

## Pharmacies Flooded NM With Opioids, AG Says As Trial Starts

By **Cara Salvatore**

*Law360 (September 6, 2022, 11:51 PM EDT)* -- New Mexico's attorney general launched an opioid-crisis trial on Tuesday against three pharmacy giants with a comparison of stewardship of drugs to that of water in his arid state, saying reckless opioid dispensing by Walgreens, Walmart and Kroger "smashed those dams wide open."

Beginning the bench trial in a Santa Fe courtroom, New Mexico Attorney General Hector Balderas stood and told Judge Francis Mathew the state has been one of the hardest hit, with overdose deaths per capita higher even than hard-hit West Virginia's from 2000 to 2010.

Pharmacies were in a "vital position" of protection and "were supposed to serve like a dam," Balderas said.

"For a state that survives generations without a lot of water, these dams are vitally important to our way of life because they protect us" by turning "massive surges into carefully measured safe levels," he said.

The three defendants, together responsible for more than half the opioid pills sold in the state, "smashed those dams wide open," he added.

In Española, population 10,000, Walgreens sold 12.4 million pills from 2006 to 2019. In Silver City, Walmart Inc. sold 8 million pills from 2006 to 2018. In Taos, population 6,000, Kroger Co. sold 4.8 million pills from 2008 to 2019, Balderas said.

The state has been "on the cutting edge of survival and developing responses," he said. "Our efforts have been easily and consistently overwhelmed by the crush and flooding of pills year after year."

Plaintiffs' attorney Dan Alberstone of Baron & Budd PC, picking up from Balderas, called the New Mexican opioid crisis "a demon" that the pharmacies had a legal duty to combat.

According to Alberstone, New Mexico law requires pharmacists to review certain red flags before prescribing drugs. They are required not simply to investigate any red flags but to resolve them and document the resolution, he said.

The state's laws also spell out that if there's a violation of required or prohibited pharmacy actions, responsibility for the violation "shall be that of the owner and the pharmacist in charge," Alberstone said, reading from a slide displaying the text of the law.

But, he said, there was an ambivalence in these pharmacies' operations. Pharmacists are told to look out for patient safety but are supervised by store managers whose motive is profit.

"There is an inherent conflict in that model," he said. "These pharmacists are charged by these defendants with dual loyalties."

A unique feature in this trial that each of the three defendants was not just a dispenser of opioids but a distributor, albeit only to itself, for many of the years in play. Distribution involves a different set of legal obligations and U.S. Drug Enforcement Administration regulations.

Alberstone then passed the baton to Jeff Gaddy of Levin Papantonio, who laid out some of the nuts and bolts. Walgreens has about 70 pharmacies in the state and self-distributed from 2006 until 2014 when it abandoned that model following a 2013 DEA settlement in which it admitted its suspicious order monitoring "did not meet DEA standards," Gaddy said.

A Walgreens compliance manager, Tasha Polster, struggled with her higher-ups to get a red flag checklist moved from paper to digital format, and a 2015 internal audit revealed that less than 60% of pharmacists were completing the checklist on every prescription fill, Gaddy said. In addition, he said, the company had reams of information on prescribers that it refused to share with pharmacists.

Moving on, Gaddy said Walmart has about 50 stores in the state and also self-distributed for a number of years. Before 2015, he said, its tactic for suspicious orders was what's called "cut and ship" — lower the size of the order but still fill part of it. The company knew from 2006 and 2007 contacts with the DEA and from a 2012 DEA presentation that the regulator had a dim view of this practice, Gaddy claimed. Walmart compliance employee Miranda Johnson asked her higher-ups for improvements in suspicious order monitoring in 2014 — to put together a real monitoring program — but got pushback and was told she needed better justification.

A policy put in place from 2015 to 2017 was set up to flag orders more than three standard deviations from the average. In a standard bell curve distribution, ignoring anything under three standard deviations automatically ignores more than 99.7% of orders. This order-size-based method also didn't fulfill a settlement Walmart reached with the DEA in 2011, Gaddy said.

A manager acknowledged in a 2011 email that "common signs of diversion" spelled out in the DEA settlement didn't make it into the company's standard pharmacy operations manual. It also had to report all refusals to fill prescriptions to the DEA for review within seven days, but pharmacists were never informed they were even allowed to refuse prescriptions, the lawyer said. "We were afraid of getting fired for refusing to fill," one pharmacist wrote in a 2015 email.

And in February 2015, there was an email sent that Gaddy said "sums up" how "callous" the company was. When he was asked whether there were any insights from the data generated from the refusal-to-fill paperwork required by the memorandum of agreement, corporate compliance employee Brad Nelson wrote back, "The MOA ... expires in 30 days. ... We have not invested a great amount of effort in doing analysis on the data."

Kroger has about 24 stores in New Mexico, branded Smith's, and distributed from centers known as Peyton's outside the state. In a 2005 DEA agreement, it was put on notice to implement a "comprehensive regulatory program," Gaddy said. The judge in this trial has sanctioned the company for

failing to turn over what the plaintiffs call an audit and the defense says was just a report. It was done by BuzzeoPDMA, hired by outside counsel Quarles & Brady LLP.

The judge heard argument on Tuesday morning before opening statements on reconsidering the sanction and refused to change his decision. What that means is it's been legally decided that Kroger's regulatory program was substandard up to the date on the Buzzeo report, March 12, 2013, according to Gaddy.

For the year and a half following the Buzzeo report, the grocery chain worked on developing a suspicious order monitoring program. That finally launched in August 2014, and two months later, hydrocodone, the only opioid Kroger self-distributed, was reclassified from Schedule III to the more stringent Schedule II. Kroger wasn't licensed for Schedule II, and all of its distribution went to a national distributor.

On the dispensing side, Gaddy said Kroger evinced a "systemic issue with lack of training" its pharmacists, who didn't know the DEA regulations and had never heard of key terms, he said.

Meanwhile, all three defendants stressed in their own opening statements that pharmacists are highly trained professionals who exercise their professional judgment in filling orders. They don't need red flag checklists, said Walmart lawyer John Majoras of Jones Day.

In fact, "the state itself has rejected many of the red flag limitations that its litigation experts now seek to mechanically and retroactively impose on pharmacists in New Mexico," he said.

And he said that pharmacies' legal obligations are limited by a key term the state didn't mention — "knowingly." Pharmacies violate their legal obligations only when they knowingly dispense irresponsibly, Majoras said. "The state will not meet its burden of showing that any pharmacist filled a prescription that he or she knew was not issued during the course of professional treatment," he said, echoing statutory language.

Majoras gave general arguments on behalf of all three defendants as well as ones specific to his own client, and also stressed Tuesday that many leaders in the state had historically come out against limiting prescribing. Some experts who will testify in the trial wrote an article in 2014 also arguing against the practice, according to Majoras.

Prescribers had a duty to check the state's prescription monitoring program database. But when New Mexico saw prescribers doing a poor job of that, it "refused to take away those doctors' licenses or even to discipline them," Majoras said. These examples "provide the most direct indication to the pharmacists of what the standard of care was in New Mexico at that time," he said.

The state medical board's Sondra Frank will testify, as will the state pharmacy board's Cheranne McCracken, and both will acknowledge the standard of care has changed over time, Majoras argued.

He also called the plaintiffs' entire red flag theme into question on the most basic legal principle. The red flag argument is an argument that some "prescriptions [like some combinations of hydrocodone] are presumptively illegitimate," he said. This means, Majoras added, the plaintiffs are "changing the burden of proof."

Kroger's lawyer, Ronda Harvey of Bowles Rice LLP, argued that pharmacists' prime concern is for their patients, not money. And like Majoras, she said the obligations of pharmacies are being distorted.

Defense expert witness Rodney Richmond will tell the court that what the state is arguing here is the pharmacy standard of care is simply not the pharmacy standard of care, Harvey said.

Harvey also questioned why Kroger, with 4% market share, was a defendant at all. And she said the 2005 DEA agreement was with a completely different Kroger division, King Soopers, not Smith's in New Mexico.

Harvey also spoke to the much-discussed audit report, saying it was natural that Buzzeo, as a consultant, would find problems with Kroger's operations: Any consultant wants more business fixing a client's supposed problems. But it's "interesting that an independent consultant would take the opinion that we were out of compliance when the DEA never had," Harvey said.

Last to speak in the six hours of opening arguments was Dan Taylor of Bartlit Beck LLP for Walgreens, who began by acknowledging, "The opioid crisis in New Mexico is real."

But, he said, Walgreens' operations were not defective. Cosigning Majoras' argument about pharmacists' professional judgment, Taylor said, "You don't practice pharmacy by algorithm."

Although the state did not mention on Tuesday the amount of money it is seeking for its abatement plan, Taylor claimed the state will be seeking \$28.7 billion over some 20 years. The most recent one-year budget for state's entire operations was \$8.72 billion, he said.

The abatement numbers were drawn up mainly by plaintiffs' expert Ted Miller, a health economist. Nearly half of the sum, \$13.7 billion, would be for transitional housing for those in treatment for opioid addiction, but Miller's numbers were based on ridiculous assumptions, Taylor suggested.

Miller got to \$13.7 billion by assuming 65% of treatment patients would opt for state housing. And where did Miller's 65% come from, Taylor asked. "That's the percentage of New Mexicans 25 to 39 who have received a COVID vaccine," Taylor said. "It's driving literally billions of dollars in Dr. Miller's abatement plan."

The state is represented by Dan Alberstone and Mark Pifko of Baron & Budd PC, Jeff Gaddy of Levin Papantonio, Anthony Majestro of Powell & Majestro PLLC and Luis Robles of Robles Rael Anaya.

Walmart is represented by John Majoras of Jones Day.

Kroger is represented by Ronda Harvey of Bowles Rice LLP.

Walgreens is represented by Steven Derringer and Daniel Taylor of Bartlit Beck LLP.

The case is State of New Mexico v. Purdue Pharma et al., case number D-101-CV-201702541, in the First Judicial Circuit of New Mexico.

--Editing by Kristen Becker.

For more of this case, see Courtroom View Network.