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SENATORS WANT PROBE OF FDA DEVICE OVERSIGHT



Durbin, Blumenthal say FDA missed opportunities to protect public, pointing to reports

By Jonathan D. Salant and Michael D. Sallah
Pittsburgh Post-Gazette
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ProPublica

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WASHINGTON — Two prominent U.S. senators are calling for a government investigation into the Food and Drug Administration's oversight of medical devices following revelations that the agency failed to protect the public from defective breathing machines capable of sending particles and fumes



into the masks of patients. Sens. Dick Durbin, D-Ill., and Richard Blumenthal, D-Conn., asked the Government Accountability Office — the investigative arm of Congress — to probe how the FDA tracks warnings about dangerous devices, oversees recalls and takes action against companies that put patients at risk. Mr. Durbin chairs the Senate Judiciary Committee and Mr. Blumenthal, who also sits on the panel, heads an investigations subcommittee that reviews violations of laws and regulations impacting



Alex Wong/Getty Images
Sens. Dick Durbin, D-Ill., left, and Richard Blumenthal, D-Conn., call for FDA accountability on patient care.

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TWO THINGS AT ONCE



Sebastian Foltz/Post-Gazette

Manaen Hu, 19, right, attempts to record her ice adventure Wednesday as she skates hand-in-hand with Tippi Li, 18, at the UPMC Rink at PPG Place, Downtown. The ice could be a little soft Thursday, when temperatures climb into the mid-40s. Weather report, **B-8**.

BIDEN IMPEACHMENT

GOP-led House approves inquiry

Partisan vote had backing of Western Pa. Republicans

By Ben Kail
Pittsburgh Post-Gazette

WASHINGTON — The GOP-led House of Representatives voted Wednesday to formalize an ongoing impeachment inquiry into President Joe Biden, with support from Western Pennsylvania Republicans.

U.S. Reps. Mike Kelly, R-Butler, Guy Reschenthaler, R-Peters, and Glenn Thompson, R-Centre, voted along with all other House Republicans to push forward with an investigation into the Biden family's finances.

Democrats united against the inquiry, citing a lack of evidence of impeachable offenses and accusing Republicans of buckling under pressure from twice-impeached former President Donald Trump, the GOP's presidential front-runner in 2024.

"With a formal impeachment inquiry

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Questions put hold on Jim Rogers settlement

By Megan Guza
Pittsburgh Post-Gazette

The city's involvement in the claims made in the aftermath of the 2021 death of Jim Rogers appeared to be near an end, but new questions arose in recent weeks that have put on hold the record \$8 million settlement the city agreed to pay to Rogers' family.

In a wide-ranging media briefing on Wednesday, city solicitor Krysia Kubiak offered an update on two pieces connected to Rogers' death: the wrongful death lawsuit filed by the Rogers family against Pittsburgh and the city's defense of the discipline meted out to the officers involved in the October 2021 incident.

The former is not hinged upon the latter in any way other than the overlapping parties: the city and Jim Rogers and, now, to a lesser

SEE **ROGERS**, PAGE A-2

Phipps 'pretty close' to a deal to purchase Irish Centre property

Vegetables and green space?

By Mark Belko
Pittsburgh Post-Gazette

A month after a Toronto developer ditched plans for a controversial condominium complex at the Irish Centre site in Squirrel Hill, Phipps Conservatory and Botanical Gardens has re-emerged as a potential buyer for the property.

Jim Graven, Irish Centre board president, confirmed Wednesday that his group is working on a deal with Phipps about a potential purchase of the Forward Avenue site, which borders Frick Park.

"We're pretty close. There are a few things we

have to work out," he said.

Phipps is back in the picture after Craft Development Corporation decided last month not to appeal an Oct. 30 Pittsburgh Zoning Board of Adjustment ruling rejecting the variances needed to build an eight-story, 160-unit condo project at the site. A Craft representative said at the time that its decision was "fairly self-explanatory" given the opposition the proposed project had generated and the ruling by the zoning board.

The condo development drew protests from Frick Park users and people who live near the

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COMING SUNDAY: THE BEST NEW RESTAURANTS OF 2023

The PG's Hal B. Klein breaks down Pittsburgh's best new restaurants in Sunday Mag. Spoiler alert: The Lilith restaurant with its Baked Alaska, left, makes the list.

Benjamin B. Braun/Post-Gazette

Pa. lawmakers complete budget deal

By Ford Turner
Pittsburgh Post-Gazette

HARRISBURG — Nearly 5½ months into the 2023-24 fiscal year, state lawmakers wrapped up the budget process late Wednesday by passing bills that freed up money for community colleges and other priorities and triggering an all-smiles, late-night news conference with Gov. Josh Shapiro.

"When we move the ball down the field it is important that we celebrate that," Mr. Shapiro, a Democrat, said at the 10:30 p.m. appearance that included top Democrats as well as Senate Republican majority leader Joe Pittman, R-Indiana. "Bipartisanship is what fires compromise."

Immediately after he spoke, Mr. Shapiro prepared to sign the budget bills. Mr. Shapiro had signed a \$45.45 billion

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Plenty of sunshine. Daytime high, 45; tonight's low, 30. **Page B-8**

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Local

Pa. lawmakers reach deal

BUDGET, FROM A-1

spending bill in early August, but money for many of the prominent items could not be distributed without the passage of other bills containing enabling language. The last group of those bills passed late Wednesday.

Their passage allowed money to start flowing in a variety of categories: More than \$260 million for community colleges; \$70 million for public libraries; \$100 million for school mental health grants, among others.

"We are very thankful that we were able to conclude this process while maintaining our fiscal stability," Mr. Pittman said. He praised the deposit of more money into the state's rainy day fund, as well as a "historic" increase of \$150 million in funding for the Educational Improvement Tax Credit program.

That program gives tax credits to businesses that make contributions to scholarship organizations and other education entities.

Mr. Shapiro reiterated his oft-stated observation that as the only governor working with a politically divided full-time legislature, compromise must be made by all parties.

Senate minority leader Jay Costa, D-Allegheny, said "we had a logjam that needed to be resolved" and that "we really laid a foundation for the future."

Earlier in the evening, with some votes still to be taken, Mr. Costa said in an interview that there had been bipartisan compromise in recent days.

"It was essential to get it done this week, and we did," he said.

It was the last scheduled session day of the year for both chambers, although some House members had previously said they might be called to meet Thursday and possibly Friday. The House had the added pressure of facing a three-month stretch in which, according to Speaker Joanna McCClinton, D-Philadelphia, its huge chamber will not be available because of repairs that must be made as a result of damage caused by a water leak.

Early in the evening, though, top Republicans in the Democrat-led House accused House Democratic leadership of failing to run the budget process fairly.

"Many of our concerns come down to the administration of the House," said Rep. Bryan Cutler, R-Lancaster and the minority leader. He said Republican

suggested amendments to bills were being consistently "excluded."

And Rep. Seth Grove, R-York and the top Republican on the House Appropriations Committee, questioned the urgency of the repairs to the House chamber and referred to the leak as "alleged."

Mr. Shapiro late last week challenged the Legislature to work together as the final session days of the year approached. When asked by a reporter about whether he should be more involved, Mr. Shapiro put it on lawmakers.

"I don't run the Legislature, right? We are separate branches of this government. They have a responsibility to govern. And if they can't figure that out, just pointing fingers at me it may make it a little easier for them temporarily, but it doesn't serve the interests of the good people of Pennsylvania," Mr. Shapiro said. "Our Legislature has to figure out how to show up to work and then they have to figure out how to work together."

On Wednesday, lawmakers worked on massive "code" bills more than 100 pages long that contained language needed to push out the money for some of the items in the spending bill.

A lengthy school code bill passed by both chambers on Wednesday included language that freed up the money for community colleges, libraries, the mental health grants and other items.

The Senate passed the bill with a 43-7 vote. Mr. Pittman noted that it was an exact duplicate of the bill that the chamber had passed on Nov. 15. When that bill reached the Democrat-led House, a committee stripped out the Republican-supported EITC program increase and sent the bill back to the Senate.

The Senate restored the EITC program to the bill, passed it again on Wednesday, and this time around the House passed it by a 175-28 margin.

The five-plus months of fiscal 2023-24 without a complete budget included several bouts of partisan finger-pointing. One of the worst came on July 5, five days into the new fiscal year, when Mr. Shapiro said he would line-item veto a voucher-style scholarship program that would let students from low-performing public schools attend private ones. He previously had supported the concept, and since then has indicated he would be willing to look at it again.



Andrea Ellen Reed/The New York Times

The Philips Respironics Omnilab Advanced+ breathing machine, one of several ventilator models the company recalled in 2021. Philips Respironics has agreed to a \$479 million partial settlement on claims over flaws in the company's breathing machines that spewed gases and flecks of foam into the airways of consumers and that spawned recalls involving millions of the devices, lawyers for plaintiffs in the lawsuit announced on Sept. 7.

SENATORS CALL FOR FDA PROBE

OVERSIGHT, FROM A-1

national health and safety.

The letter signed by the two lawmakers on Wednesday follows a yearlong investigation by the Pittsburgh Post-Gazette and ProPublica that detailed breakdowns by device maker Philips Respironics as well as the FDA in the years leading up to one of the largest and most disruptive recalls of its kind.

The news organizations found that the FDA had received hundreds of complaints about contamination inside Philips' popular continuous positive airway pressure, or CPAP, machines and ventilators long before the June 2021 recall but took no action to alert doctors or patients.

The complaints included at least 30 that described degradation of an industrial foam inside the machines that was found to break down and emit potentially hazardous material.

"It now appears that FDA missed several opportunities to mitigate the harm done to the millions of patients who have used these recalled medical devices," the senators wrote. "It is not clear whether or not FDA took action to inform hospitals, health care providers, and patients about the potential risks."

The news organizations also found that Philips, with two sprawling factories outside Pittsburgh, held back thousands of additional foam complaints from the



Even when Philips Respironics conducted an internal health hazard evaluation, which confirmed that inhaling the chemicals from the sound abatement foam could cause 'permanent impairment,' it did nothing, while patients suffered. That is unacceptable."

Sens. Dick Durbin and Richard Blumenthal
In a letter to the Government Accountability Office

government, some dating back to 2010.

The Post-Gazette and ProPublica reported that Philips carried out multiple internal tests on the devices before the recall, including health hazard evaluations that found the foam could release volatile organic compounds at dangerous levels.

"Even when Philips Respironics conducted an internal health hazard evaluation, which confirmed that inhaling the chemicals from the sound abatement foam could cause 'permanent impairment,' it did nothing, while patients suffered," the senators wrote. "That is unacceptable."

The senators asked the GAO to look at how the FDA ensures that medical device companies initiate recalls, what the agency does when manufacturers fail to comply, and what resources or legislation would be needed to improve the agency's oversight.

Mr. Durbin and Mr. Blumenthal said the inquiry would be a follow-up to a

similar GAO study more than a decade ago that found the FDA often failed to review medical device recalls to determine if they protected the public.

"Given recent reporting and the dramatic increase in recalls since then, it is clear that GAO and Congress must examine FDA's oversight of medical device recalls once again," the senators wrote.

In the Philips case, the FDA said it acted as soon as it learned of the safety concerns in April 2021, just weeks before the recall.

The agency acknowledged that it received earlier reports from Philips, including complaints that detailed "general contamination issues," but said the contamination could have been caused by external sources and not the problem foam. The FDA said it received 30 reports about the foam itself in the years before the recall but that those complaints did not indicate that any patients had been harmed.

Philips said it evaluated

foam complaints on a case-by-case basis and launched the recall shortly after the company became aware of the potential significance of the problem. The company has also said that more recent testing shows its machines are unlikely to cause "appreciable harm."

Philips and its parent company "share the same objectives as the FDA," the firm said.

In the aftermath of the news organizations' first story in September, Mr. Blumenthal asked the Justice Department to take immediate enforcement action against Philips. He later expanded his call for aggressive enforcement in a letter to FDA Commissioner Robert M. Califf and Attorney General Merrick Garland.

Calling the findings of the Post-Gazette and ProPublica "explosive," Mr. Blumenthal urged both leaders to "urgently use all of their authorities to protect current and future patients by investigating these allegations thoroughly, taking the strongest enforcement action possible, including criminal charges, if the allegations are substantiated."

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Phipps close to a deal to buy Irish Centre site in Squirrel Hill

IRISH, FROM A-1

Irish Centre, including Frick Park Friends, a group made up largely of Swisshelm Park residents.

While other bidders have expressed an interest in the Squirrel Hill property since Craft bowed out, Irish Centre officials are closer to a deal with Phipps than any of the others, Mr. Graven said.

"We're probably going to go in the direction of Phipps," he said.

A Phipps spokesman did not respond to an email seeking comment Wednesday.

The conservatory became involved in September by

submitting a plan to the zoning board offering to turn the Irish Centre site into a nursery and space for a program to bring fresh produce to city food deserts if the panel were to reject the variance requests for the condo proposal.

At the time, Phipps board chair Erica Cochran Hameen said in a letter to the zoning panel that the plan would not require any relief because the site at 6886 Forward already is zoned for community buildings and agricultural purposes. The Phipps fresh produce program is known as Homegrown and involves the installation of raised bed veg-



Mark Belko/Post-Gazette

The Irish Centre, as seen in June. Phipps Conservatory and Botanical Gardens has emerged as a potential buyer for the property, which borders Frick Park.

etable gardens in residents' backyards in city neighborhoods that are considered food deserts.

In materials submitted to the zoning board, the conservatory stated that it has been trying to find a home site for the program for several years.

It also said that it intends

to use the Irish Centre to grow plants for flower shows and as a staging area for a program it plans to start next year to establish green spaces in neighborhoods. As part of the plan, Phipps committed to reusing the vacant Irish Centre community building rather than demolishing it.

In its ruling, the zoning board stated that it did not consider the Phipps plan in its deliberations because the conservatory "did not assert any direct, substantial or immediate interest related to the application at issue."

Last month, Mr. Graven said he had not heard anything from Phipps since it

sent the letter to the zoning board in September outlining its bid. He added that it hadn't contacted anyone about an interest in the real estate in the year and a half it was on the market before Craft became involved.

But that changed in recent weeks when Phipps and Irish Centre officials started talking about a possible sale, Mr. Graven said. The two sides are now "very interested" in consummating a deal, he said.

The Irish Centre property includes the two-story community center, a two-story house, an in-ground swimming pool, and surface parking.

Frick Park Friends has urged Phipps to pursue a purchase, saying its plan fits with the zoning, would have minimal impact on the park and the character of the area, and would benefit the entire region.

Phipps Conservatory and Botanical Gardens in Oakland features a 14-room glasshouse and 23 gardens spread over 15 acres.

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