Five insights on navigating the opioid crisis

The United States is in the grip of an opioid epidemic. In 2017 alone, opioid overdoses cost over 47,000 lives.¹ According to the US Centers for Disease Control and Prevention (CDC), 36% of those deaths involved prescribed opioid painkillers even though opioid prescriptions have declined as compared to the previous few years.²

Faced with soaring social and economic costs from opioid abuse, overwhelmed communities are pressing for solutions. CDC researchers say that the crisis is costing the country $78.5 billion, a fourth of which is falling on the public sector.³ As a result, companies involved in the manufacturing, distribution, and dispensing of opioids—a $13 billion industry⁴—are under increasing pressure from a public health crisis that shows no sign of letting up.

Here are five insights for executives across the controlled substance landscape as they navigate the risks of this historically challenging environment.

Federal and state legislators are reaching across the aisle to implement demanding new requirements around opioid pain medications. Key initiatives include:

**The SUPPORT for Patients and Communities Act.** The federal SUPPORT Act, passed with bipartisan support in October 2018, has implications for controlled-substance manufacturers and distributors. Key among them is a new requirement that information from the US Drug Enforcement Administration’s (DEA’s) Automated Reports and Consolidated Ordering System (ARCOS), once the federal government makes it available in the coming year, be factored into an organization’s efforts to identify, report, and stop suspicious orders of opioids to combat diversion.

**Suspicious Order Monitoring (SOM) rule revisions and the DEA Order Clearinghouse Act.** As part of the U.S. Department of Justice’s (DOJ’s) regulatory agenda for 2018, the DEA is proposing to revise its regulations relating to suspicious orders of controlled substances. While the SUPPORT act referenced above provided some minor adjustments to the language around suspicious orders and called for the government to establish a centralized database for collecting such reports, the DEA’s proposed rule could potentially further define the term “suspicious order” and specify the procedures a registrant must follow upon receiving such orders.

In 2018, bipartisan lawmakers in the House and Senate introduced companion bills that would establish a national drug order clearinghouse to be administered by the DEA. Under this legislation, as currently written, before an order for controlled substances could be filled, the manufacturer or distributor would have to run it through the clearinghouse–essentially an automated database–where the order would undergo some analysis to try to detect for anomalous or suspicious characteristics. Both bills are currently in committee.

**Legislation at the state level.** Across the country, state legislatures have passed roughly 70 laws to address opioid-related health issues. Many of the bills impose new restrictions on the prescription of the powerful painkillers by medical professionals. Others expand availability of the overdose rescue drug naloxone. But the most active policy area has been around state-run prescription drug monitoring programs (PDMPs). While PDMPs have been around for many years, many states are now working to harness more efficiently the data they collect and implement requirements to require doctors and pharmacists to review the state’s electronic PDMP database before prescribing or dispensing certain controlled substances.

For example, The DOJ is:

- Adding more enforcement teams to target drug diversion around the country
- Increasing its data analytics capabilities to address the threat and
- Standing up entirely new initiatives through the Medicare Strike Force model to target the opioid threat specifically

As the opioid crisis has deepened, the emphasis of the annual takedowns related to health care fraud coordinated by government have shifted from bogus equipment and services to the abuse of prescription opioids. The latest one, in June 2018, resulted in the DOJ filing charges against more than 600 defendants in 58 federal districts. More than 160 of those medical professional defendants, including 32 doctors, were charged for their roles in prescribing and distributing opioids and other dangerous narcotics.

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6 Testimony of Acting DEA Administrator (page 9) where he talks about the significant increase in Tactical Diversion Squads, https://www.dea.gov/sites/default/files/pr/speeches-testimony/2018t/050818t.pdf.

7 DOJ press release referencing the department’s new data analytics capabilities. See the below hyperlink for reference: https://www.justice.gov/opa/pr/attorney-general-sessions-announces-opioid-fraud-and-abuse-detection-unit.


This increased focus on opioids has not been limited to the DOJ, either. Other arms of the federal government, such as the US Customs and Border Protection Service and the US Postal Service are expending increased resources on opioid enforcement issues as well. Given the ongoing epidemic and prescription drugs widely believed to be a factor in addiction and drug-related deaths, chances are the spotlight will stay trained on opioids.

On the civil front, meanwhile, states, counties, and cities have launched a cascade of litigation against companies across the opioid supply chain. While the litigation prowess of state attorneys general has been well known since at least the tobacco industry years, what’s new in this public health crisis is that many municipalities have formed affirmative litigation units, some of which in turn are teaming up with private attorneys well versed in bringing these types of lawsuits. The municipal litigants are asserting a wide variety of unique claims, including local versions of federal false claims, consumer fraud, and public nuisance laws, with a combination of direct and indirect damage claims.  

These lawsuits are aimed at pushing drug makers and distributors to share the costs of dealing with the epidemic. And while many of these lawsuits have been consolidated into a multidistrict federal court case, others remain filed in state courts across the country. Companies across the opioid supply chain are defending themselves against myriad sophisticated plaintiffs, a wide variety of legal theories and damages claims, and in nearly every state and federal court, with no end in sight.

One potential consequence of this explosion of litigation, which is only now beginning to be appreciated, is the very real potential for “regulation by settlement.” As litigation is resolved, and plea bargains, settlements, and court orders are entered, some defendants are likely to agree to terms above and beyond their current regulatory obligations. This has the tendency to create a floor for future settlements for other defendants, as well as undercutting arguments as to the feasibility of future heightened regulations. This has potential to create a “one-way ratchet” where individual settlements impose increasing regulation, which can ultimately become the basis for significantly heightened laws and regulations.

In past public health crises, such as with tobacco and asbestos, it wasn’t hard to understand who the defendants and plaintiffs were going to be: manufacturers on one side, putative victims and governments on the other. And with some exceptions, the legal theories were typically standard tort and consumer fraud claims.

But over time, regulators and litigators have taken a more expansive view of accountability, asserting claims against a wider variety of defendants, and using more creative, or at least novel legal theories. Combined with the nature of the prescription drug market, in which unique (but increasingly overlapping) roles are played by manufacturers, distributors, retailers, providers, prescribers and payers, the more linear nature of previous public health crisis litigation is being superseded by a three-dimensional playing field for opioid litigation. One outcome already being seen is intra-supply chain litigation where, for example, payers sue manufacturers for allegedly fraudulent promotions. The bottom line? Many players within the opioid supply chain may eventually be pulled into the litigation, and likely on multiple sides.

It’s a miscalculation to assume the government is lagging behind industry when it comes to analytics. From the CDC to Centers for Medicare and Medicaid Services (CMS) to the US Census Bureau, resources of the US government are dedicated to producing data, analyzing it, and providing it to the public. And now, between the evolving PDMPs and additional state and federal requirements such as the proposed DEA clearinghouse, federal and state governments have signaled an intention to get the most out of their datasets in their efforts to bring the opioid epidemic to heel.

For the private sector, this means keeping abreast of government expectations. For example, CDC data for 2017 shows that some counties had opioid prescribing rates seven times higher than the nation as a whole. Can opioid manufacturers and distributors identify similar hotspots across their markets—and drill down to reveal the underlying drivers? Increasingly, government enforcement agencies will expect them to do so and hold them accountable if they do not.

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12 In re: National Prescription Opioid Litigation, 17 MDL 2804 (N.D. Ohio)(Polster, J.)


The commitment to reduce opioid misuse has led some firms to increase their efforts to have an effective analytics infrastructure in place. That includes discovery and detection capabilities to identify questionable behaviors within the opioid supply chain, as well as predictive models to monitor and pinpoint emerging opioid-related risks. Beyond monitoring and reporting, the appropriate data and analytical capabilities can help in designing effective compliance programs and assisting firms that are under litigation to make the case for the settlement they aim to secure.

The opioid epidemic has required a significant ramp-up in public and private resources. Once the epidemic wanes, the resources are likely to stay. Why? Because often, the assembled resources pay for themselves. For instance, the Department of Health and Human Services Office of Inspector General (OIG) has said that for every dollar spent on healthcare-related fraud and abuse investigations, the taxpayers recover another four. If history is any guide—again, think tobacco litigation leading to asbestos litigation—those resources may then turn their attention to other, adjacent public health issues. This dynamic means the focus could shift, and risks start to rise, in related product areas. The first to be targeted may be other scheduled prescription drugs with a significant risk of abuse or with existing or potential black markets and product diversion.

The resources devoted to the epidemic are likely to remain.

Our take
Our take: Now is the time to think about forward-leaning compliance.

The opioid epidemic is far from over. In fact, it may only have reached the end of the beginning. As with other epidemics, while the present reality may make it hard to focus attention on a proactive approach, the crisis eventually should reach an inflection point and then decline. The question at that point for many in the industry could be what’s next? Opioid analgesics will still be a medically useful product that might offer welcome relief to many of the 20 percent of American adults who suffer from chronic pain. For companies looking at that future market, doing so without an appropriate mitigation strategy could risk harm to the public, significant financial losses, reputational damage, and potential criminal or civil culpability. Now is the time to put a forward-leaning compliance program in place to maintain an organization’s commitment to the health of patients in pain.

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