill market 'in the final stretch'

By Mark Belko
Pittsburgh Post-Gazette

The shelves are being stocked. Deli equipment is being installed. And plumbers, electricians and painters are working frantically to apply the finishing touches.

Some two years in the making, Salem's Market is just about ready to make its much-anticipated debut in the Hill District.

CEO Abdullah Salem said Wednesday that he is hoping to open the grocery the first week of February — "if all the stars align and everything works out."

SEE **GROCERY**, PAGE A-2

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Weather
Cold with snow at times.
Daytime high, 29;
tonight's low, 23.
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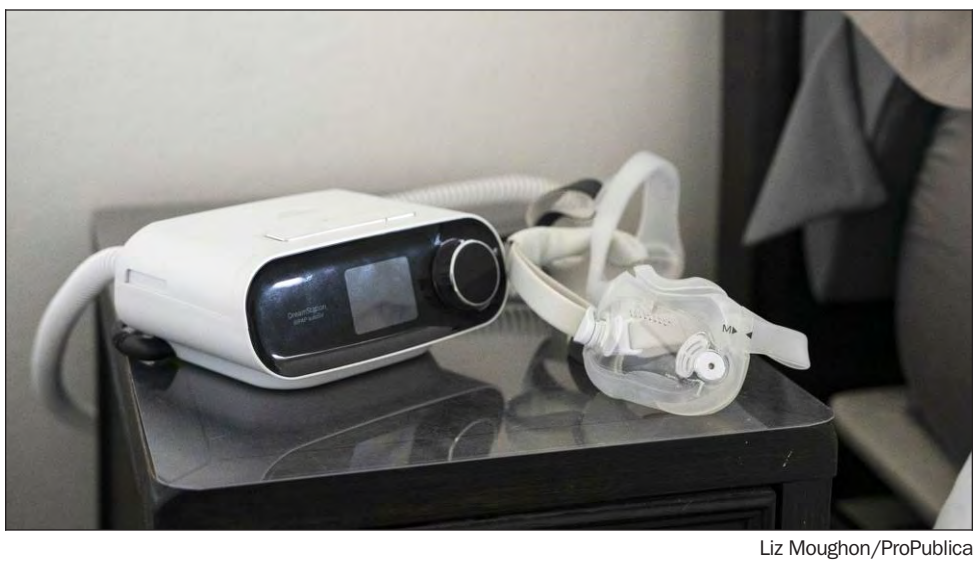
JOINT INVESTIGATION BY PG AND PROPUBLICA

WITH EVERY BREATH



Liz Moughon/ProPublica

A Philips CPAP machine. Congressional investigators are launching an inquiry into the Food and Drug Administration's oversight of medical device recalls for the first time in years. It follows reports that the agency failed to issue warnings about breathing machines capable of sending hazardous particles and fumes into the lungs of patients.

Watchdog will investigate how FDA handles recalling of medical devices

INQUIRY, FROM A-1

adequate oversight on medical device manufacturers so that Americans know the potential risks and can make informed decisions with their health care providers."

In their request to the GAO, the watchdog arm of Congress, Mr. Durbin and Mr. Blumenthal said they needed far more information about the FDA's oversight of the medical device industry, including how the agency ensures that companies initiate recalls and what happens when manufacturers fail to comply.

In an email, the GAO said it accepted the lawmakers' request to conduct an inquiry.

Philips has said that it evaluated the early complaints about its sleep apnea machines and ventilators on a case-by-case basis and launched the recall after the company became aware that an industrial foam fitted inside the devices could break down and release potentially "toxic and carcinogenic" material.

The FDA has defended its handling of the crisis, saying it received complaints about "general contamination issues" before the recall but that the debris could have been caused by external sources unrelated to foam. At least 30 of the complaints described foam degradation, but the FDA said the reports did not indicate that any patients had been harmed.

"The FDA welcomes the opportunity for GAO review of the agency's oversight of medical device recalls," the agency said in a statement last week.

Mr. Durbin and Mr. Blumenthal said the GAO inquiry would follow up on a similar probe in 2011 that called for changes to better protect patients. Safety advocates said a new investigation is badly needed and long overdue.

In 2022, the FDA received 3 million reports about malfunctioning devices — nearly 30 times more than in 2005, government records show. Nearly a third described injuries and deaths.

"At the end of the day, the public should have confidence in the products that are regulated by the FDA," said Kushal Kadakia, a public health researcher at Harvard Medical School who has written about the Philips recall.

Device safety advocates said the GAO should review whether the FDA is regularly using information in health records, insurance claims, medical device registries and other sources — data they said would greatly improve the agency's ability to track dangerous products.

> **"[The proposal] will create an efficient, accountable system for ensuring patients are routinely notified about safety recalls for medical devices. As our health system operates today, consumers and providers may never receive any information ... or may receive it too late to avoid adverse consequences."**
>
> **Chuck Bell**
> *Advocacy programs director at Consumer Reports*

The FDA moved to create a center to bring together that data years ago, but a comprehensive new system is still not in place, records and interviews show.

Former FDA analyst Madris Kinard also said the FDA should do more to ensure the safety of devices before they are marketed and sold. A controversial process at the agency allows device makers to gain clearance for a new product by showing that it is substantially equivalent to one already on the market.

Ms. Kinard said the FDA should investigate whether those older models had any safety issues before newer versions are cleared.

"Simply getting a new device to market to me isn't innovation," she said. "Innovation is only good if it's helping the patient."

Mr. Durbin and U.S. Rep. Jan Schakowsky, D-Ill., have proposed legislation aimed at ensuring that doctors and patients receive vital information about recalls by requiring the FDA to create an electronic system of communication for the agency, device makers, hospitals and other providers. The bill would also require device makers to disclose more information about health risks and instruct hospitals and health care workers to pass the information to patients.

The proposal "will create an efficient, accountable system for ensuring patients are routinely notified about safety recalls for medical devices," Chuck Bell, advocacy programs director at Consumer Reports, said in a statement. "As our health system operates today, consumers and providers may never receive any information ... or may receive it too late to avoid adverse consequences."

Medicare claim forms should also include identifying information for devices — model numbers and names of manufacturers — to make it easier to detect troubled devices and contact patients in the event of a recall, Mr. Kadakia and others said.

"Right now, we rarely know what device has been used in what patient and when," said Dr. Sanket Dhruva, a cardiologist and assistant professor at the University of California, San Francisco who has studied medical device safety and regulation. "Without this basic, really fundamental information about the device a patient has received, we can't track the device."

The GAO inquiry comes as a growing number of federal lawmakers call for investigations of Philips.

Ms. Schakowsky, the ranking member of the House Energy and Commerce subcommittee that oversees consumer product safety, said earlier this month that the company must be "fully held accountable and stopped from any future wrongdoing" if investigators determine that Philips failed to warn consumers in the years before the recall.

Ms. Schakowsky also cited new revelations, reported last month by the Post-Gazette and ProPublica, that a different foam placed inside replacement devices sent out by Philips after the recall was also found to emit hazardous chemicals, including formaldehyde, a known carcinogen.

"Americans should not be kept in the dark when it comes to the safety of their medical devices, and they certainly should not be forced to choose between a dangerous product and getting the care they need," Ms. Schakowsky said in a statement.

Philips has said the new foam is safe and does not emit chemicals at dangerous levels. The FDA, which first reported that the foam failed emissions testing in 2021, said more tests are needed.

Philips said it regrets any "distress and concern" caused by the recall and is cooperating with authorities. The company also said testing on the original foam in the months after the recall found that the chemical emissions are not at levels that can cause "appreciable harm" to patients. The FDA has challenged Philips, saying in a statement in October that the studies were not adequate and that the company had agreed to conduct additional tests.

Jonathan D. Salant: Jsalant@post-gazette.com