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THE DRUG INDUSTRY'S TRIUMPH OVER THE DEA

Amid a targeted lobbying effort, Congress weakened the DEA's ability to go after drug distributors, even as opioid-related deaths continue to rise, a Washington Post and '60 Minutes' investigation finds.

By **Scott Higham** and **Lenny Bernstein**

Oct. 15, 2017



In April 2016, at the height of the deadliest drug epidemic in U.S. history, Congress effectively stripped the Drug Enforcement Administration of its most potent weapon against large drug companies suspected of spilling prescription narcotics onto the nation's streets.

By then, the opioid war had claimed 200,000 lives, more than three times the number of U.S. military deaths in the Vietnam War. [Overdose deaths continue to rise](#). There is no end in sight.

A handful of members of Congress, allied with the nation's major drug distributors, prevailed upon the DEA and the Justice Department to agree to a more industry-friendly law, undermining efforts to stanch the flow of pain pills, according to an investigation by The Washington Post and "60 Minutes." The DEA had opposed the effort for years.

The law was the crowning achievement of a multifaceted campaign by the drug industry to weaken aggressive DEA enforcement efforts against drug distribution companies that were supplying corrupt doctors and pharmacists who peddled narcotics to the black market. The industry worked behind the scenes with lobbyists and key members of Congress, pouring more than a million dollars into their election campaigns.

The chief advocate of the law that hobbled the DEA was Rep. Tom Marino, a Pennsylvania Republican who is now [President Trump's nominee to become the nation's next drug czar](#). Marino spent years trying to move the law through Congress. It passed after Sen. Orrin G. Hatch (R-Utah) negotiated a final version with the DEA.

As Rep. Tom Marino's Pennsylvania district was reeling from the opioid crisis, he sponsored a bill that undermined the Drug Enforcement Administration's efforts to stop the flow of pain pills. (Alice Li/The Washington Post)

For years, some drug distributors were fined for repeatedly ignoring warnings from the DEA to shut down suspicious sales of hundreds of millions of pills, while they racked up billions of dollars in sales.

The new law makes it virtually impossible for the DEA to freeze suspicious narcotic shipments from the companies, according to internal agency and Justice Department documents and an independent assessment by the DEA's chief administrative law judge in a soon-to-be-published law review

article. That powerful tool had allowed the agency to immediately prevent drugs from reaching the street.

Political action committees representing the industry contributed at least \$1.5 million to the 23 lawmakers who sponsored or co-sponsored four versions of the bill, including nearly \$100,000 to Marino and \$177,000 to Hatch. Overall, the drug industry spent \$102 million lobbying Congress on the bill and other legislation between 2014 and 2016, according to lobbying reports.

[TUESDAY UPDATE: Trump announces drug czar Marino will withdraw]

“The drug industry, the manufacturers, wholesalers, distributors and chain drugstores, have an influence over Congress that has never been seen before,” said Joseph T. Rannazzisi, who ran the DEA’s division responsible for regulating the drug industry and led a decade-long campaign of aggressive enforcement until he was forced out of the agency in 2015. “I mean, to get Congress to pass a bill to protect their interests in the height of an opioid epidemic just shows me how much influence they have.”

Besides the sponsors and co-sponsors of the bill, few lawmakers knew the true impact the law would have. It sailed through Congress and was passed

by unanimous consent, a parliamentary procedure reserved for bills considered to be noncontroversial. The White House was equally unaware of the bill's import when President Barack Obama signed it into law, according to interviews with former senior administration officials.

Top officials at the White House and the Justice Department have declined to discuss how the bill came to pass.

LOBBYING EXPENSES, 2014-2016

Groups reported lobbying expenditures of more than **\$102 million** related to the Ensuring Patient Access and Effective Drug Enforcement Act and other bills.



Includes lobbying efforts of more than \$5,000.

Source: U.S. Senate Lobbying Disclosure
Electronic Filing System

Michael Botticelli, who led the White House Office of National Drug Control Policy at the time, said neither Justice nor the DEA objected to the bill, removing a major obstacle to the president's approval.

"We deferred to DEA, as is common practice," he said.

The bill also was reviewed by the White House Office of Management and Budget.

"Neither the DEA nor the Justice Department informed OMB about the policy change in the bill," a former senior OMB official with knowledge of the issue said recently. The official spoke on the condition of anonymity because of the sensitivity of internal White House deliberations.

The [DEA's top official at the time](#), acting administrator **Chuck Rosenberg**, declined repeated requests for interviews. A senior DEA official said the agency fought the bill for years in the face of growing pressure from key members of Congress and industry lobbyists. But the DEA lost the battle and eventually was forced to accept a deal it did not want.

"They would have passed this with us or without us," said the official, who spoke on the condition of anonymity. "Our point was that this law was completely unnecessary."

Loretta E. Lynch, who was attorney general at the time, declined a recent interview request.

Obama also declined to discuss the law. His spokeswoman, Katie Hill, referred reporters to Botticelli's statement.

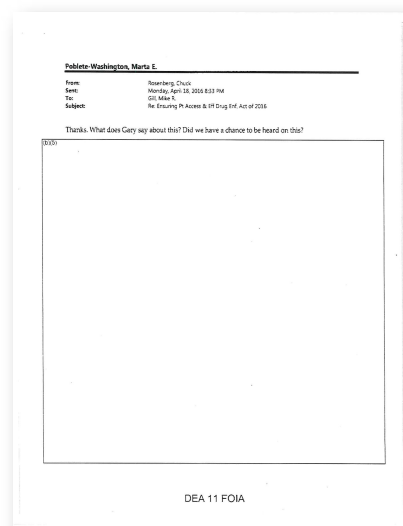
The DEA and Justice Department have denied or delayed more than a dozen requests filed by The Post and "60 Minutes" under the Freedom of Information Act for public records that might shed additional light on the matter. Some of those requests have been pending for nearly 18 months. The Post is now suing the Justice Department in federal court for some of those records.

Hatch's spokesman, Matt Whitlock, said the DEA, which had undergone a leadership change, did not oppose the bill in the end.

"We worked collaboratively with DEA and DOJ . . . and they contributed significantly to the language of the bill," Whitlock wrote in an email. "DEA had plenty of opportunities to stop the bill and they did not do so."

Marino declined repeated requests for comment. Marino's staff called the U.S. Capitol Police when The Post and "60 Minutes" tried to interview the congressman at his office on Sept. 12. In the past, the congressman has said

the DEA was too aggressive and needed to work more collaboratively with drug companies.



DEA officials redacted the information contained in the document above, which was obtained by The Washington Post under the Freedom of Information Act, citing an exemption from the law that protects internal agency discussions. [Read the bill and other documents involved in reporting this story.](#)

Drug industry officials and experts blame the origins of the opioid crisis on the overprescribing of pain pills by doctors. The industry notes that the DEA approves the total amount of opioids produced each year.

Industry officials defended the new law as an effort to ensure that legitimate pain patients receive their medication without disruption. The industry had long complained that federal prescription drug laws were too vague about the responsibility of companies to report suspicious orders of narcotics. The industry also complained that the DEA communicated poorly with companies — citing a 2015 report by the Government Accountability Office — and was too punitive when narcotics were diverted out of the legal drug distribution chain.

“To be clear — this law does not ‘decrease’ DEA’s enforcement against distributors,” said John Parker, a spokesman for the Healthcare Distribution Alliance, which represents drug distributors. “It supports real-time communication between all parties in order to counter the constantly evolving methods of drug diversion.”

But DEA Chief Administrative Law Judge John J. Mulrooney II has reached the opposite conclusion.

“At a time when, by all accounts, opioid abuse, addiction and deaths were increasing markedly” the new law “imposed a dramatic diminution of the agency’s authority,” Mulrooney wrote in a [draft 115-page article](#) provided by the Marquette Law Review editorial board. He wrote that it is now “all but logically impossible” for the DEA to suspend a drug company’s

operations for failing to comply with federal law. The agency declined to make Mulrooney available for an interview.

LINDEN BARBER: A CRITICAL CONNECTION

Barber provided a critical connection between DEA leadership, Congress, and the pharmaceutical industry.

Congress
DEA/DOJ
Lobby
Industry

APRIL 2006

Barber named top lawyer for the DEA's Office of Diversion Control.

2006-2007

Rannazzisi and **Barber** launch a crackdown on **drug distributors**.

Open full timeline ▼

Deeply involved in the effort to help the industry was the DEA's former associate chief counsel, **D. Linden Barber**. While at the DEA, he helped design and carry out the early stages of the agency's tough enforcement campaign, which targeted drug companies that were failing to report suspicious orders of narcotics.

When Barber went to work for the drug industry in 2011, he brought an intimate knowledge of the DEA's strategy and how it could be attacked to protect the companies. He was one of dozens of DEA officials recruited by the drug industry during the past decade.

Barber played a key role in crafting an early version of the legislation that would eventually curtail the DEA's power, according to an internal email written by a Justice Department official to a colleague. "He wrote the Marino bill," the official wrote in 2014.

Barber declined repeated requests for an interview.

With a few words, the new law changed four decades of DEA practice. Previously, the DEA could freeze drug shipments that posed an "imminent danger" to the community, giving the agency broad authority. Now, the DEA must demonstrate that a company's actions represent "a substantial likelihood of an immediate threat," a much higher bar.

"There's no way that we could meet that burden, the determination that those drugs are going to be an immediate threat, because immediate, by definition, means right now," Rannazzisi said.

Today, Rannazzisi is a consultant for a team of lawyers suing the opioid industry. Separately, 41 state attorneys general have banded together to

investigate the industry. Hundreds of counties, cities and towns also are suing.

“This is an industry that’s out of control. If they don’t follow the law in drug supply, and diversion occurs, people die. That’s just it, people die,” he said. “And what they’re saying is, ‘The heck with your compliance. We’ll just get the law changed.’ ”

Illustration by Eddie Alvarez/The Washington Post; Photos by Jahi Chikwendiu/The Washington Post, Jay LaPrete/ Bloomberg News, Danny Johnston/AP

‘DRUG DEALERS IN LAB COATS’

2006: 52,277 deaths from prescription opioid overdoses since 2000.

Joe Rannazzisi came to DEA headquarters as an outsider with an attitude. He worked as an agent in Detroit, where he watched prescription drugs flood small towns and cities in the Midwest.

Hundreds of millions of pain pills, such as Vicodin and oxycodone, ended up in the hands of dealers and illegal users.

Rogue doctors wrote fraudulent prescriptions for enormous numbers of pills, and complicit pharmacists filled them without question, often for cash. Internet pharmacies, supplied by drug distribution companies, allowed users to obtain drugs without seeing a doctor.

“There were just too many bad practitioners, too many bad pharmacies, and too many bad wholesalers and distributors,” Rannazzisi recalled.

Rannazzisi, a burly, tough-talking Long Islander, was assigned to head the DEA’s Office of Diversion Control. He had a law degree, a pharmacy degree and had spent years navigating the DEA’s bureaucracy.

The office was seen as a backwater operation whose 600 investigators had toiled for years over prescription drug cases with little or none of the recognition that went to those who investigated illegal street drugs like heroin or cocaine.

Rannazzisi brought an aggressive approach to the diversion control office.

The year he took over, **Linden Barber** was promoted to run diversion control’s litigation office, which crafted the legal arguments that supported the team. He was a former Army lawyer who served in Iraq. The cadre of attorneys who worked for him saw him as a tough litigator unafraid of an influential industry.

Barber and Rannazzisi formed a powerful combination that the drug companies would learn to fear. “Early on he did really good work,” Rannazzisi said. “He jumped into the Internet cases when he first came here.”

After shutting down the Internet pharmacies, Rannazzisi and Barber pursued the pain management clinics that replaced them and soon became as ubiquitous in South Florida as the golden arches of McDonald’s. To get there, drug dealers and users would take the “Oxy Express” down Interstate 75.

“Lines of customers coming in and going out,” said Matthew Murphy , a veteran DEA supervisor in Boston whom Rannazzisi hired to be chief of pharmaceutical investigations. “Armed guards. Vanloads of people from the Appalachia region driving down to Florida to get a prescription from a pain clinic and then get the prescription filled, going back to wherever they’re from.”

Back home, each 30-pill vial of oxycodone was worth \$900.

DEA officials realized they needed a new strategy to confront this new kind of drug dealer.

“They weren’t slinging crack on the corner,” Rannazzisi said. “These were professionals who were doing it. They were just drug dealers in lab coats.”

Joseph T. Rannazzisi, seen here in September, ran the DEA's division responsible for regulating the drug industry and led a decade-long campaign of aggressive enforcement until he was forced out of the agency in 2015. (Jahi Chikwendiu/The Washington Post)

Rather than focusing on bad doctors and pharmacists, Rannazzisi and Barber decided to [target the companies feeding the pill mills](#): the wholesale drug distributors, some of them massive multinational corporations.

“I developed the legal framework to pursue actions against distributors,” Barber would later say. “We initiated a record number of administrative actions; the government collected record-setting civil penalties.”

Under the Controlled Substances Act of 1970, drug companies are required to report unusually large or otherwise suspicious orders. Failure to do so can result in fines and the suspension or loss of DEA registrations to manufacture or distribute narcotics.

When the DEA suspected that a company was ignoring suspicious sales, the agency filed an “order to show cause.” That gave a company at least 30 days to explain why the agency should not revoke its registration.

In the most egregious cases, the DEA employed an “immediate suspension order,” allowing the agency to lock up a distributor’s drugs. The orders instantly halted all commerce in controlled substances on the grounds that the drugs constituted an “imminent danger” to the community.

Under Rannazzisi in the mid-2000s, the DEA repeatedly warned the companies that they were shipping unusually large volumes of opioids to customers around the country. Despite the warnings, some companies continued the shipments.

The DEA soon began bringing enforcement actions against distributors. In 2007, the agency moved against McKesson, the nation's largest drug distributor and the fifth-largest corporation in the nation, for failing to report hundreds of suspicious orders placed by Internet pharmacies. McKesson settled the case, paying a \$13.2 million fine.

LEFT: Cardinal Health Inc. paid a \$34 million fine after the DEA brought a case in 2008 that claimed the company filled “blatantly suspicious” orders from online drugstores. (Gary Gardiner/Bloomberg News) **RIGHT:** In 2007, the agency took action against McKesson, the

nation's largest drug distributor, for failure to report hundreds of suspicious orders. The company paid \$13.2 million. (Justin Sullivan/Getty Images)

In 2008, Rannazzisi and Barber targeted Cardinal Health, another large drug distributor, for filling “blatantly suspicious” orders from online drugstores. Cardinal paid a \$34 million fine.

The DEA would ultimately bring at least 17 cases against 13 drug distributors and one manufacturer. The government said it assessed nearly \$425 million in fines over a decade. Those fines reflect only a small portion of the hundreds of billions of dollars in revenue the companies receive each year.

“It’s a cost of doing business,” Murphy said.

Along the way, Rannazzisi was making powerful enemies in the industry.

“They definitely didn’t like Joe Rannazzisi,” Murphy said. “Not at all. He wasn’t viewed as a person that they could work with. And maybe that was appropriate. He didn’t want to work with industry much.”

Rannazzisi was unmoved by their complaints.

“We’re worried about their feelings being hurt because we were doing our job?” he said. “We were making them comply. We were holding their feet to

the fire.”

Murphy recalled a telling meeting with drug company representatives.

He said the president of one of the drug companies sat on the other side of the table, put his hands up and said, “ ‘You got us. What can we do to make this right?’ ” Murphy recalled.

Murphy said he had heard the same thing from drug dealers.

There was an important difference, Murphy noted.

“You know,” he said, “the heroin and cocaine traffickers didn’t have a class ring on their finger from a prestigious university.”

Illustration by Eddie Alvarez/The Washington Post; Photo from U.S. Senate

‘THIS IS WAR’

2011: 121,468 deaths from prescription opioid overdoses since 2000.

In 2011, **Linden Barber** left the DEA to join the Washington, D.C., office of the law firm Quarles & Brady. He started a practice representing drug

companies. “If you have a DEA compliance issue or you’re facing a government investigation,” he said in a promotional video for the firm, “I’d be happy to hear from you.”

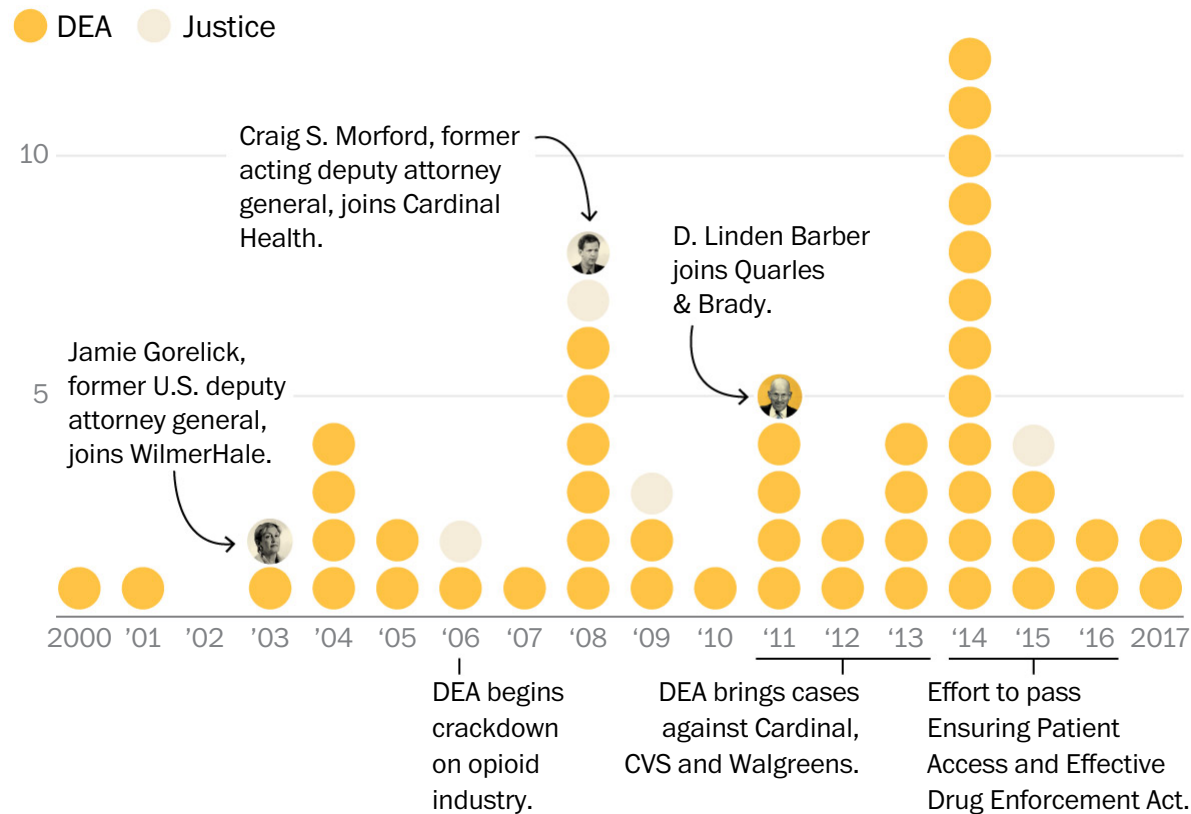
Barber’s move turned out to be a key moment in the struggle between drug companies and the government, but it was far from the only one. Dozens of top officials from the DEA and Justice Department have [stepped through Washington’s revolving door](#) to work for drug companies.

Two former U.S. deputy attorneys general have defended Cardinal, one of the “Big Three” companies, along with McKesson and AmerisourceBergen, that together control 85 percent of drug distribution in the United States. [Jamie Gorelick](#), an attorney for WilmerHale, was deputy attorney general under President Bill Clinton. Craig S. Morford, Cardinal’s chief legal and compliance officer, was acting deputy attorney general under President George W. Bush.

As Rannazzisi’s investigators increased their pressure, those lawyers began to contact their former colleagues in government.

AT LEAST 56 DEA AND JUSTICE OFFICIALS WENT TO WORK FOR THE PHARMACEUTICAL INDUSTRY

Pharmaceutical companies and the law firms that represent them hired at least 56 former officials since 2000.



Note: The dates of hire for five former DEA employees could not be specifically determined, as such they are not included in this graphic.

Source: Post analysis

In late 2011, Morford went over Rannazzisi's head to then-DEA Administrator Michele Leonhart as the agency again investigated Cardinal,

which had sent millions of doses of oxycodone to a small number of pharmacies in Florida, including two CVS stores in Sanford.

“Michele,” Morford wrote to Leonhart in October 2011, “we are committed to working with DEA to address the challenging problem of diversion and welcome the opportunity to meet with you and your team to address these issues in a non-adversarial way.” He signed the handwritten note “Craig.”

Gorelick said in an email that she wrote to then-Deputy Attorney General James M. Cole “to ask that my client be afforded due process.” Morford did not respond to requests for comment.

Around Thanksgiving, Rannazzisi said he received a call about the Cardinal-CVS case from James H. Dinan, then-chief of the Organized Crime Drug Enforcement Task Forces program at the Justice Department. Rannazzisi said Dinan told him, “We’re getting calls from attorneys, former Justice people, that are saying you guys are doing some enforcement action.”

RANNAZZISI RAMPS UP CRACKDOWN ON DRUG INDUSTRY

Congress
DEA/DOJ
Lobby
Industry

JANUARY 2006

Rannazzisi is promoted to run the DEA's Office of Diversion Control.

2006-2007

Rannazzisi and **Barber** launch a crackdown on **drug distributors**.

Open full timeline ▼

Four months later, Rannazzisi received a late-night call from Dinan summoning him to appear at Justice headquarters early the next morning to explain his actions in the Cardinal-CVS case to Cole.

“Please call me in the morning,” Dinan wrote, according to Rannazzisi. “I want to make double sure nothing unreversible happens before [Cole] is briefed.”

Rannazzisi was stunned. He had brought hundreds of these cases and had never been called to brief Cole, the second-most-powerful law enforcement official in the country.

The meeting quickly “spiraled out of control,” Rannazzisi said. “It was adversarial to say the least.”

Rannazzisi believed the message was clear: Back off.

Cole, now a lawyer in private practice, said he was not trying to pressure Rannazzisi.

“Hearing what Cardinal had to say could inform DEA of facts they may not have known,” Cole said in a statement. “I did not tell Mr. Rannazzisi how to come out on the Cardinal matter and certainly did not discourage him from going after any company in violation of any statutes or regulations,” he said.

Either way, Rannazzisi was defiant when he returned to the office from the Justice Department and sat down with his staff.

“Now this is war,” he recalled telling them. “We’re going after these people, and we’re not going to stop. We’re just going to continue to move forward. And we don’t really give a damn any more what the department wants.”

Illustration by Eddie Alvarez/The Washington Post; Photos by Karen Bleier/Getty Images, Matt McClain/The Washington Post, Nick Hagen/For The Washington Post

‘IT WAS BAD’

2013: 149,853 deaths from prescription opioid overdoses since 2000.

The field generals in the DEA's war on opioids are men and women such as Jim Geldhof, a 43-year agency veteran who managed the diversion control program in the Detroit field office. He witnessed firsthand the heartbreak pain pills were causing across the Midwest.

One night, at a town hall meeting in Portsmouth, Ohio, Geldhof sat quietly as the Portsmouth High School gym fell dark and a large screen flickered with photographs.

Geldhof was in tears.

"Sons and daughters and grandsons and granddaughters in graduation pictures," he recalled. "Some were wearing football jerseys. They had their whole lives ahead of them, and then they were gone."

 **OPIOID DEATHS** of prescription-drug overdose . . 17.741

The families always asked: What was the DEA doing to stop the flow of drugs?

By 2013, it had become increasingly difficult to answer that question. [Cases were languishing at headquarters.](#) At first, Geldhof wasn't sure why.

Behind the scenes, a major shift was taking place at DEA headquarters.

An appeals court in Washington, D.C., had been reviewing a case that Rannazzisi's investigators brought against Walgreens, alleging that some of its pharmacies in Florida were selling more than a million pain pills a year. A typical pharmacy sold 74,000.

The DEA had used an immediate suspension order against Walgreens, arguing that the drug sales constituted an "imminent danger" to the community. The DEA moved to shutter a large Walgreens distribution center in Jupiter, Fla., that supplied nearly 1,000 pharmacies along the East Coast.

Walgreens fought back.

The company's attorney, Gregory G. Garre, the former U.S. solicitor general during the second Bush administration, argued the "imminent danger" standard was vague and not supported by law. The original 1970 act did not define imminent danger.

Judges on the appellate panel voiced similar concerns during oral arguments.

No one knew how the appeals court would rule, but **Linden Barber** had argued while he was still at the DEA that the vague standard could cripple the cases the agency was building. Now Barber and other industry lawyers were making that argument on behalf of their clients. Their position was common knowledge in the diversion legal office, and it resonated with Clifford Lee Reeves II, a career Justice attorney who had recently taken the job Barber once held, according to **Jonathan P. Novak**, a lawyer who worked in the office.

The departure of so many DEA employees for the drug industry gave the distributors an unfair advantage, said Jonathan P. Novak, formerly a DEA lawyer. “There was a fear,” he said. “It comes from seeing that some of the best and brightest former DEA attorneys are now on the other side and know all of the weak points.” (Bonnie Jo Mount/The Washington Post)

“Lee kept trying to shut us down,” said Novak, now in private practice. “He kept telling us about the Walgreens case and the imminent danger standard and that we were going to lose all of our cases and we didn’t have enough information to go forward.”

The DEA declined to make Reeves available for an interview.

Rannazzisi, a lawyer himself, told the DEA attorneys that the law was on their side.

“I said, ‘Stop worrying. We have never lost an imminent danger case,’ ” he said.

The warnings by Barber and other industry lawyers divided the 15 attorneys in diversion control’s legal office.

“Linden carried a lot of weight, and people listened to what he had to say,” Novak said. “He knew all the arguments. He had the clout. He was the big gun. He put the fear of God into people.”

Frank Younker, a DEA supervisor in the Cincinnati field office and 30-year veteran of the agency, said the legal office began demanding more evidence from investigators.

Starting in 2013, shortly after the Walgreens case was argued and Reeves arrived, investigators felt they were now required to establish that their evidence was “beyond a reasonable doubt.” Previously, investigators had to show only “a preponderance of evidence.”

“We had years of very aggressive enforcement,” said Younker, who retired in 2014. “It was like we were in a Porsche and all of a sudden, someone hit the brakes.”

 **Requiring investigators to transcribe interviews and hire expert witnesses, even though there was no budget for them.** against

DEA officials later said the standards did not change.

Novak said Reeves and his second-in-command, Jason Hedges, also required investigators to transcribe their interviews and hire high-priced expert witnesses, even though there was no budget for them.

Novak said it seemed like there was never enough evidence to please his bosses.

He said they would ask: “Maybe we need an expert to explain how recording equipment works? Maybe we need an expert to explain the system for prescribing?”

“It felt, honestly, confusing and almost insane.”

The delays cost months, sometimes years.

Geldhof, the DEA program manager in Detroit, was investigating a midsize Ohio-based drug distributor. Between 2007 and 2012, Miami-Luken had shipped 20 million doses of oxycodone and hydrocodone to pharmacies in West Virginia. About 11 million wound up in one county, Mingo, population 25,000.

Despite the rising death rate in West Virginia — the highest in the nation — Geldhof said his pleas in 2013 to halt Miami-Luken's operations were ignored by the legal office at headquarters.

“First we got blown off by the company,” he said, “and then we got blown off by our own lawyers.”

The Washington Post

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Novak suspected another reason for the slowdown.

At times, he said, some of his colleagues appeared more concerned with pleasing the industry than working on behalf of the public. Some of the lawyers had simply given up fighting the industry and seemed to be preparing for a future working with the companies they were supposed to be regulating, he said.

“It was not just one person who left the office; everyone started to leave. That’s your payout. You do your time, and more and more people were auditioning for the industry. It stopped us from doing our jobs.”

The departures gave the industry an unfair advantage, Novak said.

“There was a fear,” he said. “It comes from seeing that some of the best and brightest former DEA attorneys are now on the other side and know all of the weak points. Their fingerprints are on memos and policy and emails.”

Illustration by Eddie Alvarez/The Washington Post; Photo by Mark Wilson/Getty Images

THE LAWMAKERS

2014: 164,691 deaths from prescription opioid overdoses since 2000.

The major drug companies also brought their campaign to Capitol Hill. One of their key allies was **Tom Marino**, then a two-term Republican congressman from Williamsport, Pa.

Marino was a former county and federal prosecutor with deep hometown ties to a district that was reeling from the opioid epidemic.

On Feb. 18, 2014, Marino introduced the [Ensuring Patient Access and Effective Drug Enforcement Act](#), making an effort to define what constitutes “imminent danger.” The proposal raised the DEA’s standard for suspending drug shipments by requiring that the agency establish “a significant and present risk of death or serious bodily harm that is more likely than not to occur.”

[\[Rep. Tom Marino: Drug czar nominee and the opioid industry’s advocate in Congress\]](#)

It attracted 14 Republican co-sponsors, chief among them **Rep. Marsha Blackburn** (R-Tenn.), also from a region in the grip of the epidemic.

The DEA mobilized to defeat Marino’s measure. One internal DEA memo obtained by The Post and “60 Minutes” noted that the bill essentially

eliminates the agency's power to file immediate suspension orders of drug shipments. The new law "is fixing a problem that doesn't need fixing," a DEA official wrote.

U.S. Rep. Tom Marino (R-Pa.), left, was the chief advocate of the law that weakened the DEA's enforcement abilities. Seen with Rep. Trey Gowdy (R-S.C.) in 2015, Marino is President Trump's nominee to become the nation's drug czar. (Andrew Harrer/Bloomberg)

On April 8, 2014, with the bill stalled, Marino confronted the nation's top law enforcement officer, Attorney General Eric H. Holder Jr., during a House Judiciary Committee hearing. Marino told Holder the DEA was treating the companies like "illicit narcotics cartels."

"This mind-set — it's extremely dangerous to legitimate business," Marino said.

He told Holder that he wanted the Justice Department to meet with industry executives. When Marino wrote to Holder three weeks later urging him to set up the meeting, the congressman added a handwritten note: "It would be great to work together on this. — Tom."

Within the DEA and the Justice Department, Marino's overtures to Holder set off alarms. On May 7, 2014, Matthew Strait, the DEA's congressional liaison officer, detailed ways "to push back" on Marino's bill, according to an email he wrote.

It was followed by a flurry of DEA memos. One said, "This bill is without basis in case law or Congressional findings." Another said the bill "would constitute perhaps the greatest reduction in the Attorney General's authority under the Controlled Substances Act since the Act's passage in 1970."

Later in May, Marino introduced a second version of his bill, with slightly altered language. Blackburn was again a co-sponsor, but this time two Democrats were on board: Rep. Peter Welch of Vermont and Rep. Judy Chu of California.

On June 4, Bill Tighe, Marino's chief of staff, wrote to Peter Kadzik, Justice's top congressional liaison officer, thanking him for setting up a meeting with the industry executives.

Tighe asked Kadzik to coordinate with the industry's point person: Linden Barber.

Kadzik wrote to a colleague at Justice about Barber.

"Linden Barber used to work for DEA," Jill Wade Tyson, another Justice congressional liaison officer, responded in an email. "He wrote the Marino bill."

Illustration by Eddie Alvarez/The Washington Post; Photo by Manuel Balce Centa/AP

‘OH, CRAP’

Through the summer of 2014, as the fight over the second Marino bill unfolded, the congressman and other lawmakers pressed for a meeting with the DEA to understand why Rannazzisi was so opposed. Congressional staffers set a conference call for July 2.

Rannazzisi's relationship with the Hill was already frayed, and his disdain for diplomacy had become legendary. His aides advised him against joining the call.

Rannazzisi ignored them.

At first, the conversation was cordial. Rannazzisi and DEA officials discussed the legislation with staffers from the Judiciary and the Energy and Commerce committees.

But the tone soon turned testy.

One DEA official asked why the law was necessary.

DRUG INDUSTRY PUSHES BACK

Congress
DEA/DOJ
Lobby
Industry

NOVEMBER 24, 2011

Rannazzisi learns that former Justice lawyers now representing the **drug industry** are calling his bosses about his enforcement actions.

FEBRUARY 2, 2012

Ranazzissi says he is summoned to Deputy Attorney General James Cole's office to

Open full timeline ▼

A congressional staffer responded, “We’re just trying to create a better relationship between industry and DEA.”

Rannazzisi blew up.

“You’ll be protecting criminals,” one participant recalled Rannazzisi saying.

Eric Akers, another DEA liaison to Congress, was stunned.

“As soon as he said it, I said, ‘Oh, crap,’ ” recalled Akers, who also was on the line. “It was about as undiplomatic as you could be. I don’t think he meant it as a threat. But any chance of salvaging the relationship with Congress just got immensely harder.”

The congressional staffers were furious. “We can’t work with you,” one told the DEA.

Rannazzisi refused to meet with the industry executives, saying it would be improper because many of the drug companies were under active DEA investigation or in settlement negotiations with the Justice Department.

[Joe Rannazzisi: The DEA man who fought the drug companies and lost]

On July 29, the Marino bill passed the House and went to the Senate.

The Justice Department was so concerned that it took the unusual step of having Attorney General Holder publicly oppose the bill.

“A recently passed House bill would severely undermine a critical component of our efforts to prevent communities and families from falling prey to dangerous drugs,” Holder said in a July 31 news release.

The bill stalled in the Senate.

On Sept. 18, during a congressional hearing, Marino complained to Leonhart, the DEA administrator, about Rannazzisi’s comments on the conference call.

“It is my understanding that Joe Rannazzisi, a senior DEA official, has publicly accused we sponsors of the bill of, quote, ‘supporting criminals,’ unquote,” Marino told her. “This offends me immensely.”

A week later, [Marino and Blackburn accused Rannazzisi](#) of trying to “intimidate the United States Congress” and asked the Justice Department’s inspector general to investigate.

Rannazzisi said he never said the bill would protect criminals.

“I said that this bill is going to protect defendants that we have under investigation,” he said in a recent interview. “And if they don’t like the truth, well, I don’t know what to tell ’em.”

Illustration by Eddie Alvarez/The Washington Post; Photo by Melina Mara/The Washington Post

A NEW LAW

2015: 179,972 deaths from prescription opioid overdoses since 2000.

With Rannazzisi under attack, the industry effort gained momentum.

Marino introduced yet another version of his bill in the House on Jan. 22, 2015. He announced that the Energy and Commerce Committee would hold a hearing five days later.

One of the witnesses was **Linden Barber**.

Barber told the committee about the Walgreens case. He was still pressing the industry's long-standing argument about the need for a clearer legal definition of the DEA's imminent danger standard.

The case had not ended up setting a precedent that undermined the standard. Rather than take the case to trial, the company agreed to settle and pay what was then a record \$80 million fine. Still, Barber argued the DEA faced legal jeopardy.

“Indeed, many of my colleagues believe that the [Walgreens] case would have resulted in a narrowing of DEA's authority if the agency had not settled its dispute,” Barber said. “As a supporter of DEA's mission, I urge this committee to take legislative action that clarifies the meaning of imminent danger.”

D. Linden Barber helped design the DEA's aggressive enforcement campaign. When he left to work for the drug industry in 2011, he brought knowledge of the DEA's strategy and how it could be attacked to protect the companies. (U.S. Senate)

On April 21, 2015, the House took up Marino's bill. On the floor of Congress, Marino said:

"This bill will bring much-needed clarity to critical provisions of the Controlled Substances Act. In doing so, we will ensure that the DEA's authorities are not abused and threatened by future legal challenges; foster greater collaboration, communication and transparency between the DEA and the supply chain; create more opportunities to identify bad actors at the end of the supply chain; and, most importantly, be certain that prescriptions are accessible to patients in need."

The House passed the bill by unanimous consent. Not one lawmaker opposed the measure.

That same day, Leonhart, who had supported Rannazzisi's aggressive approach, announced that she was retiring as DEA administrator amid reports that some of her agents had attended sex parties funded by Colombian cocaine cartels.

For the industry and its supporters on Capitol Hill, the pieces were falling into place.

A month later, the Justice Department named a new DEA chief who said he wanted to mend the rift between the agency and the drug industry. Chuck

Rosenberg was a former U.S. attorney in Virginia and Texas who had served as the chief of staff to then-FBI Director James B. Comey.

After Rosenberg came to the DEA, the agency began putting out a new message.

“Rosenberg wanted to paint a new face on the DEA for the Hill,” said Regina LaBelle, the chief of staff for the White House’s Office of National Drug Control Policy at the time. “He wanted to show them the softer side of the DEA, and he wanted to work with industry.”

LEFT: Michele Leonhart resigned as DEA administrator on April 21, 2015, amid reports that DEA agents had attended sex parties paid for by drug cartels. (Chip Somodevilla/Getty Images)

RIGHT: Chuck Rosenberg, who was acting administrator after Leonhart's departure, said the agency had been slow to address the industry's concerns. (Alex Brandon/Associated Press)

In October 2015, one of the last remaining obstacles to the bill was removed. Rannazzisi was pushed aside at diversion control. With the inspector general's investigation into his comments hanging over his head, Rannazzisi retired from the DEA after a 30-year career.

The investigation went nowhere. But, Rannazzisi said, "It destroyed me."

By this time, Holder had left and Lynch was the attorney general. Her office informed Marino that the DEA had met with 300 industry representatives and Justice was committed to "working more closely" with the drug companies.

"We value these opportunities to communicate and work with our partners in the pharmaceutical industry," Kadzik, Lynch's congressional affairs chief, wrote to Marino.

At the same time, the DEA was in negotiations with Hatch's staff to amend the bill for the Senate's consideration.

The newly proposed language required the DEA to show that a company's conduct posed a "substantial likelihood of an immediate threat" of death,

serious bodily harm or drug abuse before the agency could seek a suspension order.

Whitlock, Hatch's spokesman, said the new language was proposed by the DEA.

"Senator Hatch has had a strong working relationship with DEA for his entire term of service and worked collaboratively for months with DEA here. Any claim that he tried to steamroll DEA or would ever seek to steamroll DEA is simply incorrect."

A Nov. 30 email from Tyson, the Justice Department congressional liaison officer, to a Senate staffer shows that the DEA agreed to the bill with reluctance.

"DEA felt this wasn't a great solution, but was the best of the options offered to us, even if it did not fully address the concerns we had previously laid out for you," she added, according to the email, which was provided by staff of Sen. Sheldon Whitehouse (D-R.I.), one of the bill's co-sponsors.

The bill would also give drug companies the opportunity to submit "corrective action" plans — outlines of how they were going to fix problems — before the DEA could sanction them. The DEA would be required to consider those plans before imposing penalties.

THE MARINO BILL'S PATH TO PASSAGE

How the bill that weakened the DEA made it through Congress and onto President Obama's desk.

Congress
DEA/DOJ
Lobby
Industry

FEBRUARY 18, 2014

Rep. Tom Marino introduces the first version of the Ensuring Patient Access and Effective Drug Enforcement Act.

APRIL 7, 2014

After a hearing, the bill stalls in committee.

Open full timeline ▼

On March 17, 2016, the Senate passed the bill by unanimous consent. On April 12, the House approved the Senate version, also by unanimous consent.

The bill still needed the president's signature. Opposition from the DEA or Justice could derail it, but the two agencies had given up the fight.

The senior DEA official said the agency worked with Congress to improve the bill under difficult political circumstances. The agency believed earlier versions of the bill would have forced it to meet a criminal standard before issuing immediate suspension orders. “The original version of the bill was unworkable,” the official said.

The congressional affairs office at the Justice Department told the White House Office of National Drug Control Policy that it no longer objected to the bill, according to Botticelli, then chief of the office.

On April 19, Obama signed the bill. The White House issued a one-page news release announcing its enactment.

Marino also issued a release taking credit for the legislation.

“With this law, our drug enforcement agencies will have the necessary tools to address the issue of prescription drug abuse across the country. I applaud the hard work of my colleagues on both sides of the aisle in Congress and President Obama for realizing the importance of this legislation.”

Industry groups also thanked Obama. They agreed to work with the DEA “to ensure that the law is implemented efficiently and effectively,” said

John M. Gray, chief executive of the Healthcare Distribution Alliance, which represents the nation's drug distribution companies.

Two months after Obama signed the bill, Rosenberg appeared on Capitol Hill. Hatch praised him.

"I've been told the DEA's relationship with supply chain stakeholders has improved since you've taken the helm at DEA," the senator said. "I want to just say I applaud your efforts on this front."

He then asked Rosenberg how he viewed the relationship between the DEA and the opioid industry going forward.

Rosenberg said the agency had been slow to address industry's concerns and had failed to communicate with them.

"The overwhelming majority, 99 plus percent, are our allies in this thing," Rosenberg said.

Illustration by Eddie Alvarez/The Washington Post; Photo from iStock

EPILOGUE

2016: 197,713 deaths from prescription opioid overdoses since 2000.

John Mulrooney, the chief DEA administrative law judge, has been documenting the falling number of immediate suspension orders against doctors, pharmacies and drug companies. That number has dropped from 65 in fiscal year 2011 to six so far this fiscal year, according to the DEA. Not a single order has targeted a distributor or manufacturer since late 2015, according to Mulrooney's reports, which were obtained under the Freedom of Information Act.

Mulrooney said in his reports that the judges under him were handling so few cases at the DEA that they began hearing the cases of other federal agencies.

In his article planned for the winter issue of the Marquette Law Review, Mulrooney wrote: "If it had been the intent of Congress to completely eliminate the DEA's ability to ever impose an immediate suspension on distributors or manufacturers, it would be difficult to conceive of a more effective vehicle for achieving that goal."

Mulrooney's article also criticized the law for allowing companies to submit corrective action plans before the DEA could sanction them.

He likened that provision to allowing bank robbers to “round up and return ink-stained money and agree not to rob any more banks.”

The DEA [said in a statement last week](#) that it is still pursuing reckless doctors and rogue businesses with a wide variety of tools.

“We will continue fighting the opioid crisis and continue to use all the tools at our disposal to combat this epidemic,” the statement said.

Since the DEA started to crack down on the opioid industry a decade ago, pharmaceutical companies and the law firms that represent them have hired at least 46 DEA officials — 32 of them directly from the division. They include two officials who managed day-to-day operations; the deputy director of the division; the deputy chief of operations; and two chiefs of policy.

After nearly 30 years with the DEA, Matthew Murphy, Rannazzisi’s lieutenant, retired in 2011. He formed a drug industry consulting firm and went to work for the people he used to face across the table.

Matthew Murphy, formerly of the DEA, recalls a meeting with the president of a drug company who put his hands up and said, “ ‘You got us. What can we do to make this right?’ ” Murphy said he had heard the same thing from drug dealers, but “the heroin and cocaine traffickers didn’t

have a class ring on their finger from a prestigious university.” (Katie Martens Brier/For The Washington Post)

“I feel guilty,” Murphy said in a recent interview. “Because every day a lot of people die of an opioid-heroin overdose. Whether it’s a pill or heroin, people die every day because of it. And it shouldn’t be happening.”

One of the most recent departures was Jason Hedges, the senior DEA attorney overseeing pharmaceutical enforcement cases who, according to former agency supervisors and lawyers, had been demanding a higher standard of proof on cases. Hedges left the DEA in May to join the pharmaceutical and biotechnology regulatory division of Hogan Lovells, a high-powered D.C. law firm. He declined to comment, citing “client sensitivities.”

In January, Mike Gill, who had served as the chief of staff to DEA Administrator Chuck Rosenberg, left the agency to join one of the nation’s largest health-care law firms. He declined to discuss why the DEA dropped its opposition to the bill or his new job.

On Oct. 1, **Rosenberg** himself resigned from the DEA.

Last December, seven months after the bill became law, **Marino’s** chief of staff took a job as a lobbyist with the National Association of Chain Drug

Stores. Bill Tighe had served as Marino's point man on the legislation. The association was a key backer of the bill. Tighe declined to comment.

In July, Linden Barber left Quarles & Brady to join Cardinal Health as the company's chief regulatory attorney. After being the target of two DEA enforcement actions, Cardinal had become one of the biggest backers of the bill.

Marsha Blackburn, who co-sponsored the House version of the bill, received \$120,000 in campaign contributions from the pharmaceutical industry. She did not respond to requests for an interview. She announced this month that she will run for the seat of Sen. Bob Corker (R-Tenn.), who is not seeking reelection.

In addition to Blackburn, Marino and Hatch, The Post sought comment from the other nine co-sponsors of the 2016 bill. Only four responded.

A spokesman for Whitehouse said that the DEA could have expressed its opposition at any time.

"The fact that it passed the entire Senate without hearing any sort of communication that would have triggered concern of at least one senator doesn't really pass the smell test," the spokesman said.

Jim Geldhof, the DEA program manager in Detroit, retired from the agency at the end of 2015 after 43 years on the job. He said the companies were fully aware of their responsibilities under the law.

“When you’re selling half a million pills to some pharmacy and you’re telling me that you don’t know what the rules are for a suspicious order?” said Geldhof, who is now working as a consultant to lawyers suing the industry. “All we were looking for is a good-faith effort by these companies to do the right thing, and there was no good-faith effort. Greed always trumped compliance. It did every time. It was about money, and it’s as simple as that.”

Just before Geldhof left, his two-year quest to persuade the DEA to take action against Miami-Luken finally paid off. In November 2015, the DEA accused the company of multiple violations of the law for allegedly failing to report orders for tens of millions of pain pills from pharmacies, most of them in West Virginia. That case — the most recent one to target a distributor — is pending.

Of the millions of pills sent to Mingo County, many went to one pharmacy in Williamson, the county seat, population 2,924. In one month alone, Miami-Luken shipped 258,000 hydrocodone pills to the pharmacy, more than 10 times the typical amount for a West Virginia pharmacy.

The mayor of Williamson has since filed a lawsuit against Miami-Luken and other drug distributors, accusing them of flooding the city with pain pills and permitting them to saturate the black market.

“Like sharks circling their prey, multi-billion dollar companies descended upon Appalachia for the sole purpose of profiting off of the prescription drug-fueled feeding frenzy,” the lawsuit says.

People in Lycoming County, Pa., who have lost a loved one to addiction gather regularly to share stories and comfort each other. (Michael S. Williamson/The Washington Post)

Marino, now in his fourth term, continues to represent northeastern Pennsylvania and Lycoming County, population 116,000.

His nomination as drug czar, which would put him in charge of the White House Office of National Drug Control Policy, is pending.

Marino declined to be interviewed for this story, but last year he told The Post:

“We had a situation where it was just out of control because of [Rannazzisi],” Marino said. “His only mission was to get big fines. He didn’t want to [do] anything but put another notch in his belt.”

Since 2014, the year Marino first introduced his bill, 106 people have died of opioid overdoses in Lycoming County. Over six days this summer, 53 people in the county overdosed on opioids. Three of them died.

On a warm night in July, four families gathered in a large, manicured backyard in Marino’s district to share their sorrow over the children and siblings they had lost to opioids.

Around the table they went, each with a different story, each death leaving the same wreckage behind.

“I got the phone call Nov. 12 at 2:39 in the afternoon,” Tina Snyder recalled. Her 24-year-old son, Lee Winder, had been found in a shopping center parking lot near his car outside a Dunkin’ Donuts.

Winder had become addicted to pain pills and died of a heroin overdose.

“All I remember hearing is ‘Ms. Snyder, this is Chuck Kiessling, the Lycoming County coroner,’ ” she recalled. “I could literally feel my heart breaking, and I didn’t say anything. He said, ‘We found your son at 7 o’clock this morning.’

“And I just kind of like melted to the floor, started crying. And the girl I was working with took the phone and was talking to him. And I just kept begging her to tell me it wasn’t true.”

Responses from bill sponsors

Sponsors and co-sponsors of the Ensuring Patient Access and Effective Drug Enforcement Act were all contacted for this piece, their responses are below.

Highlighted names are sponsors of the bill.

Name	State	Party
Rep.Tom Marino	Pa.	R
Response		
Declined request.		

Name	State	Party
Rep. Judy Chu	Calif.	

Response

"When I cosponsored the Ensuring Patient Access and Effective Drug Enforcement Act, it was my understanding that the DEA was closely involved in advising on drafting language that would not impact their mission."

Name	State	Party
Rep. Gus M. Bilirakis	Fla.	


Response

"My hope was that this legislation would eradicate the scourge of opioid addiction while allowing seniors, Veterans and other people with significant pain to get the relief they need with a legitimate prescription," Bilirakis said in a statement.

Name	State	Party
Rep. Douglas A. Collins	Ga.	

Response

Did not respond.

Name	State	Party
Rep. Ryan A. Costello	Pa.	

Response

Did not respond.

Name	State	Party
Rep. Marsha Blackburn	Tenn.	R

Response

Did not respond.

Name	State	Party
Rep. Peter Welch	Vt.	D

Response

“I supported Rep. Marino’s bill because it clarified the rules of the road for distribution companies seeking to comply with agency directives and freed up agency resources to go after bad actors in the system. If the intent of the law is not being fulfilled, then Congress should conduct oversight hearings and make changes that address concerns raised by the DEA,” Welch said in a statement.

Name	State	Party
Sen. Orrin Hatch	Utah	R

Response

Hatch’s spokesman, Matt Whitlock, said the DEA, which had undergone a leadership change, did not oppose the bill in the end. “We worked collaboratively with DEA and DOJ . . . and they contributed significantly to the language of the bill,” Whitlock wrote in an email. “DEA had plenty of opportunities to stop the bill and they did not do so.”

Name	State	Party
Sen. Marco Rubio	Fla.	R

Response

Did not respond.

Name	State	Party
Sen. David Vitter	La.	

Response

Did not respond. No longer in Senate.

Name	State	Party
Sen. Bill Cassidy	La.	

Response

Did not respond.

Name	State	Party
Sen. Sheldon Whitehouse	R.I.	

Response

A spokesman for Whitehouse said the DEA could have expressed its opposition at any time. “The fact that it passed the entire Senate without hearing any sort of communication that would have triggered concern of at least one senator doesn’t really pass the smell test,” the spokesman said.

Note: Chu did not receive the initial request for comment. Her response has since been included.

Steven Rich, Alice Li, Alice Crites, Reis Thebault and Sarah Bowman contributed to this report. Thebault was a fellow at the Investigative Reporting Workshop at American University. Bowman was a fellow at the Medill Justice Project at Northwestern University. Graphics by

Armand Emamdjomeh. Design and development by Leslie Shapiro, Danielle Rindler and Kaeti Hinck.

CORRECTION: An earlier version of this article, and an accompanying chart, misstated how much the drug industry spent on lobbying between 2014 and 2016. It spent \$102 million, not \$106 million. Some lobbying reports were double-counted. This version has been updated.

Also, an earlier version of the chart incorrectly said that the Pharmaceutical Research and Manufacturers of America supported the Ensuring Patient Access and Effective Drug Enforcement Act. The organization listed the bill in disclosing its lobbying expenditures, but took no position on it.



 **Comments**

More stories

The DEA slowed enforcement while the opioid epidemic grew out of control

The number of enforcement cases dwindled after a change in policy by the agency.

Drug industry hired dozens of officials from the DEA as the agency tried to curb opioid abuse

Critics say the revolving door undercuts the agency's ability to curb the rising opioid epidemic.

How drugs intended for patients ended up in the hands of illegal users: 'No one was doing their job

Wholesale distributors sent pills to drugstores that fueled the opioid epidemic.
