This article originally appeared in the August 2020 issue of *America's Pharmacist*, published by the National Community Pharmacists Association, Alexandria, Va. Reprinted with permission.

CONTINUING EDUCATION

A tale of two courts – how opioid cases, evolving during the COVID-19 crisis, may shape pharmacist liability and best practices

by Linda Clark

Aug. 1, 2020 (expires Aug. 1, 2022)
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By the end of this program, pharmacists will be able to:

1. Identify the basic legal theories applicable to pharmacists in the Opioid MDL cases and parallel state cases.
2. Describe "public nuisance" theories and how pharmacies' liability in the opioid cases may turn upon on the definition attached to the term.
3. Compare and contrast case studies of litigation scenarios analogous to opioid liability cases.
4. Describe potential pharmacist liability resulting from developing precedent in the opioid cases.

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Even as the world's health care system faces the unprecedented challenges of the COVID-19 pandemic, opioid litigation continues its march through the legal system toward trial (**Figure 1**). These cases against drug companies, suppliers, and pharmacies, are expected to yield important precedent that may broadly affect pharmacist liability and practices in the emerging post-COVID world.

The lawsuits have been filed by many different plaintiffs, including cities, counties, Native American tribes, and municipalities. More than 2,500 federal lawsuits have been brought against participants in the drug supply chain including pharmaceutical manufacturers, distributors, and retailers. The claims asserted seek reimbursement for governmental expenditures arising out of opioid addictions and overdoses. The defendants have included major pharmaceutical companies such as McKesson Corp., Cardinal Health, AmerisourceBergen, Purdue Pharma, Janssen Pharmaceuticals (a subsidiary of Johnson & Johnson), Endo International, Teva Pharmaceutical, Allergan (formerly Actavis), Watson Pharmaceuticals, and Covidien. Many of these cases have been consolidated into a combined case often referred to as the "MDL" or "Multidistrict Opioid Litigation" now pending before a U.S. District Court in Cleveland, Ohio.

Two of these lawsuits, brought by Cuyahoga County and Summit County, Ohio, were recently selected to serve as "bellwether" exemplar cases. This means these suits have been selected by the court to serve as test cases, with the expectation that the results may guide and drive the ultimate resolution of the other cases in the MDL either by verdict or settlement. Components of the MDL have already been resolved through settlement. For example, the counties reached a last-minute $260 million settlement agreement with the defendant pharmaceutical distributors on the eve of trial. To date, however, no settlement agreement has been reached with the pharmacy defendants, including well-known chains such as CVS Pharmacy, Walgreens, Walmart, and Rite Aid. The MDL federal trial against these defendants is set to begin on Nov. 9, 2020.

Outside of the federal Ohio litigation, many other lawsuits have been brought in state courts by state attorneys general and local municipalities. For example, in August of 2019, after the end of the first state trial attempting to hold a pharmaceutical company accountable for the opioid epidemic, an Oklahoma judge ordered pharmaceutical giant Johnson & Johnson to pay $572 million for its role in the Oklahoma's opioid crisis. Oklahoma is one of dozens of states suing opioid drug makers and this case was the first state case to reach trial.

The allegations of the cases distill down to three main categories of potential liability:

- Opioid manufacturers, such as Purdue Pharma, Endo Pharmaceuticals, and Johnson & Johnson's Janssen Pharmaceuticals, among others, allegedly downplayed the risks of opioids, marketed drugs to the medical community as non-addicting, and targeted marketing efforts, which resulted in healthcare providers prescribing opioids more aggressively.
- Distributors — including AmerisourceBergen, McKesson Corp., and Cardinal Health — are alleged to be responsible for distributing more than 80 percent of the opioids at issue and failed to monitor, investigate, refuse, or report suspicious orders of prescription opioids, flooding states with drugs.
- Pharmacies and distributors, including Walmart, CVS, and Walgreens, are alleged to have sold high volumes of opioid drugs, thereby creating addiction and a black market. Plaintiffs claim that the defendant pharmacies disregarded certain data and other evidence of over-dispensing and violated best practices and industry standards governing the proper dispensing of potentially addictive controlled substances.

Although the bulk of the claims against manufacturers and distributors resolved through settlement, the remaining aspects of these unprecedented cases may yield precedent that could redefine the legal responsibilities of the dispensing pharmacies, which remain defendants in two high profile parallel legal proceedings pending in state and federal court and hurtling toward the "bellwether" trials.

RECENT DEVELOPMENTS ON THE FRONT LINES OF THE OPIOID LITIGATION

On April 30, 2020, the judge overseeing the litigation designated the Lake and Trumbull county actions as the initial trial cases for the pharmacy defendants, teeing up a much anticipated four-week trial in May of 2021. This trial, if it proceeds amid the COVID court delays and closures, will decide key "public nuisance" claims brought by municipalities against pharmacy defendants in their roles as distributors and dispensers for damages incurred in responding to the opioid crisis.

To establish a public nuisance claim, the Ohio MDL plaintiffs must provide evidence that shows intentional or unlawful conduct that unreasonably interferes with a legal "right common to the general public" along with a causal relationship between a defendant's conduct and a plaintiff's injuries. These elements can vary from state to state and can be very difficult claims to prove.

FIGURE 1: High-profile government and class action settlements against opioid companies, 2004–2017*

Case	Key Dates	Allegations	Settlement Details
State and local suits			
West Virginia ex rel. McGraw v. Purdue Pharma L.P.	Nov. 5, 2004 (settled)	Aggressively marketing OxyContin to state residents, many of whom became addicted Concealing from prescribers the extent to which OxyContin's qualities could lead to addiction	$10 million paid over 4 yr to support drug abuse and education programs, law-enforcement initiatives, and medical programs on drug abuse No fault admitted
State of Oregon ex rel. Hardy Myers v. Purdue Pharma L.P. et al.	May 8, 2007 (settled)	Unlawfully marketing OxyContin for off-label uses Misbranding OxyContin as "less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications"	$19.5 million Purdue pledged not to promote OxyContin for off-label uses Requires Purdue to maintain abuse- and diversion-detection program, report problem prescribing, and have field sales personnel undergo special training before selling OxyContin No fault admitted
Commonwealth of Kentucky, ex rel. Jack Conway, Attorney General v. Purdue Pharma L.P. et al.	Oct. 4, 2007 (filed) Dec. 23, 2015 (settled)	Committing Medicaid fraud by misrepresenting the risks and benefits of OxyContin, thereby costing Kentucky Medicaid millions in drug and treatment costs Engaging in false advertising by means of false and misleading package inserts, promotion, and marketing Reaping unjust enrichment by profiting from OxyContin while state paid associated medical and drug costs	$24 million paid over 8 yr, to be spent on addiction treatment No fault admitted Judge granted media request to unseal the court documents to make Purdue practices known to the public
State of West Virginia, ex rel. Patrick Morrisey v. Cardinal Health, Inc.	June 26, 2012 (filed) Jan. 9, 2017 (settled)	Violating West Virginia Controlled Substances Act by failing to diligently respond to suspicious orders Engaging in unfair and deceptive practices, in violation of the West Virginia Consumer Credit and Protection Act Creating a public nuisance because diversion of drugs led to increased crime and consumption of law-enforcement and health care resources Reaping unjust enrichment while state expended substantial resources on prescription opioid epidemic	$20 million paid by Cardinal Health (distributor) $16 million paid by AmerisourceBergen (distributor) $2.4 million paid by Miami-Luken (distributor) No fault admitted
The People of the State of California v. Purdue Pharma L.P. et al.	May 21, 2014 (filed) May 24, 2017 (settled with Teva)	Engaging in false advertising by deceptively marketing opioid drugs meant for short-term use as appropriate for chronic pain Engaging in unfair competition, in violation of the California Unfair Competition Law Creating a public nuisance under California law by engaging in deceptive marketing that led to an epidemic of opioid abuse	$1.6 million paid by Teva Pharmaceuticals, to be spent on combating the ongoing opioid epidemic impacts in Santa Clara and Orange Counties Bars Teva from deceptive marketing No fault admitted by Teva Charges against Purdue, Endo Health Solutions, Janssen, and Actavis remain unresolved, although litigation stayed by state court judge pending outcome of FDA studies related to risks of long-term opioid treatment

FIGURE 1: High-profile government and class action settlements against opioid companies, 2004–2017* (cont. from pg. 41)			
The People of the State of Illinois v. Insys Therapeutics, Inc.	Aug. 25, 2016 (filed) Aug. 18, 2017 (settled)	Violating the Illinois Consumer Fraud Act by engaging in the unfair and deceptive practices of deliberately marketing Subsys, the synthetic opioid approved for breakthrough cancer pain, for off-label purposes to high-volume opioid prescribers and paying prescribers to prescribe Subsys under a sham speaker program	$4.45 million No fault admitted Prohibits Insys from engaging in any false, misleading, or deceptive marketing and from promoting off-label use of its opioid drugs in Illinois Requires Insys to promote its opioid Subsys only to prescribers who are oncologists or who are enrolled in an applicable FDA Risk Evaluation and Mitigation Strategy
Commonwealth of Massachusetts v. Insys Therapeutics, Inc.	Oct. 5, 2017 (filed and settled)	Violating the Massachusetts Consumer Protection Act by engaging in unfair and deceptive acts of misleading health care professionals about the appropriate use of Subsys, including by promoting the drug for off-label uses and paying kickbacks to health care professionals to induce them to prescribe Subsys	$500,000 No fault admitted Prohibits Insys from engaging in any unfair or deceptive marketing practices of Subsys in Massachusetts, including for off-label purposes or by paying kickbacks to prescribers Prohibits Insys from promoting Subsys to any health care professional unless he or she provides cancer care or is enrolled in an applicable FDA Risk Evaluation and Mitigation Strategy
Federal suits			
United States of America v. The Purdue Frederick Company, Inc., et al.	May 10, 2007 (filed) June 25, 2007 (settled)	Violating FDCA by misbranding OxyContin with the intent to defraud or mislead	$600 million paid by Purdue $34 million paid by three of Purdue's top executives Parties admitted to misleading physicians and patients about product's addictiveness and misbranding it as abuse-resistant
United States of America v. Cardinal Health, Inc.; United States of America v. Kinray, LLC	Dec. 23, 2016 (settled)	Violating CSA by failing to report suspicious orders of controlled substances to pharmacies in Maryland, Florida, and New York Violating Washington record-keeping laws	$44 million, consisting of $34 million pursuant to Cardinal settlement and $10 million pursuant to Kinlay (acquired by Cardinal in 2010) settlement Cardinal admitted failure to report suspicious orders to the DEA
United States of America v. McKesson Corporation	Jan. 5, 2017 (settled)	Violating CSA by failing to maintain effective controls against diversion of controlled substances, including opioids, and to report suspicious orders to the DEA Violating 2008 administrative agreement with federal government to monitor sales and report suspicious orders to the DEA	$150 million Requires McKesson to suspend sales of controlled substances from distribution centers in Colorado, Ohio, Michigan, and Florida for 1–3 yr Because McKesson admitted failure to report suspicious pharmacy orders, it agreed to enhanced compliance with earlier 2008 agreement (which had also included a $13.25 million settlement)

FIGURE 1: High-profile government and class action settlements against opioid companies, 2004–2017* (cont. from pg. 42)			
United States of America v. Mallinckrodt, Inc.	July 11, 2017 (settled)	Violating CSA by failing to notify DEA of suspicious orders, as well as failing to implement an effective system to detect such orders	$35 million Allows DEA to analyze data Mallinckrodt collects on orders from customers No fault admitted
Foreign suits			
Canada-wide class proceedings v. Purdue Pharma et al.	June 8, 2007 (commenced) Aug. 24, 2017 (settlement approved)	Failing to disclose the known risk of addiction and withdrawal associated with OxyContin and OxyNEO to a class of persons who were prescribed and ingested these products from Jan. 1, 1996, through Feb. 28, 2017	$20 million (Canadian) settlement proposed and accepted by three of four jurisdictions overseeing the cases, consisting of $2 million to provincial health providers, $4.5 million in legal fees, and ~$13,000–$17,000 per class member

*CSA denotes Controlled Substances Act; DEA Drug Enforcement Agency; FDA Food and Drug Administration; and FDCA Food, Drug, and Cosmetic Act.

Source: The New England Journal of Medicine – www.nejm.org/doi/10.1056/NEJMp1710756

The road to the trial has been rocky and at times dramatic. The long-anticipated Ohio MDL trial was scheduled just days after the Sixth Circuit Court of Appeals decision that stayed a previously scheduled trial against the pharmacies and narrowed the scope of the claims against the pharmacies on timeliness grounds. In a highly publicized decision that was critical of the lower court, the appellate court noted that an "MDL court may not … distort or disregard the rules of law applicable" to achieve perceived efficiencies … "MDLs are not some kind of judicial border country, where the rules are few and the law rarely makes an appearance." The Sixth Circuit Court went on to overturn the lower court's decision and sent the case back for a trial on the remaining issues. In response to this decision, the Lake and Trumbull County plaintiffs then amended their respective complaints to allege new and even more inflammatory accusations against pharmacy defendants. Undeterred by the Sixth Circuit's initial refusal to excuse the judge overseeing the MDL, the pharmacy defendants have since filed yet another appeal seeking re-assignment of the case from said judge. The response of the appellate court is pending.

The revised allegations asserted against the pharmacies focus on dispensing practices. Until recently, thousands of lawsuits across the country related to the opioid health crisis have primarily focused on behavior by drug manufacturers and distributors. Cases asserted directly against retail pharmacy chains are rare. The Ohio cases may represent a redirection of claims being asserted against pharmacies. The plaintiffs in these cases allege, after amending their claims, that the pharmacy chains acted not only as distributors to their own pharmacies, but also as dispensers intentionally feeding into the opioid crisis, calling into question dispensing practices.

While the differences between a dispenser and a distributor may be minute, the allegations against pharmacy defendants are telling of the trial to come. Plaintiffs assert that chain pharmacies "violated the standard of care for a distributor by failing to: (1) control the supply chain; (2) prevent diversion; (3) report suspicious orders; and (4) halt shipment of opioids in quantities that could not be justified and signaled for potential diversion." In their introductory statements, plaintiffs write: "These distributors and pharmacies acted without regard for the lives that would be trammeled in pursuit of profit."

As dispensers, it is alleged that pharmacies dispensed opioids in a manner that represented a lack of robust policies and procedures that would have guarded against diversion into the complaining counties and focused solely on profitability. It is further alleged that certain chain pharmacies willfully and intentionally failed to analyze data relating to drug utilization and overprescribing patterns across retail stores that could have been used to help stop diversion, but they failed to do so. Instead pharmacies allegedly implemented numerous detailed policies regarding metrics to ensure the quick fill of prescriptions and an increase in the number of prescriptions dispensed, even going as far as providing such information to individual doctors in exchange for rebates and other consideration.

There are additional novel claims that have been asserted in these lawsuits. Pharmacies are accused of offering promotional seminars on pain management to pharmacists while partnering with manufacturers. The complaint also alleges improper partnerships between distributors and manufacturers. For example, it is alleged that Endo Pharmaceuticals encouraged pharmacy chains to send out patient letters encouraging the continued use of

opioid prescription pills, which is alleged to have contributed to the misuse of opioids. The complaints also allege that pharmacists were offered rewards and bonuses by national retailers for the retail stores that sold the highest amount of opioids. The complaints further assert that there are contractual clauses which serve to inhibit oversight of distributors. For example, it is alleged that certain wholesalers have added internal policies which encourages certain chain pharmacies to refuse to allow for administrative inspections as those programs would interrupt business. At the same time, retail chains allegedly dragged their feet in setting up monitoring protocols and raising thresholds for the quantities of pills dispensed. In some cases, retailers are alleged to have instructed pharmacists that they should not refuse a doctor's prescriptions even if red flags were triggered based on monitoring policies and procedures. While these allegations have yet to be tested by a trier of fact, the allegations indicate an increased focus upon the interactions and communications between supply chains participants.

As of the date of this article, pharmacy defendants, including Walmart, Walgreens, CVS, and Rite Aid, are seeking to dismiss the complaints out of Lake and Trumbull counties by alleging that a pharmacy's failure to present the diversion of drugs does not support a public nuisance claim in a civil action, as Ohio statutory provisions provide that these types of accusations would be better enforced through other means such as through the Ohio Board of Pharmacy. Moreover, public nuisance claims alleged in the complaint should be dismissed as there exists no causal connection to support liability under the alleged theories and therefore no unlawful dispensing conduct has been annotated. Furthermore, pharmacy defendants allege that allegations regarding the unlawful prescribing of opioids falls on the shoulders of the doctors prescribing, not the pharmacies and any fault arising from direct solicitation or encouragement of doctors to overprescribe falls on manufacturers. It is yet to be seen whether the court agrees and ultimately exonerates these defendants from further liability as the legal battle between the municipal plaintiffs and the pharmacy defendants continue onward.

DEVELOPMENTS ON THE STATE FRONT

While the Sixth Circuit's ruling, largely in favor of the pharmacy defendants, was a momentary glimpse of hope for the pharmacy defendants on the federal front, cases pending in state courts still continue, including a high profile case currently pending in Nassau County, N.Y. A threshold issue in this case involves complex issues of corporate responsibility. The plaintiffs allege that corporate pharmacy defendants are responsible for the actions of the retail pharmacies when the retail locations are dispensing prescription opioids. The court, however, recently dismissed these claims. The court held that the plaintiffs had failed to demonstrate that the corporate chain pharmacy defendants are responsible for the conduct of their subsidiaries. The court, however, did not dismiss claims of wrongful dispensing.

The developments in this case provide a window into the novel liability issues being addressed in cases pending in state court in New York. Here are some of the takeaways:

In the cases pending in Nassau, Suffolk and Cayuga counties, the court has recognized that under New York law, anyone who creates, contributes to or maintains a public nuisance is jointly and severally liable for the consequences thereof. This could mean they are 100 percent responsible for municipal damages. The case could follow precedent in other public nuisance cases, such as People v. Sturm, Ruger & Co., 309 A.D.2d 91 (2003), which involved municipal claims against handgun manufacturers, wholesalers and retailers. For instance, the Suffolk County Supreme Court has found that counties have been damaged not only by the illegal use of opioids but also by their legal use, through potentially wrongful targeted marketing and promotional practices. Importantly, the Suffolk County Supreme Court upheld claims that the corporate marketing strategy used by retailers caused a trickle-down effect through the supply chain that effectively caused the opioid crisis, meeting a proximate cause threshold. The Suffolk County Supreme Court wrote in an Order Denying Pharmacy Defendants' Motion for Summary Judgment:

– In addition to the obligation [Pharmacy Defendants] owe as distributors, the [c]hain [p]harmacies are subject to additional duties that require them to ensure that opioids are dispensed pursuant to legitimate prescriptions. Specifically, as dispensers of opioids, the [c]hain [p]harmacies are required to ensure that the prescriptions dispensed at their stores are dispensed pursuant to a legitimate prescription, and must not fill prescriptions without resolving "red flags" of diversion.

Rulings in these cases point to pharmacies being held to a higher duty than ever before. When presented with a prescription for a controlled substance, pharmacists must exercise their professional judgment and adhere to their corresponding responsibility to determine whether the prescription for a controlled substance has been issued for a legitimate medical purpose by an individual practitioner acting in the usual course of their

professional practice. While the responsibility for properly prescribing controlled substances falls upon the prescribing practitioner, pharmacists carry a corresponding duty to actively address and resolve red flags prior to the dispensing of controlled substances.

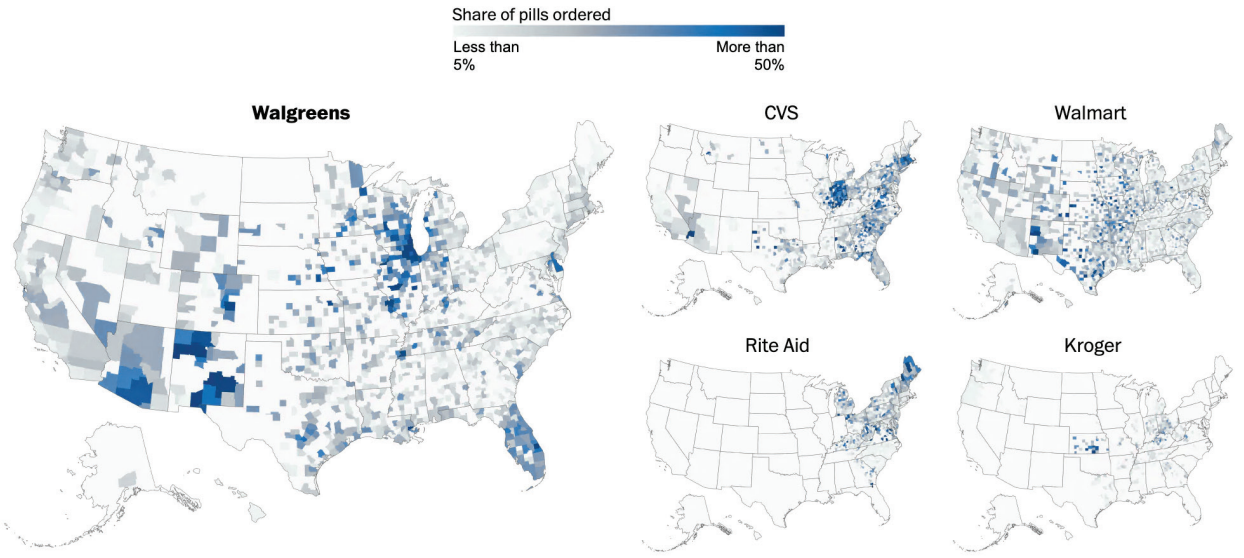
With pharmacists and pharmacies potentially susceptible to corresponding liability in certain states, pharmacies are advised to establish due diligence policies, which include checking state prescription drug monitoring programs (PDMPs) and identification of potential red flags. A red flag refers to the warning signs that may indicate a controlled substance prescription is not being obtained for legitimate medical purpose but rather for diversion or abuse. Pharmacists should evaluate and interpret the seriousness of warning signs such as forged prescriptions, prescriptions originating outside the immediate geographic area, altered prescriptions, inconsistent or early fills, cash payments, and multiple prescribers. (**Figure 2**).

FIGURE 2: Red flag warning signs related to the prescribing and dispensing of controlled substances

Presentation of the prescription	• Patients travel in groups and/or have unexplainable common factors in their relationships with each other. For example, groups of patients present prescriptions for the same controlled substance(s) from the same prescriber or multiple family members or patients living at the same address present similar controlled-substance prescriptions to the pharmacy on the same day. • A patient presents prescriptions for controlled substances written in the names of other people. This does not apply to designated caregivers presenting prescriptions for patient. • A patient presents a prescription for a controlled substance that the pharmacist knows or reasonably believes that another pharmacy refused to fill. • A handwritten prescription is presented at the pharmacy, looking altered or flawlessly thorough (contains patient address, quantity spelled out, patient's date of birth, multiple provider identifiers, lacks common abbreviations, etc.). • The pharmacist becomes aware that the prescriber's Drug Enforcement Agency (DEA) registration has been previously suspended or revoked or is pending suspension or revocation.
Patient behavior	• The patient pressures the pharmacist to dispense the controlled substance by making implied or direct threats. • The patient shows physical signs associated with controlled-substance abuse, such as appearing sedated, confused, intoxicated, or exhibiting withdrawal symptoms. • The patient obtains the same or a similar controlled-substance prescription from multiple health care practitioners without disclosing those existing controlled-substance prescriptions. • The patient obtains controlled-substance medications from one pharmacy, while having received the same or similar controlled substance(s) from another pharmacy or other pharmacies, without disclosing those existing controlled-substance prescriptions. • The patient presents prescriptions for highly abused controlled-substance medications, which may vary by region. The pharmacist should be aware of abuse trends in their area. • The patient presents several prescriptions written for controlled and non-controlled substances, but only wants the controlled-substance medication(s) dispensed. • The patient has a history of untruthfulness when filling controlled-substance prescriptions.
Medication taking/ supply	• The patient presents prescriptions for large quantities or large numbers of prescriptions for controlled substances. • There is therapeutic duplication for two or more long-acting and/or two or more short-acting opiates. • The patient presents prescriptions for highly abused "cocktails" (combination of opiate, benzodiazepine, and muscle relaxant) of controlled-substance medications.
Illicit/illegal behaviors	• The patient indicates that drugs will be shared with others or sold. • The prescriber's DEA registration or state license has expired or been suspended or revoked. • The patient presents a prescription from a prescriber who is prescribing outside the scope of his/her practice, as defined by state law. • The patient alters, forges, sells or rewrites prescriptions. • The patient is diverting/selling medication or getting drugs from others.

FIGURE 3: Share of prescription opioids ordered by retail pharmacies by county

Five pharmacy chains ordered 33 billion pills containing hydrocodone and oxycodone from 2006 to 2012. This accounts for almost half of the prescription pain pills distributed in the United States, according to a *Washington Post* analysis of data compiled by the Drug Enforcement Administration.



Source: Washington Post – www.washingtonpost.com/investigations/2019/11/07/height-crisis-walgreens-handled-nearly-one-five-most-addictive-opioids/?arc404=true

Pharmacies should also ensure they have the appropriate documentation and compliance with all applicable laws and regulations. (**Figure 2 and 3**). The policies and procedures adopted by pharmacies in dispensing opioids are more likely to be carefully scrutinized, and pharmacies are advised to ensure they are compliant with the Centers for Disease Control and Prevention guidelines for use of alternative opioid products. This compliance may include documenting the due diligence applied to prescriptions, including checking the patient's PDMP report, contacting the prescribing physician for confirmation, and speaking with the patient if decisions not to prescribe have been made. Such practice will prove to be vital in case of audits or investigations and to minimize liability.

Notably, in the Ohio MDL, the judge's recent decisions hints that pharmacies may have their prescribing practices scrutinized more carefully:

Plaintiffs' proof will look beyond the Prescribers' representations and will focus on Pharmacies' policies and procedures, through analysis of aggregate dispensing data showing the entirety of the information the Pharmacies had when dispensing opioids. After hearing this evidence, the jury will be tasked with deciding whether the Pharmacies engaged in intentional or unlawful conduct. Thus, a finding of Defendants' liability will be based on the distinct duties of the Pharmacies, involving facts largely independent of any individual Prescriber or prescription.

With courts now recognizing a pharmacy's duty to maintain proper procedures, pharmacies should take extra effort in ensuring their eCare plan and record keeping database meet applicable criteria. Information that should be maintained includes:

- Date
- Identifying information, including that of the member documenting the patient contact
- Patient presenting symptoms or concerns (e.g. medication assessment, pharmaceutical opinion, follow-up, etc.)
- Patient history summary and care plan if developed
- Information provided to or received from other caregivers
- Assessments, interventions, and recommendations where professional judgment was exercised along with the evidence on which the recommendations are based
- A follow-up plan that is sufficiently detailed to monitor the patient's progress and ensure continuity of care by the pharmacist.

In addition to these housekeeping documentation initiatives, pharmacists should be aware of various state initiatives. For example, Florida recently passed House Bill 743 mandating health care professionals inform patients of non-opioid alternatives prior to prescribing and ordering opioid drugs. This bill also requires that pamphlets with information regarding non-opioid alternatives be provided to each patient, that a discussion be had with the patient regarding the advantages and disadvantages of non-opioid alternatives, and requires the documentation of non-opioid alternatives considered within the patient's record. Furthermore, Gov. Ron DeSantis (R) re-established the Office of Drug Control and set up an opioid task force that is chaired by Attorney General Ashley Moody with the purpose of providing a unified vision to address Florida's opioid epidemic.

Along with civil litigation, federal agencies, such as the Drug Enforcement Administration and state enforcement officials, are aggressively pursuing criminal action in an effort to stem the opioid epidemic. Several pharmacy owners have faced criminal charges for engaging in particularly egregious activities related to the distribution and illegal dispensing of opioids. A review of the facts of these cases is instructive and demonstrative of how legal concepts of liability play out in the pharmacy.

Case study - New Jersey

In 2017, a New Jersey pharmacist was convicted in federal court of distributing and illegally dispensing oxycodone. In some instances, the pharmacist would fill prescriptions for oxycodone even though the prescription had apparently been "washed" or "bleached" to remove the original doctor's writing. Likewise, in 2019, a California pharmacist was sentenced to 63 months in federal prison for illegally distributing oxycodone by filling hundreds of counterfeit prescriptions. The filled prescriptions were written under the name and DEA registration number of a retired doctor.

Case study - New York

In a "first-of-its-kind" prosecution, the DEA charged one of the nation's largest drug distributors and its executives with unlawful distribution of controlled substances, conspiracy to defraud the DEA, and knowingly failing to comply with the company's legal obligation to report "thousands of suspicious orders of controlled substances to the DEA." The charges against the executives came as a shock to the pharmaceutical community, but demonstrated the government's resolve to fight the ongoing opioid crisis. The court found pharmacy executives personally liable for the distributor's actions, treating "white collar executives . . . like street dealers and traffickers," while making wholesalers responsible for prescriber behavior. Sending shockwaves throughout the pharmaceutical industry, the unprecedented prosecution of the executives shows how incredibly detrimental a failure to follow an adequate compliance program can be.

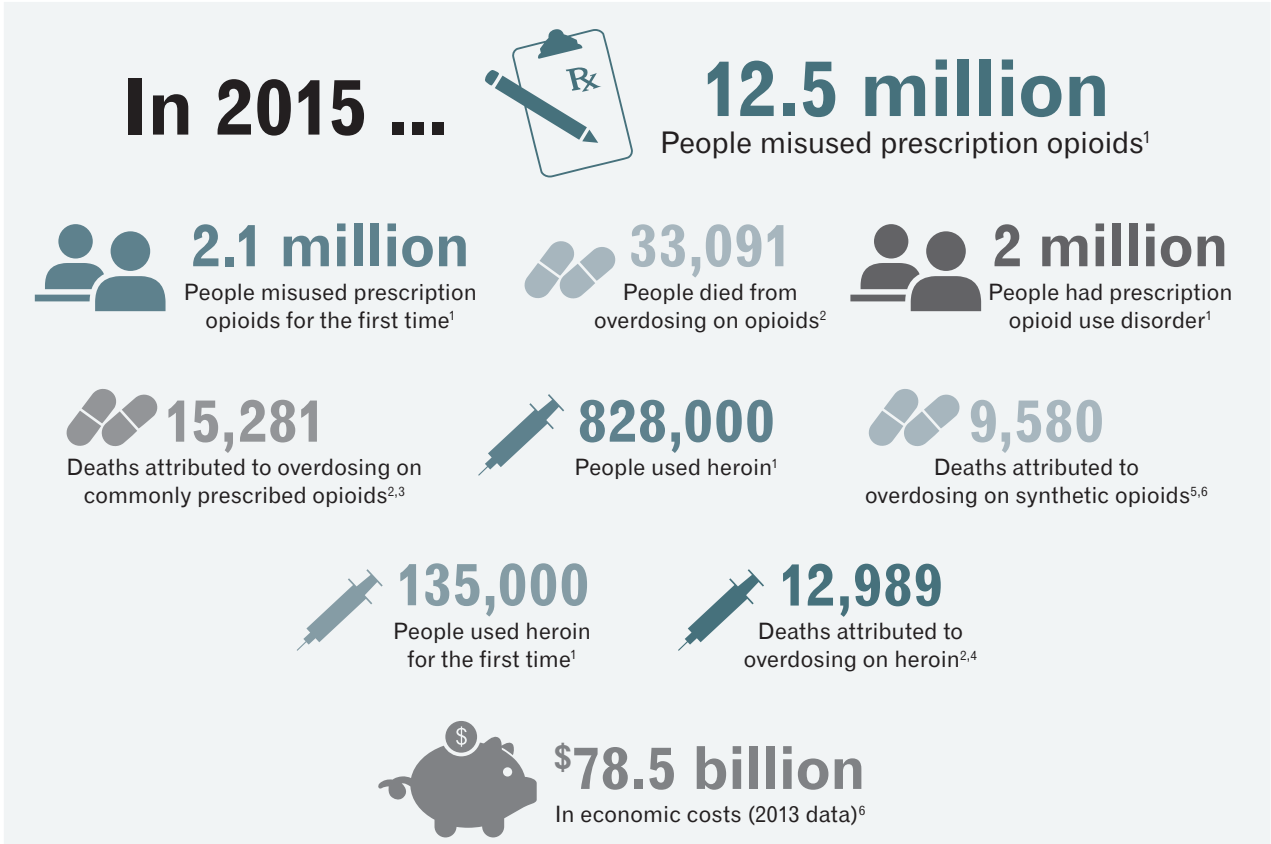
These cases should be a poignant warning of the value of stringent training protocols that a pharmacy should implement to spot faux prescriptions and address the perpetual red flags. With more than 12.5 million prescriptions written for opioid analgesics in 2015 alone, and more than 11.5 million people having self-reported that they had personally misused prescription opioids, pharmacists are advised to develop strategies that demonstrate compliance with best practices with respect to opiates (**Figure 4**). The decisions coming out of the MDL opioid litigation also provide a possible roadmap for pharmacists going forward, suggesting a baseline of inquiry that should be implemented when vetting prescription orders for opiates. Pharmacists are advised to consider the following:

- How often does the patient change doctors?
- What is this patient's prescription history in the prescription drug monitoring program?
- For what condition is the opioid being prescribed?
- How often is the same pain prescription being refilled? Is the patient seeking early refills?
- Are several members of a household receiving prescriptions for controlled substances? If so, does the pharmacy have a relationship with those family members?
- Is the pharmacist aware, or have a reasonable belief, that the prescription was refused by another pharmacy?
- Did the pharmacist determine that the prescription is being sought in order to fulfill a medical purpose and/or is in line with a physician's prescribing practices?

WHEN EPIDEMICS COLLIDE: COVID-19 AND THE OPIOID EPIDEMIC

With the nation slowly emerging from the COVID-19 pandemic, the pause in the attention placed on the opioid crisis may soon end, once again putting opioid prescribing and dispensing practices into the national spotlight. Before the first COVID-19 case in the United States, the opioid crisis was taking the lives of 130 Americans per day. The daily death rate has subsequently seen an uptick in the midst of a relaxed regulatory scheme, causing increased concerns of liability in the horizon given the convergence of COVID-19 and the hazards of opioid addiction. Consequently, liability for health care providers, including pharmacists, may remain a substantial risk for

FIGURE 4: The opioid epidemic in the U.S.



Source: [1]2015 National Survey on Drug Use and Health (SAMHSA). [2]MMWR 2016; 65(50-51); 1445-1452 (CDC). [3]Prescription Overdose Data (CDC). [4]Heroin Overdose Data (CDC). [5]Synthetic Opioid Data (CDC). [6]The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013. Florence CS, Zhou C, Luo F, Xu L. Med Care 2016 Oct 54(10) 901-6

the unprepared. As opioid cases against pharmacies in the MDL and in parallel state cases wind through the civil litigation system, pharmacists should carefully monitor the lessons to be learned that may impact the contours of liability for pharmacists.

Pharmacists are cautioned to continue to be mindful of removing opioid safeguards when implementing COVID-19 best practices. Taking away the ability to confirm prescriptions in person, or the ability to see an individual face-to-face, may bring a host of issues regarding the dispensing of opioid prescriptions without proper safeguards being followed. While COVID-19 has forced pharmacies to adjust to a climate where in-person interactions are less likely, red flags may be harder to spot through telemedicine and phone screenings. Limiting direct contact with patients puts a higher burden on pharmacies to rely on their recordkeeping and documentation procedures both in PDMPs and their own records to spot potential abuse. It is imperative for pharmacies to keep vigilant and take every measure to limit liability, even during two competing epidemics. ■

Information in this article is current as of July 13, 2020.

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For reference information and source material for this article, please contact America's Pharmacist® managing editor Chris Linville at 703-838-2680 or chris.linville@ncpa.org.

CE
QUIZ

Continuing Education Quiz

Select the correct answer.

1. True or false: The bulk of claims against manufacturers and distributors within the Multi-District Litigation resolved through a jury trial.
a. True
b. False

2. True or false: Pharmacies should only maintain proper documentation when dispensing controlled substances.
a. True
b. False

3. The following counties' claim has been selected as initial bellwether cases for pharmacy defendants in the Ohio MDL:
a. Lake County
b. Cayuga County
c. Nassau County
d. Suffolk County
e. All of the above

4. The initial Ohio MDL bellwether case will decide:
a. Pharmacies' liability for prescribing of controlled substances such as oxycodone.
b. Pharmacy owners' criminal responsibility for egregious activities related to the illegal dispensing of opioids.
c. Pharmacies' liability for not complying and maintaining adequate documentation in the dispensing of controlled substances.
d. Public nuisance claims brought against pharmacy defendants in their roles as distributors and dispensers.

5. The Sixth Circuit ruled that an Ohio MDL judge's order regarding the upcoming bellwether trial was:
a. Distorted
b. Timely
c. Untimely
d. Not appropriate for litigation

6. The parallel county cases, such as the Nassau and Cayuga County cases, will test the following:
a. Whether pharmacies are liable for not complying with adequate documentation standards and protocols in the dispensing of controlled substances.
b. Whether the actions of defendant pharmacies, as wholesale opioid distributors, affected counties and their citizens to the extent they are legally responsible for the fiscal impacts of the crisis as a "public nuisance."
c. Whether the actions of defendant pharmacies amount to criminal liability.
d. None of the above.

7. If found joint and severally liable, the pharmacy defendants would be ____ responsible for municipal damages.
a. 50 percent
b. 100 percent
c. 25 percent
d. 0 percent

8. In Strum, the court heard public nuisance case involving municipal claims against:
a. Tobacco wholesalers, manufacturers, and retailers.
b. Opioid wholesalers, manufacturers, and retailers.
c. Handgun wholesalers, manufacturers, and retailers.
d. None of the above.

9. Pharmacy executives have faced charges for the following offenses:
a. Distributing and illegally dispensing oxycodone.
b. Filling counterfeit prescriptions of a retired doctor.
c. Purposefully ignoring concerns of fraudulent prescriptions.
d. All of the above.

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▶ *Continued from page 53*

10. A "first-of-its-kind" prosecution against a drug distributor in New York was notable because:
a. It involved criminal charges.
b. It involved a street dealer and drug trafficker.
c. It was brought forth by the DEA.
d. It was the first major case to attack individual executives in the opioid showdown.

11. Pharmacists should ask the following questions when receiving prescription orders:
a. For what condition is the opioid being prescribed?
b. How many refills are ordered and does the patient seek early refills?
c. Are several members of a household receiving prescriptions for controlled substances? If so, does the pharmacy have a relationship with those family members?
d. Is the pharmacist aware, or has a reasonable belief, that the prescription was refused by another pharmacy?
e. All of the above.

12. What should pharmacists implement in order to spot faux prescriptions?
a. Red flag markers
b. Stringent training
c. A relaxed approach to identifying prescriptions
d. A carte blanche practice of filling prescriptions