The opioid crisis continues to be a top priority for legislators, regulators, and health care providers. The statistics related to overdose deaths related to prescription opioids are staggering. The Centers for Disease Control and Prevention (CDC) reports that prescription opioids are a significant contributor to the rising number of overdoses in the United States. According to the CDC, prescription opioids were involved in over 40 percent of overdose deaths in the United States in 2016. All states have been impacted by this crisis, but the states with the highest overdose rates include West Virginia, Maryland, Maine, and Utah. The nationwide crisis resulting from prescription opioid misuse is estimated to cost $78.5 billion annually.

Pharmaceutical companies have been at the center of the opioid crisis; however, the search for the root cause is never ending. Putative perpetrators include not only the drug industry but physicians, wholesale distributors, pharmacies, pharmacists, and yes, even the patients themselves. All the while, much of the tragedy stems from illegal and highly dangerous drugs being introduced from other countries and peddled on the streets of the United States.

The U.S. Drug Enforcement Administration (DEA) fights this battle on all fronts but has focused much of its attention on prescribers, wholesale distributors, pharmacies, and pharmacists, all of which are the primary focus of this article. What is the “culpability,” however, of any one of the entities mentioned above, including pharmacies and pharmacists? It is also very difficult to put on blinders and evaluate any one of these, so at some level, we need to include prescribers, wholesale distributors, pharmacies, and pharmacists collectively in the discussion about the pharmacist’s role.

The bottom line is—patients have pain. Some have mild pain, and others have pain so intolerable that it takes over their lives. It is generally agreed that, with some small exceptions, prescriptions for controlled

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substances emanate from physicians who diagnose and treat patients’ pain, with some others being counterfeit. Prescribers must issue prescriptions for controlled substances only for a legitimate medical purpose while acting in the usual course of their professional practice.\(^4\)

It is interesting to note the responsibility for the proper prescribing and dispensing of controlled substances is upon the prescriber. So how does pharmacy fit into this picture? A corresponding responsibility rests with the pharmacist who fills the prescription.\(^5,6\) This can sometimes prove a daunting task for a pharmacist. When confronted by a patient who appears to be in pain and needs relief from his or her suffering, the pharmacist is often required to make a judgment call to determine whether to dispense. The choices are not easy.

If the patient is passing an illegitimate prescription, the pharmacist may have violated his or her corresponding responsibility by dispensing it. If the prescription is legitimate and the pharmacist refuses to dispense it, the pharmacist has allowed a suffering patient in need to go untreated. At some level, the DEA has deputized pharmacists to enforce (rather than comply with) the Controlled Substances Act (CSA) and to place that law enforcement responsibility first.

There is longstanding case law dealing with pharmacists for clearly violating their responsibilities related to dispensing. Sometimes it might be clear that a pharmacist is dispensing a controlled substance for other than a legitimate medical purpose. There are certainly members of every profession who violate the law in furtherance of their own well-being. For example:

> [d]efendant pharmacist was convicted of conspiracy to distribute Schedule II controlled substances and 35 counts of distribution of Schedule II drugs under prescriptions which he knew bore false names or were not issued in the usual course of professional practice. On appeal, the court affirmed. The statute and accompanying regulation was not unconstitutionally vague and defendant, who was registered to dispense controlled substances, could still be convicted of 21 U.S.C.S. § 841 for dispensing controlled substances outside of the usual course of medical treatment. Defendant was on notice that he had a duty not to fill a prescription that he knew was issued outside of the usual course of professional treatment. The sheer volume of prescriptions filled by defendant along with their exorbitant prices supported the jury’s conclusion that defendant knew that the prescriptions were not for a legitimate medical purpose.\(^7\)

In another example:

> [a]ppellant, a pharmacist, was charged with conspiracy to distribute controlled substances and with distribution of controlled drugs on the basis of prescriptions which he knew were not issued for a legitimate medical purpose. The United States District Court for the District of Maryland convicted him of violating 21 U.S.C. §§ 841(a)(1), 846 and he challenged the judgment. The court held that there was abundant evidence from which the jury could have determined that appellant knew the prescriptions presented were bogus. The large number of prescriptions were all written by one doctor, were all presented by one person, and were ordered in uniform dosages and quantities, thus belying any conclusion that the prescriptions were ordered for individual patients.\(^8\)
More recent opioid litigation focuses on pharmacies (naming them as defendants with a number of opioid drug manufacturers). For example, a number of states, including Florida, have sued retail pharmacies for their roles in what the Florida Attorney General called the pharmacies’ “unconscionable efforts to increase the demand and supply of opioids in Florida.” The lawsuit accuses the drug manufacturers, wholesalers, and pharmacies of working “together to deceptively market and unconscionably distribute the pills—indifferent to the human cost...” causing the state of Florida to endure significant losses, including “medical costs, unemployment costs, drug treatment costs, emergency personnel costs, law enforcement costs, naloxone costs, medical examiner costs, foster care expenses, lost productivity, and lost tax revenues, among many other costs.”

Litigation is not the only avenue being taken to assess culpability for the crisis. Government agencies, including the DEA, have taken action against perceived perpetrators. This year, DEA revoked four DEA pharmacy registrations because “continued registration is inconsistent with the public interest.” Specific to the pharmacies, the lawsuit alleges that these chain retail pharmacies are “among the top distributors of opioids in Florida.”

DEA articulated a number of these “red flags,” including: (1) early fills (attempting to refill a prescription well before the patient could have exhausted the current supply); (2) unusual distance travelled; (3) filling cocktail prescriptions (opioid, a benzodiazepine, and a muscle relaxer); (4) duplicative drug therapies; (5) two prescriptions for the same drug on the same date; and (6) lack of individualized drug therapy. In addition, the DEA argued that the pharmacists violated their corresponding responsibility “by filling prescriptions for drugs such as oxycodone and hydromorphone, even though ... [the] pharmacists knew that these prescriptions presented various ‘red flags’ of diversion which were never resolved.” In addition, DEA found that the pharmacies failed to maintain proper records related to the controlled substances dispensed.

DEA has also ramped up investigations into pharmacy dispensing. It recently announced:

DEA had dramatically increased its resources to combat the opioid epidemic, including the formation of Tactical Diversion Squads throughout the United States that target multiple levels of drug diversion and who target the most egregious violators. DEA has also launched a comprehensive 360 program in cities nationwide that seek to leverage law enforcement efforts with health care community, treatment facilities, faith-based organizations, community groups, and the business community in the fight against the opioid epidemic.

DEA has also begun to use sales data to pinpoint irregularities. For example, DEA focused on a number of pharmacies in Clay County, Tennessee, when it discovered irregular patterns in purchasing from drug distributors. In its press release, DEA noted “according to sales data, these pharmacies purchased nearly 1.5 million pills...”
in 2017, a number not typically reflective of a rural area such as Clay County.\textsuperscript{20}

It also continues to take action against pharmacies who fail to maintain proper records. For example, DEA recently reached a settlement with a California pharmacy for $75,000 for failure “to properly account for highly addictive and frequently abused opioids, including fentanyl.”\textsuperscript{21} In late 2017, DEA also targeted 26 pharmacies in multiple states for “operating outside the bounds of legitimate medicine.”\textsuperscript{22} Circumstances for investigation of these pharmacies included filling “exceptionally high numbers of oxycodone prescriptions, excessive or frequent opioid purchases, multiple customers with identical addresses, or customers traveling extreme distances to specific pharmacies despite access to more convenient options.”\textsuperscript{23}

It is important to note that, with regard to pharmacies and pharmacists these are not the norm but rather the exceptions to the rule. The vast majority of health care professionals do not engage in this type of behavior but rather take great pains to follow the law and regulations affecting controlled substance prescribing and dispensing. Litigation and government enforcement, however, can help pharmacies and pharmacists preemptively identify compliance issues. In order to assist providers, the DEA makes available manuals for pharmacists, offering advice, among other things, on how to determine the legitimacy of prescriptions and meet the pharmacist’s corresponding responsibility.\textsuperscript{24}

Outside of enforcement, a number of measures have been implemented to stem the tide of the opioid crisis. In an effort to maintain the distribution of controlled substances as a closed loop system, the DEA and states have instituted prescription drug monitoring programs (PDMP) where the dispensing pharmacies must report all or select (depends on the state) dispensed controlled substance prescriptions to a state database where health and law enforcement authorities can monitor dispensing and prescribing. This was a hard-fought battle for the DEA as most states were reluctant to institute these programs, but federal money was made available as an incentive to the states. Now all but one state have some form of PDMP, and in many states, pharmacists and physicians are able to look up a patient’s very recent prescription fills for controlled substances.

The PDMPs in the various states afford pharmacists the opportunity to obtain more information on the patient’s history with controlled substances prior to dispensing. This, however, is only part of the picture in that other clinical history is not in the database and the pharmacist must still follow up where indicated. PDMPs are being criticized for things such as patient privacy and increasing law enforcement access to the data. Hopefully, the PDMPs will serve as a positive tool rather than one that creates a chilling effect on prescribers and pharmacists who may be wary of criminal action against them and be reluctant to prescribe and or dispense.

In the process, legitimate patients may be deprived of their medications. Some states have even sought to expand PDMPs to be more inclusive. For example, New Jersey recently introduced a proposal to expand its PDMP. This proposal includes expanded requirements for providers to look up patient records and would require pharmacies “to report identifying information for any individual, other than the patient for whom the prescription was written, who picks up a CDS prescription, if the pharmacist has a reasonable belief that the person may be seeking the drug for any reason other than delivering it to the patient for the treatment of an existing medical condition.”\textsuperscript{25}

In 2018, multiple pieces of legislation and policies were initiated to address the ongoing crisis. A number of these changes impact pharmacies and pharmacists. In October 2018, Congress passed
a comprehensive opioid bill which was signed into law by President Trump. Although there is criticism that the law does not go far enough to combat opioid use and addiction, it is certainly a start. The law makes modification to the Medicare Advantage and Part D programs related to electronic prescribing, requires drug management programs for at-risk beneficiaries, and expands substance abuse treatment via telemedicine. The law also addresses federal funding for state substance abuse programs, requires additional PDMP lookups, provides grants for safe drug disposal programs, and provides for the development of educational programs for providers and patients related to controlled substances.26

In addition, former Attorney General Sessions created the Department of Justice Prescription Interdiction & Litigation (PIL) Task Force to combat the opioid crisis. The PIL is empowered to hold manufacturers accountable for unlawful practices using available civil and criminal remedies. It is also using those tools to “hold distributors such as pharmacies, pain management clinics, drug testing facilities, and individual physicians accountable for unlawful actions.”27

Responses to the opioid crisis are multifaceted and involve the individual efforts of many parties. The parties across the drug distribution chain, including manufacturers, wholesale distributors, pharmacies, and prescribers, each do their part to comply with the law and minimize the opportunities for diversion. At times each of them is identified as the culprit; however, these instances are generally associated with a particular case or incident.

Considering that over four billion outpatient prescriptions (for all types of medications) are dispensed every year in the United States, the number of opioid-related incidents is rather low as a percentage. A study of the eight most frequently prescribed opioids for analgesia estimated the number of prescriptions to be about 205 million, constituting approximately 5 percent of the four billion prescriptions in the United States and including both those legitimately and not legitimately prescribed and/or dispensed.28 Nevertheless, the consequences of opioid abuse are indeed grave, and the federal and state authorities must be ever vigilant.

Pharmacies and pharmacists must remain vigilant as well. Compliance measures are integral to minimizing the risk of litigation and administrative enforcement as the federal and state authorities continue to weed out bad actors. Pharmacists and pharmacies can look to recent litigation and enforcement actions to establish best practices, including recordkeeping and identifying the red flags of diversion.

Endnotes
2. Id.
4. 21 C.F.R. § 1306.04.
5. Id.
6. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of 21 U.S.C. § 829, and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.
7. U.S. v Hayes, 595 F.2d 258 (5th Cir. 1979).
8. U.S. v Lawson, 682 F.2d 480 (4th Cir. 1982).
10. Id. at 4.
11. Id. at 4.
12. Id. at 13–14.
14. Id.
15. Id.
16. Id.
17. Id. at 7329.
18. Id. at 7305.
20. Id.
23. Id.