A decade ago, the Drug Enforcement Administration launched an aggressive campaign to curb a rising opioid epidemic that was claiming thousands of American lives each year. The DEA began to target wholesale companies that distributed hundreds of millions of highly addictive pills to the corrupt pharmacies and pill mills that illegally sold the drugs for street use.

Leading the campaign was the agency’s Office of Diversion Control, whose investigators around the country began filing civil cases against the distributors, issuing orders to immediately suspend the flow of drugs and generating large fines.

But the industry fought back. Former DEA and Justice Department officials hired by drug companies began pressing for a softer approach. In early 2012, the deputy attorney general summoned the DEA’s diversion chief to an unusual meeting over a case against two major drug companies.

“That meeting was to chastise me for going after industry, and that’s all that meeting was about,” recalled Joseph T. Rannazzisi, who ran the diversion office for a decade before he was removed from his position and retired in 2015.

Rannazzisi vowed after that meeting to continue the campaign. But soon officials at DEA headquarters began delaying and blocking enforcement actions, and the number of cases plummeted, according to on-the-record interviews with five former agency supervisors and internal records obtained by The Washington Post.

The judge who reviews the DEA diversion office’s civil caseload noted the plunge. “There can be little doubt that the level of administrative Diversion enforcement remains stunningly low for a national program,” Chief Administrative Law Judge John J. Mulrooney II wrote in a June 2014 quarterly report obtained under the Freedom of Information Act.
As diversion cases languished, the opioid death toll rose

In fiscal 2011, civil case filings against distributors, manufacturers, pharmacies and doctors reached 131 before dropping to 40 in fiscal 2014, according to the Justice Department. The number of immediate suspension orders, the DEA’s strongest weapon of enforcement, dropped from 65 to nine during the same period.

“This came to a grinding halt,” said Frank Younker, a DEA supervisor in the Cincinnati field office who retired in 2014 after 30 years with the agency. “I talked to my fellow supervisors, and we were all frustrated. It was ridiculous. I don’t know how many lives could have been saved if the process was done quicker.”

Joseph T. Rannazzisi, appearing at a Senate Judiciary subcommittee hearing in 2009, ran the Drug Enforcement Administration’s Office of Diversion Control for a decade before he was replaced and retired in 2015.
The slowdown began in 2013 after DEA lawyers started requiring a higher standard of proof before cases could move forward.

Top officials at the DEA and Justice declined to discuss the reasons behind the slowdown in the approval of enforcement cases. The DEA turned down requests by The Post to interview Mulrooney, acting DEA administrator Chuck Rosenberg, chief counsel Wendy H. Goggin and Ranazzisi’s replacement, Louis J. Milione.

The agency provided a statement from Rosenberg:

“We combat the opioid crisis in many ways: criminally, civilly, administratively, and through robust demand reduction efforts.

“We implemented new case intake and training procedures for our administrative cases, increased the number of enforcement teams focused on criminal and civil investigations, restarted a successful drug take back program, and improved outreach to — and education efforts with — our registrant community.

“We have legacy stuff we need to fix, but we now have good folks in place and are moving in the right direction.”

The Justice Department, which oversees the DEA, declined requests to interview Attorney General Loretta E. Lynch and Deputy Attorney General Sally Q. Yates.

The department issued a statement saying that the drop in diversion cases reflects a shift from crackdowns on “ubiquitous pill mills” toward a “small group” of doctors, pharmacists and companies that continues to violate the law.

Justice Department spokesman Peter Carr said diversion investigators are also increasingly using criminal procedures to force targets to surrender their licenses without administrative hearings.

“Although these reasons largely
account for the decline in administrative case filings, the department remains committed to eliminating the problem of opioid abuse,” Carr said, pointing out that the diversion control chief had recently been elevated to a “top leadership post.”

But Justice statistics show that surrenders of licenses have remained relatively constant since 2011 before dropping by more than a third in the last fiscal year. Carr could not say how many were tied to DEA enforcement actions. The former agency supervisors said the majority of surrenders do not involve DEA enforcement actions.

The epidemic began in the late 1990s after the introduction of the powerful, long-acting opioid OxyContin and an aggressive marketing campaign by the drug’s manufacturer, Purdue Pharma, to persuade doctors to prescribe it for all kinds of pain. A new philosophy of pain management resulted in a surge in demand and the U.S. addiction rate.

From 2000 to 2014, 165,000 people died of overdoses of prescription painkill-
ers nationwide. The crisis has also fostered follow-on epidemics of heroin, which caused nearly 55,000 overdose deaths in the same period, and fentanyl, which has killed thousands more. The number of U.S. opioid prescriptions has risen from 112 million in 1992 to 249 million in 2015.

Several DEA officials on the front lines of the opioid war said they could not persuade headquarters to approve their cases at the peak of the epidemic. They said they confronted Clifford Lee Reeves II, a lawyer in charge of approving their cases, to no avail. Through a DEA spokesman, Reeves declined to comment for this report.

Jim Geldhof had been with the DEA for nearly four decades and was serving as the diversion program manager in the Detroit field office when Reeves took over at DEA headquarters in 2012.

“It was like he was on their side, not ours,” said Geldhof, who retired in January. “I don’t know what his motive was, but we had people dying. You’d think he’d be more aggressive. We were in the throes of a major pill epidemic.”

In the field, Younker and other DEA supervisors said they grew to distrust Reeves and became suspicious about what was taking place at headquarters.

“We all had a feeling that someone put him there to purposely stonewall these cases,” Younker said.

Kathy Chaney, who served as the DEA’s group supervisor in Columbus, Ohio, saw the problem play out firsthand. She was responsible for 35 counties in Ohio and had overseen the agency’s efforts to curb prescription painkiller abuse in cities such as Chillicothe and Portsmouth, both at ground zero of the opioid crisis.

She said one of her cases against a distributor languished for years without action. The experience was particularly difficult, Chaney said, because she had been meeting with parents of children who had died of overdoses of oxycodone and other painkillers.

“We got so frustrated, I finally told my group, ‘We’re not going to send any cases up to headquarters,’ ” said Chaney, who retired in 2013. “In 25 years, I had never seen anything like it. It was one of the rea-
In 2004, the leaders of the DEA’s diversion office became alarmed by the rising number of overdose deaths amid a growing supply of prescription painkillers. Online pharmacies were flourishing, making it easy to buy powerful painkillers such as oxycodone and hydrocodone. The death toll had hit 8,577, a 15 percent jump in one year.

Pain-management clinics began popping up around the country. DEA diversion investigators soon realized that they were playing a real-life game of Whac-a-Mole. As soon as they shut down one facility, another would appear.

“People were dying,” said William J. Walker, a 31-year DEA veteran who headed the diversion office in 2004 and 2005.

Walker set up tactical units around the country to investigate doctors, pharmacists, distributors and manufacturers.

“We had a multilayered threat, and there was a tremendous sense of urgency,” he said.

“I turned up the heat on the workforce, and we started getting after it.”

Toward the end of 2005, Walker, a brigadier general in the National Guard, was called up for active duty and left the office. Taking his place was his top deputy,
ABOVE: Kathy Chaney, who was the DEA’s group supervisor in Columbus, Ohio, before retiring in 2013, described how one of her cases against a distributor languished for years without action. “In 25 years, I had never seen anything like it,” she said. “It was one of the reasons I left. Morale was terrible. I couldn’t get anything done. It was almost like being invisible.”

LEFT: Chaney’s mother, Barbara Ann Bransford, became addicted to Percocet after a car accident and died of an accidental overdose in 1979. “That’s the reason I got into this work,” Chaney said. “To see this happening, it makes me want to cry.”

UNNATURAL CAUSES
SICK AND DYING IN SMALL-TOWN AMERICA

Since the turn of this century, death rates have risen for whites in midlife, particularly women. In this series, The Washington Post is exploring this trend and the forces driving it. Read more at wapo.st/new-divide.
Joseph Rannazzisi, a street-smart New Yorker who held degrees in pharmacy and law. He had begun his career as a DEA street agent and then a supervisor in Detroit before working his way to the top of the diversion office at the agency’s headquarters in Arlington, Va.

Rannazzisi decided to focus on the source of the pills: the wholesale distributors of pharmaceuticals.

Drugs are manufactured by high-profile corporations such as Purdue Pharma. They rely on a lesser-known network of distributors, some of which are also multinational corporations. The distributors serve as middlemen, sending billions of doses of opioid pain pills to pharmacists, hospitals, nursing homes and pain clinics. The U.S. prescription opioid market generates $10 billion in annual sales.

There are thousands of distributors among the 1.6 million people and companies that hold DEA licenses to dispense drugs, but three of them — McKesson, AmerisourceBergen and Cardinal Health — account for 85 percent of the drug shipments in the United States. These companies, which together collect about $400 billion in annual revenue, supply the corner pharmacist as well as giant medical centers.

For years, the DEA had taken a hands-off approach to the prescription drugs flowing out of the distributors. The companies had been reporting their drug sales inconsistently or not at all. They had been largely left alone as the DEA focused on doctors and pharmacies.

“The distributors had been ignored for years and years and years,” John J. Coleman, the third-ranking administrator at the DEA in the mid-1990s, said in a recent interview.

In 2005, the Office of Diversion Control, under Rannazzisi, launched its “Distributor Initiative” and briefed 76 companies about it. The new campaign pitted the DEA against an industry with close ties to lobbyists, lawyers and politicians in Washington.

On Sept. 27, 2006, the diversion office sent a letter to distributors across the country, reminding them that they were required by law to ensure that their drugs were not being diverted to the black market.

“Given the extent of prescription drug abuse in the United States, along with the dangerous and potentially lethal consequences of such abuse, even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm,” Rannazzisi wrote in the letter.

Five months later, D. Linden Barber, then-associate chief counsel for the DEA diversion office, wrote to DEA supervisors across the country, telling them to be vigilant. Abuse of prescription drugs, he said, had become “greater than the abuse of cocaine, heroin and methamphetamine.”

Under Rannazzisi’s initiative, distributors would have to monitor their sales in real time, withhold drug shipments if they detected suspicious activity and report
those red flags to the DEA.

The diversion office deployed two weapons to ensure compliance. The first was an “order to show cause,” which permits investigators to begin a process to stop drug shipments from warehouses. The second was an “immediate suspension order,” which allows the DEA to instantly freeze shipments of narcotics from facilities where an “imminent threat” to public health exists. The immediate suspension order was especially dreaded by the distributors.

Younker, the former DEA supervisor in Cincinnati, said the agency had no other choice.

“The distributors could have stopped what was going on, but they didn’t,” he said. “They were doing the bare minimum. Why would you want to cut off a customer that’s paying you $2 million a year? They have sales reps and sales quotas and bonus structures and employees of the month. Everyone was making a lot of money.”

The DEA diversion office started small. Investigators targeted Southwood Pharmaceuticals, a mom-and-pop distributor in Lake Forest, Calif., where shipments of hydrocodone had skyrocketed over nine months in 2005, from 7,000 doses per month to 3 million. Southwood eventually lost its license to dispense controlled substances.

In 2007, the DEA raised its sights, bringing an enforcement case against McKesson — now the nation’s largest drug distributor and the fifth-largest corporation in the country. The DEA accused the company of failing to report hundreds of suspicious orders from online pharmacies.

“As a result, millions of dosage units of controlled substances were diverted from legitimate channels of distribution,” a Justice Department news release said in 2008. Without admitting liability, McKesson eventually settled the case, agreeing to pay a $13 million fine.

That same year, the diversion office filed a case against Cardinal Health, another member of the Big Three wholesalers. DEA investigators alleged that the company was sending millions of doses of painkillers to online and retail pharmacies without alerting investigators to an obvious sign of illegal diversion.

Cardinal settled the allegations in 2008, paying a $34 million fine without acknowledging wrongdoing and promising to improve its monitoring of suspicious orders. Cardinal’s chief executive at the time said the company had spent $20 million to control diversion and took its responsibility “very seriously.”

Still, the painkiller crisis raged. In 2008, 13,149 people died of opioid overdoses.

The next year, a federal law made it illegal to distribute controlled substances online and required doctors to see their patients face-to-face before writing prescriptions.

By now, the DEA’s campaign was broad and deep. Mulrooney, the agency’s
chief law judge, noted in an internal report that the agency had filed 115 charging documents in 2010, including 52 immediate suspension orders.

“Progress,” the chief judge wrote, noting that all pending cases were scheduled for hearings. “This has not been true for as long as anyone here can remember.”

In late 2011, Rannazzisi’s office filed warrants to yet again inspect the records of a Cardinal warehouse. Investigators alleged that the company was overlooking escalating oxycodone orders from pharmacies in Florida. The DEA was also targeting four drugstores supplied by Cardinal in the state, including two CVS pharmacies.

Rannazzisi’s office obtained an internal Cardinal email from 2010 showing that the company’s own investigator had warned against selling narcotics to Gulf Coast Medical Pharmacy, an independent drugstore in Fort Myers, Fla., citing suspicions that the pills were winding up on the street.

Despite the warning, Cardinal hadn’t notified the DEA or cut off the supply of drugs.

Instead, the company shipped increasing quantities of pain pills to Gulf Coast. In 2011 alone, Cardinal sent more than 2 million doses of oxycodone to Gulf Coast. The wholesaler typically shipped 65,000 doses annually to comparable pharmacies.

“I had the case of my dreams,” Rannazzisi said.

About Thanksgiving in 2011, Rannazzisi said that he received an unexpected phone call.

It was from James H. Dinan, then-chief of the Organized Crime Drug Enforcement Task Forces program at the Justice Department. Dinan worked with then-Deputy Attorney General James M. Cole, the second-most-powerful Justice Department official after Attorney General Eric H. Holder Jr.

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 said he told Dinan that warrants for Cardinal records had already been served.

Among the attorneys representing Cardinal at the time were two former deputy attorneys general, Jamie S. Gorelick, who served in the Clinton administration, and Craig S. Morford, who served in the George W. Bush administration. Both contacted the DEA, records show.

Gorelick did not respond to requests for an interview. Morford declined to comment. Instead, Cardinal referred questions to Barber, the former DEA associate chief counsel in charge of diversion litigation, who joined the law firm Quarles & Brady and is now representing distributors.

Barber told The Post that there was nothing unusual about Morford contacting the agency.

“It was not anything other than ‘we’d like to sit down and have a discussion at an early stage of the investigation,’ ” Barber said.
On Feb. 1, 2012, as Rannazzisi was preparing to sign off on immediate suspension orders against Cardinal and CVS, he said he received another call from Dinan.

Rannazzisi said Dinan told him that Cole, the deputy attorney general, known in the department as the "DAG," was demanding a briefing before the suspension orders were executed.

The next morning, at 1:36 a.m., Dinan followed up with an email.

"Please call me in the morning," he wrote, according to Rannazzisi. "I want to make double sure nothing irreversible happens before the DAG is briefed as we talked about at Thanksgiving."

That morning, Rannazzisi went to the Justice Department in Washington to meet with a number of officials, including Cole; Dinan; Goggin, the DEA's top lawyer; and Stuart M. Goldberg, Cole's chief of staff.

Rannazzisi said Goldberg did most of the talking.

"He asked me a question about what my goals were in this case, and why I was going after these corporations," Rannazzisi said. "I said, 'Before I answer that, I’ve got to ask you: I’ve done hundreds of these cases, and I’ve never been called over to the Justice Department to explain myself. I’m just curious why this case is so important.’"

Rannazzisi said Cole interrupted.

"Because I’m the deputy attorney general of the United States, and I want to know about it," he recalled Cole saying.

"Then I say, ‘Well, that doesn’t really answer the question,’" Rannazzisi said.

The meeting went downhill from there.

"It spiraled out of control," Rannazzisi said. "It got very adversarial."

Cole, who is now a partner at the Washington law firm Sidley Austin, disputed Rannazzisi’s characterization of the meeting.

"My conversation with Mr. Rannazzisi was simply to confirm whether or not he had refused to meet with Cardinal regarding a potential DEA action and, if so, share my view that it made good sense to listen to what Cardinal had to say," Cole said in a statement.

"Hearing what Cardinal had to say could inform DEA of facts they may not have known. 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.

Dinan, now the principal assistant U.S. attorney for the District of Columbia, declined to comment through a spokesman. Goldberg and Holder did not respond to requests for an interview.

Rannazzisi said he left the meeting undeterred. The same day, his office filed the suspension order against Cardinal, and two days later, DEA investigators shut down the two CVS pharmacies. A week later, DEA officials said in court documents that Cardinal’s activities constituted "an imminent danger to the public health or safety."

As the cases were pending, Goggin
wrote to Rannazzisi to inform him that CVS was attempting to go around the agency by appealing to the office of the deputy attorney general, known as ODAG.

“CVS lawyers (who used to work at DOJ) are trying to do an end run with ODAG,” Goggin wrote, according to Rannazzisi. “They want (1) to get the administrator to hold off issuing a final order until we are able (presumably) to try and work out a settlement.”

In his statement, Cole said, “I do not recall having any involvement with CVS matters while at DOJ.”

Final orders make cases public because the decisions are published in the Federal Register. A final order was issued against CVS, which ultimately paid a $22 million fine.

In 2012, Cardinal also reached a settlement. A company spokesman recently told The Post that Cardinal uses state-of-the-art techniques, including advanced analytics, to combat diversion.

To date, the company has not been fined. A federal prosecutor and company officials said negotiations are continuing.

In December 2012, a new lawyer filled the position in charge of approving cases brought by the DEA’s diversion office. A career employee of the Justice Department, Clifford Reeves had worked on the case against CVS. At first, diversion investigators were encouraged by the arrival of an experienced lawyer.

But soon, complaints arose in some of the DEA’s field offices around the country. Under Reeves, DEA attorneys began demanding additional evidence before investigators could take action.

“After Reeves arrived, everything became confrontational,” Geldhof, the retired DEA diversion manager in Detroit, recalled in a recent interview. “There were a lot of roadblocks all the time. Everything was an issue.”

Before Reeves’s arrival, Geldhof said, investigators had to demonstrate that they had amassed “a preponderance of evidence” before moving forward with enforcement cases, which are administrative, not criminal. Under Reeves, Geldhof said, investigators had to establish that their evidence was “beyond a reasonable doubt,” a much higher standard used in criminal cases.

Geldhof said he repeatedly confronted Reeves about the languishing cases.

“I said, ‘Lee, what’s going on?’ ” Geldhof said.

He said Reeves simply told him about the new higher standard.

Barbara Heath, a DEA program manager in Atlanta, said she and her investigators were frustrated by the new policy in Washington.

“It was the most significant change in my 20 years at the DEA,” said Heath, who oversaw the agency’s diversion efforts in Georgia, the Carolinas and Tennessee from 2006 until her retirement in December. “It got to the point where they wanted the same evidence as criminal prosecutions. It was very difficult to prove intent.”
In Washington, Mulrooney, the chief DEA judge, was documenting the falling caseload. In a June 24, 2013, quarterly report, Mulrooney wrote that there was “a significant drop” in the number of “orders to show cause.” Four months later, he noted “a free fall in the numbers of charging documents.” For the first time since records had been kept, he noted, no charging documents had been filed for an entire month.

Younker, the retired DEA supervisor in Cincinnati, said he, too, called Reeves to complain.

“Look, these cases are lingering here, they’re down in your shop for six to 12 months,” Younker recalled telling Reeves. “They’re sending drugs out and people are dying, and this is like the emperor has no clothes on.”

Younker said Reeves replied: “Who’s the emperor?”

“I said, ‘You’re the emperor. You can’t sit on these things like this.’ ”

Seeing what was happening in the field, Rannazzisi said he became furious with Reeves.

“At one point, I said: ‘I’ve lost all faith in the counsel, and you’ve become a hindrance and not a help, and all these people are dying,’ ” Rannazzisi said.

Chaney, the former DEA supervisor in Columbus, said her office in 2011 began investigating an Ohio distributor that sent tens of millions of pain pills to doctors and pharmacies in Florida over three to four years.

Chaney said there was no reason to ship that many pills to Florida from Ohio, because the company already had a distribution facility in Florida. The DEA also had previously taken action against some of the doctors who were writing prescriptions for opioids filled by the Florida pharmacies.

“It was a righteous case,” she said.

But the lawyers at DEA headquarters disagreed. The original DEA attorney assigned to the case was removed and replaced by a lawyer who stalled the case at every turn, Chaney said.

“It was never enough,” she said. “We could never satisfy them.”

Chaney declined to identify the company because no legal action was taken.

At the end of 2013, she retired from the DEA.

“We were all very dedicated, and we were all deeply disappointed that the program was being manipulated this way,” she said.

Chaney said she had joined the DEA because of a personal loss: Her mother became addicted to Percocet after a car accident and died of an accidental overdose.

“That’s the reason I got into this work,” she said. “To see this happening, it makes me want to cry.”

In Washington, Mulrooney was becoming increasingly frustrated, his quarterly reports show. In a June 24, 2014, report, the judge wrote that the DEAs legal office had filed only seven show-cause orders and one immediate suspension
order in the previous three months.

“These numbers continue to reflect an alarmingly low rate of Agency Diversion enforcement activity on a national level relative to historical data,” Mulrooney wrote.

He noted that the drop in cases coincided with “a leadership transition” in the legal office. He wrote that he couldn’t determine who was to blame — the field offices or the lawyers at headquarters. Mulrooney divided the operating budget of the diversion office by the number of cases that were being approved. He found that each case was costing taxpayers nearly $11 million.

“Assuming also that opioid-related deaths remain at over 20,000 per year (2010-2011 levels), this would mean that the Agency is on course to institute one administrative enforcement action for every 625 fatalities,” he wrote.

Three months later, Mulrooney reported that the diversion caseload was so low, his judges had little to do. He began permitting them to hear cases from other federal agencies, including the Bureau of Prisons and the Treasury Department.

In the summer of 2014, Rannazzisi said that he received an unusual request. To foster better relations with industry, the Justice Department wanted to meet with senior representatives of drug distributors and pharmacy chains.

Rannazzisi said he was appalled. Some of the companies were either under investigation or in the midst of settlement negotiations with the DEA diversion office, he said.

But Rannazzisi said that he objected and that the meeting did not take place.

That summer, lobbying by the pharmaceutical industry intensified on Capitol Hill. Several members of Congress, led by Reps. Tom Marino (R-Pa.) and Marsha Blackburn (R-Tenn.), were proposing a measure that critics said would undercut the DEA’s ability to hold drug distributors accountable.


In July 2014, Rannazzisi was asked to explain his opposition to the bill in a conference call with congressional staffers.

“I said, ‘This bill passes the way it’s written we won’t be able to get immediate suspension orders, we won’t be able to stop the hemorrhaging of these drugs out of these bad pharmacies and these bad corporations,’ ” Rannazzisi recalled telling them.

“What you’re doing is filing a bill that will protect defendants in our cases.”

His remarks enraged Marino, the chairman of the House Judiciary subcommittee on regulatory reform.
In a Sept. 18, 2014, congressional hearing, Marino tore into then-DEA Administrator Michele Leonhart, Rannazzisi’s boss. By then, the legislation had passed the House; the bill was about to be introduced in the Senate.

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

Marino told Leonhart that Congress was sending the DEA a message: “You should take a serious look at your regulatory culture and seek collaboration with legitimate companies that want to do the right thing.”

Marino mentioned Holder’s desire to meet with representatives of the pharmaceutical industry. At a hearing, Marino said he was “disappointed that DOJ staff has not made this a priority.”

Seven days later, Marino and Blackburn, who represent districts in states that have been hit hard by the opioid epidemic, demanded that the Justice Department’s inspector general investigate Rannazzisi’s remarks. They said he had tried to “intimidate” members of Congress. An investigation was launched. Rannazzisi was replaced in August 2015 and retired last October.

“That led to his undoing,” said Matthew Murphy, a DEA official who worked with Rannazzisi in the diversion office. Rannazzisi had “very, very strong views” on what was happening on the street, Murphy said. “He wasn’t going to change his opinion because of some heat.”

Marino said the conflict boils down to one person — Rannazzisi.

“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.”

The legislation passed in 2016. It raises the standard for the diversion office to obtain an immediate suspension order. Now the DEA must show an “immediate” rather than an “imminent” threat to the public, a nearly impossible burden to meet against distributors, according to former DEA supervisors and other critics. They said the new law gives the industry something it has desperately sought: protection from having its drugs locked up with little notice.

DEA officials, who declined to speak on the record, said the agency retains its power to issue immediate suspension orders under the new law.

Four months after Rannazzisi left, representatives from drug distributors and pharmacy chains got the meeting they had long wanted with key government officials, including Rosenberg, the acting DEA administrator, and Milione, Rannazzisi’s replacement.

Afterward, the DEA issued a news release declaring that it had established a new relationship with the companies.

“The pharmaceutical industry has a vital role on the front lines of preventing drug misuse and abuse across America, as
do we,” Rosenberg said in the release, “and we plan to work closely with them.”

The new relationship had been in the making for years.

“One longstanding Congressional criticism of DEA’s diversion control division has been a lack of communication with its registrants,” Carr, the Justice Department spokesman, said in the recent statement. “Upon his arrival at DEA in May 2015, in response to these concerns, Acting Administrator Rosenberg made it a priority to improve communication with registrants and strengthen partnerships with the regulated industry.”

John M. Gray, president and chief executive of the Healthcare Distribution Alliance, the wholesalers’ trade association, praised the new approach.

“HDA is pleased with the willingness of the new leadership at the DEA to meet with and engage registrants, and is encouraged by the Administration’s desire to ‘reset the relationship’ with our industry,” Gray said in a recent statement to The Post.

Rannazzisi said he views the new relationship as a surrender to industry.

“This idea that they’re going to say, ‘I’m sorry I violated the law, give me another chance and I’ll make it right,’ without having some type of punishment, to me is outrageous,” he said. “Every time I talked to a parent who lost a kid, I’m pretty sure they didn’t want me to say, ‘Oh, give them another chance because corporate America needs another chance.’”

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Steven Rich, David S. Fallis, Alice Crites and Josephine Peterson contributed to this report. Peterson is attached to The Post’s investigative unit through a program at American University.
As diversion cases languished, the opioid death toll rose
Red flags didn’t halt flow of pills to black market

Wholesalers provided painkillers to drugstores, fueling deadly epidemic

by Lenny Bernstein, David S. Fallis and Scott Higham

For 10 years, the government waged a behind-the-scenes war against pharmaceutical companies that hardly anyone knows: wholesale distributors of prescription narcotics that ship drugs from manufacturers to consumers.

The Drug Enforcement Administration targeted these middlemen for a simple reason. If the agency could force the companies to police their own drug shipments, it could keep millions of pills out of the hands of abusers and dealers. That would be much more effective than fighting “diversion” of legal painkillers at each drugstore and pain clinic.

Many companies held back drugs and alerted the DEA to signs of illegal activity, as required by law. But others did not.

Collectively, 13 companies identified by The Washington Post knew or should have known that hundreds of millions of pills were ending up on the black market, according to court records, DEA documents and legal settlements in administrative cases, many of which are being reported here for the first time. Even when they were alerted to suspicious pain clinics or pharmacies by the DEA and their own employees, some distributors ignored the warnings and continued to send drugs.

“Through the whole supply chain, I would venture to say no one was doing their job,” said Joseph T. Rannazzisi, former head of the DEA’s Office of Diversion Control, who led the effort against distributors from 2005 until shortly before his retirement in 2015. “And because no one was doing their job, it just perpetuated the problem. Corporate America let their profits get in the way of public health.”

A review of the DEA’s campaign against distributors reveals the extent of the companies’ role in the diversion of opioids. It shows how drugs intended for millions of legitimate pain patients ended up feeding illegal users’ appetites for prescription narcotics. And it helps explain why there has
been little progress in the U.S. opioid epidemic, despite the efforts of public-health and enforcement agencies to stop it.

At the peak of the crisis, the DEA retreated from the battle. A Post investigation published Sunday revealed that beginning in 2013, some officials at DEA headquarters began to block and delay enforcement actions against wholesale drug distributors and others, frustrating investigators in the field.

Several former DEA officials told The Post that the shift in approach undercut the cases against some of these distributors, who were ignoring signs that their customers were ordering suspicious quantities of narcotics.

“We could not get these cases through headquarters,” said Frank Younker, a DEA supervisor in the Cincinnati field office who retired in 2014 after a 30-year career. “We were trying to shut off the flow, and we just couldn’t do it.”

The 13 companies include Fortune 25 giants McKesson, Cardinal Health and AmerisourceBergen, which together control about 85 percent of all pharmaceutical distribution in the United States. They also include regional wholesalers such as Miami-Luken and KeySource Medical, both based in Ohio, as well as Walgreens, the nation’s largest retail drugstore chain. Many of the distributors are tiny operations with just a few employees.

It is not clear how many other cases exist. Because the DEA handles its enforcement actions administratively, few details surface unless the agency or the company discloses them, or if one side appeals in civil court.

The DEA declined to disclose how many enforcement actions it has brought against distributors, requiring a Freedom of Information Act request that The Post filed in April. The request is pending. The DEA also would not make any officials available to discuss this article, but it provided a statement from acting administrator Chuck Rosenberg defending the agency’s enforcement actions.

“We now have good folks in place and are moving in the right direction,” he said.

Some of the 13 companies have fought the DEA’s enforcement efforts in court and in hearings before the agency’s administrative law judges. Except in two pending cases, all have lost or settled. Using its civil authority, the DEA stopped the flow of narcotics from some company warehouses, and U.S. attorneys levied fines totaling more than $286 million.

Most of the 13 wholesalers involved in these cases declined to be interviewed. In court filings and congressional testimony, they said they have developed large and sophisticated systems to help prevent drug diversion. They have complained that it is difficult to police the activities of far-flung

Wholesalers distributed pills that fueled opioid epidemic
ABOVE: The Hillsborough County Sheriff’s Office raids a pain-management clinic in Tampa in a 2010 crackdown on pill mills. 
LEFT: Jim Geldhof, a former DEA diversion supervisor, said Ohio-based Miami-Luken ignored agency warnings about excessive sales of prescription opioids.
TOP: Frank Younker, a retired DEA supervisor, said it became difficult to get the agency’s headquarters to approve cases against distributors beginning in 2013.
drug dispensers and have noted that drugs could not be sold to illegal users without prescriptions written by corrupt doctors. They also criticized the DEA’s past approach to the problem as punitive and its rules as vague and confusing.

But the problem is clearly ongoing. Prescription narcotics cause more overdose deaths every year than any street drug, including heroin. The painkiller epidemic has taken 165,000 lives since the turn of the century, with the number of deaths soaring from 3,785 in 2000 to 14,838 in 2014.

Opioid overdoses, mainly from prescription drugs, are also the leading cause of the recent unexpected rise in the mortality rate of middle-aged white Americans, particularly women in rural areas, after decades of steady decline.

But it is impossible to estimate how much of the opioid supply is siphoned away to illicit use.

“No one knows, because it’s impossible to track what happens to an individual prescription once it leaves the pharmacist,” said Susan Awad, director of advocacy and government relations for the American Society of Addiction Medicine.

One of the first wholesalers targeted by the DEA under its “Distributor Initiative” was Southwood Pharmaceuticals, a small company based in Lake Forest, Calif., that sent controlled substances to Internet pharmacies. Because these online businesses typically allowed people to obtain drugs without being seen by a doctor, they were ripe for abuse.

In 2005, for example, Southwood supplied one Florida online drugstore, Medi-pharm-Rx, with 8.6 million doses of hydrocodone — the opioid found in Vicodin and Lortab, according to the DEA.

But Southwood failed to file a single suspicious order report, even after the DEA warned the

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**Where the most opioids are prescribed, the most drug overdoses happen**

Counties with high prescription opioid rates tend to have high drug overdose rates — as seen in Appalachia, the California-Oregon border, Pennsylvania, Oklahoma and Arizona.

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**Graph:**

- **Grams of prescription opioids delivered per 1,000 people:**
  - 0
  - 600
  - 900
  - 1,200
  - 2,642

- **Highest quarter of overdose rates**

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**Sources:** DEA, Centers for Disease Control and Prevention
company in July 2006 about the growth in the volume of its shipments. The DEA had seen the trend in its own monitoring of drug-sales data.

“Even after being advised by agency officials that its internet pharmacy customers were likely engaged in illegal activity, [Southwood] failed miserably to conduct adequate due diligence,” Michele Leonhart, then the DEA’s deputy administrator, wrote in a 2007 decision to revoke the company’s license to distribute narcotics.

“The direct and foreseeable consequence of the manner in which [Southwood] conducted its due diligence program was the likely diversion of millions of dosage units of hydrocodone,” Leonhart wrote, adding that the company had reason to know that the 44 million doses of hydrocodone it distributed were probably being diverted.

That amount would provide a 30-day supply of narcotics for everyone in the city of Dallas, according to Express Scripts, a pharmacy benefit management company.

Southwood got out of the business of selling controlled substances and six years later lost its pharmacy license in California.

The company’s president, John Sempre, recently told The Post that the company did not understand at first that it was supplying Internet pharmacies. He said it is very difficult for companies to monitor the sales of faraway retailers.

“If companies like McKesson can’t control it, what does that tell you?” Sempre asked.

In 2008, McKesson, the nation’s largest drug distributor, settled a case that accused three of its U.S. warehouses of failing to report hundreds of suspicious orders from Internet pharmacies. “As a result, millions of doses of controlled substances were diverted from legitimate channels of distribution,” the Justice Department said in a news release. The company paid a $13 million fine to U.S. attorney’s offices in Florida, Maryland, Colorado, Texas, Utah and California.

“By failing to report suspicious orders for controlled substances that it received from rogue Internet pharmacies, the McKesson Corporation fueled the explosive prescription drug abuse problem we have in this country,” Leonhart, then the acting DEA administrator, said in a statement at the time.

Seven years later, after being caught up in a second diversion case, McKesson agreed to pay a $150 million fine and accepted license suspensions at four warehouses, according to a company filing with the Securities and Exchange Commission. No other details of that case have become public, and both the company and the DEA declined to discuss it.

A McKesson spokeswoman said in a statement to The Post, “We welcome the ongoing dialogue with the DEA aimed at developing effective controlled substances monitoring programs and successfully mitigating prescription drug abuse and diversion.”

AmerisourceBergen, another member
of the so-called Big Three distributors, lost its license to send controlled substances from an Orlando warehouse on April 24, 2007, amid allegations that it was not controlling shipments of hydrocodone to Internet pharmacies. The facility was back in business by August of that year and did not pay a fine, according to a company spokeswoman.

Few details of the case have surfaced.

Cardinal, the third member of the Big Three, paid a $34 million fine in 2008 after seven of its warehouses across the country filled thousands of suspicious orders from Internet pharmacies without reporting them, despite an earlier warning from the DEA, according to a Justice Department news release.

On Oct. 5, 2010, when Cardinal investigator Vincent Moellering visited Gulf Coast Medical Pharmacy, a drugstore in Fort Myers, Fla., he found evidence of diversion everywhere, records show, including suspicious customers who came in groups to fill their prescriptions.

The pharmacy’s owner told Moellering that he could sell even more narcotics if Cardinal would supply them, according to Moellering’s report, which the DEA introduced in a court proceeding.

Moellering labeled the drugstore “high risk” and wrote: “I am not convinced that the owner is being forthright pertaining to his customers’ origin or residence. I have requested permission to contact DEA to resolve this issue.”

But Cardinal didn’t notify the agency or cut off Gulf Coast’s drug supply, the DEA contends. Instead, the shipments kept going out. In 2011 alone, Cardinal sent more than 2 million doses of oxycodone to Gulf Coast. Cardinal typically shipped 65,000 doses of the opioid annually to comparable pharmacies, the DEA said.

Even as Cardinal was increasing its shipments to Gulf Coast, another wholesale drug distributor, H.D. Smith, was cutting off its supply of painkillers to the pharmacy. Smith took action after one of its compliance officers visited Gulf Coast and found “impaired and lethargic” customers “with glassy eyes” in November 2010, a few weeks after Moellering’s visit, court records show.

The Smith inspector learned that the pharmacy filled 300 prescriptions a day,

**DEA enforcement actions against opioid distributors**

- Southwood Pharmaceuticals, 2007
- AmerisourceBergen, 2007
- Richie Pharmacal, 2007
- Belco Drug, 2007
- Cardinal Health, 2008
- McKesson, 2008
- Masters Pharmaceutical, 2009
- Sunrise Wholesale, 2010
- Harvard Drug Group, 2011
- KeySource Medical, 2012
- Cardinal Health, 2012
- Medical Arts, 2012
- Walgreens, 2013
- McKesson, 2015
- Masters Pharmaceutical, pending
- Miami-Luken, pending

*Sources: DEA records and news releases, court documents, SEC filings and news reports.*
nearly half for controlled substances. Smith considered anything over 20 percent to be a red flag.

Gulf Coast owner Jeffrey R. Green and manager Karen S. Hebble sometimes waited after hours to sell narcotics, even without a pharmacist present, court records show.

Drug dealers said they brought groups of fake patients — known in the trade as “spuds” or “skidoodies” — to Gulf Coast to fill bogus prescriptions obtained from cooperating prescribers, court records state. They always paid cash.

One drug dealer would call ahead to make sure Gulf Coast had enough pills for his fake customers. Cardinal only stopped shipments to Gulf Coast in October 2011, shortly before the DEA demanded information from the distributor. The next month, Gulf Coast surrendered its license.

Green and Hebble were ultimately convicted in federal court of conspiracy and money-laundering charges.

Cardinal contended that volume of drug sales alone is not an accurate measure of lack of compliance. The company noted that Gulf Coast served a hospital complex and hundreds of physicians.

In 2012, Cardinal settled the administrative case, but no fine has been levied. Negotiations are ongoing, according to a federal prosecutor and the company.

In a statement to The Post, Brett Ludwig, Cardinal’s vice president of public relations, said the company deploys “advanced analytics, technology, and teams of anti-diversion specialists and investigators who are embedded in our supply chain. This ensures that we are as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity.”

At Walgreens, an employee at one of the 13 warehouses the drugstore chain operated in the United States grew suspicious of the large orders being sent to some of its pharmacies, court records show.

Kristine Atwell, who managed distribution of controlled substances for the company’s warehouse in Jupiter, Fla., sent an email on Jan. 10, 2011, to corporate headquarters urging that some of the stores be required to justify their large quantity of orders.

“I ran a query to see how many bottles we have sent to store #3836 and we have shipped them 3271 bottles between 12/1/10 and 1/10/11,” Atwell wrote. [A bottle sent by a wholesaler generally contains 100 doses.] “I don’t know how they can even house this many bottle[s] to be honest. How do we go about checking the validity of these orders?”

Walgreens never checked, the DEA said. Between April 2010 and February 2012, the Jupiter distribution center sent 13.7 million oxycodone doses to six Florida stores, records show — many times the norm, the DEA said.

In March 2011, the situation became so alarming at two Walgreens drugstores in
the small town of Oviedo, Fla., that Police Chief Jeffrey Chudnow wrote to the company’s top executives, Alan G. McNally, who was chairman; and Gregory D. Wasson, then the president and chief executive.

Chudnow asked that they prohibit Walgreens pharmacists from filling orders where the quantities of narcotics were split over two prescriptions.

“These types of prescriptions overtly denote misuse and possible street sales of these drugs,” Chudnow wrote. He said he never heard back from the executives.

In 2012, the DEA launched a six-month investigation of Walgreens’s Jupiter facility. The probe found that Walgreens failed to maintain an effective system for detecting suspicious orders or reporting them to the DEA.

Even when suspicious orders were identified, the warehouse often shipped the drugs anyway, without making inquiries, the DEA said in court papers. A company spokesman said Walgreens would have no comment on the case.

Walgreens settled with the DEA in 2013, agreeing to pay an $80 million fine — a record for a diversion case at the time. The company acknowledged that its “suspicious order reporting for distribution to certain pharmacies did not meet the standards identified by DEA.”

One case that was underway became entangled in that shift, according to interviews and records.

Beginning in 2011, the DEA had repeatedly warned Miami-Luken, an Ohio-based distributor, about suspicious sales of opioids, according to Jim Geldhof, then the agency’s program manager in Detroit.

“We went to management of the company and told them they have to look at their sales. They are pretty extraordinary,” said Geldhof, who retired in January after more than four decades with the agency. “We spoke to them on multiple occasions, and we were pretty much ignored.”

Yet investigators couldn’t persuade lawyers at DEA headquarters to allow them to take action.

Geldhof said orders to show cause that he requested in 2013 were not issued until November 2015.

“It sat there for two years. I don’t know why there was a delay,” Geldhof said. “We went back and forth. The ball was always moving. We had all of this going on, overdose deaths, what part of this are we not getting them to understand. We said, ‘You tell us what you want and we’ll give it to you.’ ”

Inside Miami-Luken headquarters, employees had also seen troubling signs. Two of them sent word up the chain. A pharmaceutical buyer and a customer-service representative were concerned about large oxycodone orders by a southern Ohio pain clinic.

The warnings reached senior com-
pany officials, including then-chief executive Anthony Rattini. But little changed.

Cindy Willet, the senior pharmaceutical buyer, told investigators in 2015 that she eventually “stopped talking to [Rattini] about her concerns because he wasn’t doing anything about it. It was as if it was falling on deaf ears. Tony never stopped an order.”

The pain clinic, Unique Pain Management, was based in Wheelersburg, Ohio, a town of 6,500 at the epicenter of the opioid epidemic. The clinic was run by a father-daughter team of physicians, John and Margy Temponeras. Between December 2009 and June 2010, the clinic’s monthly orders of oxycodone rose from 67,800 doses to 104,400. Miami-Luken did not investigate the surge, according to the DEA.

Despite signs that something was amiss, “Miami-Luken not only continued to ship Dr. [Margy] Temponeras oxycodone, but also shipped increased amounts,” the DEA alleged.

But Margy Temponeras ordered so much OxyContin from Miami-Luken that in August 2010 she drew the attention of Purdue Pharma, the drug’s manufacturer. Purdue cut Miami-Luken’s OxyContin supply by 20 percent, prompting Miami-Luken to halt drug shipments to Temponeras, records show.

Last year, a federal grand jury indicted the Temponerases and a pharmacist on charges that they conspired to illegally sell medication, alleging that at least eight people had died of overdoses connected to the drugs.

Three of those people died while the clinic was receiving drugs from Miami-Luken between November 2008 and August 2010, according to the indictment and DEA records. It is unclear whether Margy Temponeras also purchased drugs from other distributors, or whether any of those who died consumed drugs distributed by Miami-Luken.

The Temponerases are scheduled to stand trial early next year. Their attorneys declined to comment. An attorney for the pharmacist, Raymond Fankell, who is also scheduled to stand trial next year, said Fankell’s involvement was limited to helping Margy Temponeras set up the dispensary in her office and to filling her prescriptions at his drugstore.

During one of their interviews with Rattini, DEA investigators asked how the company documented suspicious orders. Rattini pointed to his compliance officer, who put a finger to his head. “It’s all just up here,” he said.

The agency is now attempting to revoke Miami-Luken’s license. The company has asked for a hearing before a DEA administrative law judge and is battling the DEA in federal court over a subpoena for agency records.

Miami-Luken is one of two distributors identified by The Post whose cases are pending in civil court. Eleven other companies have agreed to settlements, taken corrective steps or given up their licenses to distribute controlled substances, records
show.

“We’re taking this to a hearing because we strongly dispute the government’s characterizations,” said Richard H. Blake, an attorney for Miami-Luken.

The company said in court filings that it has purchased software to better identify suspicious orders and added staff to its compliance efforts. Its chairman, Joseph Mastandrea, intends to testify that he removed Rattini from his role supervising compliance “as DEA’s inquiries increased” and that he “realized that Mr. Rattini was not fulfilling the company’s DEA compliance obligations,” according to court filings.

Rattini did not return calls seeking comment. The chairman “will accept responsibility for the company’s past failings,” the court documents state.

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Alice Crites contributed to this report.
Wholesalers distributed pills that fueled opioid epidemic

WASHINGTON — Federal health officials charge that some wholesale drug distributors and pharmacies failed to properly report suspicious orders involving hydrocodone during 2013 and 2014, even though the companies were warned by the Drug Enforcement Administration to do so.

The DEA said it has launched a series of enforcement actions against wholesalers and pharmacies that failed to follow the rules and has brought civil cases against the firms. At the peak of the crisis, the DEA estimated that it was overseeing enforcement actions against wholesalers that handled 70% of the nation’s hydrocodone.

The DEA declined to disclose the names of the wholesalers or pharmacies involved, saying it has to maintain ongoing investigations. But the names of Key cosmetics, such as Purdue Pharma LP, have been released in court records related to the lawsuits.

Purdue, the maker of OxyContin, was involved in a lawsuit settlement in 2007 that requires it to spend millions of dollars to fund a program aimed at preventing abuse of opioid pain relievers and other drugs. In a recent court filing, the DEA said it was “actively investigating” Purdue for its compliance with the 2007 settlement.

In July, the Justice Department released a federal grand jury indictment against the company’s former chief executive officer, Raymond S. LaHue, 67, and other executives, including Paul R. McNamara, 71, the company’s senior vice president of policy and government affairs.

The DEA said it was investigating whether the drug company had submitted false statements to the DEA about how it was distributing opioids.

But the problem is clearly on-going, and the DEA said that it is investigating other companies.

The DEA said that it is investigating five companies for distributing opioids, including Purdue Pharma, Cardinal Health and Cardinal Health and Bellco Drug.

Purdue, which makes the opioid pain reliever OxyContin, has faced multiple investigations related to its marketing practices and has agreed to pay $8 billion to settle claims that it artificially inflated the demand for its products.

The DEA said that it is investigating whether Purdue and other companies have violated the Controlled Substances Act, which is the federal law that governs the manufacture, distribution and dispensing of opioids.

The DEA said that it is also investigating whether the companies have failed to comply with state laws that require them to report suspicious orders.

Despite the ongoing investigations, Purdue, one of the nation’s largest drug distributors, has not been named in any criminal charges.

The DEA said that it is investigating whether Purdue and other companies have failed to comply with state laws that require them to report suspicious orders.

The DEA has stated that it is “actively investigating” Purdue for its compliance with the 2007 settlement.

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Senators ask Lynch for DEA data on opioid cases

by Scott Higham and Lenny Bernstein

Two senators asked Attorney General Loretta E. Lynch Wednesday to explain a sharp drop in the number of enforcement actions against large pharmaceutical distributors and others by the Drug Enforcement Administration.

Sen. Patrick J. Leahy (D-Vt.) and Sen. Ron Wyden (D-Ore.) requested a wide variety of information about cases brought by DEA’s Diversion Control Division in the wake of a Washington Post investigation published over the weekend.

The DEA division enforces laws written to prevent the diversion of opioid painkillers to the black market, where they can fall into the hands of substance abusers and drug dealers.

The senators’ four-page letter asks Lynch to explain why the office has filed few administrative charges in recent years, whether a law approved by Congress earlier this year has hamstrung the diversion division and what standard the DEA uses before deciding to take an enforcement action.

The senators also asked for more information about a 2015 settlement with pharmaceutical giant McKesson that has remained largely confidential, aside from the company’s disclosure in federal filings that it would pay a $150 million fine for its actions. And the lawmakers asked why no fine has been levied against Cardinal Health, another major distributor, despite a settlement in a diversion case against the company in 2012. The senators singled out a drop in cases from 131 in 2011 to 40 in 2014.

“This startling decrease in enforcement activity occurred just as our nation began to confront the scope of the opioid
epidemic — and just as the over-prescription of powerful opioid painkillers was recognized as a major driver of the crisis,” Leahy and Wyden wrote.

About 165,000 people have died of painkiller overdoses between 2000 and 2014.

Leahy is the ranking Democrat of the Senate Judiciary Committee, which oversees criminal justice and drug enforcement policy. Wyden is the ranking Democrat of the Senate Finance Committee.

Justice Department spokesman Peter Carr said, “We will review the letter.”

The Post reported Sunday that, beginning in 2013, DEA lawyers started to delay and block enforcement efforts against large opioid distributors and others, requiring investigators in the field to meet a much higher burden of proof before they could take action.

Five former DEA supervisors told The Post that they were alarmed and frustrated by the sharp drop in enforcement actions. The supervisors’ concerns were echoed in reports filed by the DEA’s chief administrative law judge that were obtained by The Post under the Freedom of Information Act.

[How hundreds of millions of painkillers ended up in the hands of illegal users]

Investigators said they unsuccessfully confronted Clifford Lee Reeves II, the attorney in charge of the DEA unit that approves administrative cases.

“It was like he was on their side, not ours,” said Jim Geldhof, the diversion program manager in the Detroit field office when Reeves took over in late 2012. “I don’t know what his motive was, but we had people dying.”

The former head of the diversion office, Joseph T. Rannazzisi, said he was summoned to an unusual meeting in 2012 with then-Deputy Attorney General James M. Cole. Rannazzisi said the meeting came during an investigation of Cardinal Health and CVS Health, and he said he was and chastised “for going after industry.” Cole told The Post he was trying to ensure that Rannazzisi was getting all of the facts from the companies. Rannazzisi was replaced in 2015 and retired from DEA later that year.

Acting DEA Administrator Chuck Rosenberg sent a message to staffers on Monday: “Are there things we need to fix? You bet. We can — and should — learn from fair and thoughtful criticism.”

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For next president, an ACA conundrum

Some health policy experts are trying to determine how to handle the Affordable Care Act next year, but as the election nears, it's unclear how the ACA will fare. The law's fate is uncertain, with both candidates expressing opposing views on the act.

Senators ask Lynch for DEA data on opioid cases

Senator Ron Wyden (D-Ore.) and Senator Patrick J. Leahy (D-Vt.) have asked Acting DEA Administrator Joseph T. Rannazzisi to explain why the DEA has not taken more enforcement action on opioid distributors and others, despite the DEA's publications over the weekend.

Research debunks myth of HIV's 'Patient Zero'

A study published in the New England Journal of Medicine found that the origin of HIV is more complex than previously thought, challenging the myth of a single 'Patient Zero.' The study suggests that HIV spread worldwide, with multiple origins and routes of transmission.

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More senators ask about DEA’s slow opioid action

BY LENNY BERNSTEIN
AND SCOTT HIGHAM

Seven more senators demanded information Friday about a steep decline in enforcement actions by the Drug Enforcement Administration against large wholesale companies that distribute opioid painkillers.

Six Democrats and one independent expressed “serious concern” that “over the last few years, the [DEA] has scaled back its enforcement efforts” against distributors who violate laws designed to prevent painkillers from falling into the hands of illicit drug users.

In a four-page letter to Attorney General Loretta E. Lynch and the DEA’s acting administrator, Chuck Rosenberg, the senators cited the findings of a Washington Post investigation published last weekend.

“The allegations in the Washington Post article are especially troubling given the opioid-abuse epidemic that is claiming nearly 30,000 lives in the United States annually,” they wrote.

The letter was signed by Democratic Sens. Edward J. Markey (Mass.), Richard J. Durbin (Ill.), Joe Manchin III (W.Va.), Amy Klobuchar (Minn.), Tammy Baldwin (Wis.), Richard Blumenthal (Conn.) and independent Bernie Sanders (Vt.). On Wednesday, Sens. Patrick J. Leahy (D-Vt.) and Ron Wyden (D-Ore.) sent a similar request to Lynch.

A Justice Department spokesman said the department would review the letter. The DEA did not immediately respond to an email requesting comment.

The Post reported Sunday that beginning in 2013, DEA lawyers started to delay...
and block enforcement efforts against large opioid distributors and others, requiring investigators in the field to meet a much higher burden of proof before they could take action.

About 165,000 people died of overdoses caused by prescription narcotics between 2000 and 2014, and tens of thousands more succumbed to overdoses of heroin and fentanyl, according to the Centers for Disease Control and Prevention.

Five former supervisors from the DEA’s Diversion Control Division told The Post that they were frustrated by the sharp drop in enforcement actions. The supervisors’ concerns were echoed in reports filed by the DEA’s chief administrative law judge.

Investigators said they unsuccess-

fully confronted Clifford Lee Reeves II, the attorney in charge of the DEA unit that approves administrative cases against people and companies suspected of diverting painkillers to the black market.

On Friday, the senators asked whether actions against painkiller distributors and others had indeed dropped from 131 in 2011 to 40 in 2014 — the Justice Department figures cited by The Post — and if so, why. They requested an explanation for the higher standard imposed on investigators in the field and sought information about whether companies had turned to then-Deputy Attorney General James M. Cole for relief from DEA efforts.

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The risk of developing SSPE was rising panencephalitis, or infected with measles and later registered at 12 to 15 months of age. Mostly because of the growing against measles. Vaccinating everyone possible virus to reactivate, and there is logical disorder that can lie dormant measles, mumps and rubella. The vaccine known as MMR, for measles, mumps and rubella.

Dr. Amy C. Cherry, a study author and specialist in pediatrics and infectious diseases at UCLA's medical school, said his attorney, Monica Foster. The new sentence that Whitley added to the law named for him, called "Paul's Law," which allows alternative medicine organizations, under the annual meeting of measles that kills children.

The European <nowiki>Commission</nowiki> of professional infectious-disease organizations, under a preliminary injunction, ruling everyone gets vaccinated. "Unfortunately, they're mistaken. We trebled the number of people who have not been previously inoculated are still protected, Cherry said. Another surprising finding is the number of children who have been vaccinated, and infectious diseases at UCLA's medical school.

"This is really frightening, and we could see that everyone gets vaccinated."

"The allegations in the Washington Post story are false," said James Ramos, the attorney for the family. "We trebled the number of people who have not been previously inoculated are still protected, Cherry said. Another surprising finding is the number of children who have been vaccinated, and infectious diseases at UCLA's medical school."
The Washington Post

FRIDAY, DECEMBER 23, 2016

UNNATURAL CAUSES

Do drug firms hobble DEA by hiring its experts?

This article was written by Scott Higham and reported by Lenny Bernstein, Steven Rich and Alice Crites

Pharmaceutical companies that manufacture or distribute highly addictive pain pills have hired dozens of officials from the top levels of the Drug Enforcement Administration during the past decade, according to a Washington Post investigation.

The hires came after the DEA launched an aggressive campaign to curb a rising opioid epidemic that has resulted in thousands of overdose deaths each year. In 2005, the DEA began to crack down on companies that were distributing inordinate numbers of pills such as oxycodone to pain-management clinics and pharmacies around the country.

Since then, the pharmaceutical companies and law firms that represent them have hired at least 42 officials from the DEA — 31 of them directly from the division responsible for regulating the industry, according to work histories compiled by The Post and interviews with current and former agency officials.

The number of hires has prompted some current and former government officials to ask whether the companies raided the division to hire away DEA officials who were architects of the agency’s enforcement campaign or were most responsible for enforcing the laws the firms were accused of violating.

“The number of employees recruited from that division points to a deliberate strategy by the pharmaceutical industry to hire people who are the biggest headaches for them,” said John Carnevale, who was director of planning for the White House’s Office of National Drug Control Policy and now runs a consulting firm. “These people understand how DEA operates, the culture around diversion and DEAs goals, and they can advise their clients how to stay within the guidelines.”

The DEA’s Diversion Control Division, tasked with preventing prescription drugs from reaching the black market, yields enormous power within the phar-
Drugmakers’ DEA hires raise questions

maceutical world. The small division, with about 300 employees at its Arlington, Va., headquarters, can suspend or revoke the licenses of doctors, pharmacies and pharmaceutical companies that fail to comply with federal law.

From 2000 to 2015, nearly 180,000 people died of overdoses from prescription painkillers in what public health authorities have called an epidemic. States including Massachusetts, and most recently Virginia, have declared public health emergencies as the number of deaths has escalated.

It is not unusual for corporations to hire federal employees directly away from the government. Their expertise and inside knowledge can be invaluable, but there are laws and regulations to slow the “revolving door” in Washington and prevent potential conflicts of interest.

The restrictions include a lifetime ban on participating “personally and substantially” on a “particular matter” that the official had handled while working for the federal government. There also is a two-year ban on switching sides on a wider array of matters that were in the employee’s official purview. State bar associations impose additional post-employment restrictions for government lawyers.

An industry spokesman said former DEA diversion officials are hired for their expertise.

“Our industry is highly specialized, and the function of drug diversion experts even more so,” said John M. Gray, president and chief executive of the Healthcare Distribution Alliance, which represents drug distributors. “As such, for these individuals who want to continue to grow in their areas of expertise, it is logical for them to pursue government and industry roles that are closely aligned with their professional experience.”

While The Post did not find evidence that the officials violated conflict-of-interest regulations, the number of hires from one key division shows how an industry can potentially blunt a government agency’s aggressive attempts at enforcement.

The DEA diversion officials who have gone to the industry since 2005 include two executive assistants who managed day-to-day operations; the deputy director of the division; the deputy chief of operations; two chiefs of policy; a deputy chief of policy; the chief of investigations; and two associate chief counsels in charge of legal affairs and enforcement actions against pharmaceutical companies.

“It’s obvious that they targeted the office,” said Joseph T. Rannazzisi, who ran the diversion division for a decade before he was removed from his position and retired in 2015. “If you want to understand how we were doing our investigations, the best way to do it is to take our people who are doing the investigations and put them
ABOVE: Drug giant McKesson's headquarters in San Francisco. RIGHT: A Drug Enforcement Administration officer at a Little Rock clinic in May 2015, when a multistate crackdown on prescription drug abuse in the South was underway, with raids at pain clinics, pharmacies and other locations.
in place in your company. It’s not difficult to understand why you would take these guys. They know the law.”

Most of the DEA officials went to work for the pharmaceutical industry and law firms within weeks of leaving the agency. Among the 31 DEA diversion employees, 22 began their new jobs within weeks of leaving the DEA, according to work histories the officials posted on LinkedIn, as well as news releases and biographies published by the companies and law firms that hired them.

The Post found that several high-ranking DEA supervisors from outside the diversion division also took top jobs with industry: four special agents in charge and three assistant special agents in charge of field operations in some of the nation’s largest cities, including New York, Washington and Atlanta.

In responses to questions from The Post, the DEA said in a statement that former employees must follow the law and ethics regulations in taking jobs in the private sector.

“Many who serve in government possess expert knowledge in a wide variety of fields. It is not uncommon for former government officials to use or rely on such expertise when they transfer to the private sector following their public sector service,” DEA spokesman Rusty Payne said in the statement. “Employees who leave DEA and other government agencies for private sector work are expected to abide by the applicable laws and ethics rules that govern their private sector activities.”

At least five of the 31 DEA employees were hired by McKesson — the nation’s largest drug distributor and fifth-largest corporation. McKesson has been the subject of two publicly disclosed DEA enforcement actions, which resulted in $163 million in fines after allegations that the firm failed to report hundreds of suspicious orders for millions of pain pills from Internet pharmacies and others.

“McKesson has put significant resources towards building a best-in-class controlled substance monitoring program to help identify suspicious orders and prevent prescription drug diversion in the supply chain,” the company said in a statement. “It is only natural that this team is comprised of a broad range of experts, including individuals who have spent time at DEA, as they bring deep knowledge of effective strategies to prevent diversion. Our team is deeply passionate about curbing the opioid epidemic in our country.”

The Post contacted a dozen former DEA officials who went to work for the drug industry, but few agreed to be interviewed. Those who did said they followed federal ethics guidelines designed to prevent potential conflicts of interest for officials who switch from government to the industries they once regulated.

“I don’t feel like I took off the white hat and put the black hat on,” said Larry P. Cote, who left as the associate chief counsel for the DEA’s diversion division in May.
2012 to become a partner at the law firm Quarles & Brady. “That’s really not what’s going on. It’s trying to get the best people in place to make sure that companies are staying compliant. And frankly, that benefits the DEA as much as it benefits the companies.”

At Quarles & Brady, Cote serves as co-director of the firm’s DEA Compliance and Litigation Practice Group and provides legal advice to some of the nation’s largest pharmaceutical companies.

Cote said he obtained an ethics opinion from the DEA that advised him on which cases he could and could not handle in the private sector.

Ethics experts said revolving-door issues have been a long-standing concern across the government, with some of the most notable cases coming from the Defense Department. President-elect Donald Trump recently criticized the revolving door at the Pentagon, saying high-ranking officials “should never be allowed to go work” for companies in the defense industry.

The ethics experts said the number of officials switching sides at the DEA raises serious questions about whether the ability of the diversion division to carry out its mission has been compromised by the pharmaceutical industry.

“The findings that so many DEA officials have switched from their roles preventing, detecting and investigating illegal drug use to working for those involved in the supply chain is disturbing,” said Scott H. Amey, general counsel for the Project on Government Oversight, a watchdog group in Washington. “It’s also another reminder of how well the revolving door is greased and how the revolving door can negatively impact government operations. It’s not a surprise that DEA isn’t as vigilant as it once was when so many ex-feds are working for the companies that they once investigated.”

In 2004, DEA officials became alarmed by the increasing number of overdose deaths. The following year, the agency’s diversion division launched an initiative designed to hold distributors of narcotics accountable for the hundreds of millions of pills that were being diverted to the black market.

The DEA pursued cases against some of the largest opioid distributors in the country, including McKesson, Cardinal Health and AmerisourceBergen, as well as CVS and Walgreens, which distribute opioids to their own pharmacies. In general, the companies did not admit wrongdoing and said they were taking steps to address illegal diversion.

In 2008, McKesson settled one of those cases, paying a $13 million fine without admitting liability. That same the year, the DEA filed a case against Cardinal. That company also settled, paying a $34 million fine. Cardinal promised to improve monitoring of its drug shipments.

The DEA’s initiative was sharply curtailed in the face of pressure from the pharmaceutical industry beginning in 2013,
according to a Post investigation published in October. In fiscal 2011, civil case filings against distributors, manufacturers, pharmacies and doctors had reached 131. By 2014, they had fallen to 40.

The slowdown came after DEA lawyers began to require a higher standard of proof before cases could move forward. Supervisors in the field said they were frustrated that their cases were being stalled at DEA headquarters. Top DEA and Justice Department officials have declined to discuss the reasons behind the slowdown.

Government ethics experts said regulators often join the industries they oversee, lured by substantially higher salaries.

“That high rate of turnover makes you really wonder whether those officials were acting in the interests of the DEA rather than the companies they were regulating,” said Craig Holman, an expert on revolving-door issues for Public Citizen, a government watchdog group in Washington. “Just by seeing your colleagues going that way, that tells you that you can shape your future employment prospects if you behave accordingly.”

Once senior employees leave for jobs in the industry, they are in positions to help pharmaceutical companies comply with the complex laws and regulations that govern controlled substances. But ethics experts said they also can exploit weaknesses they are aware of within the DEA.

One of the key players in the DEA’s diversion initiative went to work for a law firm that represents the companies he used to regulate.

D. Linden Barber, who served as associate chief counsel from 2006 to 2010, guided cases against some of the largest pharmaceutical companies in the country.

In 2008, Barber’s office filed its first diversion case against Cardinal, accusing it of failing to properly monitor shipments of painkillers. Barber conducted extensive meetings with DEA attorneys assigned to the case and was deeply involved in crafting a “memorandum of agreement” to settle the allegations against Cardinal, according to a DEA document. The case resulted in the $34 million settlement with Cardinal.

In September 2011, Barber, who had been serving as the DEA’s regional diversion counsel in the Midwest, left for the law firm Quarles & Brady. His colleague, Larry Cote, had taken over as associate chief counsel at DEA headquarters.

The next month, the DEA served warrants seeking records from Cardinal as part of a second case against the company.

Quarles & Brady’s clients include Cardinal.

Seven months later, in May 2012, Cote, who helped to coordinate the second Cardinal case while at the DEA, joined Barber at Quarles & Brady, becoming co-director of compliance and litigation. Cote had appeared in court on behalf of the DEA in the case against Cardinal three months earlier, records show.

Barber said he sought advice from Roberto D. DiBella, the DEA’s ethics lawyer, before and after leaving the agency.
Barber declined to say whether he asked DiBella for advice about representing Cardinal, but he said his representation of his clients complied with ethics laws.

“The rules governing my work as an attorney make it inappropriate for me to discuss work I did for DEA and any other clients,” he said in a statement to The Post. “However, the records of DEA will show that I followed the rules. I never worked on a matter for DEA and then worked on the same matter for the other party. I am proud of the work I did for DEA and of the work I do in private practice for clients who want to work with DEA to stop the abuse of prescription drugs.”

The DEA provided The Post with a copy of DiBella’s ethics opinion. It shows that Barber asked for guidance on his representation of Cardinal. DiBella told him that he was banned for life from representing Cardinal on any issues connected to the 2008 memorandum of agreement (MOA).

“Your representation of Cardinal to address an alleged violation of the MOA would on its face appear that you switched sides on a matter that you participated in as a DEA employee,” DiBella wrote.

DiBella did not respond to interview requests. The DEA said the ethics opinion was reviewed by DiBella’s supervisor to double-check the advice Barber was given.

Cote said he, too, asked DiBella for an ethics opinion before leaving the agency in 2012.

“I provided him with a fairly comprehensive list of the cases that I worked on,” he said in a recent interview.

The DEA provided a copy of the opinion to The Post. It noted that Cote had participated “personally and substantially” in specific matters relating to at least 10 companies while he was at the DEA. It said he was banned for life from communicating with or appearing before the DEA or any other federal agency on behalf of those companies on the specific matters he handled.

The companies include some of the largest drug distributors and retailers in the nation, including McKesson, AmerisourceBergen, CVS, Walgreens, Rite Aid and Walmart.

Cote said he has followed the opinion, which also singled out his work for the DEA on the Cardinal case.

“I did not and really have not represented Cardinal since I left DEA,” Cote said. “Our firm does do work for Cardinal, but I’ve been really walled off from it because some of these matters are still pending and I just didn’t want to go there.”

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