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PAY HIKE SET FOR SOME COUNTY WORKERS

Innamorato also plans increase in vacation time, changes to employee sick, family leave policies

By Steve Bohnel
Pittsburgh Post-Gazette

In her first press conference as Allegheny County executive, Sara Innamorato announced on

Wednesday an increase in hourly wages for some county employees, more vacation time and a change to a longstanding policy so that they can use sick and family leave as soon as they begin work.

The moves to raise the minimum wages paid by county government and to otherwise change employment policies came a day after the Democrat was sworn into office, and they mark a policy shift from previous administrations.

Ms. Innamorato's wage changes apply to a group of non-union employees — a few hundred full-time workers and a few dozen

part-timers. For 2024, the full-time employees will make at least \$18 an hour, increasing annually to \$22 an hour by 2027.

Affected part-time workers will see a \$3-per-hour base increase, meaning they'll be paid a minimum of \$15 an hour, effective immediately.

SEE **CHANGES**, PAGE A-2



Benjamin B. Braun/Post-Gazette
Sara Innamorato at her first news conference as county executive.

JOINT INVESTIGATION BY PG AND PROPUBLICA WITH EVERY BREATH



Pittsburgh Post-Gazette
Respironics founder Gerald McGinnis designed the CPAP and later oversaw the first mass production of these devices that were created to save lives.

RECALL CRISIS OVERSHADOWS LEGACY OF RESPIRONICS FOUNDER

'Disappointment and embarrassment,' CPAP inventor says

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By Michael Korsh,
Michael D. Sallah
and Mike Wereschagin
Pittsburgh Post-Gazette

Nearly 30 years before medical device powerhouse Philips Respironics launched one of the largest and most chaotic recalls of its kind, inventor Gerald

McGinnis faced a crisis that threatened to cost his burgeoning company millions.

The Respironics founder, who had been widely credited for creating the first mass-produced breathing machine in the United States, had discovered that another of his inventions had a serious flaw.

A resuscitation bag and mask known as the BagEasy was breaking down when it was supposed to push air into the lungs of patients struggling to breathe.

Respironics was a growing company in 1993, heralded for the continuous positive airway

SEE **RECALL**, PAGE A-7

COUNTY ASSESSMENTS

Towers get big property tax cuts

Breaks could upend city, schools budgets

By Mark Belko
Pittsburgh Post-Gazette

Three Downtown skyscrapers, including U.S. Steel Tower and PNC's headquarters, have won huge reductions in their property assessments, with officials predicting that it could be the part of a wave of cuts that could upend the local tax base.

The assessment on the Tower at PNC Plaza, the bank's Wood Street nerve center, has been cut by more than half, from \$147.2 million to \$72.3 million for 2022 and 2023, a reduction of \$74.8 million.

At U.S. Steel Tower, the city's tallest building, the assessment has been slashed by \$81.2 million from \$233.2 million to \$151.9 million for 2022 and by \$91.6 million to \$141.5 million for last year.

And at Three Gateway Center, where the owner is mulling a residential conversion, the assessment for 2022 and 2023 has been hacked by nearly \$27.2 million from \$62.7

SEE **ASSESS**, PAGE A-2

Iran blasts kill dozens at gathering

Rite was for general who died in U.S. drone attack

By Jon Gambrell
Associated Press

DUBAI, United Arab Emirates — Two bombs exploded and killed at least 95 people Wednesday at a commemoration for a prominent Iranian general slain by the U.S. in a 2020 drone strike, Iranian officials said, as the Middle East remains on edge over Israel's war with Hamas in Gaza.

No one immediately claimed responsibility for what appeared to be the deadliest militant attack to target Iran since its 1979 Islamic Revolution. Iran's leaders vowed to punish those responsible for the blasts, which wounded at least 211 people.

The blasts were minutes apart and shook the city of Kerman, about 510 miles southeast of the capital, Tehran. The second blast sprayed

SEE **IRAN**, PAGE A-6

These goats are hungry: Your Christmas Tree is on the menu

By Sydney Carruth
Pittsburgh Post-Gazette

All the goats at Allegheny GoatScape want for Christmas is your old tree.

A nonprofit that uses goats to clean up invasive vegetation in public spaces year round has opened its two farms for Christmas tree disposal. The goats love the greenery, and what they don't eat — basically, the trunk — will be turned into mulch for the

farms.

The trees are beneficial to the goats and the environment, said Allegheny GoatScape executive director Gavin Deming.

"If we're able to make use of something like a Christmas tree and give it a second and third life, really, why not? And the goats like it as a snack," Mr. Deming said.

The trees are a bright spot of

SEE **GOATS**, PAGE A-12



Tim Robbbaro/For the Post-Gazette

A goat munches on a discarded Christmas tree at the Allegheny GoatScape farm on the North Side. What's left is ground up for mulch.



ONLINE TODAY:
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post-gazette.com

Weather

Morning snow showers.
Daytime high, 35;
tonight's low, 21.
Page B-8

Bridge E-6
Business D-1
Classified C-11
Comics E-5
Crosswords E-6
Editorials A-10

Food E-1
High Schools C-8
Horoscope E-6
HotList WE-2
Local News B-1
Lottery B-2

Obituaries B-4
Perspectives A-11
Scoreboard C-7
Sports C-1
Television C-9
Weekend Mag WE-1



6 08136 26301 8

CPAP INVENTOR TROUBLED BY RECALL CRISIS

RECALL, FROM A-1

pressure (CPAP) machines that were helping patients sleep through the night, but still subject to the ups and downs of a tumultuous industry.

That year, Mr. McGinnis met with his engineers from the company's Murrysville headquarters. Then he ordered all of 50,000 BagEasy devices — the second recall of the masks in as many years — pulled from the shelves.

The company's stock would plunge by 11% after the news broke, but the 59-year-old founder of Resprionics was resolute.

"It wasn't even a question," recalled engineer Eric Kulikowski, the director of operations at the time.

Those who worked with Mr. McGinnis said it was a particularly difficult episode for the medical device inventor who had changed the lives of millions of people suffering from sleep apnea, a chronic and potentially deadly disorder that causes breathing to stop and start through the night.

But it was also an event that defined the way he ran his company, which grew to 4,900 employees and more than \$1 billion in sales by 2007 — the year that the Dutch conglomerate Royal Philips swept in with a tantalizing offer.

Sixteen years after Royal Philips bought his company and renamed it Philips Resprionics, Mr. McGinnis said he struggles to make sense of a new crisis that threatens to overshadow the legacy he built for nearly a half century.

In 2021, Philips pulled millions of CPAPs and ventilators off the shelves after it was found that foam placed in the devices could degrade into tiny particles and fumes and potentially send toxic chemicals into the respiratory systems of users.

A Pittsburgh Post-Gazette and ProPublica investigation found the company kept thousands of warnings about the breakdown secret for years and only turned over many of the reports about the problem to the government after the recall.

The Food and Drug Administration has received more than 370 reports of deaths, 2,000 cases of cancer and more than 17,000 cases of respiratory ailments tied to the devices.

In a statement, Philips said its first priority is patient safety and that it regretted "the distress and concern" caused by the recall and that it would "continue to work hard to resolve this for our patients and customers."

Philips said complaints about the foam were limited in the years before the recall and that when the company became aware of the potential significance of the problem in early 2021, it initiated the recall out of "an abundance of caution."

The revelations about the company's handling of the defects has left Mr. McGinnis fearful that patients will lose faith in a critical area of medicine that he once championed.

In an extensive interview — his first in the aftermath of the recall — the 89-year-old engineer described his profound disappointment in what happened to the brand that he created as well as concerns about company practices that risked the safety of millions.

"If you hurt somebody, the game is over," he said. "You've got to take responsibility."

Mr. McGinnis and his former employees in the United States and Europe say the crisis that has engulfed Philips and its customers shows how the company veered from the safety standards established decades ago when Resprionics was forging a

reputation as one of the world's leading medical device companies.

As a biotech inventor who had spent years working alongside doctors at Allegheny General Hospital — where a medical wing is now named after him — Mr. McGinnis questions why Philips didn't tell the government or its customers of disturbing reports about the foam and quickly make repairs.

"You act on these right away. You don't wait," he said. "We'd get a complaint from a customer, [we would] really jump into the complaint, see what he was talking about so it wouldn't turn into anything."

Lifesaving device

Mr. McGinnis, who lives with his wife in Oakmont, not too far from the massive Resprionics factory that he once opened, grew interested in the need for breathing machines when he served as the director of surgical research at Allegheny General.

While making rounds with doctors beginning in 1969, he witnessed the cost of the medical device pitfalls first-hand.

For patients whose windpipes had closed, doctors at the time relied on a procedure called endotracheal intubation, where a plastic tube was snaked into a patient's throat. Doctors would then use a syringe to push air into an inflatable cuff at the base of the tube, forcing open the windpipe.

But the cuff could overinflate. And as pressure built against the throat's inner walls, the delicate tissue could stretch until the trachea burst, causing irreparable damage. Doctors had no way of knowing when they were about to push too far.

Mr. McGinnis was driven to solve the problem and would spend the next several years working from his home on the outskirts of Pittsburgh on a small balloon-like device that would automatically release excess pressure before it rose to dangerous levels.

Soon hundreds of the small pouches were hanging from his basement ceiling, "like rubber stalactites," he said.

With a portion of his wife's inheritance and loans from doctors totaling \$13,000, he founded his first medical device company in 1971 in a move that would change his career. Five years later, he launched his flagship, Resprionics.

Soon, the work that he had carried out to help patients avoid the pain of endotracheal tubes caught the attention of a young pulmonologist who was trying to solve a problem that had confounded doctors for years.

Dr. Mark Sanders had been exploring treatments for a little-known disease called obstructive sleep apnea, which can be deadly if



Resprionics employees assemble sleep apnea machines in December 1990 in Murrysville.

Post-Gazette Archive photos



Benjamin B. Braun/Post-Gazette

The sprawling Resprionics manufacturing center in Murrysville — one of the largest makers of sleep apnea machines in the world — was purchased by Royal Philips in 2008.

left untreated.

For those who suffer from the condition, pauses in breathing through the night can last mere seconds or stretch into minutes, making deep sleep all but impossible.

Tapping into the technology that he developed, Mr. McGinnis and the doctor collaborated with others on a new device named the SleepEasy, a machine that gently pushed air through a mask with just enough pressure to keep the airway open.

The prototype was a loud, clunky contraption. When Mr. McGinnis hooked the machine up to one of his first test subjects, a high school principal, he thought it might be too unwieldy to work at all.

"He put this ugly face mask over his mouth and turned the really noisy blower around. I said, 'I doubt you're gonna be able to go to sleep,'" Mr. McGinnis recalled.

But the groundbreaking device showed promise. "He closed his eyes and didn't wake up for three hours," Mr. McGinnis said.

In 1984, the FDA cleared the device for the open market and by the next year, thousands were being ordered.

Resprionics, after years of financial struggles, was suddenly rushing to meet the demand.

"We couldn't make them fast enough," said Gene Scarberry, the company's former technical director. "It was so intense that the doctors were calling in to Gerry McGinnis, saying, 'Look: I'm going to sue you if you don't get me a SleepEasy right now.'"

The work of Resprionics was noted in medical circles

around the world, partly because of the relationships it built with customers. "They provided us with everything we needed," said Dr. Gustavo Moreira, a sleep medicine specialist who treats hundreds of patients in Brazil.

Forging a connection between employees on the factory floor and the vulnerable people who ultimately used the machines would become a key part of the culture of the expanding company, said Mr. Kulikowski, the former director of operations.

"Gerry would say, 'Assume that device is going to be used on or by the person you love the most. Now make your decision,'" Mr. Kulikowski said.

Tackling problems

During quarterly meetings, top managers from across the company would review quality control systems and delve into the most frequent complaints from consumers, former employees said.

Engineers probed for defects in the products they were shipping, and if multiple complaints emerged about the same problem, those reports were given a top priority.

"Gerry set the expectation of us very early on that talking about problems is OK — and hiding problems is not," Mr. Kulikowski said.

He and others acknowledge that Resprionics wasn't perfect. The 1993 recall of the resuscitation mask was one of at least five times the company had to warn customers of a defect and pull its products from the shelves. In 2003, Resprionics recalled 5,000 nasal masks after its engineers found patients were at risk of inhaling too much carbon dioxide.

In 2007, Forbes magazine took into account the company's regulatory history and financial practices and named Resprionics one of "America's Most Trustworthy Companies."

By then, Amsterdam-based Royal Philips, known for its televisions and light bulbs, had embarked on a buying spree of U.S. medical equipment companies. Resprionics was squarely in the company's sights.

The multinational corporation offered to buy the company for \$66 a share when its stock was trading at \$53. The board of Resprionics, chaired by Mr. McGinnis, had turned down an earlier offer. This time, the board had little choice but to accept or Philips was prepared to take the deal to the shareholders.

The sale was announced on Dec. 21, 2007, with Royal Philips disclosing in earnings reports that the company would become the "centerpiece" of a division that offered medical devices for patient monitoring.

Mr. McGinnis was forced to the sidelines and later retired. "I never did see the inside of the shop after they sold it," he said.

Former employees described a sudden shift in the way the new company responded to complaints about troubled devices. At Resprionics, employees and their managers were expected to find answers and move quickly, they said.

Philips was a far larger international corporation with its headquarters in Europe, thousands of miles away from the main factories for CPAPs and ventilators in Western Pennsylvania.

Laura Adorni, a former sales director at Philips in Italy, said the lines of communication between division leaders rapidly deteriorated as complaints about defective products came in.

"We never had any information on how to report anything," said Ms. Adorni, who left the company in 2013. "Things were piling up and people were looking at each other and saying, 'Who should I give this to? Who should I contact?'"

Margaret "Maggie" Yanov, who helped track customer complaints at the company, said the kind of teamwork that defined Resprionics for years was no longer felt in the workplace. She left Philips months after the sale. "It's not the same company anymore," she said.

In 2010, with many long-time managers gone, Philips started to receive complaints from customers and others about black particles turning up on pillows and contamination in the air tubes and reservoirs of their devices, ProPublica and the Post-Gazette found.

At first, the complaints trickled in but by 2015, the company had been hit with hundreds of reports about foam degrading inside the machines, records show.

Dangerous defect

Patients using the devices later said they began grappling with unexplained illnesses — coughs that wouldn't go away, mouth and throat cancers in people who'd never smoked, and kidney and liver diseases.

When Philips announced the recall, the company said the foam in the machines could release chemicals or break into particles capable of causing life-threatening injuries, but has since changed course and said further testing showed the devices do not pose appreciable harm to patients.

Three experts who reviewed test results on the foam for the Post-Gazette and ProPublica disputed that claim, saying the material tested positive for genotoxicity, the ability of a chemical to cause cells to mutate, which can lead to cancer.

Mr. McGinnis, who took calls from former employees and others in the past two years describing the massive recall, said the news was a "disappointment and embarrassment."

Though he no longer had an ownership stake in Philips, he said he worried that his old company — once a symbol of Pittsburgh's economic transformation from a steel town into a hub of biomedical innovation — was now cast in a different light.

On a recent afternoon inside his one-story house, Mr. McGinnis, who suffers from Parkinson's disease, gripped the handles of his walker and stepped carefully down the hallway, past rooms adorned with plaques commemorating the company he once built.

He has been granted more than a dozen U.S. patents for medical devices and has been recognized across the country for developing the CPAP and making it available to patients around the world. An endowed chair bears his name at Harvard Medical School in the study of sleep medicine.

But he remains worried that thousands of people may have been hurt by machines that still bear the Resprionics name and were made in a facility that he once opened to save "many thousands of lives."

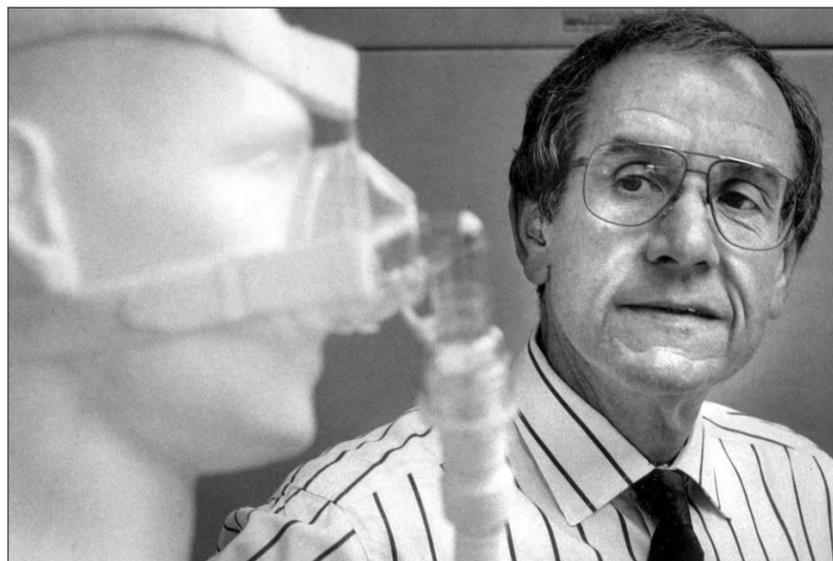
Audrey McGinnis, his wife of 63 years, said she stopped using her last name in public for fear of being tied to the ongoing crisis. For Mr. McGinnis, the failures that led Resprionics to this point all tie back to an ethos that seemed to disappear with the team he had assembled years ago.

He said when his engineers discovered flaws in devices, the company "shut them down. And we did. We just said, 'Christ, we can't do this.'" Ultimately, "this is a product we're selling that a patient is dependent on."

"The culture at Resprionics was they cared about the patient," he said. "The people really understood what they were doing. And [they] took it very seriously."

After Philips bought the company, most of the managers who had worked for him were moved out, he said, and in the years to follow, "the Resprionics culture died."

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Gerald McGinnis with one of Resprionics' CPAP machines in November 1991.