# Bloomberg Law

## **Ex-Drug CEO's Criminal Trial Raises Stakes for Opioid Producers**

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A novel opioid trial against a drugmaker CEO could put executives in the painkiller space on alert and deter companies from pursuing innovative medications for fear of liability.

Laurence F. Doud III, former head of Rochester Drug Co-Operative Inc., is on the hook for allegedly scheming to distribute addictive drugs to pharmacies that were previously flagged for questionable practices, and for allegedly blocking efforts to report them to the government. A Manhattan jury began deliberations Tuesday.

Doud, who could face life in prison, is among the few drug company higher ups to face criminal charges for fueling America's addiction epidemic. It's also the first time federal prosecutors are trying to leverage Drug Enforcement Administration requirements meant for distributors against an individual executive, legal analysts say.

"There's been a lot of criminal charges brought against various cogs in the wheel of Big Pharma over their supposed role in the overdose crisis, and corporate executives have been insulated from that," said Leo Beletsky, a Northeastern University law professor who specializes on the law's impact on public health.

Doud's jury trial began on Jan. 18. Some legal experts say a verdict against him could make companies reluctant to pursue drugs that in many instances benefit patients who suffer from pain, although have harmful side effects if misused.

"As much as it's been demonized, the slow-release opioids that came out as an innovative product in the mid-nineties is hugely beneficial," Trevor Burrus, a research fellow at the Cato Institute, said. A guilty verdict would put a "dent" in attempts at further opioid innovations.

#### **Novel Charges**

Pharmacies, doctors, and corporate behemoths have all been targets in the sprawling years-long opioid litigation that has played out across multiple states. The C-suite, however, has been

largely shielded from such actions, with notable exceptions like Purdue Pharma's Sackler family dynasty hit with civil charges.

A verdict in the Doud case "could further expand the already large universe of these opioid lawsuits," Beletsky said.

In spring 2019, the DEA and the U.S. attorney for the Southern District of New York announced the "first ever felony criminal charges" against an opioid distributor and its leadership. U.S. Attorney Geoffrey S. Berman alleged in his complaint that Doud was aware his company was distributing "dangerous, highly addictive opioids" that "were being sold and used illicitly" by pharmacies.

Rochester Drug Co-Operative "supplied tens of millions of oxycodone, fentanyl, and other dangerous opioids to pharmacy customers that its own compliance personnel determined, and reported to Doud, were dispensing those drugs to individuals who had no legitimate medical need for them," according to the complaint.

Other pharma executives have faced criminal charges related to the opioid epidemic. But Doud's case involves fresh arguments under the law, attorneys say.

"SDNY is arguing that, by not filing 'suspicious order report' forms with the DEA that were required under the Controlled Substances Act, RDC and Doud engaged in 'drug trafficking,'" Harry Nelson, founding partner at life sciences firm Nelson Hardiman LLP, said.

Doud, who is over 75 years old and spent 25 years at the helm of Rochester, is on the hook for conspiring to violate U.S. narcotics laws, particularly to up revenue and individual salaries. His lawyer, Robert Gottlieb, has framed the DEA's attack as an attempt to smear Doud, alleging the agency is trying to use his client as a scapegoat.

### 'Living in Fear'

Some legal experts say the charges set an unfair precedent, dropping normal protections against business figureheads for the actions of a company that could have negative consequences downstream.

Under the DEA's theory, Nelson said pharmaceutical companies need to "take such a conservative stand on compliance" that it becomes a priority above all else. That means additional policing in the supply chain, holding distributors accountable for pharmacy actions.

"Not only do I do my job, but I do yours, too, if you're below me in the chain," Nelson said.

Some say the case could have a negative impact on companies working in pain reduction.

Evidence against Doud "seems fairly damning in terms of intentional malfeasance," Burrus said. But "the problem is how much the prosecution of seemingly innocuous behavior will chill the production and distribution of opioids, which we forget are valuable drugs."

Doud's fate also may rattle the drug world beyond opioids. Pharmaceutical companies may be wary of pursuing medical innovations around controlled substances, a category that includes medicines like Valium and Xanax.

"The implication for everyone else is, you need to be living in fear of what's going to happen if you run afoul of how the DEA sees the law," Nelson said.

#### Leveling the Playing Field

Some attorneys say that Big Pharma is unlikely to stop pursuing innovations.

"It might just set a precedent in the future for CEOs to be a little less aggressive over pursuing those questionable sales," said Robert Mikos, a law professor at Vanderbilt University specializing in drug law.

It's difficult to prosecute and indict CEOs, Mikos said, but if "the federal government commits to the task, it might get these companies to think twice."

Some attorneys also say efforts to hold Doud accountable are a cheap attempt at victory that's unlikely to benefit victims of the opioid crisis.

"I view the SDNY as trying to seem like a white knight, when in fact this issue is a sideshow against a middleman that made the mistake of not pivoting as quickly as its bigger competitors," Nelson said. "Drug distributors, like pharmacies and physicians, have been beaten into submission. I find the effort to paint Doud as a villain is over the top."

But others note that the trial marks a refreshing attempt to hold an individual high in the distribution chain accountable while many users and dealers have landed in prison for their behavior.

"It's been maddening to see friends of mine sit in jail or prison for minor possession charges whereas large corporations and the individuals at the helm who weren't just complicit but essentially crafted the marketing around weaponizing the American medicine cabinet with these medications are able to just walk free," said Ryan Hampton, an advocate and author in recovery who focuses on the addiction crisis.

Doud's case "is definitely a warning shot to other corporate heads that they can't just run a reckless company without some sort of consequences," said Hampton. "Will it bring my dead friends back? No. But it will start to even the playing field and even prevent future egregious behaviors by heads of these massive corporations."