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## DOJ Flexes New Muscles In Opioid Fight

By **Emily Field**

Law360 (February 13, 2019, 4:37 PM EST) -- The U.S. Department of Justice opened a new front in its war against the opioid crisis when it temporarily shut down two pharmacies it says were linked to overdoses and deaths, signaling the agency may be willing to flex new muscles to stem the flow of pills into the market.

The agency last week **won a temporary restraining order** closing Xpress Pharmacy and Dale Hollow Pharmacy in Celina, Tennessee. That means pharmacy owners who let opioid prescriptions go unchecked now face the possibility the DOJ will temporarily shut them down at the beginning of a Controlled Substances Act case, instead of months into an administrative process for removing a pharmacy's registration with the U.S. Drug Enforcement Administration.

The move, a first for the DOJ, shows the agency is upping the ante as it keeps the Trump administration's promise to prioritize the opioid crisis in health enforcement. And, attorneys told Law360, it means everyone in the opioid supply chain can expect to see this tool used more frequently.

"The fact that DOJ came out in the press release and they referred to it as a novel approach, it seems to be that they're signaling that this may be the way they now bring these actions," said John Gilbert of Hyman Phelps & McNamara PC.

The two pharmacies, owned by Thomas Weir, allegedly turned a blind eye to red flags like filling prescriptions for unusually high doses of the drugs and for people who traveled long distances to pick them up, according to the suit, which also accuses the companies of violating the False Claims Act with invalid billing to Medicare.

And the DOJ scored its TRO against the companies without having to give them advance notice, according to the judge's order, which found that if the companies were aware a raid was coming, they may have destroyed evidence in the case.

The DOJ's ability to obtain a temporary shutdown at the beginning of its case "gives you some sense of the strength of the evidence, because it's a very unusual move for a judge to go in and issue a temporary restraining order in a case like this," David Schumacher of Hooper Lundy & Bookman PC and former deputy chief of the Massachusetts U.S. Attorney's Office health care fraud unit told Law360.

"Normally there's just a civil lawsuit and the target of the lawsuit can keep going on about its business until the case is resolved," Schumacher said.

Between 2015 and 2018, Dale Hollow, in the small town nestled on the Cumberland River just south of the Kentucky border, ordered enough buprenorphine — the opioid mostly used to prevent withdrawal symptoms from other opioids — from distributors to provide the equivalent of almost one and a half pills of maximum strength Vicodin for every man, woman and child in the county, according to the DOJ. And the specific formulation dished out by Dale Hollow lacked the anti-abuse safeguard in its formula required by Tennessee law, the agency said.

Opioids dispensed by the pharmacies are linked to at least two overdose deaths and a dozen overdoses, including one that allegedly happened inside the Xpress bathroom, prompting a

pharmacist to call 911, according to the DOJ. In 2016, a woman died of an overdose shortly after filling her prescriptions for alprazolam — the generic name for Xanax — and oxycodone, according to filings in the case..

Samantha Rogers, the DEA agent charged with monitoring Dale Hollow, reported a litany of abuses at the pharmacy, including filling controlled substances prescriptions early and a habit of ignoring red flags like the overwhelming percentage of customers who paid cash for the pills, which Dale Hollow was selling in June 2018 for \$5 apiece.

Rogers also said in her affidavit that in an earlier investigation of the pharmacy, the pharmacist-in-charge told her that most people in Celina needed buprenorphine just to function, and that he was often told by Weir to fill prescriptions early.

Normally, the government would go through the administrative route of seeking to yank the pharmacies' registration with the U.S. Drug Enforcement Administration or seek an immediate suspension order. The process of shutting down a pharmacy that's breaking the rules can take months, although the government has the option of seeking a temporary suspension order as it goes through the process of showing cause that it has evidence to yank its DEA registration.

But a 2016 amendment to the CSA required the DEA to identify an "imminent danger" before it could temporarily suspend a dispenser's registration, a move that may have taken the teeth out of the agency's ability to prevent bad actors from dispensing controlled substances.

That law, the Ensuring Patient Access and Effective Drug Enforcement Act, made the DEA unhappy because the agency believed the new rules might water down the standard for seeking an immediate suspension order, Gilbert, a former attorney in the DEA's chief of counsel office, told Law360.

Since the change in the law, there has been **one case** where the DEA issued an immediate suspension order against a Louisiana-based drug distributor for failing to report suspicious orders.

The DEA ultimately withdrew the suspension after the company was able to get a temporary restraining order against the agency.

Gilbert said that experience may have swayed the DOJ and DEA into believing that seeking declaratory and injunctive relief in federal court was a more effective way to immediately stop these pharmacies from dispensing opioids, rather than meeting the newly raised bar to justify an immediate suspension order.

It also gave the government another tool: the ability to seek civil money penalties and False Claims Act penalties at the same time.

"I'm thinking that the reason they were afraid to go for immediate suspension now was that they could have said, you've known about what this pharmacy has been doing for a while, why take so long to try to really suspend them — whereas when they went in for an injunctive relief before a federal judge, they were actually able to make the case," Gilbert said.

The government will still have to go through the administrative process to suspend Xpress and Dale Hollow's registrations permanently, Gilbert said.

The case also showcases how the DOJ has been using data analytics to pinpoint outliers and identify prescribers or dispensers that write or fill suspicious orders of opioids, Schumacher said.

For example, in Friday's suit, the DOJ noted that there are about 68,000 community pharmacies in the U.S., and only three of those bought more opioid doses per capita than Dale Hollow over the last three years.

U.S. attorneys across the country have also been sending warnings to doctors who have prescribed opioids in significantly higher numbers than their peers or who have written a prescription to a patient who later died from an overdose.

Miranda Hooker, a former assistant U.S. Attorney who prosecuted health care fraud cases and is now

a partner at Pepper Hamilton LLP, noted that the two pharmacies were not only statistical outliers in terms of what they were selling, but that they also had a history of run-ins with the DEA.

The owner himself seemed to have a hazy grasp of a pharmacy's responsibilities with regards to prescriptions for controlled substances, according to filings in the DOJ's case. In a 2018 inspection of Dale Hollow, Weir told DEA agents that his pharmacies weren't required to make sure they were filling legitimate prescriptions.

"Doctors need to be investigated. They are the ones writing prescriptions. We just fill them. The pharmacist is not responsible," Weir is quoted saying in the complaint.

That quote is bolded in the filing, Hooker noted.

"I think the government put that in there because this is exactly the message the government is trying to send — that the pharmacy will be and the pharmacists will be held responsible if there is dispensing of opioids that are illegally prescribed and a pharmacy ignores red flags around that," she said.

The government is represented by Ross Goldstein and Donald Lorenzen of the DOJ's Consumer Protection Branch, Scott Dahlquist of the DEA's Office of Chief Counsel and Ellen Bowden McIntyre of the U.S. Attorney's Office for the Middle District of Tennessee.

Counsel information for the defendants couldn't be immediately determined.

The case is U.S. v. Oakley Pharmacy Inc. et al., case number 2:19-cv-00009, in the U.S. District Court for the Middle District of Tennessee.

--Editing by Kat Greene and Pamela Wilkinson.

*Correction: A previous version of this story misidentified the Drug Enforcement Administration. The error has been corrected.*