Bloomberg Law

Pharmaceutical Law & Industry Report®

Drug Safety

Against the Backdrop of a 'National Emergency,' Are Opioid Manufacturers Ready for the Enforcement Spotlight?



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On Thursday, August 10, 2017, President Trump announced his intention to designate the opioid crisis a ''national emergency.'' Hours later, the White House issued a statement that the President had ''instructed his administration to use all appropriate emergency and other authorities to respond to the crisis caused by the opioid epidemic.'' This has become, as recognized on the evening news each day, in the homes of people across all sectors of our society, a national crisis of increasingly epic proportions.

The prosecutorial community is, without doubt, signaling its focus on the crisis. On July 13, 2017, Attorney General Jeff Sessions announced that charges had been filed against over 400 individuals, including doctors, nurses and pharmacists, across the country in the largest, coordinated federal health care fraud enforcement action undertaken to date. According to the government, the schemes involved approximately $1.3 billion in false billings to federal programs—and over 120 of those charged, including doctors, were charged in connection with crimes relating to the prescription or distribution of opioids or other narcotics.

Then, on August 2, 2017, Sessions announced the creation of the Opioid Fraud and Abuse Detection Unit, a pilot program that would use data analytics to identify and prosecute individuals contributing to the opioid epidemic. According to Sessions, opioid-related data analysis can ''tell us important information about prescription opioids—like which physicians are writing opioid prescriptions at a rate that far exceeds their peers; how many of a doctor's patients died within 60 days of an opioid prescription; the average age of the patients receiving these prescriptions; pharmacies that are dispensing disproportionately large amounts of opioids; and regional hot spots for opioid issues.'' In addition, Sessions announced that this new Unit would fund 12 Assistant U.S. Attorneys from 12 different districts, to work for a three-year period exclusively on cases involving pill mills, drug diversion, and other opioid-related issues. Sessions stated that these prosecutors – in Alabama, California, Florida, Kentucky, Maryland, Michigan, Nevada, North Carolina Ohio, Pennsylvania, Tennessee, and West Virginia – were drawn from districts ''where we know enforcement will make a difference in turning the tide on this epidemic.''

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 ISSN 1542-9547

Indeed, the human toll from drug overdoses has been staggering. As the Attorney General noted in his August 2nd announcement, nearly 60,000 people died from drug overdoses in the U.S. last year. Over 52,000 deaths resulted from drug overdoses in the U.S. in 2015, according to a recent report issued by the U.S. Centers for Disease Control and Prevention (''CDC''). As that report explained, in 2015, more than 63.1% of those deaths involved an opioid, approximately half of those involved opioids prescribed by healthcare practitioners (''HCPs''), and an estimated 2 million people in the U.S. were addicted to prescription opioids. The CDC estimates that the economic burden of prescription opioid overdose, abuse, and dependence to be $78.5 billion each year in the U.S.

Why the explosion in opioid prescriptions? While opioids had historically been reserved for severe acute pain, postsurgical pain, and palliative, end-of-life care, the increase in addiction and death over the past 15 years (an estimated tripling over this time period) has resulted primarily from the increased use of opioids to treat chronic, non-cancer-related pain. Use of opioids to treat chronic conditions increased the average lengths of time for which opioids were prescribed, and the average dosages of opioids tended to be higher for patients who were prescribed opioids for longer periods of time, effectively increasing the average amount of opioids delivered per prescription.

The question remains, though: why the increased use of opioids to treat chronic, non-cancer pain, and at higher dosages, for longer periods of time? Prosecutors and regulators are increasingly answering that question by pointing the finger at pharmaceutical manufacturers, specialty pharmacies, and the HCPs involved with the dispensing of this highly-addictive class of drugs. While a handful of opioid manufacturers are among those that faced enforcement actions in years past, the spotlight is now sharply on everyone, with local, state and federal authorities, including Congress, undertaking various actions, with public opinion squarely in their corner and at their backs.

Will the current state of compliance programs of opioid manufacturers, specialty pharmacies and others involved with the opioid supply chain withstand this intense scrutiny? Do they have the right policies and controls in place, and know how they are working through appropriate monitoring? As the unwanted spotlight turns to them, the answer better be 'yes,' or they better get to work on it.

The National Opioid Crisis

That the U.S. is facing an opioid crisis has become a fixture in the news and part of the public consciousness. Major news sources to local outlets address the ''opioid epidemic'' and ''opioid crisis'' virtually every day, and prosecutors are talking about dealing with the crisis itself rather than just the cases that come along with it at compliance conferences. Before addressing the enforcement and regulatory landscape and specific compliance considerations for opioid manufacturers, it is important to understand the opioid epidemic our nation is facing, and some of the key available statistics.

- Opioid consumption in the U.S. vastly exceeds that of any other country;
- Since 1999, the number of prescription opioid and heroin overdose deaths and amount of prescription opioids sold in the U.S. have quadrupled;
- In a 2014 study, 75% of heroin users in treatment for opioid addiction started with prescription opioids; and
- Every day, 91 Americans die from an opioid overdose, with nearly half of the deaths involving prescription opioids.

These alarming statistics—and the almost daily, harrowing accounts of how opioids have impacted individuals, families, and communities—have unsurprisingly captured the public's attention.

The economic burden of this epidemic on the government also cannot be ignored. For example, from 2006 to 2015, Medicare Part D spending on prescription opioids increased by 165%—reaching more than $4 billion. A 2016 report from the Office of Inspector General for the U.S. Department of Health and Human Services reported that, in 2015, 30 percent (i.e., nearly 12 million) of Part D beneficiaries received at least one commonly abused prescription opioid. In addition, the number of opioid-related hospital visits increased dramatically between 2005 and 2014 across all sexes and age groups, significantly impacting many states. The epidemic appears to be transcending party lines; one of the reported sticking points in the recent healthcare legislation debates was the impact that the bill's anticipated cuts would have on the states' ability to fight this crisis. Another notable figure is the combined global opioid revenue estimates; last year, one market research firm estimated that global opioid revenues will exceed $42 billion between 2015 and 2021. These numbers make it is easy to see why regulators and law enforcement have been emboldened, crossing traditional political lines to undertake joint investigations, in their pursuit of opioid prescribers and manufacturers.

All Eyes on Opioid Manufacturers

While many are tuned in to see how the U.S. will address the epidemic, the media focus on opioid abuse and its impact on individuals, families, and communities has motivated others to take action. State attorneys general are coordinating investigative efforts and reportedly reconnecting with plaintiffs' counsel from tobacco litigation cases as part of their efforts. On August 4, 2017, the U.S. Drug Enforcement Administration proposed a 20 percent reduction in the manufacture of certain commonly prescribed opioid painkillers for next year. As some have observed, not since the suits against tobacco manufacturers has one group of manufacturers similarly galvanized communities, the press, politicians, and prosecutors.

To date, state attorneys general from nine states have initiated enforcement actions against opioid manufacturers, alleging that these companies contributed to the crisis through deceptive marketing practices. Most recently, on June 15, 2017, a coalition of state attorneys general—including Texas, Massachusetts, Illinois, and Nevada—announced a joint investigation into the sales and marketing practices of opioid manufacturers. This investigation was announced shortly after a number of counties in New York filed suit against opioid manufacturers alleging that they fraudulently minimized the

  PLIR ISSN 1542-9547

risks of prescription opioids, contributing to the opioid epidemic. These counties appear to be following in the footsteps of the City of Chicago and certain California counties that, in 2014 and 2015, sued opioid manufacturers, including Purdue and Cephalon, demanding that they help offset the cost of dealing with the epidemic caused by alleged fraudulent and deceptive marketing practices.

The federal government has made its own recent announcements. On March 29, 2017, President Trump signed an executive order creating a new national opioid commission, to be led by New Jersey Governor Chris Christie. In a draft report issued on July 31, 2017, the Commission stated, ''America is enduring a death toll equal to September 11th every three weeks,'' and its ''first and most urgent'' recommendation, among others, was to urge the President to declare a national emergency. The Commission has a deadline of October 1st to issue a final report, before it is supposed to dissolve in November. As detailed further below, federal agencies and Congress – not just the White House – are publicly addressing the crisis. For example, on June 19, 2017, HHS Secretary Tom Price held two listening sessions with opioid addiction specialists, providers, treatment facilities, and other stakeholders, as part of his multi-state listening tour on the crisis.

It appears that everyone involved in the prescription and synthetic opioid supply chain—from manufacturers and distributors to individual prescribers and pharmacists—is in the firing line. In this article, we will focus on the enforcement and regulatory activity, risks, and scrutiny that manufacturers are facing, beginning with the scrutiny from lawmakers.

Under the Lens: Lawmakers Launch Wide-Ranging Investigation

U.S. Senator Claire McCaskill, a top ranking member of the Senate Homeland Security and Government Affairs Committee (''HSGAC''), observed the following about the opioid crisis: ''All this didn't happen overnight—it happened one prescription and *marketing program* at a time.'' Importantly, the HSGAC launched a wide-ranging investigation into the sales and marketing practices of the top five opioid manufacturers (based on 2015 sales).

On March 28, 2017, Senator McCaskill sent letters to these opioid manufacturers, asserting the following: ''This epidemic is the *direct result of a calculated sales and marketing strategy* major opioid manufacturers have allegedly pursued . . . to expand their market share and increase dependency on . . . painkillers. To achieve this goal, manufacturers have reportedly sought . . . to downplay the risk of addiction . . . and encourage physicians to prescribe opioids for all cases of pain and in high doses.''

Such commentary should serve as a warning about the lens through which manufacturers will likely be viewed by the HSGAC and regulators. In these letters, Senator McCaskill requested information related to almost every aspect of their sales and marketing practices, including:

- Reports summarizing compliance audits of sales and marketing policies;
- Marketing and business plans;
- Speaker program materials;
- Documents relating physician entertainment;
- Continuing medical education (CME) and other educational presentations for HCPs; and
- Contributions to third-party advocacy organizations.

Notably, one of the manufacturers who received the Senator's letter requested that she include other opioid manufacturers in the investigation. On July 26, 2017, Senator McCaskill sent letters to four more manufacturers requesting information from the companies. According to McCaskill, this latest request focuses on the distribution of opioids and their efforts to monitor, report, and investigate the diversion of drugs for illicit use. (Notably, three distributors also received letters from the Senator requesting information.)

While we await further developments, another government player has taken the stage: the FDA.

A Call to Action: FDA's New Opioid Policy Steering Committee Asked to Take ''Forceful Steps''

While FDA Commissioner Scott Gottlieb had announced, in his inaugural blog post, that the FDA would take ''forceful steps'' to combat the crisis, the agency surprised many when it asked an opioid manufacturer to voluntarily stop selling its product. The FDA stated that, if the manufacturer declined to voluntarily remove the product, the FDA would formally require its removal by withdrawing approval of the drug. Faced with that hand, the manufacturer agreed to stop sales of its product.

A few weeks earlier, on May 23, 2017, the Commissioner announced the creation of an Opioid Policy Steering Committee (''OPSC''), tasked with developing strategies to confront the opioid epidemic and addressing the following questions:

- Is the ''FDA [] using the proper policy framework to adequately consider the risk of abuse and misuse as part of the drug review process for the approval of these medicines?''
- Is the FDA ''doing enough when [] evaluat[ing] new opioid drugs for market authorization, and [whether the FDA] need[s] additional policies in this area?''
- ''Should [the] FDA take additional steps . . . to [ensure] that the number of opioid doses that an individual patient can be prescribed is more closely tailored to the medical indication?''

While the OPSC's findings may impact opioid manufacturers bringing new products to market, they will also likely affect those with approved products (e.g., manufacturers with existing products may have to reassess the ''fair balance'' in marketing materials and other components of their sales and marketing practices).

The OPSC's current agenda, including its focus on whether the FDA should take further steps to ensure that treatment (e.g., dosage) is ''closely tailored'' to

''medical indication,'' raises the questions of whether additional regulatory requirements may be imposed on opioid manufacturers.

Indeed, efforts to address the opioid epidemic had been announced even earlier by the FDA. For example, in September 2016, the FDA released an ''FDA Opioids Action Plan,'' that set forth seven initiatives that the FDA would take to combat the opioid epidemic. One of these initiatives was focused on strengthening opioid post-marketing reporting requirements.

This heightened attention should, in turn, spur manufacturers to reassess sales and marketing behavior and whether sales goals may be perceived as unreasonable or otherwise encouraging potentially non-compliant behaviors.

Enforcement Actions from Past to Present: A Sign of Things to Come?

Prior enforcement actions against opioid manufacturers reveal some sales and marketing practices that have been and continue to present significant risks. In 2008, for example, Cephalon reached a $425 million civil and criminal settlement with the U.S. Attorney's Office (''USAO'') for the Eastern District of Pennsylvania to resolve allegations that, between 2001 and 2006, the company's management had encouraged the sales force to promote its opioid, the Actiq lollipop, for off-label uses. Actiq was indicated for opioid-tolerant cancer patients with breakthrough cancer pain (''BTcP'') and to be prescribed by oncologist or pain specialists familiar with opioids. However, the government alleged that, using the mantra ''pain is pain,'' the company had instructed its sales force to detail the product to physicians who were not oncologists, including general practitioners, for general pain. In addition, the government alleged that Cephalon encouraged off-label uses by:

- Training sales reps to prompt off-label conversations with HCPs;
- Designing sales quotas and bonus structures that effectively required off-label promotion to meet goals;
- ''[I]nstructing sales representatives to coach the physicians on what diagnostic codes to record in their documentation'' so that Cephalon's drugs would be reimbursed by insurers and third-party payors (e.g., Medicaid);
- Providing over $80 million in grants to fund CME programs that promoted off-label uses of Cephalon's drugs; and
- ''[R]egularly'' sending ''doctors [based on prescribing habits] to lavish resorts for supposed 'consultant' meetings to hear discussions about off-label uses of its drugs.''

In the other most notable opioid case from the past decade, in 2007, Purdue reached a $600 million civil and criminal settlement with the USAO for the Western District of Virginia to resolve allegations that, between late 1995 and mid-2001, the company misbranded its drug, OxyContin, as less addictive, less subject to abuse and less likely to cause other side effects than other pain medications, all while knowing these claims were false and misleading. The government alleged that, among other things, sales representatives drew fake scientific charts, which they then distributed to doctors, to support the misleading claims.

The company pled guilty to a felony charge of misbranding. In addition, in what was a watershed moment for enforcement in the industry at the time, after the government invoked the *Park* doctrine, three Purdue executives (the CEO, GC, and CMO) each pled guilty to a misdemeanor charge of misbranding, paid fines of $34.5 million, and were excluded by the Office of Inspector General from participation in federal healthcare programs. The parent company, Purdue Pharma L.P., like Cephalon, also entered into a five-year corporate integrity agreement (''CIA'').

A Look Ahead: Possible Compliance Risk Mitigation Strategies

In many ways, the problems and practices covered in the preceding section are not unique to opioid manufacturers. However, the intense spotlight on (1) how addiction has impacted individuals and communities nationwide and (2) significant government spending (on prescription opioids and addiction treatment) sets opioid manufacturers apart. And, under these circumstances, with communities, politicians, regulators, and law enforcement on the attack, these companies may be subjected to stiffer penalties and exclusion—especially if regulators come to believe that the conduct posed a potential threat to patients or government programs. As such, the focus on the U.S.'s opioid epidemic, recent headlines, and prior enforcement actions should send a clear message to opioid manufacturers and other organizations involved in the prescription pain space: matters of public concern and increased attention typically lead to increased exposure.

In a very real sense, the race is on. Opioid manufacturers must quickly assess and improve their compliance programs while keeping pace with others who are keeping watch (e.g., FDA, lawmakers, prosecutors). While not the only source of risk, opioid manufacturers can focus on specific activities that previously landed similarly-situated manufacturers in trouble to help mitigate known risks.

1. Compliance Program, Generally Numerous articles and opinions have addressed the dangers of a ''paper'' compliance program. Life science companies would be wise to heed the DoJ's enforcement actions as fair warning that it will not tolerate ''paper'' programs that appear to check the compliance box but do not have the necessary processes, controls, and resources to put such programs into practice. More than one prosecutor out there would opine that if given the opportunity to ask just one question about a compliance program, it would be: ''What is your compliance budget? / What are your compliance resources?'' While this holds true for all life sciences companies, the current environment—especially on the heels of the guidance that the DoJ issued earlier in February—suggests that it is imperative that opioid manufacturers ensure each compliance program component is adequate and appropriately tailored to address known risks, and resourced to manage the challenges.

2. Code of Conduct, Policies, and Procedures Opioid manufacturers must ensure that they not only have a Code of Conduct and related policies and procedures

   ISSN 1542-9547

that are expected, but that such documentation helps guide employees on the proper way to conduct day-to-day activities. In addition, the compliance policies and procedures should effectively provide clear guidance to the Compliance Department and others in the company who have been ''deputized'' or are in ''gatekeeper'' positions. Such documentation should not merely contain a general overview of the laws and regulations, but should clearly articulate how, in light of the complex legal and regulatory landscape, employees are expected to handle high-risk activities and interactions. For example, at the very least, the following topics should likely be addressed:

- Sales goals, including the process for evaluating the reasonableness of goals in light of any guidance promulgated by the FDA's OPSC or another agency (e.g., whether goals require sales representatives to promote opioids for higher doses or longer periods than proven safe and effective, or for off-label indications);
- HCP target lists, including the process for determining appropriate targets, and reviewing and updating the list periodically, especially with respect to any HCPs with specialties that may be more compliance-sensitive than others (e.g., pediatricians and others who prescribe medications for children, or pain practitioners rather than oncologists);
- HCP interactions, including meals and the ''dos and don'ts'' of sales calls (e.g., the importance of fair balance and the dangers of minimizing safety and risk information, including addiction-related risks);
- Dissemination of educational materials (e.g., reprints, clinical guidelines) to HCPs, including disclosure of any financial ties between the manufacturer and authors / HCPs who developed the publication / guidelines;
- Dissemination of ''unbranded'' materials, including ensuring that these materials do not contradict the product's safety and risk information;
- Handling inquiries from HCPs related to billing codes and other reimbursement-related topics (e.g., ensuring that the company, through its employees or relationship with specialty pharmacies, is in no way helping HCPs submit false information—such as diagnostic codes—to health insurers to obtain coverage for uses that would not otherwise be covered); and
- Handling requests for off-label information (e.g., prohibiting employees from prompting questions).

3. Training Training, delivered in multiple formats, and addressing the specific areas noted in the section above, and others, is important to help ensure that all employees understand what is expected of them. Such training should include examples, in the form of a FAQs or case studies, to highlight how, in a real world setting, the company's compliance principles may be tested and the appropriate response to such tests. With training, the company can help bring its compliance policies and procedures to life.

4. Auditing and Monitoring In many ways, thanks to prior enforcement actions and increased attention, opioid manufacturers likely have more notice than manufacturers of other types of drugs about the specific activities and conduct perceived to be problematic by regulators and prosecutors. Fortunately, this notice can be utilized as a roadmap to help opioid manufacturers avoid known pitfalls. As such, it is imperative that opioid manufacturers focus auditing and monitoring on activities that previously landed opioid manufacturers in trouble, at a minimum. By assessing, via regular auditing (e.g., periodic and for-cause) and monitoring (e.g., data reviews and live), whether their policies and procedures, training, and other risk mitigation efforts are working, opioid manufacturers can identify and address potentially problematic activities. In addition, through this process, weaknesses in controls designed to prevent such activities and conduct will be detected, providing the opportunity to strengthen the controls to help prevent future issues.