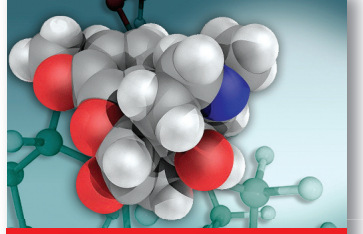

The Opioid



COVER STORY

Abuse Epidemic

Turning the Tide

BY KEVIN M. BINGHAM, ALIX MICHEL, DAVID WARD, AND RANDOLPH GORDON, MD

During the past decade, the United States has witnessed an alarming increase in the use of opioids. Today, Americans, who represent just 4.6% of the world's population, consume 80% of the global opioid supply, 99% of all the hydrocodone, and two-thirds of the world's illegal drugs, overall.[1] According to the U.S. Centers for Disease Control and Prevention, deaths from an overdose of opioid pain relievers now exceed the number of deaths linked to heroin and cocaine, combined.[2] In 2009, drug-overdose deaths actually surpassed the number of deaths from motor vehicle accidents, for the first time since the government began tracking drug-related fatalities in 1979.

In his November 15, 2012, CNN special "Let's End the Prescription Drug Death Epidemic,"[3] Dr. Sanjay Gupta noted that one American dies every 19 minutes from an accidental overdose. And the most vulnerable members of our society have been particularly affected: the number of newborns with neonatal abstinence syndrome (NAS) has tripled in the last ten years, because more and more pregnant women are abusing opioids.[4]

Here, we investigate why we're seeing a surge in opioid use, and then offer some heartening news: physicians, law enforcement agencies, attorneys general, and organizations are all working to combat this alarming epidemic. However, doctors and the companies that insure them will need to keep a close eye on an emerging phenomenon: an increase in claims wherein a physician is held to be responsible, at least in part, for the drug-related death of an individual.

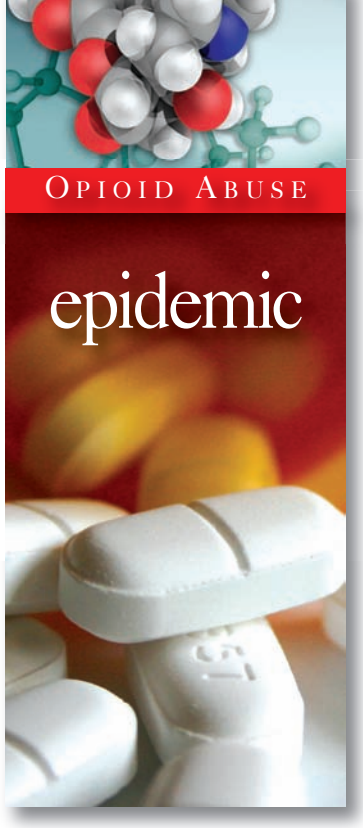
Prescription drug diversion

Prescription drug "diversion" is best defined as the channeling of licit drugs to illicit purposes. The drugs are diverted from legal and medically necessary uses to applications that are illegal and typically neither medically authorized nor necessary.[5] When taken as directed for legitimate medical purposes, prescription drugs are safe and effective. However, they are just as dangerous and deadly as illegal drugs when they are taken for non-medical reasons.

Here's how prescription drugs are typically "diverted":

1. ***Taking a medication prescribed for another person.*** People contribute, unknowingly, to this form of abuse when they give their unused pain medication to family members or friends. Some simply neglect to monitor the contents of their medicine cabinets.

2. ***Taking a drug in a higher quantity, or in a manner other***



than what was prescribed. Most prescription drugs are dispensed orally in tablets, but abusers sometimes crush the tablets and then snort or inject the powder, thereby circumventing their time-release function. The drug then enters the bloodstream and the brain rapidly, and the impact of the drug is greatly amplified .

3. ***Taking a drug for a purpose other than what the doctor prescribed.*** Students and athletes may abuse medicines for attention deficit hyperactivity disorder, to increase alertness and capacity for concentration.

4. ***Doctor-shopping to find a physician willing to prescribe opioids; forging prescriptions.***

5. ***Committing burglaries or robberies of pharmacies.*** Some drug addicts pass themselves off as legitimate home buyers, going to realtors' "open house" events to steal prescription drugs from medicine cabinets and bedroom dressers.

6. ***Rogue physicians selling prescriptions for monetary gain.***

7. ***Rogue pharmacists falsifying records, to distribute/sell prescription drugs.***

8. ***Making purchases from illegal Internet pharmacies.***

The public needs to know about the scope of this epidemic, and physicians need new educational opportunities to learn more about it. The 2010 National Survey on Drug Use and Health contains some surprising results: Among people aged 12 or older who reported using pain relievers for non-medical reasons in the past year, approximately 71% had gotten the drugs from a friend or relative (either free, purchased, or by theft). Another 17% said they had obtained them from one doctor. But fewer than 5% reported that they'd gotten their pain medications from a drug dealer.[6]

Neonatal abstinence syndrome

In fact, NAS comprises a constellation of problems that occur in a newborn after exposure to addictive illegal or prescription drugs during fetal development. The prevalence of babies born with NAS has increased greatly, in tandem with the epidemic in opioid abuse in the general population. According to a 2010 Substance Abuse and Mental Health Services Administration study, 4.5% of pregnant women aged 15 to 44 had used illicit drugs during the month prior to the study survey[7] There were 4,131,019 births in the United States in 2009[8]; it is estimated that there were approximately 186,000 babies born to mothers who used illicit drugs in that year and somewhere between 55% and 94% of neonates exposed to opioids in utero developed withdrawal signs.[9] Between 2000 and 2009, the incidence of NAS among newborns nearly tripled, increasing from 1.20 to 3.39 per 1,000 hospital births per year.[10] In 2009, approximately one baby, every hour, was born with signs of drug withdrawal,[11] and that number rose to 1.5 in 2010.

Symptoms of NAS vary widely, and may include irritability, hypertonia (or augmented muscle tone), tremors, intolerance to nourishment, seizures, and respiratory distress. In addition, low birth weight is more common in babies with this syndrome. Mean hospital charges for infants with NAS rose from $39,400 in 2000 to $53,400 in 2009.[12] The long-term effects of in utero opioid exposure on the development and health of NAS babies are unknown.

States and federal agencies fight back

In June 2011, Florida Governor Rick Scott signed the Anti-Pill Mill Bill (HB 7095) into law. Championed by Florida Attorney General Pam Bondi, the bill toughened criminal and administrative penalties for doctors and clinics that traffic in prescription drugs. The bill establishes standards of care for doctors who prescribe narcotics, requiring them to register with the Department of Health, while banning doctors from dispensing the most frequently abused narcotics.

For pharmacies and wholesale distributors, the bill tough-

"The earlier we can identify and effectively intervene in these pain management cases, the better results we see in getting people back to work and off narcotics. With early intervention, 78% of cases end up released to return to work. Naturally we see lower costs and better overall health in these cases, too."

Dr. Steven Moskowitz, Senior Medical Director, Paradigm Management Services

In 1987, medical losses represented only 46% of the dollars spent on workers compensation claims. Today, medical losses represent roughly 60% of the dollars spent on these claims.

ened oversight and strengthened the effectiveness of the prescription drug database, by decreasing the amount of time allowed for entering required data on pain medications. Attorney General Bondi's Pill Mill Initiative website describes Florida's Prescription Drug Diversion and Abuse Roadmap (2012–2015) and discusses the drivers that led to the crisis. It explains the role of the Statewide Drug Task Force, Regional Strike Force Co-Chairs, drug courts, and the state's program for substance abuse treatment.[13]

On June 11, 2012, the State of New York passed the Internet System for Tracking Over-Prescribing Act (I-STOP), the first law in the United States to mandate that physicians consult a database of a patient's prescription history before prescribing a controlled substance. Introduced by Attorney General Eric. T. Schneiderman, the bipartisan legislation passed by an overwhelming majority in the Assembly (116–0) and in the Senate, by 58–0.[14] By requiring doctors and pharmacists to report and track controlled narcotics in real time, I-STOP focuses on preventing doctor shopping and stolen or forged prescriptions. It eliminates automatic refills for hydrocodone, and includes provisions aimed at reducing the number of patients addicted to painkillers.

On June 26, 2012, West Virginia Attorney General Darrell McGraw filed a lawsuit against pharmaceutical drug distributors. In the complaint, West Virginia noted that medical providers, pharmacies, and distributors of controlled substances cost West Virginia hundreds of millions of dollars, every year. The complaint also noted that defendants acted negligently, recklessly, and at times illegally—all in contravention of West Virginia law. The lawsuit has definitely raised eyebrows among pharmaceutical distributors and their insurers.

In October 2012, Tennessee district attorneys kicked off a statewide campaign, Deceptive Danger, to combat the increasing use of prescription medication and synthetic drug abuse among the state's youth. The campaign includes an educational outreach effort for public middle schools and high schools throughout the state.[15]

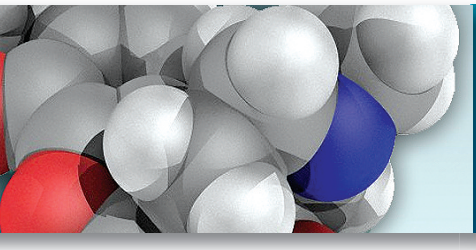
Across the country, the U.S. Drug Enforcement Administration (DEA), along with state and local agencies, is aggressively prosecuting individuals who prescribe opioids illegally and those who operate "pill mills." In some cases, doctors, physicians, nurse practitioners, and pharmacies have been compelled to surrender their federal licenses to dispense controlled substances; in more serious cases, they've had to forfeit their medical licenses to state medical/pharmacy boards. The DEA has also begun to revoke the registration of some pharmacies, banning them from selling controlled substances like OxyContin, Vicodin, Ritalin, and Xanax.

Physicians and medical boards taking action

Physicians and medical boards are also attacking the problem. The Federation of State Medical Boards provides guidance to physicians on the responsible prescribing of opioids. The website www.fsmb.org/pain-resources.html provides links to resources from federal and state governments, medical-specialty society sites, educational materials, pain assessment tools, treatment consensus statements, guides, and guidelines.

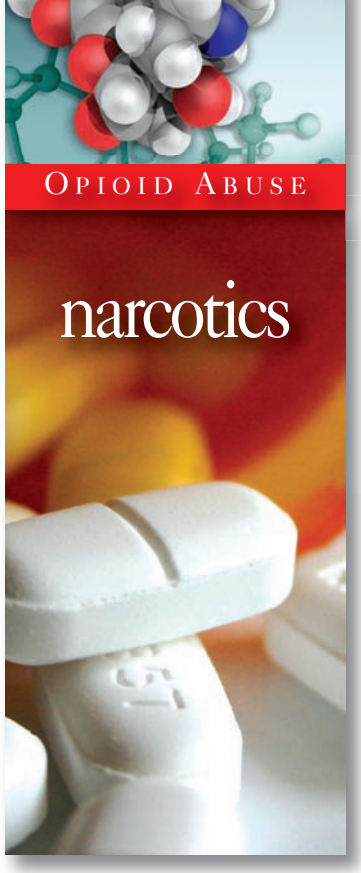
The mission of Physicians for Responsible Opioid Prescribing (PROP) is "to reduce morbidity and mortality resulting from prescribing of opioids and to promote cautious, safe and responsible opioid prescribing practices." Their website, www.supportprop.org, provides an opioid-prescribing guide called *Cautious, Evidenced Based Prescribing*, which documents the myths vs. facts about chronic opioid therapy, and lists the dos and don'ts for acute pain management and chronic pain management. The site also provides educational videos, links to other websites, and news stories on opioid prescribing and the opioid-abuse crisis.

The number of physicians who've had their license suspended by state medical boards for unlawful distribution of controlled substances and prescription drug fraud is on the rise. Medical boards are actively addressing the inappropriate and



"The defense of a long-acting opioid claim may be compromised if discovery reveals the insured did not take a REMS program covering information that may have prevented it."

Dave Troxel, MD
Medical Director
The Doctors Company



illegal prescribing of drugs. With more stories making the news about doctors forging prescriptions, becoming illegally involved with pain clinics, creating fictitious patients, not taking preventive steps on behalf of patients dying from overdoses, not checking into patients' history of prescription drug use, and more, it's clear why medical boards have been compelled to take action.

Insurance companies

The State of West Virginia's lawsuit against pharmaceutical drug distributors is already impacting insurance companies, as distributors look to their commercial general liability and commercial umbrella policies to pick up the costs of defending against the lawsuit. However, some insurers, like Cincinnati Insurance Company (CIC) are making sure that policyholders understand what their policies do and do not cover. In its October 2012 Complaint for Declaratory Judgment against their insured, CIC documents why the insurance policies they issue do not require that a company defend or indemnify the insured. The 23-page document walks the reader through CIC's policy language, specifically addressing items such as the insuring agreement, the definition of an occurrence, and the definitions of bodily injury and property damage; it also provides details on when the insurance protection does not apply.

It is not always apparent, however, which patients have a legitimate need for pain control vs. those who are merely feeding an addiction or want the drugs for later resale.

With prescription drug costs accounting for approximately one-fifth of all workers' compensation (WC) medical expenses, WC insurers are doing more to control the cost of these drugs.[16] They've been setting up comprehensive prescription drug networks, supporting tort reform efforts, promoting evidence-based pain diagnoses, performing utilization reviews, weaning injured workers off of addictive prescriptions drugs, and helping workers return to work more rapidly. The Pennsylvania Commonwealth Court issued a recent decision which found that an injured worker's overdose is compensable under workers comp coverage, *J.D. Landscaping v. WCAB (Heffernan)*, so WC insurers will need to stay focused on what happens with policyholders' opioid medications.

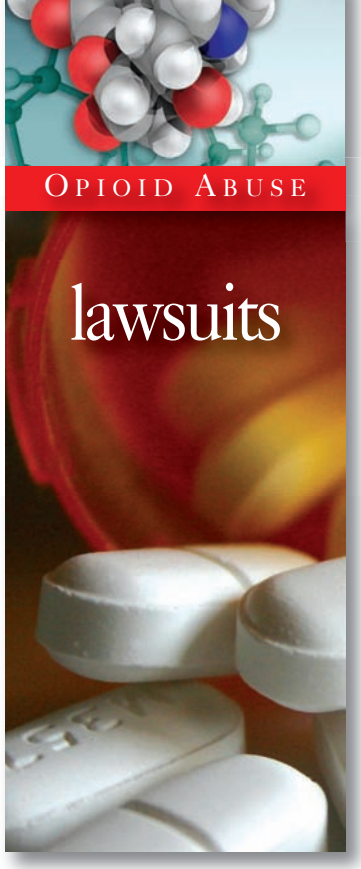
For the medical professional liability (MPL) insurers of physicians and hospitals, medication errors from faulty prescribing, incorrect charting of allergies, improper dosing, and poor handwriting have been around for many years. An analysis of 2,646 claims closed by The Doctors Company in 2011 revealed that 5.8% contained medication-related errors. These claims, 17.5% of which were related to narcotic analgesics, involved all of the medical specialties. The errors identified in these claims include:

- Wrong medication (32%)
- Monitoring errors (21%) (most involved Coumadin, Lovenox, and Gentamicin)
- Wrong dosage (17.5%)
- Failure to follow guidelines or protocols (13.5%)
- Drug administration errors (10%)
- Ordering errors (6.5%).[17]

With the expanding use of electronic medical records, computerized physician order entry, risk management training, and government efforts, there's been some progress in reducing medication errors. However, the impact of opioid addiction, on both patients and their families, is just beginning to emerge as a cause of action in MPL claims. With the news media shining a bright light on hospitals and physicians, we may see more lawsuits for wrongful death, for physicians' prescribing patterns that are allegedly conducive to drug addiction, and improper supervision of mid-level healthcare professionals in the very near future.

In December 2012, Newsday.com reported that Long Island State Supreme Court Justice William B. Rebolini is allowing the family of a victim in the deadly Haven Drugs pharmacy robbery to proceed with a wrongful-death lawsuit against the doctor who prescribed the shooter's prescription medication. The judge stated that "a medical provider may owe a duty to protect the public from the actions of a drug addict, and he may be found to have breached that duty if he creates or maintains the addiction through his own egregious conduct." Even though the victim is not the doctor's patient, the doctor's role in overprescribing pills to the pharmacy shooter may create a duty to protect the public from the actions of a drug addict.[18]

It will be important for MPL insurers to monitor cases like the Haven Drugs pharmacy robbery. Could this ruling signal an emerging trend toward broadening the scope of what constitutes a physician's duty in opioid prescribing? As courts across the country add further clarification about the physician's role in protecting patients and the public from opioid addiction, insurers should take advantage of federal, state, and physician efforts



like PROP for ongoing education of their insureds on new opioid-related laws and court cases, as well as strategies for minimizing risk, such as the Food and Drug Administration's Risk Evaluation and Mitigation Strategy (REMS).

Physicians in a dilemma

The vast majority of physicians are first committed to caring for their patients according to the Hippocratic maxim, "First, do no harm." Most physicians are well aware that some addicts will do just about anything to get drugs, and they will make it as difficult as possible for these addicts to gain access to opioids. Otherwise, they do harm to these addicts by feeding their addiction.

It is not always apparent, however, which patients have a legitimate need for pain control vs. those who are merely feeding an addiction or want the drugs for later resale. There is no test that is 100% accurate in identifying the motivation of those who request strong drugs like opioids in an office visit. The physician must decide based on the personality and history of the patient in front of him, and use his best judgment to determine whether the patient has a legitimate need for pain control and, if so, if an opioid is appropriate. On one hand, denying a legitimate need for pain control harms those patients who really are in pain. On the other, feeding opioids to an illicit drug seeker harms him, by enabling his illicit and self-destructive activity.

Deciding where to draw the line can be very difficult; in many cases, the physician is caught in a "damned if you do, damned if you don't" dilemma. Education may be helpful, but physicians have been wrestling with the question of just how to differentiate patients with valid requests for pain medication from those likely to abuse these drugs, ever since their medical school days. So mandating additional training may be considered unnecessary and burdensome: just look at some of the reactions posted on the American Academy of Family Physicians website to the notion of mandatory CME.

In contrast, the methods and databases that enhance a physician's ability to filter out drug seekers from patients with legitimate needs are welcomed by physicians when they are convenient and add new knowledge. As the federal government, MPL insurers, and boards of medicine all look to find better ways to help physicians sort through this dilemma, they need to bear in mind that, in the vast majority of cases, the problem lies with the addiction per se, and the individuals who are trying to benefit from the situation. Physicians can, and should, be part of the solution. Doctors' efforts to determine which patients are looking for legitimate pain control, vs. those with illicit uses in mind, should be supported in a way that recognizes that their intent is, "First, do no harm."

Conclusion

So, while the United States has admittedly seen an epidemic in opioid abuse, substantiated by the sobering statistics presented in the article, the tide seems to be turning:

- *States* are passing new laws, imposing stiffer penalties, educating citizens, and coordinating with federal agencies, in order to prosecute wrongdoers more aggressively.
- *Medical associations and medical boards* are educating their members, encouraging the practice of well-informed pain management, and suspending the licenses of physicians and clinics who abuse the trust of patients.
- *Physicians* are recognizing the importance of pain management through educational campaigns, training, and the efforts of organizations like PROP.
- *WC insurers* are taking good advantage of states' efforts, evidenced-based guidelines, utilization reviews, and pain management specialists to help injured workers.

However, given the relentless coverage of the opioid abuse epidemic by the news media, the states, medical boards, judges, and jurors are increasingly likely to find individual physicians, pain clinics, distributors, and insurance companies culpable for this epidemic. The time is now: everyone involved in prescribing for and managing pain should take another hard look, to see how they can help in resolving this crisis. PIAA

For related information, see www.deloitte.com.

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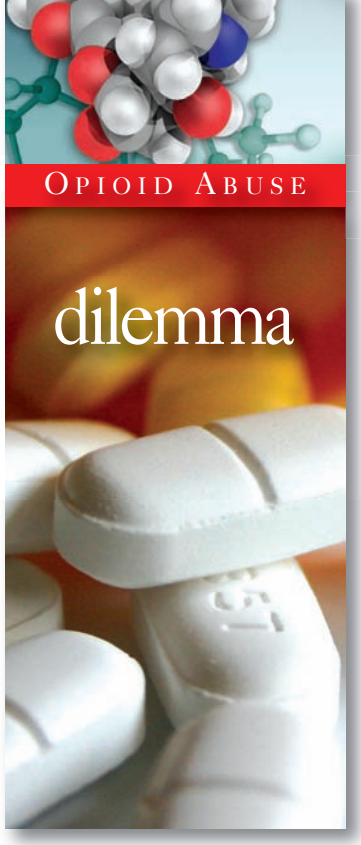

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