

Assembly Bill 623 – Opioid Abuse Prevention

Assemblymember Jim Wood

EXISTING LAW

Current law allows a health care service plan to require use of particular drugs or “step-therapy” prior to accessing other types of drugs. Currently, pharmacists are required to provide counseling to patients or representatives when requested or when the pharmacist believes it is warranted.

BACKGROUND

Abuse of opioid medications has steadily increased in the past decade and we are now facing a crisis.

- More than 60 people die every day in the US from prescription drug overdoses.
- Approximately 6.5 million people in the US abused prescription drugs in 2013, more than double those that abused heroin, cocaine and hallucinogens combined.
- Drug overdose is the third leading cause of injury and premature death in Los Angeles County.

The crisis is particularly acute with our youth.

- Almost 1.5 million Californians (age 12 and over) are estimated to have abused painkillers in a year.
- More than half of the nonmedical users of pain relievers, tranquilizers, stimulants, and sedatives aged 12 or older got the prescription drugs they most recently used "from a friend or relative for free."

The cost to society and our health care system is significant.

- Prescription opioid abuse is estimated to cost the United States about \$56 billion annually due to health costs, criminal justice costs and lost productivity.
- Annual medical costs for abusers are approximately \$11,000 higher than non-abusers.

One of the new tools to help in the fight against abuse are abuse deterrent formula (ADF) opioids. Traditional opioids are crushed or dissolved for the purpose of snorting, smoking or injecting the drug to achieve a faster and more potent high. While it is estimated that these methods account for 30% of the abuse, this form of abuse results in the majority of ER visits, hospitalizations and deaths.

Abuse Deterrent Formulation (ADF) incorporates technology designed to prevent tampering while providing patients with needed pain relief. The FDA has approved five ADF opioids and has an additional thirty in the pipeline for approval, including ADF generics.

The FDA considers the development and approval of ADF products to be a high public health priority. Researchers have found this technology has resulted in cost savings associated with reduced abuse of \$430 M in medical care and almost \$100 M in the criminal justice arena.

Additionally, opioids with ADF lose their street value since they are more difficult to abuse.

Not all patients require ADF opioids and since many prescriptions will continue to be written for the more traditional formula, efforts are needed to minimize abuse in those cases as well. To assist in reducing the number of pills in circulation and potentially available for abuse, informal policies that may exist encouraging a monthly supply for patients should be addressed and anyone receiving opioids that can be manipulated should be counseled on the potential for abuse. Education for patients on how to properly store and dispose of these medications is a valuable tool for raising awareness and heightening sensitivity.

A variety of states are considering legislation related to opioid abuse and ADF opioids now that a number of ADF opioids have been approved by the FDA and are available. These states include Colorado, Connecticut, Florida, Kansas, Maryland, Mississippi, New Jersey, Oklahoma, Rhode Island, Tennessee, Vermont and Virginia.

BILL SUMMARY

AB 623 attempts to address opioid abuse by pursuing multiple strategies. Various approaches are necessary because there is not one simple solution to combating opioid abuse. The bill does the following:

- Requires health plans to allow a provider to prescribe and provide coverage for less than a 30 day supply of opioids.
- Prohibits health plans from requiring step therapy where a patient must try and fail on an opioid before getting access to an opioid with ADF technology.
- Requires health plans to have the same prior authorization process for opioids with and without ADF.
- Requires a pharmacist to inform patients how to store and dispose of opioids as part of their counseling.

SUPPORT

Patient Organizations:

American Chronic Pain Association
Power of Pain Foundation
US Pain Foundation
Partnership for Drug Free Kids
The Wall Las Memorias
Healthy African American Families
Lupus Foundation of Southern CA
Neuropathy Action Foundation
International Foundation of Autoimmune Arthritis
CA Hepatitis C Task Force
The Western Neuropathy Association
Spondylitis Association of American

Providers:

California Pharmacists Association
CA Society of Physical Medicine & Rehabilitation
CA Academy of Physician Assistants
California Urological Association
CA Academy of Family Physicians
American Academy of Pain Management
American College of Private Physicians
Alliance of Patient Access

Law enforcement:

CA State Sheriffs Association

Veteran Groups

American GI Forum of California



STATUS

Assembly Health Committee – 4/21

FOR MORE INFORMATION

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WHAT PEOPLE ARE SAYING ABOUT AB 623

"The solution to combatting the abuse of common street drugs and prescription medications is anything but simple. It is a multi-agency, multi-layered, multi-communities problem that cannot be solved with any one policy or plan. Instead of turning our heads from this, we must chip away at drug abuse with the tools that we do have."

"I have seen firsthand the correlation between drug abuse and crime and the lives lost and destroyed as a result. I view these abuse deterrent formulations as a substantial step in facing opiate abuse and reducing crime and cutting law enforcement costs."

- Brent Meyer, Sacramento police officer and the statewide vice president of PORAC
"Drug problem at the root of crime" - Capitol Weekly 2/12/15

"These abuse-deterrent formulations will reduce the abuse of prescription drugs, and ultimately, along with more education and other interventions, improve the health of our community."

"Prescription drug abuse affects mostly our youngest and most vulnerable, those between the ages 12 and 17. For these young children, prescription drugs are easy to find, and even easier to ingest or snort, by crushing, cutting or grinding. And since the opioids provide an almost instantaneous high, the potential for abuse of these formulations is intensified."

- Pedram Salimpour, MD, and Rocky Delgadillo, President and CEO of the Los Angeles County Medical "Abuse-deterrent opioids will help curb prescription drug deaths"
- Los Angeles Daily News 3/12/15

"This technology is only part of the solution; but it is a solution nonetheless. Patients that have struggled with addiction or substance abuse in the past, those who live with others who are current or recovering addicts and those who live with teens or young adults who may seek opioids for recreational use can all benefit from ADFs."

"For the sake of those with legitimate, life-altering pain and for the safety of those prone to use these medications for non-medical use, I urge our lawmakers to stand up for policies that preserve and improve patient access to this new technology. Failing to do so would be failing to do all we can to protect our residents."

- Barby Ingle, chairman of the board for the Power of Pain Foundation "Tamper-proof pain drugs deserve support" - Palm Springs Desert Sun 2/28/15

"These new formulations will not eradicate prescription drug abuse in the United States. But they can go a long way in curbing access to medications that can be used for illicit purposes, and to providing humane pain management to those who truly need it. We owe that to the men and women who have served in combat and suffer from unimaginable pain caused by injuries that, in past eras, would have killed them."

- Robert O'Neill, Vietnam-era veteran and chairman emeritus of the VetFund Foundation "Pain relief for vets doesn't have to lead to deadly prescription drug addiction" - Sacramento Bee 12/12/14

Los Angeles Daily News

Abuse-deterrent opioids will help curb prescription drug deaths: Guest commentary

By Rocky Delgadillo and Pedram Salimpour

Los Angeles is one of the greatest cities in the world, but we have our share of problems. While celebrity drug overdoses get the vast majority of the media attention devoted to the topic, little notice is drawn to the issue as it relates to the family living right on your block. And as it turns out, drug overdoses have grown to become the third-leading cause of injury and premature death in Los Angeles County.

This is no small problem. Los Angeles is the 17th largest economy in the world and home to about 12 million people. That means that the problem is, well, scalable. Buoyed by the abuse of easily accessible prescription drugs, this epidemic is insidiously and quietly tearing at the fabric of our community. Unfortunately, as Los Angeles goes, so goes the rest of the country.

As members of this community first, but also as representatives of the Los Angeles medical community, the problem of prescription drug abuse has become of growing concern. As doctors, our mission is to provide unimpeded health care to individuals, but one of the biggest hindrances to providing that care safely today is self-abuse.

Every day more than 60 people in the United States die from prescription drug overdose. An unbelievable 70 percent of these opioids are obtained from a friend or relative. Overall, 84 percent of the opioids that cause unintentional deaths are obtained through a prescription, and then somehow abused or misused. Our clinical community ought to create solutions, a way to work to prevent these avoidable deaths.

What makes these numbers even more tragic is that prescription drug abuse affects mostly our youngest and most vulnerable, those between the ages 12 and 17. For these young children, prescription drugs are easy to find, and even easier to ingest or snort, by crushing, cutting or grinding. And since the opioids provide an almost instantaneous high, the potential for abuse of these formulations is intensified.

Still, the problem of prescription drug abuse isn't just about the health of individuals. Hospital staff and resources are by necessity allocated to dealing with overdoses that can be prevented. Due to lost productivity, health resources and justice system expenditures, prescription drug abuse costs the U.S. in excess of \$56 billion annually. Imagine those resources dedicated to education or medical research.

What are the viable solutions? Education and diversion programs are wonderful long- and short-term programs. But the problem also rests in the chemistry of the compounds. To help, researchers are developing abuse-deterrent formulations (ADF), medication that will provide the same pain relief as conventional opioids, but which contain chemical or physical properties that make crushing, cutting, or grinding pointless — when manipulated, ADF blocks the instantaneous euphoric effect of the drug, making it far less enticing to abuse.

These abuse-deterrent formulations will reduce the abuse of prescription drugs, and ultimately, along with more education and other interventions, improve the health of our community. The California Medical Association (CMA) understands this, which is why in December it approved a resolution supporting the FDA's ongoing efforts to evaluate and label ADF technology. The CMA also opposes the imposition of administrative roadblocks that decrease access to and coverage of prescription drugs with abuse-deterrent properties.

Los Angeles is our home, and its residents are our neighbors. The abuse of prescription pills not only harms the health of our community, but puts at risk the lives of our loved ones as well — and it can be stopped. This is why our legislators ought to do whatever is necessary to create a path for abuse deterrent formulations to reach their constituents. We live in the greatest city in the world. We are on the cutting edge of a lot of things. We believe that our community deserves a chance at deterring abuse, and in leading the nation at reducing the unnecessary deaths that inevitably follow.

Rocky Delgadillo is CEO of the Los Angeles County Medical Association; he was Los Angeles city attorney from 2001-2009. Pedram Salimpour, M.D., is president of the Los Angeles County Medical Association.



OPINIONS

Drug problem at the root of crime



BY **BRENT MEYER** POSTED 02.12.2015

As a public safety officer for nearly 20 years, I am often asked what I believe is an effective way to suppress crime in our nation. The answer is simple: Solve our drug problem.

And while many envision street drugs as the problem, the misuse of prescription drugs is a huge crisis with no bias toward any community in this state. Prescription opioid abuse is estimated to cost the United States about \$56 billion annually due to health costs, criminal justice costs and lost productivity.

The solution to combatting the abuse of common street drugs and prescription medications is anything but simple. It is a multi-agency, multi-layered, multi-communities problem that cannot be solved with any one policy or plan. Instead of turning our heads from this, we must chip away at drug abuse with the tools that we do have.

In fact, 62 percent of abusers inhale opiates nasally and 26 percent take them through intravenous injection.

One of these tools is an emerging technology in the way pain killers are formulated to prevent some of the most deadly forms of abuse. This technology, often called "Abuse Deterrent Formulations" of commonly prescribed opiate painkillers, have been used to provide patients with the same pain relief as conventional opioids, but incorporate breakthrough science designed to protect against tampering and abuse.

Chewing or altering narcotic pills are popular because users report a more intense and faster high from injecting and inhaling the substance. In fact, 62 percent of abusers inhale opiates nasally and 26 percent take them through intravenous injection.

Several states including California are considering legislation this year to improve and safeguard patient access to these new formulas of painkillers. I have seen firsthand the correlation between drug abuse and crime and the lives lost and destroyed as a result. I view these abuse deterrent formulations as a substantial step in facing opiate abuse and reducing crime and cutting law enforcement costs.

According to a 2010-2011 government survey, almost 1.5 million Californians, ages 12 and over, were estimated to have abused painkillers in the year prior. More alarming is that drug overdose is currently the third-leading cause of injury and premature death in Los Angeles County.

Certainly, nobody would suggest that abuse-proof pills are end-all solution for the epidemic of narcotic abuse, but they can be part of a real solution. People who have struggled with addiction or substance abuse in the past, those who live with others who are current or recovering addicts and those who live with teens or young adults seeking opioids for recreational use can all benefit from abuse deterrent formulations.

A common opioid reformulated with abuse deterrent technology was associated with cost savings due to reduction in abuse, including \$430 million in medical costs, almost \$100 million in criminal justice costs and \$476 million in workplace productivity.

Abuse deterrent formulations have received widespread support as part of a comprehensive effort to combat prescription drug abuse and promote appropriate pain management. Included in this support were the Office of National Drug Control Policy, the Community Anti-Drug Coalitions of America, members of Congress and the National Association of Attorneys General.

An overwhelming majority of us working within the criminal justice system know full well that there is no one fix for the rampant non-medical use of strong prescription painkillers. We also understand that there are people living with legitimate pain who have the right to have access to relief. But if there is a way to make even the smallest of dents in the problem, we must embrace and encourage it.

The medical, law enforcement and local neighborhood communities should stand together in support of a policy that allows doctors to prescribe these abuse-deterrent formulas when they believe that their patients need and should responsibly have access to them.

I urge our lawmakers to stand up for policies that preserve and improve patient access to this new technology. This is an issue of critical importance not only to members of my profession, but California citizens as well.

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Ed's Note: Brent Meyer is a Sacramento police officer and the statewide vice president of PORAC, the largest group of police officers and deputy sheriffs in the country.

Pain relief for vets doesn't have to lead to deadly prescription drug addiction

By Robert O'Neill -
Special to The Bee

12/11/2014 4:00 PM

Updated: 12/12/2014 12:00 AM



Kimberly Mitchell weeps at the Houston National Cemetery for her husband, Chad, an Iraq war veteran who died of an accidental drug overdose after returning home. Jay Janner / Austin American-Statesman file

The epidemic of prescription drug abuse in the United States has become rampant and deadly. Unfortunately, those who have served our nation are disproportionately prone to abusing powerful narcotics that have been prescribed for combat injuries.

The wars in Iraq and Afghanistan, along with other operations across the globe, have led to a sharp increase in the number of opioids being prescribed to military personnel. Those who suffer from dependence and addiction to these medications doubled from 2002 to 2005 and almost tripled between 2005 and 2008, according to the National Council on Alcoholism and Drug Dependence.

It is imperative that injured and recovering veterans have access to pain relief. But promising new technology from certain drugmakers can help offer palliative care, while also helping to curb abuse of opioid drugs.

The U.S. Food and Drug Administration has approved several new formulations of narcotic painkillers that are made “tamper proof” to prevent abusers from crushing pills to inhale, inject or snort them – most often the cause of overdose and death from the misuse of prescription pain medications.

According to a July 2014 report from Human Rights Watch, more than 1 million U.S. veterans are estimated to take prescription opioids for pain. Dependence on and abuse of these drugs are often linked with depression, homelessness and suicide among veterans. The report found that half of all accidental deaths were caused by prescription drug overdose.

Prescription drug abuse often begins with legitimate prescriptions but can disintegrate into a dangerous spiral if medications can be altered for abuse. Family members and others with access to these pain medications also are at risk of addiction and misuse.

Research on new formulation of OxyContin, the first opioid approved by the FDA to make abuse-deterrent claims, found that inhalation and injection abuse dropped from 70 percent to 40 percent, and poison control center calls declined by 32 percent.

These new formulations will not eradicate prescription drug abuse in the United States. But they can go a long way in curbing access to medications that can be used for illicit purposes, and to providing humane pain management to those who truly need it. We owe that to the men and women who have served in combat and suffer from unimaginable pain caused by injuries that, in past eras, would have killed them.

The help and support of the military, veterans groups and caregivers are key to helping our veterans recover from drug dependence and live happy, productive lives. As veterans, we applaud the makers of these painkillers for choosing to be part of a big-picture solution that will help to balance pain management with the cost that prescription drug abuse has on society.

We encourage pharmaceutical companies to continue this important research and urge our policymakers to enable them to bring these to market.

Robert O'Neill is a Vietnam-era veteran and chairman emeritus of the VetFund Foundation, a nonprofit that raises awareness and money to support California veterans.

Barby Ingle: Tamper-proof pain drugs deserve support

Barby Ingle, Special to The Desert Sun 3:04 p.m. PST February 28, 2015

It's no secret that the abuse of pain medications has led to a growing public health problem across the country. The numbers are alarming, and they are growing.

But also alarming is the number of people who suffer with chronic pain, including many who come to the desert seeking the arid climate for relief.

The problems are complex and multi-layered and I always applaud solutions that help to balance pain management with the cost that prescription drug abuse has on society. Promising technological advancements in recent years are proving to be an important part of the battle. Among these are so-called "abuse deterrent formulas" of commonly prescribed narcotic painkillers that are being developed to prevent some of the most deadly forms of pain pill abuse.

Since 2002, I have been battling Reflex Sympathetic Dystrophy (RSD), a progressive neuro-autoimmune condition that affects multiple systems in the body. I know firsthand how difficult the journey for relief can be, particularly the sidelong glances and disbelief from medical professionals. One in three people (116 million) in the United States are affected with a condition that causes pain.

But what if there were medications that can offer pain sufferers relief, while also protecting those who might be prone to abuse them?

There are. These little known, new tamper proof formulas of strong narcotic pain medications provide patients with the same pain relief as conventional opioids, while incorporate breakthrough technology designed to protect against tampering and abuse.

Several states are considering legislation this year to improve and safeguard patient access to these new formulas of painkillers.

Abuse-deterrent formulations have received widespread support as part of a comprehensive effort to combat prescription drug abuse and promote appropriate pain management, including from the Office of National Drug Control Policy, the Community Anti-Drug Coalitions of America, members of Congress, and the National Association of Attorneys General — including California Attorney General Kamala Harris.

Abuse of pain medications has led to a growing public health problem in California and nationwide. Each year approximately 4.5 million Americans use prescription pain medications for non-medical purposes, contributing to more than 16,000 deaths annually.

This technology is only part of the solution; but it is a solution nonetheless. Patients that have struggled with addiction or substance abuse in the past, those who live with others who are current or recovering addicts and those who live with teens or young adults who may seek opioids for recreational use can all benefit from ADFs.

Abuse-deterrent formulations have received widespread support as part of a comprehensive effort to combat prescription drug abuse and promote appropriate pain management, including support from the Office of National Drug Control Policy, the Community Anti-Drug Coalitions of America, members of Congress and the National Association of Attorneys General.

To date, the Food and Drug Administration (FDA) has approved abuse-deterrent labeling for four drugs, with other abuse-deterrent opioids in various stages of development.

For the sake of those with legitimate, life-altering pain and for the safety of those prone to use these medications for non-medical use, I urge our lawmakers to stand up for policies that preserve and improve patient access to this new technology. Failing to do so would be failing to do all we can to protect our residents.

Barby Ingle is a chronic pain educator, patient advocate and chairman of the board for the Power of Pain Foundation.

KCET

Bill Seeks to Reduce Prescription Drug- Related Deaths in California

By: Monica Luhar

Prescription drug abuse is among the top leading causes of death in L.A. County. To address the epidemic here and across California, Assemblymember Jim Wood (D-Healdsburg) last month introduced new legislation limiting access to opioids -- medications, like OxyContin, morphine, and codeine, that alleviate pain.

One of the main features of AB 623 would be to allow health care providers to prescribe pain relievers that take the form of abuse-deterrent opioids. Described as ADF, for abuse-deterrent formula, this type of medicine blocks the effect drug abusers seek when the pill is manipulated by crushing, cutting, or dissolving.

The bill would also help pharmacists instruct patients on how to protect oneself from harm by properly storing and disposing the medicine and for health care providers to write prescriptions for less than 30-days.

According to the CDC, prescription drug overdose in people ages 25 to 64 caused more deaths than motor vehicle traffic crashes in 2012. Out of the 22,767 related pharmaceutical overdose deaths in 2013, approximately 71 percent involved opioid or prescription pain relievers, reports the CDC.

People susceptible to drug abuse often crush, snort, or inject opioid drugs into their system. Alternatively, ADF medication is not easily destructible, which makes it difficult to abuse or sell on the streets.

In L.A. County alone, 8,265 drug-related deaths occurred between 2000 and 2009. According to a study published in 2013 by the Department of Public Health, approximately 61 percent of those deaths involved an over-the-counter prescription drug.

"Pills without ADF have high street value, so people who don't abuse them can make a lot of money selling them. There is not one solve-all solution to this problem. The White House, FDA, and others have identified multiple steps that can be taken to reduce abuse. AB 623 addresses a few of them," explained Wood, a dentist by trade. "Tragically, I also saw my share of people attempting to engage in 'doctor shopping' to feed an addiction or pattern of abuse."

Wood said the FDA is currently in the process of drafting a guidance document that would require any new opioid on the market to include ADF technology to reduce opioid abuse. "The FDA considers the development of these products a high public health priority and continues to strongly encourage development of opioids that deter abuse."

Under current law, physicians are required to explain the dangers of opioid abuse, and enter specific prescription information about controlled substances into a special database called CURES. "AB 623 would ensure that if a physician writes a prescription for 10 days, only that amount will be dispensed," Wood noted.

Mendocino County, which is represented by Wood, currently has nearly double the statewide average of deaths and rehabilitation from prescription drugs, he told KCET in an email. He added that while AB 623 will not completely stop the abuse of prescription drugs, it does contain some important steps that will reduce it.

"If patients get only the pills they need, there won't be extras for people to abuse or sell on the street," he said. "This is an important step toward addressing our rapidly growing prescription drug abuse problem and now is the time to make these changes."

Monica Luhar is the site editor for "SoCal Connected" and a reporter for KCET's Agenda. Her bylines have appeared in NBC Asian America, Southern California Public Radio, The Aerogram, among others.

The Wall Street Journal

FDA Offers Guidance on Developing Opioid Less Prone to Be Abused

By: Thomas M. Burton

The Food and Drug Administration issued a set of suggestions to help the drug industry develop new opioid painkillers that potentially would be less susceptible to abuse than current pills.

The federal agency said in its guidance document that it hopes to encourage painkiller formulations that are more difficult to crush, inject or snort to produce a more intense high. But the FDA acknowledged that even such abuse-deterrent versions of the pills aren't "abuse-proof."

The tendency for addicts to use narcotic painkillers has turned into an epidemic in the U.S., with more than 16,000 people each year estimated to die from overdosing on opioid-based pills. The FDA has been struggling with the balance between making powerful painkillers available to patients with severe chronic pain, and yet limiting the drugs' abuse potential.

"We hope that this guidance is going to provide an incentive for real abuse-deterrent products," said Dr. Douglas Throckmorton, deputy director of regulatory programs at the FDA's center for drug evaluation. "We hope industry will find that this guidance lays out a road map" for how to make abuse-deterrent drugs that will gain FDA approvals.

The FDA document recommends the types of studies that will be needed to prove a given drug can deter abuse. It suggests ways such research can be conducted and evaluated, and discusses labeling claims that will be allowed following such trials.

Agency officials said that about 30 drug manufacturers have come in to the FDA lately to talk with them about how to make abuse-deterrent products. Dr. Throckmorton said it is possible the agency can give priority review status to such applications, to speed them to the market.

Some physicians weren't overwhelmed by the plan.

"It does very little," said Dr. Andrew Kolodny, president of Physicians for Responsible Opioid Prescribing. "The ability of so-called abuse-deterrent formulations to have impact on our opioid abuse problems is limited."

The FDA guidance document acknowledged the difficulty, saying, "because opioid products must in the end be able to deliver the opioid to the patient, there may always be some abuse of these products."

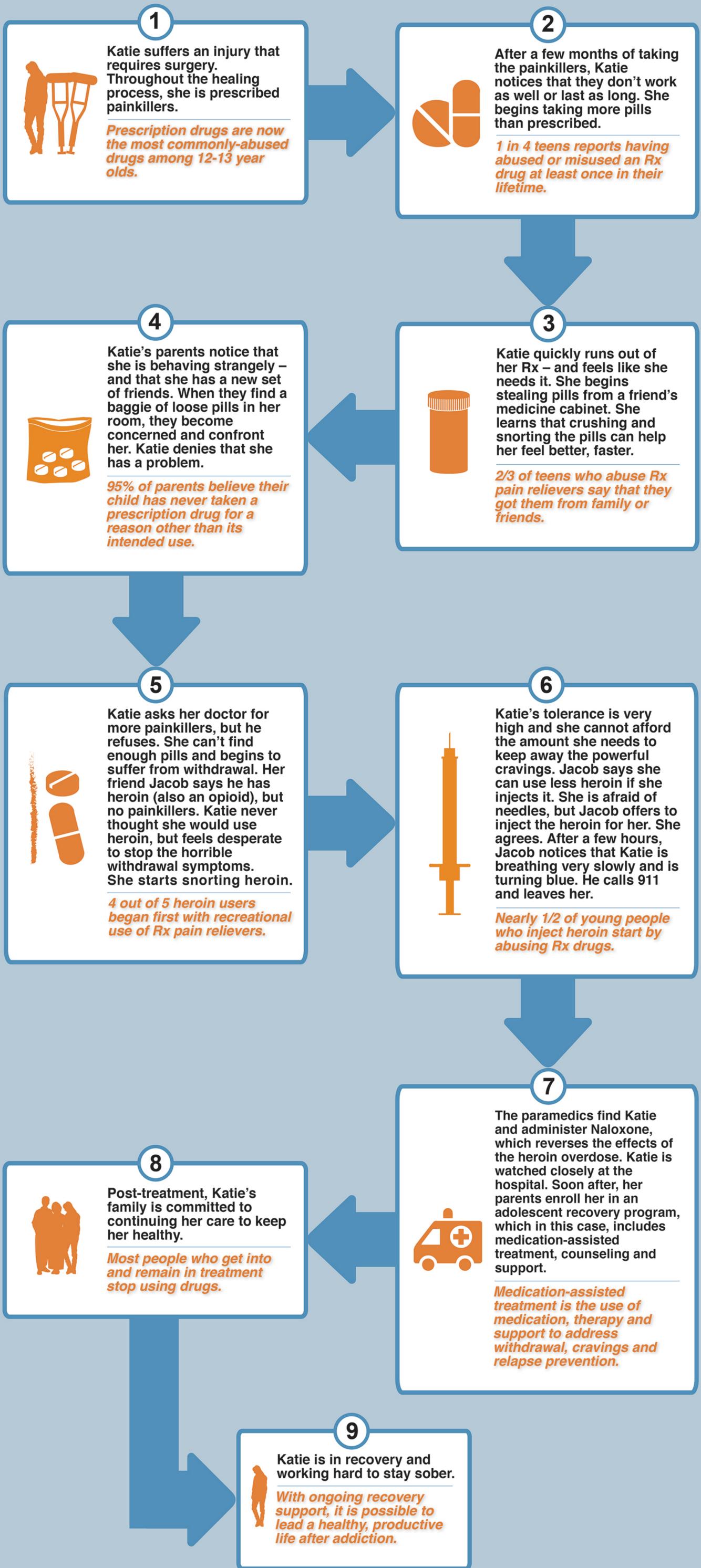
In Dr. Kolodny's view, some other fairly simple steps may be more effective. The agency, he contends, could take larger dosages off the market. Also, he said, it could prohibit marketing of such powerful narcotics for certain conditions such as low-back pain, which he said is responsible for about 60% of the people on opioids.

From Rx to Heroin

Nearly half of young people who inject heroin start by abusing Rx drugs.

Teen abuse of prescription (Rx) pain medicine, also known as opioids, usually starts in two ways. Some teens start abusing it at a party or with friends because they're curious or think it will make them feel good. Others start taking it legitimately when prescribed by a doctor after an injury or dental procedure – but in some cases, legitimate use turns to dependence, abuse, addiction and then heroin use.

Follow **Katie's journey** below and learn more about how Rx drug abuse can lead teens to heroin use.



Is there a teenager in your life on a path similar to Katie's? Find help and resources at drugfree.org.



Parents can also call our toll-free helpline: 1-855-DRUGFREE (1-855-378-4373)

