The Pharmacist Activist

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"I have chosen the way of truth; I have set my heart on your laws." Psalm 119:30

Editorial

Opioid Misuse and Overdoses: Part 2

Dispensing Opioid Prescriptions Should be Restricted to Pharmacies Owned by Pharmacists

My editorials in the July 15 and August 1 issues of *The Pharmacist Activist* have resulted in readers sharing with me additional heartbreaking experiences of opioid addictions and overdoses. There has been reduced media attention to these tragedies as a result of the challenge of COVID-19 infection, but the opioid-related problems have not abated. If anything, they have increased because of the concurrent consequences of COVID-19 including isolation, unemployment, depression and other mental health challenges, and desperation. Some have responded by seeking relief with the use of drugs, and others who were already misusing drugs have increased their use of them. My focus on the opioids should not be misinterpreted to minimize the importance of addictions to other drugs (e.g., amphetamines, benzodiazepines), alcoholic beverages, and nicotine. However, the addiction to opioids is second to no other, and the greater likelihood of immediate and potentially fatal consequences with opioid overdoses, warrants priority attention to their misuse. Regardless of the reason(s) for which one became addicted, EVERY individual who is addicted needs and deserves as much support as we can provide. Although a small percentage of those addicted to drugs are effective in stopping their use "cold turkey," the vast majority are not able to do that in spite of multiple personal attempts and other interventions. We must never underestimate the power of the cravings and the agony of withdrawal symptoms when the cravings are not satisfied.

Who is vulnerable?

Some individuals are more vulnerable to opioid addiction and overdoses than others for reasons of injuries/illnesses, life circumstances, genetics, recreational use, and other factors. However, no one should ever consider themselves to be immune to addiction (i.e., "that will never happen to me!"). Indeed, such an over-confident attitude may actually be a source of risk.

Many pharmacists, physicians, and other health professionals have become addicted to opioids and other drugs. In a response to my recent editorials, one of my former students shared, "My wife has asked me, why do even health professionals get hooked on these drugs when they know the potential harm that can happen?" Ironically, the best response to that question that I am able to provide is one that I learned from this pharmacist's classmate, Ken Dickinson, whose experience I shared briefly in my August 1 editorial. When Ken would speak with my students, he would caution them about what he designated as the "magical thinking" of health professionals, particularly pharmacists. He indicated that pharmacists think we know so much about medications that we think we will not become addicted if we were treated or experimented with them for a short time. If a pharmacist gets too "high" on one drug, he/she knows which other drug will bring her/him back "down."

Illegal opioids

A large fraction of the supply of opioids that have caused the addiction and death of tens of thousands Americans have been smuggled or otherwise illegally brought into the country, or have been stolen or diverted within this country. In addition to the inherent addictive potential of the drugs, these supplies are often contaminated/"spiked" with fentanyl. Just traces of fentanyl or its other super-potent analogs can be deadly, and even addicted individuals who consider themselves knowledgeable about the drugs and the amounts they need to attain a "high" and to avoid withdrawal symptoms, fall victim to the highly variable composition, quantities, and contaminants of the products they thought they could manage. The risk is even greater for those who are experimenting or engaging in occasional recreational use of these products.

There is nothing that health professionals can do to cut off these illegal supplies of opioids. However, there are actions we can take such as facilitating the availability of naloxone for immediate use in overdoses, supporting and participating in intervention programs, educating the public regarding the risks of opioids with a warning that the actual content of illegal products can't be known or trusted, and supporting law enforcement and other agencies/individuals who are attempting to prevent the illegal distribution of opioids.

Death is a frequent outcome of the use of illegal opioid products, and

the "exporters," smugglers, distributors, and local dealers should be charged with murder and penalized accordingly. A "defense" that the victims made the choices of seeking, purchasing, and using the drugs is not acceptable.

"Legal" opioids

Another large fraction of the supply of opioids that have caused addiction and death has been manufactured and supplied by pharmaceutical companies, distributed by pharmacy wholesalers, prescribed by physicians, and dispensed by pharmacists. Diversion and theft, as well as illegal and unprofessional conduct can occur at each of the steps in the supply and distribution channels for legal opioid products. Several thousand lawsuits seeking adjudication in amounts of many billions of dollars have been filed by states, local governments, and others against the pharmaceutical companies and major wholesalers. Settlements have been reached in some situations but most are pending. These situations are very serious but beyond the scope of this commentary, and I will focus on the responsibilities of physicians, pharmacists, and corporations that own pharmacies.

A very small percentage of physicians and pharmacists have acquired the reputation of being "pill-mill" physicians and "pill-mill" pharmacists who prescribe and dispense opioids for individuals who do not have legitimate medical needs for them. I do not rule out the possibility that the illegal actions of some of these physicians and pharmacists have resulted from being threatened or blackmailed, or initially becoming "entrapped" in such activity by doing a favor for a "friend." However, these situations are the exception and the pill-mill physicians and pharmacists fully recognize the implications and potential consequences for the "patients" who typically pay substantial amounts of cash for the prescriptions and the drugs.

As with the use of illegal supplies of opioids, death is a frequent outcome of the knowingly inappropriate and excessive prescribing and dispensing of opioid products that are legally available. Should the penalties for such activity on the part of some physicians and pharmacists be any less than those for the suppliers, dealers, and pushers of the illegal opioids? Some would respond that, if anything, the penalties for the pill-mill physicians and pharmacists should be even greater because, in addition to increasing the risk for the addicts and/or those to whom they sell the products, they are also betraying their professions.

Challenges for pharmacists

There are physicians who specialize in the treatment of diseases that are characterized by severe and persistent pain, and it can be expected that they will be prescribing more prescriptions for opioids and other analgesics than physicians in other specialties. However, there are also some physicians who prescribe opioids excessively and pharmacists are well positioned to identify pill-mill doctors. This begins a sequence of events in which pharmacists are in the middle. When receiving a suspicious prescription for an opioid from a new "patient," the pharmacist is faced with numerous questions.

- Should I check the state's prescription drug monitoring program for pertinent information?
- Should I contact the physician to seek confirmation that the patient has a legitimate medical need for the opioid?
- Should I question the patient regarding the use of the prescribed medication?
- Should I decline to dispense the prescription and lie to the patient by saying we don't stock the product or that we are out of it?
- Am I placing myself and other employees at risk of harm by declining to dispense the prescription?
- Should I ask or say nothing and dispense the prescription?
- Should I contact the police regarding what I consider to be a forged or otherwise inappropriate prescription?
- Will my employer/management support the decision(s) I make?
- Are my decisions/actions consistent with my personal values and conscience, as well as my ethical and professional responsibilities?

Experienced pharmacists often consider these questions intuitively and quickly, but evaluating, confirming, and dispensing, or declining to dispense, any prescription for an opioid requires more of the pharmacist's time than would be needed in dispensing most other prescriptions. In addition, their decisions and actions may be challenged by the "patient," prescriber, and even the pharmacist's own employer/manager. Some pharmacists choose the path of least resistance, and a few succumb to greed and illegal actions and become pill-mill pharmacists.

In addition to a commitment to serve their patients with a legitimate need for opioids for pain management, pharmacists must give priority attention to fulfilling the legal, professional, and ethical standards of practice. This includes the responsibility for protecting the supply of medications against diversion and other inappropriate uses. Declining to dispense suspicious prescriptions is not enough.

Many pharmacists make the best decision to decline to dispense certain suspicious prescriptions but then face a personal ethical dilemma of whether to lie about the reason for not doing so (e.g., "we are out of stock of this medication and will not have more for several days"). I can't defend even well-intentioned lying, and owners of pharmacies should have policies to guide pharmacists in responding to the presentation of suspicious prescriptions. Such a policy could start with a provision that prescriptions for opioids (and other controlled substances) are only to be dispensed for patients who live in the community, and are known to the pharmacists who have previously provided them prescriptions and other healthcare services. The policy should also include provisions for new patients who have not previously used the pharmacy (e.g., those who have recently moved into the community) that require verification of the medical condition and the prescription with the prescriber and/or other steps to assure compliance with regulations. It is my expectation that patients with a legitimate need for opioid analgesia will understand and appreciate these policies in spite of additional time being needed to obtain their medication, whereas individuals trying to obtain opioids for misuse or diversion are likely to leave and not return.

Chain management complicity

In many situations in which chain pharmacists are committed to fulfilling their professional responsibilities in reducing the misuse and overdoses of opioids, their greatest barrier is their own management. My August 1 editorial includes the experience of Walmart pharmacists in wanting to decline to dispense prescriptions for opioids written by doctors whom they knew were running pill mills. Walmart management refused to support their pharmacists and, by doing so, federal prosecutors alleged that opioids dispensed by Walmart pharmacies had killed customers who overdosed. Also shared in that editorial is the experience of a CVS pharmacist who appropriately declined to dispense a prescription for Vicodin to a customer, only to be told by his district leader that he should have just turned his head and filled it, and threatened to terminate the pharmacist if the patient went to the news and complained.

In addition to filing lawsuits against pharmaceutical companies and major pharmacy wholesalers, state and local governments are now also suing large chain pharmacies for their role in the epidemic of opioid overdos-

es. "West Virginia sues CVS, Walmart for aiding opioid epidemic," is the title of a recent article (*The Hill*; August 18; Nathaniel Weixel), in which it is also noted that West Virginia had filed similar lawsuits against Rite-Aid and Walgreens in June. Although many of these lawsuits are not based on specific prescriptions, customers, or overdoses, they claim that aggregate purchasing and dispensing information in the many stores in the chain, to which management had access, should have resulted in recognition and action in situations in which the extent of purchasing and dispensing in particular pharmacies and regions far exceeded the anticipated legitimate market demand.

The management of chain pharmacies who had access to this data that clearly show purchases and dispensing of opioids by their stores that far exceed anticipated legitimate levels, have a responsibility to investigate and initiate appropriate actions. But they haven't done that! When the deadly consequences of their negligence and lack of action are exposed and lawsuits are initiated, their excuses are already well-rehearsed and include the following:

"Our company does not manufacture or prescribe any opioids."

"We only dispense legal prescriptions for opioids that are written by licensed physicians."

"We fill the prescriptions accurately in providing the drug that the physician has prescribed."

"We place instructions for use on the label of the container that are exactly what the physician has designated."

"Our company and our pharmacies have fulfilled our responsibilities and shouldn't be faulted for not doing more."

"The opioid crisis is not our fault. It is the physicians who are at fault and, in fact, we are suing them."

"While pharmacists are highly trained and licensed professionals, they did not attend medical school and are not trained as physicians."

"Prescriptions for opioids are not included in any metrics our pharmacists and managers are expected to attain." (This statement ignores the fact that prescriptions for opioids require more of a pharmacist's time that detracts from the time available to attain the metrics for other prescriptions).

"We are an industry leader in supporting educational programs to increase public awareness of the dangers of opioid misuse."

These excuses are disingenuous and highly insulting to their own pharmacists by denying their professional responsibilities, and must be rejected! The priority that the executives and managers of large chain pharmacies give to profits and metrics has deadly consequences for which they should be held personally responsible.

Criminal charges in situations like this are extremely difficult to prove if there is not irrefutable evidence. Therefore, most lawsuits that have been filed seek recovery for financial damages. My expectation is that these lawsuits will be successful in achieving settlements in amounts of many billions of dollars. However, regardless of the amount of the financial settlement, the plaintiffs should not permit the chains to financially settle the litigation with the provision they "acknowledge no wrongdoing." There has been wrongdoing, and to permit such a disclaimer makes a mockery of the entire legal process.

The executives and managers of these chains view the settlements of these lawsuits that they must pay as a cost of doing business. NO ONE IS HELD ACCOUNTABLE! There is no remorse for the deadly consequences of their negligent or criminal inaction, particularly if they are permitted to personally escape by "acknowledging no wrongdoing." There is also reason to question whether there will be any substantial changes in the profitable "business as usual" practices of the chains.

The situation described above is in sharp contrast to the consequences for pill-mill physicians and pill-mill pharmacists in an independent pharmacy. These physicians and pharmacists, when caught, typically have their licenses revoked and receive prison terms, and the guilty pharmacists who own a pharmacy must often close or sell it. I deplore their actions that have increased opioid misuse and overdoses but there is clearly a double standard that permits chain pharmacies to escape such consequences via large financial settlements. When chain pharmacies are implicated in activities with such devastating consequences, the licenses of the individual pharmacies involved should be revoked and/or they should no longer be permitted to dispense controlled substances. Consideration should also be given to prohibiting all of the pharmacies in the offending chain from participating in government-funded prescription programs. These are the actions that are more fitting for what they have done and much more likely to result in substantial reforms.

Chain pharmacy executives continue to refuse to accept the responsibility for the consequences of their opioid abuse-enabling actions, or inaction. Policies and activities regarding the dispensing of opioids should no longer be entrusted to individuals who are not pharmacists. The dispensing of prescriptions for opioids should be restricted to pharmacies owned by pharmacists. Yes, there will always be a few rogue pill-mill pharmacists. However, the vast majority of pharmacists will do the right things in the interest of serving their patients and protecting against opioid misuse and diversion. A secondary incentive will be the knowledge of the personal consequences (i.e. loss of license, prison term) if they do the wrong things.

Can the chains reform?

In Walmart's desperate but successful attempt to avoid criminal charges for inappropriate policies and actions that resulted in opioid overdoses, it tried to claim that it had reformed with statements such as the following:

"Walmart has created a best-in-class opioid stewardship program that reflects the Company's prioritization of patient safety over any business metric."

"Walmart streamlined the process to refuse a prescription and has directed its pharmacists to fill an opioid prescription only after the pharmacist resolves any concerns about the prescription. Pharmacists are encouraged to blanket refuse to fill prescriptions from any prescriber who has concerning prescribing habits."
(Editor's note: This latter statement is the exact opposite of a Walmart executive's previous refusal to let its pharmacists do that).

"Walmart pharmacists counsel patients using the CDC guidelines on pain management."
(Editor's questions: Is that accurate, Walmart pharmacists? Does the company actually provide the time and encouragement for you to do that?).

"Walmart recently implemented strict limits on opioid prescriptions to treat an initial acute pain event, prohibiting pharmacies from dispensing more than a 7-day supply of opioids or dosages exceeding

> 50 MME per day. Walmart is the first national pharmacy chain to impose such a limit on supply and dosage strength."
> *(Editor's interpretation: Walmart's executives, in spite of their previous flawed and dangerous decisions, still think they know what the best company policies should be, thereby preempting the opportunity for their pharmacists to exercise their professional judgment in determining the best course of action in widely-varying individual situation(s).*

Isn't it amazing what reforms can be made when there is a threat of criminal charges? But who will be responsible for implementing and monitoring these reforms? The same Walmart executives and managers whose irresponsibility resulted in the civil and attempted criminal charges. They couldn't be trusted then and they shouldn't be trusted now!

The other extreme

Stung by their companies being caught and exposed for activities that increased misuse and overdoses of opioids, some chain executives have now gone to the other extreme in wanting to become the opioid police. They have imposed restrictions on dispensing opioids that are a disservice to the patients who have a legitimate need for them. On June 16, 2020, the American Medical Association sent a letter to the CDC to identify its concerns that the guidelines that have been issued by the CDC "have been consistently misapplied by State legislatures, national pharmacy chains, pharmacy benefit management companies," and others. The AMA letter specifically identifies CVS and Walgreens for having inappropriate policies that misapply the CDC guidelines in ways that result in harm for patients.

News provided by *Seeking Justice for Pain Patients* (August 10, 2020) provides a commentary, titled, "Seeking Justice for Pain Patients: Class Action Lawsuits Filed Against CVS, Walgreens and Costco for Refusal to Fill Opioid Prescriptions for Chronic Pain Patients." The lawsuits allege that the refusal to dispense legitimate prescriptions for opioids in the dosages and quantities prescribed is in violation of the Americans with Disabilities Act, the Rehabilitation Act of 1973, and the antidiscrimination provisions of the Affordable Care Act. The commentary describes a patient's experience in filing a complaint with CVS corporate headquarters, being promised that the matter would be investigated, but never hearing back from CVS. Another patient complained to Walgreens corporate, but they were dismissive of her concerns. The commentary includes the statement:

> "CVS, Walgreens, and Costco have implemented nationwide policies that have resulted in their pharmacies treating patients who present a valid prescription for opioid medications as if they are a drug abuser, interfering with the customer's relationship with his or her treating doctor, and improperly refusing to fill legitimate prescriptions for opioid pain medication or imposing medically unnecessary limitations or other requirements before agreeing to fill the prescriptions."

The pharmacists at these chain stores have the knowledge, sensitivity, and good judgment to handle prescriptions for opioids in a caring and effective manner IF they were provided the autonomy and TIME to do so. However, the time needed for pharmacists to evaluate, dispense, and counsel with respect to prescriptions for opioids is viewed by management as being too valuable for these services to be "cost-effective" and could jeopardize attaining metrics. Therefore, the executives determine "one size fits all" policies and impose them on their pharmacists and customers. And pharmacists who violate corporate policies will be terminated. Chain pharmacists are trapped in a dilemma of wanting to exercise their professional judgment and taking the best course of action, or complying with company policies to avoid being fired.

The ultimate hypocrisy

An article titled, "Abusive Prescribing of Controlled Substances – A Pharmacy View," was published in the September 12, 2013 issue of *The New England Journal of Medicine*. The authors are two employees of CVS, a pharmacist and the physician medical director of CVS. The article focuses almost exclusively on abusive prescribing, pill mill doctors, bogus pain clinics, and an analysis of the prescriptions written by physicians identified by CVS as "high-risk prescribers." It is noted that "pharmacists must *(my emphasis)* evaluate patients to ensure the appropriateness of any controlled-substance prescription," and that "pharmacists have an ethical duty, backed by both federal and state law, to ensure that a prescription for a controlled substance is appropriate."

It is further noted that "chain pharmacies …have the advantage of aggregated information on all prescriptions filled at the chain," and that "At CVS we recently instituted a program of analysis and actions to limit inappropriate prescribing."

Conspicuously missing in this analysis and commentary of abusive prescribing is any evaluation or even mention of error-prone abusive practices and metrics in CVS pharmacies. CVS has highly-detailed data for everything in its operations but information regarding errors and lawsuits is a closely-guarded secret.

The commentary notes that pharmacists have responsibilities and an ethical duty with respect to prescriptions for controlled substances, but it fails to acknowledge that the profit-driven corporate metrics do not allow time for pharmacists to fulfill their professional and ethical responsibilities, but can result in termination of pharmacists who do not attain those metrics. From every appearance, complaint and lawsuit, errors and misuse and overdoses of opioids dispensed by CVS stores seem to have increased since the self-serving commentary was published in 2013. How has the aggregated information on all prescriptions filled at the chain been used advantageously as claimed? Why are the responsibilities and ethical duties of CVS executives and managers who are obsessed with profit and the value of company shares completely ignored, or are they not expected to have ethical duties? This is the ultimate hypocrisy!

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