



BNA's Health Care Fraud Report™

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Five Questions Companies That Handle Controlled Substances Should Ask



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I. Introduction

A bipartisan coalition of state attorneys general recently [joined](#) a growing list of enforcement authorities seeking to hold life sciences and healthcare companies liable for the nation's epidemic of prescription drug abuse. Recent cases have raised familiar allegations of misleading marketing, but also novel legal theories that threaten companies far removed from direct misconduct. Expansive Drug Enforcement Administration regulations and common law theories like "public nuisance" have played key roles in recent enforcement efforts. The Department of Justice, state attorneys general, and municipalities—often represented by private contingent-fee counsel—continue to press aggressive cases up and down the distribution chain. Meanwhile, the DOJ's Office of the Inspector General [is looking into](#) whether DEA should be more aggressive in its enforcement actions, despite hundreds of millions of dollars in recent settlements against DEA registrants.

In this heated environment, life sciences and healthcare companies that make or handle controlled substances should carefully reexamine their compliance programs in light of the ongoing opioid abuse epidemic and related enforcement actions. Recent cases underscore the need for all levels of the supply chain to take steps to guard against diversion of controlled substances, no matter how far removed a company may seem from diversion itself. This article provides a recap of recent enforcement activity and sets out five questions companies that deal with controlled substances should ask themselves as they look to do their part to address the problem of prescription drug abuse and limit the associated regulatory risk.

II. Enforcement Landscape

Today's enforcement surge has its roots in Purdue Pharma's 2007 agreement to pay \$600 million to resolve DOJ allegations that it misbranded the opioid pain reliever OxyContin by understating its addictiveness. Soon after, DEA and DOJ began taking actions against major pharmaceutical distributors that supplied oxycodone and other opioids to pharmacies and clinics that allegedly dispensed the opioids to illegitimate users. In those

cases, DOJ claimed that the distributors failed to meet their obligation under DEA regulations to monitor their direct customers' purchases for "suspicious orders." DOJ has since pressed that theory further: on June 11, 2017, DOJ announced that it reached a \$35 million settlement with a pharmaceutical manufacturer to resolve allegations that the company should have monitored "suspicious" orders between third-party wholesalers and pharmacies downstream in the distribution chain.

The recent wave of enforcement actions combines both strands of enforcement—targeting allegedly misleading marketing on the one hand, and failure to detect and prevent harm by third parties on the other. States and municipalities have led the way. From the City of Chicago to the State of Mississippi, government authorities have brought high-profile cases alleging that manufacturers engaged in misleading marketing practices and failed to take sufficient steps to warn and guard against the risks posed by their products. West Virginia, among the states hit hardest by the epidemic, and several of its counties have filed suit against numerous distributors and pharmacies alleging that those companies violated state law and created a public nuisance by failing to monitor, detect, and report suspicious orders for their drugs. In 2017 alone, the City of Everett, Washington; multiple counties in New York, Tennessee, and West Virginia; St. Clair County, Illinois; the state of Ohio; and the Cherokee Nation have all filed suit on similar theories. Meanwhile, DEA has continued to rack up penalties against distributors, pharmacies and healthcare systems for regulatory violations related to addictive products. And a newly reported multistate coalition of attorneys general promises more investigations are on the way.

The leading theory in many of these cases is that opioid manufacturers overstated the safety of their drugs for long-term treatment of chronic pain, which led to the prescription of opioids to patients who, over time, came to abuse the medication. Although some suits allege misleading direct marketing, such as understanding the risk of addiction, others allege more indirect theories. The City of Chicago, for example, claims that opioid manufacturers funded third parties known to be "pro-opioid" and effectively tainted independent and widely recognized treatment guidance. Similarly, Ohio alleges that manufacturers violated state consumer protection laws by funding "key opinion leaders" who promoted "a pro-opioid message, even in activities that were not directly funded by" the manufacturers. Ohio also claims that manufacturers paid millions to independent professional organizations that issued educational materials that overstated the benefits and downplayed the risks of long-term opioid use.

A second category of claims—asserted in many state cases and nearly all federal ones—alleges that companies involved in the production and distribution of controlled substances failed to take adequate steps to prevent their products from falling into the wrong hands. Many cases allege violations of broad DEA regulations for which the agency has provided little practical guidance, such as the duty to monitor for "suspicious orders" of controlled substances ([21 C.F.R. 1301.74\(b\)](#)) and to maintain "effective controls" against diversion of medication from legitimate channels ([21 C.F.R. 1301.71\(a\)](#)). Nearly all of the state cases brought under these theories assert claims based on amorphous common law concepts like negligence, public nuisance, and unjust enrichment. For example, the Cherokee Nation's complaint argues that distributors and pharmacies breached a common law duty not to create a foreseeable risk of harm to others, alleging that "[e]ach participant in the supply chain shares the responsibility for controlling the availability of prescription opioids." Similarly, the City of Everett, Washington, alleges that a manufacturer fell short of its DEA-prescribed duty to monitor and report "suspicious orders," violating its duty of care to residents and giving rise to liability for negligence, public nuisance, and violations of Washington's Consumer Protection Act.

These theories closely echo the claims states brought against tobacco companies in the 1990s, and there are indications that some states are looking to leverage the tobacco litigation playbook. In fact, some of the state attorneys who litigated cases against Big Tobacco have been retained as private lawyers for government plaintiffs. Traditional plaintiff-side law firms have also appeared in several of the opioid cases, giving rise to controversy (most publicly in New Hampshire) about the proper role of contingency fee counsel in the enforcement context. So far, the suits have continued despite those concerns.

All these factors—in addition to the seriousness of the continuing opioid crisis—point to expanding enforcement and litigation by all levels of government. Those efforts will no doubt focus on opioids, but recent activity has been by no means limited to pain medication. Producers of medication for anxiety, sleep loss, and other conditions have also come under scrutiny, and the precedents set by recent DEA settlements promise to shape future controlled substances enforcement across the board.

III. Five Questions Companies Handling Controlled Substances Should Ask Themselves

All life sciences and healthcare companies that handle controlled substances should take this opportunity to assess both their outward communications (if they market a product) and their internal controlled substance compliance programs. We suggest beginning with five questions:

1. Do our marketing efforts or third-party relationships present risk under consumer protection theories?

Most companies already understand the need to take particular care in making direct marketing claims related to controlled substances, particularly about safety and addictiveness. But companies should also consider carefully the pros and cons of engagement (financial or otherwise) with third-party organizations, researchers and speakers that may later be construed as promotional in nature. Many state suits are looking to hold manufacturers liable for marketing strategies that fall well outside the scope of typical DOJ or FDA promotional cases. Although recent First Amendment decisions in the pharmaceutical space provide increasing cover for non-misleading speech, state authorities may leverage consumer protection statutes and common law theories to argue that manufacturers should have done more to highlight the risks associated with their products.

2. Is our suspicious order monitoring program consistent with DEA's recent expectations?

Companies that handle controlled substances at any level of the supply chain must comply with DEA regulations. For manufacturers and distributors, those regulations include the duty to monitor and report suspicious orders for controlled substances—specifically, those of unusual size, frequency or pattern. Aside from two letters to DEA registrants in 2006 and 2007, DEA has provided little guidance on how to satisfy that obligation. However, recent settlements provide important clues regarding the scope and sophistication DEA expects from manufacturers' and distributors' suspicious order monitoring programs. In particular, registrants should consider using a wide range of available information to help them to monitor and report potentially suspicious transactions, involving not only their own customers, but also those downstream in the supply chain.

3. Are we doing enough due diligence on our customers?

DEA expects manufacturers and distributors to conduct meaningful "diligence" on customers before a sale takes place. Although the regulatory basis for DEA's expectations is slim, informal guidance and industry practices have evolved into best practices that can include "diligence files" on customers and follow-up investigation when red flags are identified. Companies that manufacture controlled substances should even consider conducting targeted diligence on their customers' suspicious order monitoring and due diligence programs. Similarly, DEA regulations require pharmacists dispensing drugs to patients to refrain from knowingly providing medication that will be abused. But in reality the DEA's expectations are much higher. DEA has taken increasingly stringent views on pharmacists' "corresponding responsibility" to confirm the legitimacy of prescriptions and has not hesitated to refer cases to DOJ for potential civil penalties.

4. Does our recordkeeping comply with DEA requirements?

DEA's recordkeeping regulations are complex and highly technical. Often, DEA will simply allow registrants to correct minor issues in response to a warning. Still, the Controlled Substances Act provides for penalties of up to \$10,000 for each violation, no matter how trivial. In an enforcement context, those penalties provide substantial leverage for the agency in its pursuit of weightier (but more tenuous) legal theories. Any company handling controlled substances should, therefore, be acutely aware of DEA's recordkeeping requirements and invest in compliance efforts, both to ensure effective controls around their products and to limit potential exposure in an enforcement action.

5. Is there more we can do to address the problem of prescription drug abuse?

Many companies have taken steps to address the abuse of their products that go far beyond what is required by regulation. From education efforts, to sponsorship of anti-abuse programs, to sophisticated monitoring systems, companies have made significant strides in reducing the likelihood their products will be abused or misused. Those steps not only reduce the risk of attracting enforcement attention in the first place—and put compliance foot faults into perspective—but can ultimately save lives.

