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HEALTHCARE LAWYERS

# Client Alert: Opioid Litigation Turns Against Pharma Execs: The Sideshow Continues

**Breaking News and Analysis** Opioid Litigation Turns Against Pharma Execs: The Sideshow Continues

With opioid prescribing at its lowest rate in fifteen years and opioid overdose deaths at an all-time high, one might hope that la enforcement would target the real sources of opioid harm—the forces driving the toxic supply of synthetic chemicals onto America's streets. Instead, however, if the latest opioid litigation is any indication, the federal government has misdirected its resources at pharmaceutical executives and lost sight of the fundamental purpose of drug enforcement policy, which is saving lives.

In the past, corporate entities shielded c-suite decision-makers from civil and even criminal liability for actions taken on behalf the corporation. The corporation itself would enter into settlements, pay penalties, or seek bankruptcy protection from liabilitie when necessary. In July 2021, for example, opioid distributors McKesson, Cardinal Health, and AmerisourceBergen agreed to pay $21 billion in settlements. Similarly, drug makers Abvie, Johnson & Johnson and Teva, either settled or went to trial for th roles in the epidemic. In all cases, the executives were shielded personally.

Lately, however, executives have become opioid litigation targets. First, on February 2nd in New York, a federal jury convicted Larry Doud, the former CEO of prescription opioid distributor, Rochester Drug Co-Operative, of corporate noncompliance with DEA requirements. He stood trial for not having conducted the necessary due diligence on pharmacy accounts to which controlled substances were distributed. In a second case, this past December, Judge Colleen McMahon, a 2nd Circuit appella judge, tossed out a global bankruptcy settlement between Purdue Pharma and thousands of plaintiffs seeking compensation the company's egregious contribution to the opioid epidemic. The $4.5 billion settlement would have protected members of th Sackler family (Purdue Pharma's owners) from further civil liability, despite their clear involvement driving the company's deceptive marketing campaign for OxyContin, the opioid which was ground zero for the epidemic. In the meantime, the Sackl family, Purdue, and the greater majority of plaintiffs are trying to reinstate the mediated bankruptcy agreement, filing for an appeal in early January.

It is worth noting that litigation involving drug manufacturers differs substantially from claims against drug distributors. Suits against opioid manufacturers typically allege that the companies perpetuated false and misleading advertising. In the case of OxyContin, Purdue falsely claimed that there was a "low risk of abuse" or a "low danger of addiction." In contrast, cases again distributors are premised on, what experts call, "diversionary theory." The underlying principle is that distributors have a legal obligation to police their clients and to intervene if they suspect that some of their opioids are being *diverted* to illicit purposes. In some cases, this process can be useful; we appreciate when credit card companies notify us of "suspicious activity" on our accounts. However, when it comes to access to pain medications, many observers think the pendulum has swung too far, to a point where the government sees "suspicious activity" even when *legitimate* doctors submit prescriptions to *legitimate* pharmacies for *legitimate* patients suffering terrible pain. The underlying irony is that increasing opioid order volume by smalle pharmacies was a byproduct of extreme DEA pressure that scared larger national pharmacy chains out of opioid dispensation altogether, leading patients in need to migrate to small, local, drugstores. One of the primary allegations against Rochester Drug's CEO is that he did not allocate sufficient company personnel to scrutinize new accounts or large order volume. In som ways, Rochester's "crime" was moving more slowly than its larger competitors to realize that the government clamp down on opioid prescribing was going to escalate irrespective of the consequences for patients with genuine medical needs.

What makes the case against Doud precedent setting is that it is the first time the Department of Justice has brought *felony* charges against the executives of any pharma distributor. Many industry observers have pointed out that Rochester Drug's behavior, and that of its former CEO, did not differ substantively from the activities of other large distributors, such as McKesson, AmerisourceBergen, or Cardinal Health. By making an example of Larry Doud, the DOJ is paving new ground, sending an alarming message that individual executives and owners may be personally liable for what the government perceives as inadequate allocation of corporate resources to compliance.

It is interesting to compare the aggressive Doud prosecution to the gentle treatment accorded the Sackler family in the Purdu bankruptcy agreement. In pre-filing discussions, the Sacklers agreed to contribute $4.5 billion toward a settlement, "if – and o if – every member of the family could "achieve global peace" from all civil (not criminal) litigation, including litigation by Purdue to claw back the money that had been taken out of the corporation." The family maintained that none of the claimants against Purdue and its owners, including dozens of states, cities, Indian territories, would see a penny in restitution if the Sacklers did

not receive a global release of liability from both current and any future claimants. After all, the family had relocated the $10.4 billion in profits they withdrew from Purdue between 2008 and 2017 (leaving only enough free cash flow to keep the company solvent) to spendthrift trusts and offshore accounts in places like the Channel Islands and the Bailiwick of Jersey, where their fortune was out-of-the reach of U.S. law enforcement. Judge Drain, who oversaw and approved the bankruptcy agreement af plaintiff lawyers acceded to the family's argument, noted the injustice:

"This is a bitter result. B-I-T-T-E-R. It is incredibly frustrating that the law recognizes, albeit with some exceptions, although fa narrow ones, the enforceability of spendthrift trusts. It is incredibly frustrating that people can send their money offshore in a way that might frustrate U.S. law. It is frustrating, although a long-established principle of U.S. law, that it is so difficult to hold board members and controlling shareholders liable for their corporation's conduct."

Nevertheless, he concluded:

"[…] I am not prepared, given the record before me, to risk [the parties'] agreement. I do not have the ability to impose what I would like on the parties."

The appellate court's decision to vacate the bankruptcy, rejecting the idea that the court had the power to protect the individua family members, might be deemed more just, but it will translate to prolonged litigation with doubtful prospects for recovery fro the family's vast personal fortune.

**In the end,** both of these cases are a distracting sideshow. While attention is focused on identifying and holding individuals accountable, Americans are dying in record numbers. The surge in fatal opioid overdoses—rising above 100,000 a year—is due to illicit fentanyl production. Prescription opioids are more tightly regulated today than at any point in the past, while toxic drugs on our streets are the real threat. Illicit fentanyl is 30-50 times more potent than heroin, its production is ten times less expensive, which essentially makes fentanyl (and fentanyl analogues) 99 percent cheaper per dose. The chemical industry in China is the main source of fentanyl and similar synthetic compounds. Inexpensive production combined with the fact that the drug is potent in minuscule quantities create opportunities for wholesalers to purchase the drug over the dark web, and use common carriers (e.g. FedEx or UPS) for delivery. The ease in which an individual can obtain a kilogram of pure fentanyl without "leaving the comforts of home" stymies traditional drug enforcement that focuses on large seizures and reducing over market supply. The government must stop fighting yesterday's "war on drugs," and instead focus on finding ways to lower the toxicity of the drug supply and reduce fatalities.

A recent study published by the Brookings Institution recommended several innovative ideas, many of which are still awaiting broader adoption:

1. **Distribute Fentanyl Test Strips:** Because fentanyl is so cheap and obtainable, dealers mix fentanyl with other opioids, such as heroin, in order to boost their potency, as well as non-opioids like cocaine and methamphetamines. Overdoses occur because of a lack of transparency, as the mis-advertised drug is used in a routine manner without adjusting for th presence of fentanyl. The Biden administration recently proposed making fentanyl test strips available, akin syringe distribution programs. This approach not only reduces fatalities, but is also a creative way to disincentivize drug dealers who adulterate traditional illicit drugs by immediately impugning their (literal) "street credibility."

1. **Sell Fake Fentanyl Online:** Fentanyl is ubiquitously sold across the dark web. The moment one website is shut down b authorities, a mirror website is created in its stead. It would be far better if the government created spoof websites. The fake sales would allow the government to collect commercial data, more importantly, fake fentanyl websites would creat uncertainty in the marketplace, raising the costs of fentanyl production.

1. **Buy Fentanyl from International Sources:** Authorities need to improve their understanding of the illicit opioid market. Purchasing quantities through the internet allows authorities to stay current about how drugs are being transported, thei manufacturing sources, and stay updated about potency and recent chemical alterations.

1. **Focus on Violence and Toxicity:** Instead of indiscriminately criminalizing opioid commerce throughout the entire supp chain, law enforcement should prioritize those criminal elements that are the most violent and those that produce and purvey the most potent and lethal varieties if synthetic opioids. If non-violent and less toxic opioid commerce is generall ignored by law enforcement, manufacturers will be incentivized to produce less deadly forms of fentanyl.

1. **Ease Access to Prescription Opioids for those in Pain:** There is a growing consensus in the medical community tha government reaction to the opioid epidemic has *over*-regulated prescription painkillers. Many providers stopped prescribing opioids for their own self-preservation, leaving patients without safe and legal options, driving countless Americans to turn to illicit, and far more dangerous, sources.

All of these steps are small pieces of the puzzle. It is past time to change the conversation from who to blame to how to save more lives.

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