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Sunday

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WITH EVERY BREATH



Clockwise from top left: Michael J. Ermarth/FDA via Associated Press; Liz Moughon/ProPublica; Manuel Balce Ceneta/Associated Press

WILL EFFORT TO COMBAT OPIOID CRISIS FALL SHORT?

Pitt study: Bill aiming to expand methadone access still leaves gaps

By Hanna Webster
Pittsburgh Post-Gazette

For years, Sommer Nolette has taken an Uber every week to a methadone clinic in Washington, Pa., often heading there before sunrise to make it to her job by 8:30 a.m. She estimates a monthly expense of \$80 in commuting fees to secure the drug that has kept her heroin-free for seven years.

That expenditure of time and money in seeking methadone is not unique to Ms. Nolette, 29. Nationwide, hundreds of thousands have faced challenges in accessing a drug approved by the Food and Drug Administration decades ago to treat opiate addiction.

An estimated 111,877 people died of drug overdoses in the U.S. between June 2022 and June 2023, up 2.5% from the year prior, according to the National Center for Health Statistics.

Amid the country's worsening opioid crisis, a bill introduced this year is meant to help knock down such hurdles. The Modernizing Opioid Treatment Access Act, or MOTA, calls for expanding who can prescribe methadone to address gaps in availability that disproportionately impact those in less populous areas.

The U.S. Senate will take up the bill on Tuesday.

SEE **OPIOID**, PAGE A-6

A FAILURE TO PROTECT

How the FDA failed to shield millions of people from tainted breathing machines

By Michael D. Sallah and Michael Korsh
Pittsburgh Post-Gazette
Debbie Cenziper
ProPublica

In 2021, after Philips Respironics sold millions of defective medical devices to those who struggle to breathe, the federal agency charged with protecting the health of the American public swept in.

The Food and Drug Administration accused the global powerhouse of a succession of mistakes — casting aside test results and health risks — long after the company discovered an industrial foam embedded in its breathing machines could break down and send tiny particles and fumes into the lungs of patients.

The FDA maintains that it acted as soon as it learned of the safety concerns in April 2021, just weeks before Philips launched one of the largest recalls of its kind.

But a Pittsburgh Post-Gazette and ProPublica investigation found that in the years leading to the recall, the FDA repeatedly failed one of its most critical missions: alerting the public about devices that can inflict serious harm.

Over the course of a decade, the agency missed a pattern of warnings from health care workers, patients and others that something was very wrong

SEE **FDA**, PAGE A-10



Bill Haber/Associated Press

Former Louisiana Attorney General Richard Ieyoub is shown with his wife, Caprice, at a 2003 press conference. He died earlier this year.

A warrior's final battle

Louisiana's attorney general battled Big Tobacco. He died years later fighting Philips Respironics

By Michael Sallah and Mike Wereschagin
Pittsburgh Post-Gazette

In a state where cigarette smoking had sickened and killed tens of thousands of residents, Louisiana Attorney General Richard Ieyoub was getting ready to launch one of the most difficult legal battles of his career.

With billions of dollars at stake, the tobacco industry was already geared up to fight back.

More than a dozen lawyers for the

industry descended on the attorney general's office in March 1996 and made it clear: If he filed suit, they would take steps to derail his political career, he later recalled.

The lawyers said the tobacco companies would not only oppose his planned primary run for the U.S. Senate that year, they would also win whatever case he filed against them.

"They proceeded to tell me that this was a frivolous case," Mr. Ieyoub said.

SEE **BATTLE**, PAGE A-9

Real estate commissions in crosshairs

Home sellers take a stand after landmark ruling

By Tim Grant
Pittsburgh Post-Gazette

A landmark verdict on real estate commissions could send shockwaves through the housing industry — and fundamentally change how homes in the U.S. are bought and sold. The reverberations are already being felt in Pittsburgh.

A Missouri court on Oct. 31 handed down a \$1.8 billion class action ruling that said brokers Keller Williams and HomeServices of America had systematically coerced sellers to pay an artificially high 6% agent commission fee, which is split by the listing and buyer's agent.

Homebuyers are told that it doesn't cost anything to have an agent represent them in sales because the seller pays the commission. But when sellers add the commission to the listing price, buyers who finance their home over 30 years could end up paying six figures for the agent commissions.

Other lawsuits followed, some within minutes of the Missouri ruling.

Locally, a suit was filed last week in the U.S. District Court for the Western District of Pennsylvania naming West

SEE **COMMISSIONS**, PAGE A-5

Above, left: Dr. Jeff Shuren, the FDA's top regulator of medical devices, pictured in 2016. At top right, a version of one of the Philips CPAP machines included in the June 2021 recall. At center, the Food and Drug Administration building in Silver Spring, Md.

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How we uncovered a hidden flaw in the FDA's medical device warning system

To report this story, the Pittsburgh Post-Gazette and ProPublica analyzed a database of more than 17 million complaints about medical device malfunctions, patient injuries and deaths submitted to the U.S. Food and Drug Administration's Manufacturer and User Facility Device Experience, or MAUDE, tracking system. Because the FDA system is cumbersome and difficult to navigate, the news organizations paid for a subscription to a proprietary database of MAUDE reports called Device Events, developed by former FDA analyst Madris Kinard.

Reporters used these government

records to better understand the reporting practices of Philips Respironics and more than two dozen other large medical device manufacturers. The records showed how often companies, including Philips, submitted timely reports about potentially dangerous devices to the government and how often the reports were late.

During this analysis, reporters discovered that the FDA directs device makers to update the dates they first became aware of a defect when submitting follow-up information to the government. The new dates are put into the agency's public tracking

system, overriding original dates and obscuring how long companies had the warnings in hand before turning them over to the government.

In a first-of-its-kind analysis, reporters compared the dates on file in the government's public tracking system to the dates on the original reports, which were maintained by Device Events. In all, the news organizations compared the dates on more than 100,000 reports from more than two dozen companies dating back to 2013.

Students at Northwestern University's Medill Investigative Lab helped read and

sort hundreds of the reports.

To better understand the FDA's ability to monitor its tracking system and respond to problem devices, the reporting team interviewed current and former FDA administrators, quality assurance experts for medical device companies as well as public health practitioners who have studied and written about the agency. Over the course of the investigation, the team also examined years of FDA warning letters, inspections, recall notices and safety alerts along with Department of Justice consent decrees and criminal filings.

La.'s AG battled Big Tobacco. He died years later while fighting Philips Respironics

BATTLE, FROM A-1

"That it was foolish for me to put my political career on the line. And that they would be wholeheartedly against me."

The day after the tense meeting, Mr. Ieyoub said he filed the sweeping case on behalf of his state, accusing major cigarette makers of concealing the hazards of smoking in what grew into the largest litigation ever waged against the U.S. tobacco industry.

The lawsuit he helped advance with other states was built partly on internal documents from the industry that showed tobacco executives knew as far back as 1963 that cigarettes were addictive and could cause cancer, despite the testimony of the industry's top executives who appeared before Congress in 1994 and said no such evidence existed.

The case would prompt the companies to settle for hundreds of billions of dollars in 1998, cementing Mr. Ieyoub's legacy as one of the state's most impactful attorneys general.

But before his sudden death in April at the age of 78, he would wage another legal battle in a case with striking parallels to his earlier fight and with far more at stake for him personally.

Troubling evidence

After a battle with oral cancer in 2017 and a painful operation that led to reconstructive surgery of his jaw, he was alerted to the massive recall by the global medical device maker Philips Respironics in 2021 of its breathing machines, including two of the same models that he had used to treat his sleep apnea.

In interviews with the Pittsburgh Post-Gazette and ProPublica before he died, Mr. Ieyoub said he launched his own inquiry with his lawyers into whether the continuous positive airway pressure device that he strapped to his mouth every night to help him sleep may have triggered the cancer.

As he learned more about the company's practices prior to the recall, he decided to file a lawsuit in federal court in Pittsburgh in 2021, accusing the company of selling machines that were dangerously defective. Philips Respironics has two plants near Pittsburgh that make its CPAP and ventilator devices.

Mr. Ieyoub has since emerged as one of the best-known figures to take on the industry powerhouse in a case that now involves hundreds of plaintiffs across the nation.

Long known for tackling tough lawsuits as the top law enforcement agent in Louisiana, he said he was confronting what he called a level of "corporate abuse and dishonesty" that he hadn't seen in decades and threatened millions of people worldwide.

"The fact that I was involved in the tobacco lawsuit made it even more necessary for me to stand up and try to do what I could to bring about some accountability," he said.

Mr. Ieyoub, who settled contentious civil rights cases and fought for con-

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sumer protections during his 12 years in office, said he was angered when evidence emerged in court that showed Philips had known of the defect in the machines for years but didn't tell consumers until the recall.

After he filed his case — now being taken up by his estate — he learned that emails showed that Philips engineers were aware as early as 2016 that foam placed in the devices to reduce noise was breaking down into tiny particles.

In a written statement to the Post-Gazette and ProPublica, Philips said "the health and well-being of patients are a top priority" for the company, and "we regret the distress and concern that the Philips Respironics recall has caused to affected device users, including Mr. Ieyoub and his family."

The company said it launched the massive recall two years ago "out of an abundance of caution" and that tests performed by Philips in the wake of the recall now show the foam does not pose any "appreciable harm to health in patients." There is no causal link between the devices and cancer, the company said.

But the Food and Drug Administration, which oversees the medical device industry, issued a statement in October saying tests by the company were not adequate and that further evaluations needed to be done.

Three experts who reviewed the company's test results for the Post-Gazette and ProPublica said the sleep apnea machines and ventilators tested positive for genotoxicity, the process that causes cells to mutate and can lead to cancer.

"You can't make the argument that it's safe. That's bad science," said an engineer familiar with the Philips testing.

Mr. Ieyoub said he believed the company "consciously decided not to reveal" evidence the machines were potentially dangerous. "That could have saved a lot of lives or prevented many, many people from having to go through extensive treatment," he said.

'He got visibly mad'

At the time of the recall, Mr. Ieyoub was years into recovery from his bout with cancer that led to a 17-hour surgery at the MD Anderson Cancer Center in Houston, where surgeons stripped back part of his face, removed a piece of his jaw and replaced it with bone cut from his lower right leg.

"I was wondering whether I would be disfigured for the rest of my life," he said.

Mr. Ieyoub began to piece together the potential connection between the Philips SystemOne and Philips Remstar CPAPs he had been using for years and the can-



Liz Moughon/ProPublica

Richard Ieyoub's family in Baton Rouge, including his son, Phillip, wife, Caprice, daughters, Khoury and Anna Michael, and son, Christian, say they will continue to press their late father's legal case against Philips in federal court in Pittsburgh.



Liz Moughon/ProPublica

Richard Ieyoub during an interview with the Pittsburgh Post-Gazette and ProPublica in March at his home in Baton Rouge. He died two weeks later from complications of an aortic aneurysm at the age of 78.

cer that the doctors had removed.

He had never smoked, and the kind of cancer removed from his mouth was frequently found in patients who had used tobacco products, records show.

"I felt like I needed to look further and do a little bit more investigation," he said.

With every piece of evidence that was surfacing, he said he encouraged his lawyers to keep pressing his case with the goal of uncovering the inner workings of a company that should have made decisions that were "best for the people and not worry so much about profits," he said.

Art Murray, his son-in-law and one of his lawyers, said Mr. Ieyoub was motivated not just by his own case, but by the sheer number of people impacted by the health crisis.

"He got visibly mad," said Mr. Murray, a New Orleans attorney. "Most people didn't survive what he went through."

In the months before he died April 10 of an aortic aneurysm, he would frequently talk to family members about his battle with Big Tobacco and the similarities surfacing in his own legal challenge against Philips.

"The irony was not lost on me and it wasn't lost on him," said Mr. Murray.

Motivated by politics

For Mr. Ieyoub, a Democrat who first won public office in 1984 as district attorney for Calcasieu Parish in

southwest Louisiana, the fight that he waged more than two decades ago defined him as a person and also took a toll on his political life, said those who knew him.

After he filed the lawsuit against the cigarette makers, joining Mississippi and three other states, the industry poured soft money in campaigns against him, he told The Advocate newspaper in 2003. "I don't know how much, but they did contribute heavily, and it was a very close race," he said.

Just before the Senate primary in 1996, he was accused by the National Republican Senatorial Committee of improperly spending campaign money — allegations he vehemently denied — and was eventually defeated in the race, missing a runoff by 13,586 votes.

The Justice Department launched an inquiry into the campaign expenses and other matters, but eventually ended the investigation with no action taken.

Michael Moore, the former attorney general of Mississippi who first approached Mr. Ieyoub about joining other states in challenging the tobacco companies in 1996, told the Post-Gazette that none of the allegations held up and that they were motivated by politics.

"There was no case," said Mr. Moore. "They tore him and his family apart. I walked step by step with him through all that. It really hurt him because he knew

he had not done anything wrong."

At the time, both the Republican governor, Mike Foster, and the state health secretary, Bobby Jindal, a Republican who was later elected governor, filed affidavits opposing the suit. "It took a lot of courage for him to file at that point, because, you know, he did have a lot of opposition," said Mr. Moore.

Mr. Ieyoub told the Post-Gazette that it didn't matter that some of the top lawmakers didn't favor the litigation. He was moved by two factors: The tobacco companies knew years earlier the products they were selling could cause serious illnesses and concealed it, he said. And he was especially upset over the discovery that the companies were targeting young people using cartoon characters in marketing campaigns.

"One of the results of that lawsuit was to prevent them from doing that kind of advertising. We fought very hard to bring it out," he said.

Mr. Ieyoub's wife, Caprice, an attorney who was married to him for 28 years, said her husband didn't waver in his stance, despite criticism from some of Louisiana's powerbrokers.

"He sacrificed so much to serve," she said. "When Richard was faced with tough, hard choices, we used to say if you ever lose your job for doing it, we can live with that."

Ultimately, Louisiana would reap \$4.6 billion in the tobacco settlement to be paid

over 25 years. In the ensuing years, Mr. Ieyoub would win two more terms as attorney general and lose a close primary race for governor in 2003 before leaving office the next year.

In an interview with the Post-Gazette and ProPublica at his home two weeks before he died, Mr. Ieyoub said that much of his passion for politics was influenced by his father, who emigrated from Lebanon as a teenager and who frequently spoke about the oppression that his family felt because of their Catholic faith.

"He said, 'Son, you are so lucky to have been born in this country.' And so that was planting seeds."

In 2016, the year before his cancer diagnosis, he was appointed by Gov. John Bel Edwards as the state commissioner of conservation, which regulates the oil and gas industry, a post he held until his death.

The last legal battle

For much of his career, he said he fought on behalf of constituents, but the last legal battle he waged against Philips was for himself — and even then, he was conscious of the millions of other people whose lives were impacted by the recall.

"To think that so many people are going to have to suffer," said Mr. Ieyoub. "It's a tragedy."

On April 10 — the day before evidence was released in court that showed Philips' own tests found the breathing machines posed "unacceptable" risks to patients — Mr. Ieyoub died. His funeral Mass was held at St. Joseph Cathedral in Baton Rouge, where one of the speakers was Mr. Edwards.

He was recognized for his years in public service, with flags flown at half staff and a moment of silence at the state capitol, but his calling was not about ceremony, said his wife.

"He was never willing to even consider not stepping up" when faced with challenges, "and while some saw it as courageous, he just saw it as part of the role he was called to serve."

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