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Investigations

‘We feel like our system was hijacked’: DEA agents say a huge opioid case ended in a whimper

By Lenny Bernstein and Scott Higham
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After two years of painstaking investigation, David Schiller and the rest of the Drug Enforcement Administration team he supervised were ready to move on the biggest opioid distribution case in U.S. history.

The team, based out of the DEA’s Denver field division, had been examining the operations of the nation’s largest drug company, McKesson Corp. By 2014, investigators said they could show that the company had failed to report suspicious orders involving millions of highly addictive painkillers sent to drugstores from Sacramento, Calif., to Lakeland, Fla. Some of those went to corrupt pharmacies that supplied drug rings.

The investigators were ready to come down hard on the fifth-largest public corporation in America, according to a joint investigation by The Washington Post and “60 Minutes.”

The DEA team — nine field divisions working with 12 U.S. attorney’s offices across 11 states — wanted to revoke registrations to distribute controlled substances at some of McKesson’s 30 drug warehouses. Schiller and members of his team wanted to fine the company more than $1 billion. More than anything else, they wanted to bring the first-ever criminal case against a drug distribution company, maybe even walk an executive in handcuffs out of McKesson’s towering San Francisco headquarters to send a message to the rest of the industry.

“This is the best case we’ve ever had against a major distributor in the history of the Drug Enforcement Administration,” said Schiller, who recently retired as assistant special agent in charge of DEA’s Denver field division after a 30-year career with the agency. “I said, ‘How do we not go after the number one organization?’ ”

But it didn’t work out that way.

Instead, top attorneys at the DEA and the Justice Department struck a deal earlier this year with the corporation and its powerful lawyers, an agreement that was far more lenient than the field division wanted, according to interviews and internal government documents. Although the agents and investigators said they had plenty of evidence and wanted criminal charges, they were unable to convince the U.S. attorney in Denver that they had enough to bring a case.

Discussions about charges never became part of the negotiations between the government lawyers in Washington and the company.

“It was insulting,” Schiller said. “Morale has been broken because of it.”

The result illustrates the long-standing conflict between drug investigators, who have taken an aggressive approach to a prescription opioid epidemic that killed nearly 200,000 people between 2000 and 2016, and the government attorneys who handle those cases at the DEA and the Justice Department.

None of McKesson’s warehouses would lose their DEA registrations. The company, a second-time offender, had promised in 2008 to be more diligent about the diversion of its pills to the street. It ultimately agreed to temporarily suspend controlled substance shipments at four distribution centers and pay a $150 million fine.

“Within the ranks, we feel like our system was hijacked,” said Helen Kaupang, a DEA investigator and supervisor for 29 years who worked on the McKesson case in Denver before retiring in September.

While the fine set a record for drug distributors, it is only about $50 million more than the compensation last year for McKesson board chairman and chief executive John H. Hammergren, the nation’s third-highest-paid chief executive. McKesson has 76,000 employees and revenue of almost $200 billion a year, about the same as ExxonMobil.

The Justice Department declined repeated requests for comment.

“The McKesson settlement was a groundbreaking conclusion to a successful multi-district investigation into the role of a distributor’s failure to detect and report suspicious orders, many of which were tied to independent and small chain pharmacy customers ordering opioid medications,” the DEA said in a statement. “More importantly, McKesson accepted responsibility and accepted terms beyond the requirements of the [Controlled Substances Act].”

A senior agency official, who spoke on the condition of anonymity, said the fine was a significant penalty, the company agreed to an independent monitor, and the case prompted McKesson and other distributors to be more diligent about reporting suspicious orders.

“We could have fined them out of existence, or indicted the company and put them out of business,” the official said. “I’d rather have one of the largest drug distributors be the poster child for detection and reporting of suspicious orders.”

At the time of the settlement, McKesson said it had instituted “significant changes” to its program designed to flag suspicious orders of narcotics. “We continue to significantly enhance the procedures and safeguards across our distribution network to help curtail prescription drug diversion while ensuring patient access to needed medications,” Hammergren said in a statement.

The company also has said that addressing the opioid problem requires the cooperation of everyone involved — doctors, pharmacists, distributors and manufacturers.

In a recent interview, Geoffrey E. Hobart, McKesson's lead attorney, said that the prospect of criminal charges or a $1 billion fine against the company were never raised by government lawyers during nearly three years of negotiations.

"While I am not privy to any of the government team discussions that may have taken place behind closed doors in this particular settlement, I can tell you that the DEA investigators, the U.S. attorney's offices and others would have had plenty of opportunity to raise their views during the process," said Hobart, a former federal prosecutor who is now a partner at Covington, one of the most influential law firms in Washington. "While individual DEA investigators and agents are entitled to their opinions, their agency may ultimately take a different view."

"If the lawyers for the government believed there was criminal conduct here, they would have told me about it," Hobart added. "That would have increased the leverage they had, and that never happened."

DEA investigators, agents and supervisors who worked on the McKesson case said the company paid little or no attention to the unusually large and frequent orders placed by pharmacies, some of them knowingly supplying drug rings.

Instead, the DEA officials said, the company raised its own self-imposed limits, known as thresholds, on orders from pharmacies and continued to ship increasing amounts of drugs in the face of numerous red flags.

"They had multiple chances to correct their behavior going back to the Internet pharmacy days. They promised everyone they were going to correct their behavior, and a year or two later, they were doing it again," said Jim Geldhof, a DEA program manager who worked on the McKesson case in Detroit before retiring in 2015 after a 43-year career. He is now advising law firms suing opioid manufacturers and distributors, including McKesson.

The DEA agents and investigators contend that lawyers stationed at the chief counsel's office in the agency's Division of Diversion Control were "intimidated" and retreated from the battle with McKesson and its legal team, which included a former top DEA official from that division.

Schiller said DEA lawyers would repeatedly ask: "Why would you go after a Fortune 50 company that's going to cause all these problems with Ivy League attorneys, when we can go after other [DEA registration holders] that are much lower, that are going to put up no fight?

"And I said, 'That's exactly why you want to go after McKesson. They're the prize. They're the ones that are going to send a message to the thousands of mom-and-pops, to other big distributors, to the manufacturers, that this is no longer acceptable.' "

'The pills kept coming'

In 2008, McKesson paid a $13.25 million fine for failing to report hundreds of suspicious hydrocodone orders from Internet pharmacies — even after being warned by the DEA three years earlier that it was shipping excessive amounts of the drug commonly called Vicodin. The online pharmacies took orders from customers who had obtained bogus prescriptions, resulting in criminal prosecutions.

"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," then-DEA Administrator Michele M. Leonhart said in a statement announcing the settlement.

As part of its agreement with the Justice Department, McKesson pledged to temporarily suspend distribution of narcotics from two of its 30 distribution centers and to improve its system for monitoring and reporting suspicious drug orders.

McKesson caught the attention of the DEA again in 2012, when state and local law enforcement began to investigate Platte Valley Pharmacy in Brighton, Colo., a suburb 25 miles northeast of Denver on the banks of the Platte River. The population was 38,000.

Pharmacist Jeffrey Clawson was selling as many as 2,000 pain pills per day.

With state and local law enforcement, the DEA's Denver field division began a criminal investigation into Clawson, making undercover buys and monitoring the size of his drug purchases.

Most of the drugs came from McKesson's warehouse in Aurora, northeast of Denver, records show. Under federal law, McKesson is required to notify the DEA about any orders of unusual size, frequency or pattern and hold off on shipping the drugs until those issues are resolved.

But McKesson filled 1.6 million orders from the Aurora warehouse and reported only 16 as suspicious between June 2008 and May 2013. None of the 16 involved Platte Valley, and the company reported them only after the DEA began its investigation.

"We would have a pharmacy in a small town out in Colorado, 200 miles from Denver, that is getting the same number of pills or perhaps exceeding a pharmacy that is located next to a medical center in the city of Denver," said Kaupang, the DEA investigator who worked on the Colorado case. "There was no legitimate reason for that pharmacy in that little town in remote Colorado to be getting hundreds of thousands of pills over a several-year period. None. There was no justifiable reason.

"And yet, the pills kept coming."

Clawson ordered so much oxycodone that he repeatedly bumped up against thresholds McKesson had set for his pharmacy. The company raised those limits and sent him more, DEA agents and investigators said.

“The company would raise thresholds so pharmacies could order more pills without setting off suspicious monitoring alarms inside the company,” Kaupang said. “Did they think we wouldn’t look at them again? I don’t know. But they almost acted that way.”

Hobart, McKesson’s lawyer, denied that the company raised thresholds to avoid scrutiny.

Schiller and his DEA colleagues in Denver believed they had enough information, at a minimum, to bring an administrative complaint against McKesson that could result in stiff fines and the revocation of the Aurora distribution center’s registration to handle controlled substances.

In December 2012, the DEA asked attorneys at headquarters to issue an “immediate suspension order” against McKesson, an enforcement tool reserved for the most serious threats to public health and safety, Schiller and Kaupang said.

But the immediate suspension order was never approved. Schiller said lawyers at DEA headquarters told him he needed more evidence that the drugs from the warehouse were posing an immediate danger to public health and safety.

“They said, ‘You don’t have enough evidence to prove it’s an immediate danger,’ but they created the lack of immediacy because they delayed the case for nearly a year,” Schiller said. “They were just looking for an excuse not to issue the order.”

The senior DEA official contended that the Denver field division did not submit documents supporting the request for the immediate suspension order until February 2013. Agency lawyers in headquarters did not believe the company’s threat to the public could be considered “immediate” because too much time had passed, the official said.

The investigators tried again in March 2014, this time seeking an “order to show cause” that would bring McKesson to a hearing, where the DEA could argue for the need to halt drug shipments from Aurora before an administrative law judge.

But DEA attorneys declined to approve that request, as well. Schiller said he was told that he still needed more evidence — even after he said the team submitted eight boxes of documents to the attorneys.

“It still wasn’t enough,” Schiller said.

The senior DEA official said that settlement negotiations with McKesson had begun and the show-cause order would have interfered with the talks.

At the same time the administrative case against McKesson was languishing, the criminal case against Clawson was moving ahead.

A Colorado grand jury had indicted him in 2013 along with 14 others on drug trafficking charges. The indictment noted that McKesson was the main supplier of Platte Valley Pharmacy and said that the company had an obligation to report suspicious orders of narcotics to the DEA.

“From 2008-2011, the percentage increase for oxycodone 30 mg orders supplied by McKesson to Platte Valley Pharmacy was approximately 1,469%,” the grand jury wrote.

Clawson was convicted on drug trafficking charges and is serving a 15-year sentence. McKesson was not charged in the indictment.

‘The gloves came off’

As Schiller’s team was examining the Aurora warehouse, he took steps to broaden the investigation beyond Colorado to determine whether McKesson was ignoring the agreement it had reached with the Justice Department in 2008 to tighten its procedures. Schiller and the Denver DEA division took the lead as eight divisions in other parts of the country began to collect information on McKesson’s activity.

In all, the DEA would pursue administrative cases involving 12 McKesson distribution centers. A DEA memo outlined the investigative findings:

- “Supplied controlled substances in support of criminal diversion activities.”
- “Ignored blatant diversion.”
- “Pattern of raising thresholds arbitrarily.”
- “Failed to review orders for suspicious activity.”
- “Ignored own procedures designed to prevent diversion.”

In addition to Aurora, investigators found that McKesson warehouses in Livonia, Mich., and Washington Court House, Ohio, were supplying pharmacies that sold to criminal drug rings, according to internal government documents obtained by The Post and “60 Minutes.”

As they were working on the administrative cases, Schiller and Joseph T. Rannazzisi, who led the DEA’s diversion office during part of the McKesson case, said investigators also were compiling information in preparation for a potential criminal case against the corporation for knowingly supplying the corrupt pharmacies.

In the summer of 2015, “on two occasions, I was briefed by my staff, and talked to the Denver field division, and they believed they had more than enough to go after the corporation criminally,” said Rannazzisi, who now works as a consultant to lawyers suing drug companies.

John F. Walsh, then the U.S. attorney in Denver, said he had discussions with Schiller and others about possible criminal charges against McKesson.

“We were not presented with a case that had adequate evidence,” said Walsh, now a partner at WilmerHale, a global law firm.

Schiller said that his team had amassed “more than enough” evidence and presented it to Walsh.

“I said, ‘We have everything we could possibly want on a silver platter,’ ” Schiller said. “We had corrupt pharmacies that were being supplied by McKesson, and they were turning a blind eye to everything that was going on.”

In a recent response to The Post, a McKesson spokeswoman said, “We categorically deny any criminal intent or the violation of any criminal law in our handling of opioids, and in our discussions with the government, they never suggested otherwise.”

In October 2014, Schiller requested a meeting at DEA headquarters in Arlington, Va. On one side of the table were DEA Chief Counsel Wendy Goggin and Clifford Lee Reeves II, the associate chief counsel. On the other side sat Schiller and his agents and investigators.

The meeting started off on a cordial note as they began to review the facts of the case.

“And then the gloves came off,” Schiller said. “It was one of the most stressful conversations I’ve ever had in my life.”

Reeves declined to comment, and the DEA declined to make Goggin available for an interview.

“They were attacking the things we did, how we did it,” Schiller recalled. “Not one time did they say, ‘All right, here’s what else we need. It’s been a great case. We know about the previous settlement.’ That never came up. It was, ‘We are going to settle.’ ”

‘I have a bad feeling’

With a settlement looming, representatives of the nine DEA division offices descended on the agency’s headquarters a month later, in November 2014, to make sure that their attorneys knew they wanted take a hard line against McKesson.

“It is clear that [McKesson] does not appreciate the gravity or extent of their violations,” the group wrote in an internal document obtained by The Post and “60 Minutes.”

They demanded four-year “surrenders” of McKesson’s DEA registrations to distribute controlled substances in Washington Court House, Livonia and Aurora, as well as two-year surrenders in Methuen, Mass., and Lakeland, Fla.

The company balked. McKesson’s lawyer, Hobart, called the proposed surrenders a “dealbreaker,” according to an internal Justice Department memo.

McKesson insisted that its registrations be “suspended” rather than “surrendered,” the memo said. A surrender would cost the company accreditations it needed for state regulatory boards, and McKesson would have to reapply for DEA registrations when the penalties expired. That would trigger a new round of inspections of company operations.

A suspension would allow each warehouse to keep its registration.

McKesson wanted something else as part of a settlement: A provision that would allow the Livonia and Washington Court House distribution centers to continue to send drugs to facilities that serve the federal prison system, Veterans Affairs and the Indian Health Service. McKesson holds a $31 billion federal contract to supply VA centers and other sites.

But some DEA officials wanted to take a hard line with the company because it had already been sanctioned for its behavior in 2008, documents show.

“Notwithstanding, their bad acts continued and escalated to a level of egregiousness not seen before,” Imelda L. Paredes, a DEA official working on the case, wrote in a memo on March 30, 2015. “They were neither rehabilitated nor deterred by the 2008 [agreement].”

She also noted that McKesson received an exception for VA in 2008. She said that allowing McKesson to continue to distribute narcotics was “inconsistent with the public interest.”

“How then, can the Government say it is inconsistent with the public interest for McKesson to distribute to the general public; however, they are ‘good enough’ to serve veterans?”

McKesson and government officials argued that punishing the company would disrupt the flow of drugs and hurt veterans. But Paredes and other DEA officials said there would be no disruption if the contract was turned over to one of McKesson’s competitors, Cardinal Health or AmerisourceBergen.

“Find other distributors,” Paredes wrote.

The next day, Schiller wrote to Paredes, saying he had heard that the DEA and the Justice Department were on the verge of settling instead of taking the company to court.

“I have a bad feeling about this,” he wrote to her on March 31, 2015.

Paredes replied that she was being overruled by lawyers in the DEA’s legal office.

“I’m totally against settling, but how do we hold their feet to the fire if counsel refuses to litigate?” Paredes wrote. “Our attorneys have us over a barrel with their refusal to go to court.”

Paredes, who has left the DEA, declined to comment.

Schiller’s fears were justified. The same day that Schiller wrote to Paredes, Arthur G. Wyatt, chief of the Justice Department’s Narcotic and Dangerous Drug Section, recommended in an internal document that McKesson’s registrations should be suspended but not surrendered. It was a big win for the company. Wyatt said that the assistant U.S. attorneys working on the case believed that suspensions were “satisfactory” in light of the “overall scope of the settlement.”

In September 2015, McKesson and the government reached a tentative settlement. McKesson’s registrations would be suspended in Aurora for three years, in Washington Courthouse for two and in Livonia for two. The company would be barred from distributing for one year one type of narcotic, hydromorphone, from its Lakeland, Fla., warehouse.

There would be no criminal charges. No administrative case. No $1 billion fine.

The case took more than a year to come to a conclusion. In January, the Justice Department announced that it had finalized a deal with McKesson that included the $150 million fine and the four warehouse suspensions. The company also agreed to increase staffing and retain an independent monitor to assess its compliance.

Schiller said he and his team were left demoralized.

“It’s on the front lines of everybody’s dinner table conversation, kids, adults,” he said. “McKesson was at the forefront. But DEA wasn’t going to go after them? We were going to settle. How do you settle? How do you say it’s okay, just ‘Here, write this check this time and — and close this place for a little bit, sign this piece of paper.’ ”

In Washington, the House Energy and Commerce Committee has begun an investigation into how drug distributors, including McKesson, sent 780 million pills over six years into West Virginia — 433 doses for every man, woman and child in the state. Sen. Claire D. McCaskill (D-Mo.) has also launched an investigation into the role of drug distributors and manufacturers in the opioid epidemic.

Across the country, 41 state attorneys general have banded together to sue the opioid industry.

“One of the things we have to do is begin to hold the pharmaceutical companies accountable,” said Sen. Maggie Hassan (D-N.H.), whose state suffers from the second-highest drug overdose rate in the nation. “Right now, when you see a fine for the McKesson company for a hundred-fifty million when they make a hundred million a week in profits, that isn’t going do it.”

She noted that it was state attorneys general who had won a settlement against the tobacco industry for more than $200 billion in the 1990s.

“This in many ways reminds me of the situation with Big Tobacco,” Hassan said. “I think it’s one of the reasons you see attorneys general around the country beginning to file lawsuits against the pharmaceutical industry, to hold them accountable for the cost of this terrible epidemic.”

Alice Crites contributed to this report.

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