The facts seem all too clear. In 1999, 8,200 people died from opioid overdose. Fifteen years later, that number had more than quadrupled to 33,091. And the trend has been accelerating (see chart). Today, more people die of opioid overdose in just two years than died during all of the Vietnam war.

According to many, the cause of the opioid epidemic is just as clear. “We now know that prescription opioids are a driving factor in the 15-year increase in opioid overdose deaths,” notes the Centers for Disease Control and Prevention (CDC). “Since 1999, the amount of prescription opioids sold in the U.S. nearly quadrupled, yet there has not been an overall change in the amount of pain that Americans report.”

If you assume the problem is doctors writing too many prescriptions for opioids, the solution is painfully obvious: just clamp down on prescribers. That is precisely what an increasing number of states are doing, according to Jennifer P. Schneider, MD, PhD, a nationally recognized expert in the management of chronic pain with opioids and a prolific author on the subject.

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“They are telling primary care physicians that they can’t prescribe more than a low dose, typically the starting point for treatment, without consulting a pain specialist.” But Schneider points out there are nowhere near enough pain specialists to make this practical. “That’s why it’s such a useless and destructive approach,” she says, “because the primary care doctors (who are generally the ones prescribing opioids) just say, ‘I’m not going to prescribe this stuff anymore.’ And that means millions of legitimate chronic pain patients will be deprived of effective treatment.”

But what if the driving force behind the epidemic is not simply irresponsible over-prescribing? What if, contrary to the CDC’s assertion, there has been an increase in the amount of pain Americans are experiencing?

That is the conclusion suggested by Princeton economists Angus Deacon and Anne Case. In 2015, the husband-and-wife team discovered a startling reversal in the life expectancy of middle-aged white Americans with less than a high school education. After more than a century of decline, the mortality rate of this group began to increase 15 years ago and has been climbing ever since. The immediate causes were clear, Deacon told NPR. “We knew suicides were going up rapidly, and that overdoses mostly from prescription drugs were going up, and that alcoholic liver disease was going up. The deeper questions were why those were happening.”

The reason, the economists propose, has been a collapse in the labor market. Deacon, who won the Nobel Prize in 2015, explains it this way: “If you go back to the early ’70s when you had the so-called blue-collar aristocrats, those jobs have slowly crumbled away and many more men are finding themselves in a much more hostile labor market with lower wages, lower quality and less permanent jobs. That’s made it harder for them to get married. They don’t get to know their own kids. There’s a lot of social dysfunction building up over time. There’s a sense that these people have lost this sense of status and belonging. And these are classic preconditions for suicide.”

The Deacon-Case study helps explain why opioid abuse has grown so dramatically over the past 15 years, and why according to the CDC, the growth has been concentrated among older white Americans. Rather than a rise in irresponsible physician prescriptions, the opioid epidemic seems to have been fueled, in large part, by the same massive economic and social dysfunction driving what Case and Deacon have called “deaths of despair.”

![Graph: Drug overdose deaths involving opioids: US 2000-2014](Graph)


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**UPCOMING LIVE COURSES**

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May 19-21 | Florida

**THE PBI LAWS, RULES, & ETHICS COURSE**
Florida Edition
May 19 | Florida

**PBI MEDICAL RECORD KEEPING COURSE**
May 20-21 | Florida

**THE PBI PRESCRIBING COURSE:**
Opioids, Pain Management, and Addiction
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**PHARMACY ETHICS AND PROFESSIONALISM**
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**WE WANT TO KNOW WHAT YOU THINK**

**PLEASE LET US KNOW WHAT YOU THINK OF THE PRACTICAL PROFESSIONAL, AND WHAT YOU’D LIKE TO SEE IN UPCOMING ISSUES.**
O BEGIN WITH, MEDICAL SCIENCE NOW RECOGNIZES
THREE TYPES OF PAIN. The most common is the pain
you feel when you hit your thumb with a hammer. Such basic
“nociceptive pain” arises when sensory neurons (nociceptors)
experience damaging or potentially damaging stimuli. The
cause may be a misguided hammer or a malignant tumor,
but the pain-processing mechanism is essentially the same:
healthy nerves respond to a stimulus by sending pain signals to
the brain.

Neuropathic pain, on the other hand, is generated by damage
to the nerves themselves, which send pain signals to the brain
regardless of any external stimulus.

In addition to these two well-established types of pain,
researchers now believe that there is a third type, triggered
by emotionally traumatic experiences, such as child abuse.
According to a 2016 article in The Journal of Family Practice
(JFP), “Research demonstrates through objective means that it
is possible for a person to feel real pain in response to purely
psychological factors that have sensitized the nervous system
over weeks and months, in the absence of tissue injury.”

OPSIODS HELP RELIEVE BASIC CHRONIC PAIN SAFELY AND
EFFECTIVELY. While neuropathic pain is often adequately
treated by non-opioid medications, such as gabapentin (with
the addition of opioids if needed), opioids are well suited to
treating chronic nociceptive pain. The goal of such treatment is
two-fold: to relieve the pain and improve the person’s ability to
function. Opioids are often very effective at relieving the pain,
says Schneider, which allows patients to engage in other types
of treatment—physical therapy and exercise, for example—that
can help them meaningfully improve their functioning.

Schneider, who teaches a PBI course on Prescribing, tells those
in her class that once most legitimate pain patients understand
the importance of the non-opioid therapies, they are usually
compliant. Doctors need to follow up to make sure, but since
the patients’ goal is to improve their quality of life, not get
high, they are more than willing to do what they need to. In
fact, some patients are so worried about becoming addicted to
opioids that they resist not the physical therapy and exercise,
but the medications themselves. That’s a mistake based on
the common misperception that physical dependence and
addiction are one and the same.

PHYSICAL DEPENDENCE IS VERY DIFFERENT FROM
ADDICTION. A person is considered physically dependent on
a drug if stopping it abruptly causes withdrawal symptoms.
People become physically dependent on a wide range of
substances, not just opioids. If you regularly drink a lot of
caffeinated coffee, for instance, and suddenly stop, you’re
likely to suffer a number of withdrawal symptoms, including,
headache, sleepiness, irritability, lethargy and lack of
concentration. The way to end physical dependence on caffeine
without suffering withdrawal is to taper off gradually. The same
is true of most physical drug dependency. Whether the drug
is caffeine, an antidepressant, a corticosteroid or an opioid,
patients whose dosage is carefully reduced generally avoid the
hardship of withdrawal.

WHAT PHYSICIANS
NEED TO KNOW
ABOUT CHRONIC PAIN
AND OPIOIDS

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Addicts, too, could avoid the pain of withdrawal by tapering off their drug of choice. The problem is they can’t. That’s part of what it means to be addicted. In fact, the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, defines addiction as a cluster of three basic behaviors. People who suffer from “Substance-Related and Addictive Disorders” (1) lose control over their drug use, (2) are unable to stop using their drug despite increasingly severe adverse consequences and (3) become obsessed with obtaining and using the drug, and increase the amount they take over time.

This last characteristic gets to the heart of addiction. Addicts use opioids not to relieve pain but to gain a sense of euphoria. Since tolerance to this mood-altering effect develops rapidly, addicts have to keep using more of their drug to achieve the same high.

The process is very different among pain patients. To minimize unpleasant side effects, such as sedation or nausea, these patients are generally started on a low dose of an opioid. Their bodies quickly develop a tolerance to the unwanted side effects. As the nausea or sedation fades, the dosage is gradually increased until their pain is sufficiently relieved. At this point, the legitimate pain patient is generally content to level off, which is why, studies show, addiction is rare among people who take opioids for pain.

In short, for the vast majority of chronic pain patients, the use of opioids leads to improved functioning not addiction. And properly managed by a trained physician, these drugs are safe. In fact, the American Geriatric Society has said they are safer than nonsteroidal anti-inflammatory drugs (NSAIDs) for geriatric patients.

**OPIOIDS HELP RELIEVE EMOTIONALLY-INDUCED PAIN IN TWO WAYS.** Once someone has suffered serious emotional trauma, whether in childhood or as an adult, explains Schneider, “Their nervous system can be viewed as being ramped up.” These patients have become more sensitive to pain, as if their bodies are on high alert for signs of danger. Their physical pain is heightened by their often unrecognized emotional pain.

Such emotionally traumatized patients are often convinced that they are benefiting from opioid treatment, in part because some opioids are also effective in treating psychological issues such as anxiety and depression (Oxycodone, for example, is an effective anti-anxiety drug). Schneider cautions, however, that such patients often resist including other forms of therapy along with their use of opioids. These other therapies, which are important to the patients’ long-term recovery, might include a home exercise program to strengthen their muscles, physical therapy, counseling, Eye Movement Desensitization and Reprocessing Therapy (EMDR) and antidepressant or anti-anxiety drugs.

Better still is diagnosing the emotional component of a patient’s chronic pain upfront, before they become accustomed to the emotional/physical relief opioids offer. The authors of the JFP article suggest that physicians include assessments of anxiety, depression and developmental trauma as a regular part of their initial assessment. Schneider advises physicians in her Prescribing class to have patients fill out the Adverse Childhood Experiences (ACE) questionnaire, which helps identify different types of abuse and neglect patients have suffered, as well as other hallmarks of a rough childhood.
Although larger societal forces may be causing the opioid epidemic, physicians still have a significant role to play in helping to end it. By improving their management of pain patients, doctors can significantly reduce drug abusers primary source of opioids—friends and relatives with legitimate prescriptions.

Addicts get their drugs any way they can. Surprisingly few buy them on the street from pushers. Some get them from dishonest doctors and pharmacists, who write and fill prescriptions for money—so called Pill Mills. But according to the annual National Survey on Drug Use and Health, “75% of all opioid misuse starts with people using medication that wasn’t prescribed for them.”

The CDC reports, “Most people who abuse prescription opioids get them for free from a friend or relative.” Even among those who are most at risk of an overdose, more than half get their drugs from friends and relatives, either free or by buying them. In some cases, addicts steal the drugs from friends and relatives.

All of which begs the question, why aren't physicians stopping this practice? Some patients may be foregoing their own pain relief to “help” an addicted relative or to make some extra cash. More commonly, one assumes, patients find ways to restock their supply. They tell their doctor they lost their pills; they claim they need a higher dose; or they request early refills because of, say, an upcoming trip. Each of these strategies should be a red flag to doctors that diversion is a likely possibility, at which point, it is the physician’s obligation to discern what’s going on and take immediate action to stop any diversion.

The physicians (mostly primary care physicians) and pharmacists (see below) who fail to heed the warning signs, are the ones sent by their boards to remedial classes like the one Schneider teaches. What they learn in class, among other things, is how they can provide their patients with the most effective treatment and prevent the diversion of patient prescriptions. The following is an abbreviated list of these best practices:

**A Thorough Assessment is the First Step in Treating a Pain Patient.** In addition to a detailed medical history and physical exam, it’s important to determine how pain has curtailed the patient’s functioning and to establish goals for the therapy. There should be a base line urine drug test and an assessment of the patient’s risk of opioid abuse (see Resources for opioid risk assessment tools).
URINE DRUG TESTING (UDT) SHOULD BE CONDUCTED RANDOMLY AND FOR CAUSE. The tests can determine if the patient is taking prescribed medication or diverting it, or taking any drugs not prescribed. Physicians should be aware of the usual practices of labs they use and request additional tests as needed. A common problem is that some prescribed drugs yield metabolites that were not prescribed.

STATE MONITORING PROGRAMS ARE AN IMPORTANT RESOURCE. All but one state have Prescription Monitoring Programs (PMP) that provide an up-to-date list of patients’ prescriptions for controlled substances. A check online will tell the physician if a patient is filling prescriptions from multiple providers.

PROVIDING STRUCTURE. It’s important for the patient and physician to agree upfront to basic ground rules, usually by signing an agreement that spells out what each can expect. Breaches of the agreement are evaluated on a case-by-case basis. Typically, agreements include such items as:

- Only one physician prescribes opioids for the patient.
- The patient uses only one pharmacy of their choice.
- Patient will not change the dose without first consulting with physician.
- Physician will not give early refills (unless there is a valid reason).
- Patient agrees to consultations or physical therapy referral by physician.

- Patient does not use illegal drugs.
- Patient agrees to urine drug testing whenever requested by physician.

INITIATING OPIOID THERAPY. To minimize negative side effects, it is often best to start out with low doses of immediate-release opioids, and titrate up until an effective dose is reached. At that point, Schneider recommends converting patients to sustained-release formulations, which now include abuse-deterrent factors (which ironically have led to increased heroin abuse among addicts, see “ ‘Safer’ OxyContin Caused Thousands of Heroin Deaths, Researchers Find”).

FOLLOW-UP VISITS: EVALUATING TREATMENT OUTCOMES. Patents on opioids need to be seen regularly, usually every one or two months, to assess the effectiveness of the current plan and make changes as needed. The physician should ensure that the patient is following the plan agreed to, including any imaging studies, urine tests, physical therapy, etc. A handy way to remember the key elements of these follow-up visits are the five A’s:

- ANALGESIA—level of pain on a scale of 1-10
- ACTIVITIES OF DAILY LIVING—be as specific as possible to assess improvements in functioning
- ADVERSE EFFECTS—ask about side effects, which commonly include constipation
- ABERRANT DRUG—related behaviors — these might include requests for early refills or UDT positive for cocaine
- AFFECT—is the patient showing signs of depression, for example

KEEPING THOROUGH RECORDS IS CRUCIAL WHEN TREATING PATIENTS WITH OPIOIDS. In addition to documenting all of the items mentioned above, it is important to keep careful track of all prescriptions for a controlled substances, whether written or phoned in—preferably in one easily accessed section of the patient’s records. Keeping accurate and complete records ensures the best possible care for patients and affords physicians important protections if decisions or actions are ever questioned by authorities. While keeping extensive records is time consuming, the growing use of specialty-trained scribes offers a possible solution. One study even suggests that scribes actually pay for themselves by enabling doctors to see an average of two more patients per day.

EXIT STRATEGIES. Given the complexities of safely tapering patients off opioids, it’s best to establish a plan upfront for how this will be accomplished if needed.

WE WANT TO KNOW WHAT YOU THINK

PLEASE LET US KNOW WHAT YOU THINK OF THE PRACTICAL PROFESSIONAL, AND WHAT YOU’D LIKE TO SEE IN UPCOMING ISSUES.
PHARMACISTS are the LAST LINE of DEFENSE

According to the California State Board of Pharmacy, Pharmacists “are the last line of defense in preventing controlled substances from getting into the wrong hands.” A precedential case in 2013 established that pharmacies have a “corresponding responsibility” to ensure that every prescription they fill for a controlled substance is for a legitimate medical purpose. If they fail in this obligation, they are subject to the same penalties as the physician who wrote the prescription.

State laws differ slightly, but in general, pharmacists must use their own professional judgement to determine if the prescription is legitimate. Jack H. Raber, Pharm.D., has more than 40 years of experience in a variety of clinical settings and now teaches pharmacy risk assessment and management at the University of Southern California School of Pharmacy. Raber, who is also a PBI faculty member, explains, “Pharmacists have to use their training, their education, their skill—the totality of their experience—to determine if a prescription should leave the pharmacy as written or if it needs further investigation.” If the pharmacist has good reason to suspect a problem, he or she must decline to fill the prescription.

High profile prosecutions have brought home the seriousness of this obligation. In 2016, the U.S. Attorney in Massachusetts announced that CVS Pharmacy, Inc. had agreed to pay $3.5 million and entered into a three-year compliance agreement with the DEA to resolve allegations that 50 of its stores violated the Controlled Substances Act by filling prescriptions that were incomplete, lacked DEA numbers, or were for substances prescribed outside the scope of the prescriber’s usual course of professional practice.

RED FLAGS FOR PHARMACISTS.
To help pharmacists quickly and effectively determine if they should fill a prescription, the California Board put together the following list of Red Flags. A pharmacist who notices one or more of these warning signs has reason to be suspicious.

- Irregularities on the face of the prescription itself
- Nervous patient demeanor
- Age or presentation of patient (e.g., youthful patients seeking chronic pain medications)
- Multiple patients all with the same address
- Multiple prescribers for the same patient for duplicate therapy
- Cash payments
- Requests for early refills of prescriptions
- Prescriptions written for an unusually large quantity of drugs
- Prescriptions written for duplicative drug therapy
- Initial prescriptions written for strong opiates
- Long distances traveled from the patient’s home to the prescriber’s office or to the pharmacy
- Irregularities in the prescriber’s qualifications in relation to the type of medication(s) prescribed
- Prescriptions that are written outside of the prescriber’s medical specialty
- Prescriptions for medications with no logical connection to an illness or condition

AWARENESS OF THE LOCAL SITUATION AND PLAYERS IS ALSO IMPORTANT.
In addition to knowing their state’s requirements for dispensing controlled substances, pharmacists should know the popular drugs of abuse for their area, and get to know local prescribers (and their signatures) as well as their patients.

OTHER BEST PRACTICES INCLUDE:
- Using your state prescription drug monitoring program and paying attention to enforcement actions.
- Requiring a government-issued photo identification prior to dispensing controlled substances.
- Calling the number listed in the pharmacy’s system rather than the phone number on the prescription.
- Communicating with other pharmacies if you receive a prescription that was denied by them or if you deny a prescription.
- Communicating with law enforcement and regulatory agencies (State Board of Pharmacy, State Medical Board, local DEA office, and local sheriff’s office or police department).

This year, the Department of Justice announced that Costco Wholesale would pay $11.75 million to settle allegations that the company’s pharmacies, among other things, violated the Controlled Substances Act by filling prescriptions that were incomplete, lacked DEA numbers, or were for substances prescribed outside the scope of the prescriber’s usual course of professional practice.
RESOURCES

2 COMMONLY USED OPIOID RISK ASSESSMENT TOOLS ARE:

1. The 5-item Opioid Risk Tool (ORT) Questionnaire
2. The Screener and Opioid Assessment for Patients in Pain (SOAPP), which is available in varying lengths.

Find your state’s Prescription Monitoring Program HERE.

RELEVANT READING

“A Practical Introduction to the Use of Opioids for Chronic Pain,” by Jennifer P. Schneider

“Opioid Addiction Is a Huge Problem, but Pain Prescriptions Are Not the Cause,” by Maia Szalavitz

“Safer OxyContin Caused Thousands of Heroin Deaths, Researchers Find,” by Zachary Siegel

Understanding the Epidemic, CDC

The Forces Driving Middle-Aged White People’s ‘Deaths Of Despair,’ NPR

Drug Overdose Deaths in the United States, 1999–2015, CDC

The Pharmacist’s Role in Preventing Prescription Drug Abuse

Corresponding Responsibility, It’s the Law, California State Board of Pharmacy

THE PBI LAWS, RULES, & ETHICS COURSE: FLORIDA EDITION

5 CME CREDIT HOURS

This course is taught by Florida attorney(s) who specialize in administrative healthcare law and select PBI faculty whose practices focus on medical ethics and risk reduction. Participants will: Become current on relevant healthcare laws & regulations impacting clinical practice, Obtain knowledge of federal & state prescribing laws regulating opioids, Learn to reduce the risk associated with pain management, AND much more.

Available in Orlando May 19th and November 17th, 2017

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