HB

268

<TARGET><BILL>HB 268</BILL><SUBJECT>HB 268</SUBJECT><COMM>HHSS30</COMM></TARGET>

ALASKA STATE LEGISLATURE

REPRESENTATIVE LES GARA

SPONSOR STATEMENT
SSHB 268
Patient Advisory On Potential Addiction from Prescription Opioid Drug Use

House Bill 268 seeks to help address the opioid addiction crisis in Alaska, by making sure patients are advised of the potential addictive dangers of these prescription drugs. Opioid drugs include oxycodone, hydrocodone, and other pain reducing drugs. In many cases these drugs are needed to address acute physical pain, but the facts show that these drugs can also have powerful addictive effects. Furthermore, studies show many heroin users started as opioid drug users. The relatively low cost of heroin as a substitute drug can lead to the transition by many Americans and Alaskans to heroin. Obviously, this can occur when a medical provider will no longer provide additional prescription medication. A small but troubling percentage of people who become addicted to opioid drugs later become heroin addicts.

These addictions can destroy families, destroy a person's ability to hold employment, and destroy lives. Addiction treatment is costly for consumers, who pay indirect insurance costs, as well as for the state, which often covers and pays for addiction treatment. In the worst case, overdose deaths also result from opioid use. According to the Department of Health and Social Services, 14,000 Americans died from opioid use in 2014 and 91 Americans die every day. Alaska's per capita death rate is twice the national average. According to the Department, between 2009-2015, 774 Alaskans died from opioid overdose.

This bill recognizes a reality. Since 1999, the number of opioid prescriptions have tripled. More Americans and Alaskans have been prescribed these often useful, but potentially dangerous drugs.
House Bill 268 is a patient information bill. It requires prescribers to let patients know about the potentially addictive qualities of these drugs when they are prescribed, and that they can potentially lead to opioid abuse and addiction. Providers must also offer information about opioid use being a potential risk factor for future heroin addiction. Patients can then use this knowledge to help themselves and their family members guard against overuse and abuse when prescribed these medications.

To keep the requirements flexible, and as non-burdensome as feasible, while still protecting patients, medical providers who prescribe these drugs will be required to provide this information to their patients in their "own words".

The bill also requires the Department of Health and Social Services to prepare a very short handout with some facts on the dangers of opioid addiction, and the potential association between opioid addiction and heroin use. To increase the chances that this information will be presented in a form that is useful, it is required to be concise, and may include graphics. The handout is Important because it recognizes that the patient-provider discussion may not be long and detailed, and a patient may not remember what is told to them by a medical provider in this regard. It also serves to reinforce the information.

This bill does not create opportunities for new civil lawsuits against providers, thus protecting the patient-provider relationship. Instead of imposing civil liability, and raising the specter of lawsuits, the enforcement mechanism in the bill allows the providers' Board to consider sanctions for "habitual" violations of this statute that occur without "good cause".

Exceptions to the legislation's requirements, borrowed from a similar statute passed in New Jersey, include medical services where opioids may be necessary such as for opioid addiction treatment and hospice care.

Please feel free to contact our office with any questions.

ALASKA STATE LEGISLATURE ~ REPRESENTATIVE LES GARA
January-May: State Capitol • Juneau, AK 99801-1182 • (907) 465-2647 • Fax (907) 465-3518
June-December: 1500 W. Benson Blvd. • Anchorage, AK 99503 • (907) 269-0106 • Fax (907) 269-0109
Rep.Les.Gara@akleg.gov

ALASKA STATE LEGISLATURE

REPRESENTATIVE LES GARA

SSHB 268
Sectional Analysis

Sponsor Substitute For HB 268: Informed Understanding By Patients On Potential Opioid Use Dangers

Section 1. Bill Name is Consumer Advisory On Potential Heroin Addiction From Opioid Use Act.

Section 2. Legislative Findings.

Section 3. Enforcement of Bill: Board power to consider discipline for dentists who "habitually" violate bill requirements; potential board discipline, but no additional legal civil liability cause of action created by bill, to protect against hostile legal relationship between patient and provider.

Section 4. Duties of Opioid Prescribing Dentists: Inform patients, in provider's "own words", of potential addiction dangers from extended opioid use; and any reasonable treatment alternatives, if they exist, to the recommended opioid prescription; distribute Department of Health and Social Services short handout on same potential dangers.

Section 5. Enforcement of Bill: Board power to consider discipline for medical, osteopathy and podiatry providers who "habitually" violate bill requirements; potential board discipline, but no additional legal civil liability cause of action created by bill, to protect against hostile legal relationship between patient and provider.

Section 6. Duties of Opioid Prescribing Medical, Osteopathy and Podiatry Providers: Inform patients, in provider's "own words", of potential addiction dangers from extended opioid use; and any reasonable treatment alternatives, if they exist, to the recommended opioid prescription; distribute Department of Health and Social Services short handout on same potential dangers.

Section 7. Enforcement of Bill: Board power to consider discipline for registered nurses who "habitually" violate bill requirements; potential board discipline, but no additional legal civil liability cause of action created by bill, to protect against hostile legal relationship between patient and provider.

Section 8. Duties of Opioid Prescribing Registered Nurses: Inform patients, in provider's "own words", of potential addiction dangers from extended opioid use; and any reasonable treatment

alternatives, if they exist, to the recommended opioid prescription; distribute Department of Health and Social Services short handout on same potential dangers.

Section 9. Enforcement of Bill: Board power to consider discipline for registered optometrists who "habitually" violate bill requirements; potential board Discipline, but no additional legal civil liability cause of action created by bill, to protect against hostile legal relationship between patient and provider.

Section 10. Duties of Opioid Prescribing Optometrists: Inform patients, in provider's "own words", of potential addiction dangers from extended opioid use; and any reasonable treatment alternatives, if they exist, to the recommended opioid prescription; distribute Department of Health and Social Services short handout on same potential dangers.

Section 11. Department of Health and Social Services may adopt conforming regulations.

January-May: State Capitol • Juneau, AK 99801-1182 • (907) 465-2647 • Fax (907) 465-3518
June-December: 1500 W. Benson Blvd. • Anchorage, AK 99503 • (907) 269-0106 • Fax (907) 269-0109
Rep.Les.Gara@akleg.gov

FACT SHEET:
Opioid Use Disorders and Medication Assisted Treatment

Division of Behavioral Health

Alaska, along with the rest of the United States, is in the midst of an opioid epidemic. This fact sheet explains opioid use disorders and medication assisted treatment (the evidence-based best practice for treating them).

Medication assisted treatment (or MAT) is the use of counseling and behavioral therapies plus medication to provide a holistic approach to treating patients with opioid use disorders. The Alaska Division of Behavioral Health supports its use as part of the division's standard of using evidenced-informed practices for mental health and substance use disorder treatment.

What is an Opioid?

An opioid is a drug that affects the brain. Opioids are used to relieve pain and to address other health problems such as severe coughing. "Opioid" is a broad term that refers to both prescription pain medication (such as oxycodone, OxyContin, fentanyl) and illegal substances (heroin and carfentanil). When abused, opioids increase the risk of certain infections, accidents, and death.

Opioids can be Addictive

People may become dependent on or addicted to prescription opioids. This can happen when taking them long-term, misusing or abusing them (taking a prescription improperly, buying prescription opioids illegally, or snorting, injecting or smoking them), or by use of illegal opioids such as heroin. When a person becomes addicted, they begin to experience cravings for opioids, as well as a loss of control over their use. Misuse of legal opioids is often linked to use of illegal opioids.

Substance Use Disorders (addiction) is a medical condition like heart disease or diabetes.

Opioid Addiction is Treatable

MAT treats dependence and addiction by using medication to ease withdrawal and ongoing cravings, and must include counseling to address root causes of the dependence and to strategize recovery plans. Taking medication for opioid addiction is much like taking medication to control diabetes or heart disease: use of appropriate medications greatly improves treatment outcomes and quality of life for patients and decreases costs and medication may need to be taken for a period of years. MAT has been shown to increase patient survival, reduce the risk of human immunodeficiency virus (HIV) infection and viral hepatitis by reducing needle sharing, increase patient's participation in treatment, decrease illegal opioid use, increase patient's ability to get and keep employment, and improve birth outcomes for pregnant women with substance use disorders who are pregnant. Some people are eventually able to stop using MAT and maintain long-term recovery.

MAT Medications

The federal Drug Enforcement Agency (DEA) and the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA) have approved three medications for medication assisted treatment.

Methadone

There is a large body of research supporting methadone's efficacy in treating patients with opioid addiction[1]. Methadone is a "full agonist" — it allows the areas of the brain affected/damaged by the abused drug to feel normal again. However, methadone at appropriate maintenance doses does not make patients feel intoxicated, or "high". Patients can participate normally in work, school, or other productive activities. Methadone prevents symptoms of opioid withdrawal and reduces cravings.

Methadone is administered on a daily basis by mouth in a clinic at the beginning of treatment; however as treatment progresses, a patient may be able to take the medication on their own at home. Some patients need methadone treatment for a matter of months; others may need methadone treatment for the rest of their life. If patients stop using methadone, they must do so gradually under a physician's care.

Buprenorphine

Buprenorphine is a "partial agonist" —it has a "ceiling effect", which means larger doses do not generally increase the effect of the medication. Buprenorphine can be used for medically supervised withdrawal, as well as for addiction treatment. Buprenorphine can be prescribed by providers with special approval from the Federal government and is taken by mouth at home. Buprenorphine patients generally do not experience a "high" because of the "ceiling effect". If a patient choses to stop using buprenorphine, they need to be monitored as they go through withdrawal.

Suboxone®, is buprenorphine mixed with naloxone. Naloxone (Narcan®) is an "antagonist", which means that it blocks the effect of opioids if the drug is misused by injecting it. Thus, Suboxone decreases withdrawal symptoms and blocks the chance of experiencing a "high", which helps discourage patients in recovery from abusing buprenorphine or other opioids. Another treatment medication is Subutex®, which is buprenorphine without naloxone.

Patients need to discuss what buprenorphine medication works best for them in treating their opioid use disorder.

Naltrexone

Naltrexone injection (Vivitrol®) works differently than methadone or buprenorphine. Naltrexone is an "opioid antagonist" — it completely blocks the effects of opioids. This means that if a patient attempts to abuse opioids they do not experience a "high". This also means that a patient must be completely off of opioids for 7 to 10 days prior to the initiation of naltrexone in order to prevent instant withdrawal upon receiving the medication. This medication can be given once a month as an injection, or by daily pills. Naltrexone is most appropriate for those who are highly motivated, can completely change their social situation, and cannot risk any impairment.

Opioid Addiction Recovery

MAT should be provided as part of a comprehensive treatment plan which is intended to support to support how patients function in all aspects of their lives. In MAT, patients must be assessed and monitored by a medical provider, meet consistently with a behavioral health professional, and follow treatment plans based on the patient's goals for treatment. Providers and patients must both comply with safety requirements. Medication, counseling, and support from loved ones are all important factors that contribute to success in recovery.

Additional information and references for:

1. MAT in drug courts: store.samhsa.gov/shin/content//SMA14-4852/SMA14-4852.pdf
2. MAT for providers and the public: www.samhsa.gov/medication-assisted-treatment/treatment
3. MAT for families and friends: go.usa.gov/xNX5S
4. Methadone: www.samhsa.gov/medication-assisted-treatment/treatment/methadone
5. Buprenorphine: www.samhsa.gov/medication-assisted-treatment/treatment/buprenorphine
6. Naltrexone: www.samhsa.gov/medication-assisted-treatment/treatment/naltrexone
7. The U.S. opioid epidemic: www.cdc.gov/drugoverdose
8. Practice guideline for MAT: https://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf
9. Naltrexone side effects and highly motivated individuals: https://store.samhsa.gov/shin/content/SMA12-4444/SMA12-4444.pdf10. More about naltrexone: https://store.samhsa.gov/shin/content//SMA14-4892R/SMA14-4892R.pdf
10. Opioid prevention in Alaska: www.opioids.alaska.gov.

A look at the numbers

The Economic Costs of Drug Abuse in Alaska, 2016 Update - *McDowell Group Report for March 2017*

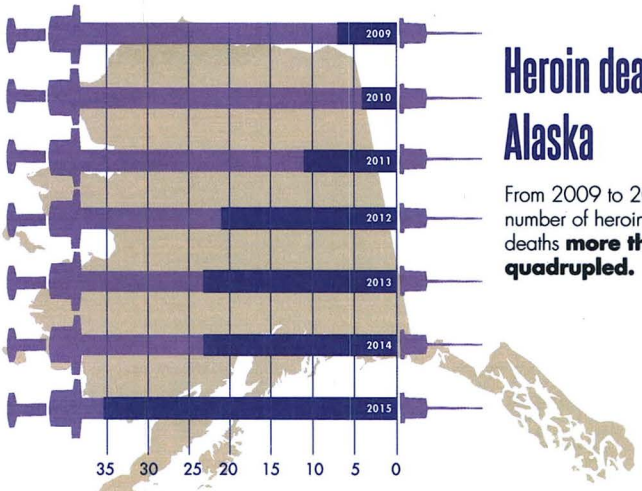
Consistent with national trends, heroin overdose deaths have continued to increase steadily every year in Alaska since 2010. Drug overdose death rates remained highest among males and middle-aged adults. The regional distribution of drug overdose deaths was considerably higher in regions with urban centers and growing populations, although all Alaska regions were affected.

HEROIN USE IS ON THE RISE IN THE LAST FRONTIER

The number of people reporting **heroin dependence or abuse** in the United States more than doubled between 2007 and 2013.

Between 2011 to 2013 **45%** of people in the U.S. who used heroin were also abusing or addicted to prescription opioid painkillers.

Heroin deaths in Alaska



From 2009 to 2015, the number of heroin-associated deaths **more than quadrupled.**

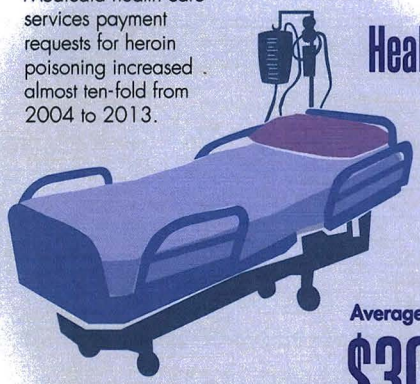
From 2009 to 2013 in Alaska

Heroin arrests increased 140% from 64 to 151.

The amount of heroin seized in Alaska has increased 18-fold from 3 pounds in 2009 to 55 pounds in 2013.

Health care in Alaska

The number of Medicaid health care services payment requests for heroin poisoning increased almost ten-fold from 2004 to 2013.



Inpatient hospital discharge rates coded for heroin poisoning increased almost six-fold from 2010 to 2012.

Average inpatient costs:

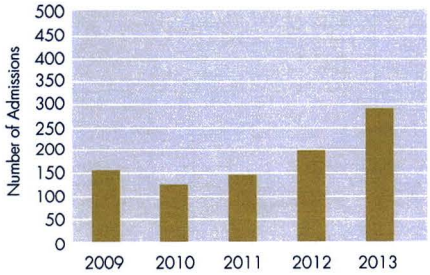
$30,000

Public health impact of heroin use:

- Deaths
- Higher health care costs due to substance abuse treatment and long-term health problems such as liver, kidney, cardiovascular, and arthritic diseases
- Increased transmission of HIV and hepatitis C virus because of people sharing needles
- Increased crime
- Decreased stability in families and communities

Drug abuse treatment

The number of treatment admissions for patients from 21 to 29 years old who report heroin as their primary substance of choice increased by 74 percent between 2009–2010 and 2012–2013.



What can be done?

- **PREVENT** dependence on opioid drugs
- **REDUCE** addiction by recognition and treatment
- **REVERSE** the life-threatening effects of overdose

Want to learn more? dhss.alaska.gov/dph/Director/Pages/heroin-opioids/default.aspx

TREATING PAIN: WHAT ALASKANS SHOULD KNOW.

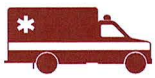
If you've had an injury, surgery or dental work, you are likely to have pain. Some pain can be a normal part of healing.

Talk with your doctor to find the most effective treatment with the least risk.

WHY BE CAUTIOUS WITH OPIOIDS?

Opioid medications are chemical cousins of heroin, with serious risks of addiction and overdose, even when taken as directed:

Drug overdose was Alaska's leading cause of accidental death for 2016. Opioid addiction is driving the epidemic.



More than 3 out of 5 drug overdoses involve an opioid.

Centers for Disease Control and Prevention, Alaska Department of Health and Social Services

Nationally, 4 out of 5 heroin users started out misusing prescription opioids.

American Society of Addiction Medicine

7% of Alaska youth have used a prescription pain medication without a doctor's prescription, or differently than how a doctor told them to use it, in the past 30 days.

2017 Alaska Youth Risk Behavior Survey

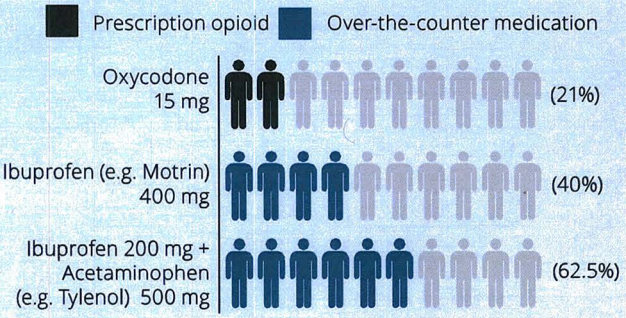
More than 2 out of 5 teens who misused or abused a prescription drug took it from their parent's medicine cabinet.

Partnership for Drug-Free Kids

NON-OPIOID PAIN TREATMENT

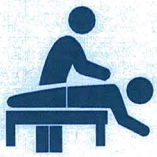
When taking medication for pain, it is often best to start with non-opioid pain treatments. Consider other options that may work just as well, but have far fewer risks.

Over-the-counter options are effective. This graph shows people getting 50% pain relief from acute pain after an operation with:



1/NNT, Cochrane Reviews, adapted from graph compiled by Dr. Don Teater, Teater Health Solutions

Depending on the kind of pain, there may be non-medication pain treatment options to consider:



Physical therapy, massage and acupuncture

Counseling with a psychologist, social worker, psychiatrist or other therapist for help managing the emotional aspect of pain

Exercises such as walking, pilates, core exercises, swimming, dancing, yoga and meditation

Other options such as diet and nutrition, art and music therapy, functional medicine, traditional medicine

» Opioid medications are sometimes the right choice for treating severe pain, such as from cancer or immediately after a surgery. If you and your provider choose an opioid, here's what you should know.

BEFORE YOU'RE PRESCRIBED AN OPIOID, DISCUSS WITH YOUR PROVIDER ...

- Managing your pain better without taking prescription opioids.
- Prior exposure to trauma, psychiatric history including anxiety or depression, and any history of substance use disorder in you or your family.
- Medications, alcohol or other substances you may be using.
- Dosing and timing of opioid medication. The fewer days you're on an opioid, and the lower the dose, the lower the risk of dependence will be. Ask for the lowest dose possible, for the shortest amount of time.
- Side effects associated with your prescription, and signs of overdose.

For acute pain and injury, opioid prescriptions should ideally be for no more than a three day supply (often this is as few as 10 pills).

"IS IT AN OPIOID?"

Examples of opioid medication include:

Codeine
Fentanyl
Hydrocodone (Vicodin)
Hydromorphone (Dilaudid)
Meperidine (Demerol)
Methadone
Morphine (MS Contin, Kadian)
Oxymorphone (Opana)
Oxycodone (OxyContin, Percocet)
Tramadol

There are many others, so be sure to ask if your medication is an opioid.

HELP KEEP YOU AND THOSE AROUND YOU SAFE.

Help prevent prescription opioid misuse in Alaska:

SECURELY STORE MEDICATION out of reach of children, teens and others who may misuse them.

SAFELY DISPOSE OF UNUSED MEDICATION IN FAIRBANKS using one of these 3 methods:

1. Unused medication can be taken to Denali Pharmacy, North Pole Police Department, Fairbanks Police Department, North Pole Prescription Lab, Fort Wainwright Basset Community Hospital or Eielson AFB Medical Group Clinic.
2. Pick up a disposal kit at the Public Health Center to safely dispose of your medications at home.
3. Visit takebackday.dea.gov to find out about upcoming National Prescription Drug Take Back Day disposal events.

NEVER SHARE OPIOIDS. Sharing puts people at unnecessary risk for addiction, overdose and even death. Opioids are controlled substances — sharing is illegal.

ACKNOWLEDGEMENTS:
Adapted from materials produced by the Bree Collaborative and the Washington Health Alliance

ADDITIONAL SOURCES:
Effect of a Single Dose of Oral Opioid and Nonopioid Analgesics on Acute Extremity Pain in the Emergency Department: A randomized Trial, JAMA, November 2017. Volume 318, No. 17.

JAMA | Original Investigation

Effect of a Single Dose of Oral Opioid and Nonopioid Analgesics on Acute Extremity Pain in the Emergency Department
A Randomized Clinical Trial

Andrew K. Chang, MD, MS; Polly E. Bijur, PhD; David Esses, MD; Douglas P. Barnaby, MD, MS; Jesse Baer, MD

Editorial page 1655

Supplemental content

IMPORTANCE The choice of analgesic to treat acute pain in the emergency department (ED) lacks a clear evidence base. The combination of ibuprofen and acetaminophen (paracetamol) may represent a viable nonopioid alternative.

OBJECTIVES To compare the efficacy of 4 oral analgesics.

DESIGN, SETTINGS, AND PARTICIPANTS Randomized clinical trial conducted at 2 urban EDs in the Bronx, New York, that included 416 patients aged 21 to 64 years with moderate to severe acute extremity pain enrolled from July 2015 to August 2016.

INTERVENTIONS Participants (104 per each combination analgesic group) received 400 mg of ibuprofen and 1000 mg of acetaminophen; 5 mg of oxycodone and 325 mg of acetaminophen; 5 mg of hydrocodone and 300 mg of acetaminophen; or 30 mg of codeine and 300 mg of acetaminophen.

MAIN OUTCOMES AND MEASURES The primary outcome was the between-group difference in decline in pain 2 hours after ingestion. Pain intensity was assessed using an 11-point numerical rating scale (NRS), in which 0 indicates no pain and 10 indicates the worst possible pain. The predefined minimum clinically important difference was 1.3 on the NRS. Analysis of variance was used to test the overall between-group difference at $P = .05$ and 99.2% CIs adjusted for multiple pairwise comparisons.

RESULTS Of 416 patients randomized, 411 were analyzed (mean [SD] age, 37 [12] years; 199 [48%] women; 247 [60%] Latino). The baseline mean NRS pain score was 8.7 (SD, 1.3). At 2 hours, the mean NRS pain score decreased by 4.3 (95% CI, 3.6 to 4.9) in the ibuprofen and acetaminophen group; by 4.4 (95% CI, 3.7 to 5.0) in the oxycodone and acetaminophen group; by 3.5 (95% CI, 2.9 to 4.2) in the hydrocodone and acetaminophen group; and by 3.9 (95% CI, 3.2 to 4.5) in the codeine and acetaminophen group ($P = .053$). The largest difference in decline in the NRS pain score from baseline to 2 hours was between the oxycodone and acetaminophen group and the hydrocodone and acetaminophen group (0.9; 99.2% CI, −0.1 to 1.8), which was less than the minimum clinically important difference in NRS pain score of 1.3. Adverse events were not assessed.

CONCLUSIONS AND RELEVANCE For patients presenting to the ED with acute extremity pain, there were no statistically significant or clinically important differences in pain reduction at 2 hours among single-dose treatment with ibuprofen and acetaminophen or with 3 different opioid and acetaminophen combination analgesics. Further research to assess adverse events and other dosing may be warranted.

TRIAL REGISTRATION clinicaltrials.gov Identifier: NCT02455518

Author Affiliations: Department of Emergency Medicine, Albany Medical College, Albany, New York (Chang); Department of Emergency Medicine, Albert Einstein College of Medicine, Montefiore Medical Center, Bronx, New York (Bijur, Esses, Barnaby, Baer).

Corresponding Author: Andrew K. Chang, MD, MS, Department of Emergency Medicine, Albany Medical College, 16 New Scotland Ave, MC-139, Albany, NY 12208 (achang3@yahoo.com).

JAMA. 2017;318(17):1661-1667. doi:10.1001/jama.2017.16190

The United States is facing an opioid epidemic with almost 500 000 individuals dying from drug overdoses since 2000.[1] Despite the epidemic, opioid analgesics remain the first-line treatment for moderate to severe acute pain in the emergency department (ED). Based on data from 2006-2010, opioids were prescribed for 18.7% of ED discharges.[2]

Acute extremity injuries are a common painful presenting condition seen in emergency practice. Depending on the degree of discomfort, patients are often treated with a single dose of an oral analgesic while awaiting further care. There are many analgesic options, but evidence to inform clinical choice in this context is sparse.

Relatively few ED studies[3-7] have compared the efficacy of the 3 most commonly used opioid analgesics in the ED and none has compared them in a single study. Although opioids are considered to provide stronger analgesia than nonopioid analgesics, 1 ED-based study found that adding combination oxycodone and acetaminophen to naproxen did not improve pain relief at 1 week in patients with acute low back pain.[8] Several postsurgical studies have found combination nonopioids to be as effective as a combination of codeine and acetaminophen.[9-12]

Changing prescribing practices is an important step in addressing the opioid epidemic and its adverse effects on US communities, and research suggests that even short-term opioid use may confer a predisposition to opioid dependence.[13,14]

The objective of this study was to compare the degree of pain reduction at 2 hours after ingestion of 4 oral combination analgesics. One of the analgesics was opioid-free, whereas the other 3 contained an opioid, and all 4 were combined with acetaminophen (paracetamol).

Key Points

Question Do any of 4 oral combination analgesics (3 with different opioids and 1 opioid-free) provide more effective reduction of moderate to severe acute extremity pain in the emergency department (ED)?

Findings In this randomized clinical trial of 411 ED patients with acute extremity pain (mean score, 8.7 on the 11-point numerical rating scale), there was no significant difference in pain reduction at 2 hours. Mean pain scores decreased by 4.3 with ibuprofen and acetaminophen (paracetamol); 4.4 with oxycodone and acetaminophen; 3.5 with hydrocodone and acetaminophen; and 3.9 with codeine and acetaminophen.

Meaning For adult ED patients with acute extremity pain, there were no clinically important differences in pain reduction at 2 hours with ibuprofen and acetaminophen or 3 different opioid and acetaminophen combination analgesics.

Methods

Overview

In this randomized double-blind clinical trial, adult patients were enrolled during an ED visit for acute extremity pain. Patients received a single dose of an oral combination analgesic (ibuprofen and acetaminophen, oxycodone and acetaminophen, hydrocodone and acetaminophen, or codeine and acetaminophen) and were asked to rate their pain intensity using a verbal numerical rating scale (NRS) from 0 to 10 at 1 and 2 hours following ingestion. The Albert Einstein College of Medicine institutional review board provided ethical oversight and study approval. All participants provided written informed consent in either English or Spanish. Data were collected between July 2015 and August 2016. The protocol and statistical analysis plan as well as additional post hoc analyses appear in Supplement 1.

Study Setting

This study was conducted in 2 EDs of the Montefiore Medical Center. The Moses division is an urban teaching hospital with more than 100 000 adult visits annually, and is located in the west Bronx, New York. The Weiler division is a community hospital with more than 70 000 adult visits annually, and is located in the east Bronx, New York. Salaried, trained, full-time, bilingual (English and Spanish) research associates staffed the ED 24 hours per day, 7 days per week during the accrual period.

Participant Selection

Patients were considered for inclusion if they were adults aged 21 years through 64 years who presented to the ED for management of acute extremity pain, which was defined as pain originating distal to and including the shoulder joint in the upper extremities and distal to and including the hip joint in the lower extremities. Eligible patients were required to have a clinical indication for radiological imaging (based on judgment of the ED attending physician) that would provide a built-in delay during which most patients would be able to provide 1- and 2-hour pain scores. The need for imaging also was considered to be a proxy for more severe injury, thus increasing the likelihood that an oral opioid analgesic might be an appropriate choice for pain relief in the judgment of the ED attending physician.

Patients were excluded for the following reasons: past use of methadone; presence of a chronic condition requiring frequent pain management such as sickle cell disease, fibromyalgia, or any neuropathy; history of an adverse reaction to any of the study medications; had taken opioids within the past 24 hours; had taken ibuprofen or acetaminophen within the past 8 hours; pregnant according to either a urine or serum human chorionic gonadotropin test; breastfeeding (per patient report); history of peptic ulcer disease; report of any prior use of recreational narcotics; medical condition that might affect metabolism of opioid analgesics, acetaminophen, or ibuprofen such as hepatitis, renal insufficiency, hypothyroidism or hyperthyroidism, Addison disease, or Cushing disease; presence of any medicine that might interact with 1 of the study medications (eg, selective serotonin reuptake inhibitors or tricyclic antidepressants).

Interventions

After randomization, all patients rated their pain immediately before taking the study analgesic and again both 1 and 2 hours after taking the medication while remaining in the ED.

Patients discharged prior to 2 hours were reached at the 2-hour time point via a previously confirmed cell phone number. Patients who required rescue analgesics (based on the discretion of the ED attending physician) received an unblinded 5-mg dose of oral oxycodone, which could be administered at any point during the 2-hour study period. Additional analgesia could also be administered based on the discretion of the ED attending physician.

All patients received 3 identical, opaque capsules containing a total amount of 400 mg of ibuprofen and 1000 mg of acetaminophen; 5 mg of oxycodone and 325 mg of acetaminophen; 5 mg of hydrocodone and 300 mg of acetaminophen; or 30 mg of codeine and 300 mg of acetaminophen. Three capsules were used because the amount of analgesic administered was more than would fit into either 1 or 2 blinded capsules small enough for patients to comfortably swallow. All study analgesics were taken under direct observation to confirm ingestion.

Randomization and Blinding

A research pharmacist performed the stratified randomization in blocks of 8 using an online randomization plan generator. The pharmacist masked the analgesics by placing them into identical unmarked opaque capsules, which were packed with small amounts of lactose to equalize weight and then sealed. The pharmacist created research packets, each with 3 tablets containing the masked investigational medication. Research packets were removed by nurses from the Pyxis automated medical dispensing system located in the ED, and administered to the study patients. The randomized allocation schedule could only be accessed by the research pharmacist, who had no role in dispensing the medication.

Outcome Measures

Pain intensity was assessed using an 11-point NRS in which a score of 0 indicates no pain and a score of 10 indicates the worst possible pain. The NRS is commonly used in EDs for assessing initial pain at triage and changes in pain levels during evaluation and treatment. The primary outcome was the between-group difference in mean change in NRS pain score among patients receiving 1 of the 4 combination analgesics, measured from the time before ingestion of the study medication to 2 hours later. Secondary outcomes included between-group differences in mean NRS scores at 1 hour and responses to a 4-point Likert scale rating pain as none, mild, moderate, or severe. The data collection instrument went through several iterations and the Likert scale was not included in the final data collection instrument. The minimum clinically important difference was defined as a mean NRS pain score of 1.3 based on the standard previously derived and independently validated definition.[15-17]

Additional outcomes not described in the original protocol included the proportion of patients receiving rescue analgesics, the total amount of analgesics in morphine equivalent units, and an analysis of patients with either documented fractures or a pain score of 10. Demographic characteristics were collected to describe the population from which the sample was drawn.

Sample Size Calculation

The following parameters were used to calculate the sample size: an overall 2-sided significance level of .05 (.008 for all pairwise comparisons using the Bonferroni correction),[18] 80% power, between-group difference for change in mean NRS pain score of 1.3, and a within-group SD of 2.6 based on estimates of variability from our prior work.[3-5] Using these parameters, we estimated that 100 patients would be needed per group for a total of 400 patients.

Analysis

An intention-to-treat analysis was performed. All patients who were enrolled and met inclusion criteria were analyzed in the groups to which they were randomized. Those with missing NRS data (1 per group) had their missing values calculated by imputation. Details of the imputation analysis appear in Supplement 2. The primary analysis was a 1-way analysis of variance testing the null hypothesis that there is no difference in the effect of the medications on mean change in pain from baseline to 2 hours with a significance level of .05. The Bonferroni method was used to adjust the overall significance level of .05 to account for multiple comparisons when all pairwise mean differences in pain were compared, resulting in 99.2% CIs.

Four patients were missing 1, 2, or 3 NRS scores (**Figure**). Multiple imputation using chained equations was used to keep these patients in the intention-to-treat analysis. In a post hoc analysis, NRS scores at 2 hours were imputed for patients who received rescue medication. This was done to address bias that could be introduced if receipt of rescue medication differed by treatment group. If the distributions differ, the 2-hour NRS scores would reflect the combined effect of the initial and rescue analgesics, thus attenuating differences between treatment groups. The imputation model included baseline and 1-hour NRS scores, receipt of rescue analgesia, language of interview, age, sex, site, ethnicity, treatment group, diagnosis, and nonpharmacological interventions. For all analyses, we used SPSS Statistics version 22 (IBM) and Stata version 14.0 (StataCorp).

Results

During a 13-month period beginning in July 2015, 416 patients were randomized (Figure). Of these, 5 patients received nonopioid analgesia within the past 8 hours (an exclusion criterion) and were inadvertently randomized and later excluded from the analysis. Of the remaining 411, 48% were female, 60% were Latino, and 31% were black. Baseline characteristics were similar in all groups (**Table 1**). Baseline pain intensity was initially high (mean NRS pain score, 8.7 [SD, 1.3]) and did not differ between groups (**Table 2**).

Pain intensity declined over time in all treatment groups (Table 2). At 2 hours, the mean NRS pain score decreased by 4.3 (95% CI, 3.6 to 4.9) in the ibuprofen and acetaminophen group; by 4.4 (95% CI, 3.7 to 5.0) in the oxycodone and acetaminophen group; by 3.5 (95% CI, 2.9 to 4.2) in the hydrocodone and acetaminophen group; and by 3.9 (95% CI, 3.2 to 4.5)

Figure. Flow of Patients Through Acute Extremity Pain Trial

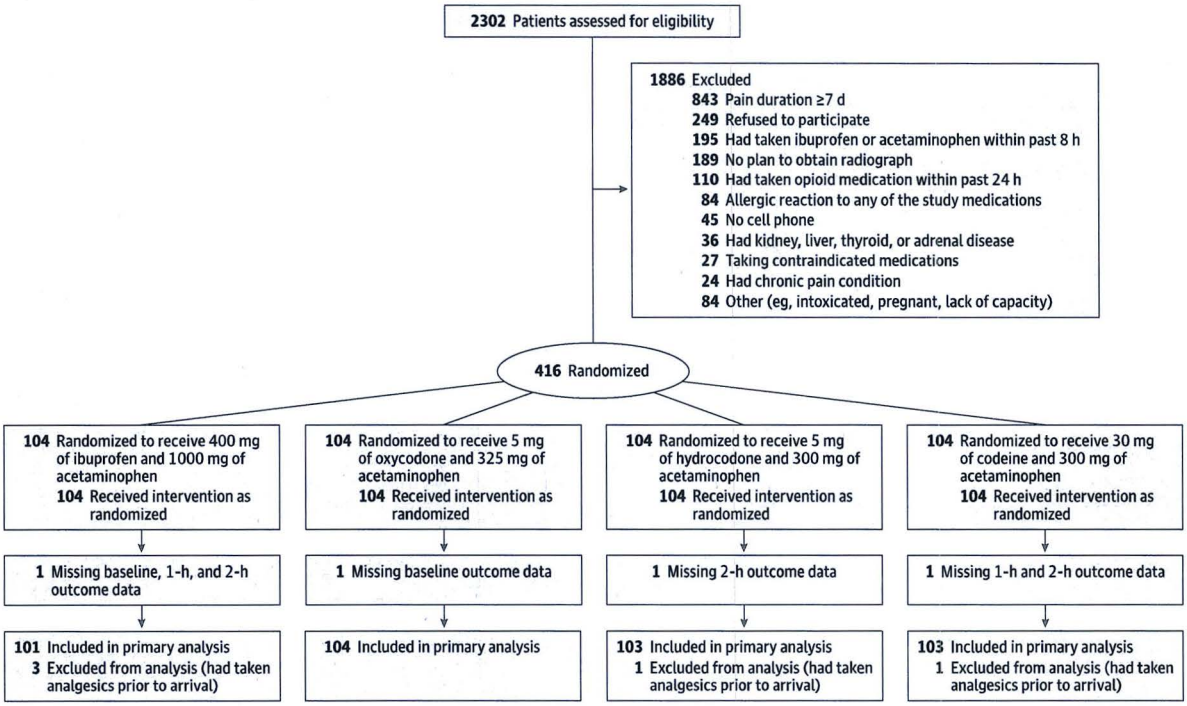


Table 1. Patient Characteristics

	Ibuprofen and Acetaminophen[a]	Oxycodone and Acetaminophen[b]	Hydrocodone and Acetaminophen[c]	Codeine and Acetaminophen[d]
No. of patients	101	104	103	103
Female sex, No. (%)	54 (54)	50 (48)	51 (50)	44 (43)
Age, mean (SD), y	37 (11)	37 (12)	37 (13)	37 (12)
Diagnosis, No. (%)				
Sprain or strain	64 (63)	66 (64)	59 (57)	67 (65)
Extremity fracture	21 (21)	23 (22)	21 (20)	24 (23)
Muscle pain	8 (8)	9 (9)	12 (12)	7 (7)
Contusion	4 (4)	3 (3)	7 (7)	2 (2)
Other	4 (4)	3 (3)	4 (4)	3 (3)
Nonpharmacological ED interventions, No. (%)				
Elastic bandage	39 (39)	37 (36)	23 (22)	36 (35)
Splint	12 (12)	20 (19)	18 (18)	10 (10)
Cast	10 (10)	14 (14)	6 (6)	11 (11)
Ice	7 (7)	11 (11)	10 (10)	4 (4)
Other	11 (11)	5 (5)	15 (15)	16 (16)

Abbreviation: ED, emergency department.

[a] Patients received 400 mg of ibuprofen and 1000 mg of acetaminophen.

[b] Patients received 5 mg of oxycodone and 325 mg of acetaminophen.

[c] Patients received 5 mg of hydrocodone and 300 mg of acetaminophen.

[d] Patients received 30 mg of codeine and 300 mg of acetaminophen.

in the codeine and acetaminophen group. The overall test of the null hypothesis that there is no difference in change in pain by treatment group from baseline to 2 hours (the primary outcome measure) was not statistically significant ($P = .053$). There was also no significant difference at 1 hour ($P = .13$) (Table 2).

Table 3 shows the comparisons in mean change in pain between each pair of analgesics. None of the differences between analgesics was statistically significant or met the a priori definition of a minimally clinically important difference in mean NRS pain score of 1.3.

Seventy-three patients (17.8%) received rescue analgesics within the 2-hour period (**Table 4**). The distribution of receipt of rescue analgesia was not statistically significant, but the estimates varied by as much as 9% (oxycodone and acetaminophen vs codeine and acetaminophen). Results of the analysis with multiple imputations of the NRS pain scores for

Table 2. Numerical Rating Scale (NRS) Pain Scores and Decline in Pain Scores by Treatment Group

	NRS Pain Score, Mean (95% CI)[a]				
	Ibuprofen and Acetaminophen[b]	Oxycodone and Acetaminophen[c]	Hydrocodone and Acetaminophen[d]	Codeine and Acetaminophen[e]	*P* Value[f]
No. of patients[g]	101	104	103	103	
Primary end point: decline in score to 2 h	4.3 (3.6 to 4.9)	4.4 (3.7 to 5.0)	3.5 (2.9 to 4.2)	3.9 (3.2 to 4.5)	.053
Baseline score	8.9 (8.5 to 9.2)	8.7 (8.3 to 9.0)	8.6 (8.3 to 9.0)	8.6 (8.2 to 8.9)	.47
Score at 1 h	5.9 (5.3 to 6.6)	5.5 (4.9 to 6.2)	6.2 (5.6 to 6.9)	5.9 (5.2 to 6.5)	.25
Score at 2 h	4.6 (3.9 to 5.3)	4.3 (3.6 to 5.0)	5.1 (4.5 to 5.8)	4.7 (4.0 to 5.4)	.13
Decline in score to 1 h	2.9 (2.4 to 3.5)	3.1 (2.6 to 3.7)	2.4 (1.8 to 3.0)	2.7 (2.1 to 3.3)	.13

[a] Pain intensity was assessed using an 11-point NRS in which a score of 0 indicates no pain and a score of 10 indicates the worst possible pain.
[b] Patients received 400 mg of ibuprofen and 1000 mg of acetaminophen.
[c] Patients received 5 mg of oxycodone and 325 mg of acetaminophen.
[d] Patients received 5 mg of hydrocodone and 300 mg of acetaminophen.
[e] Patients received 30 mg of codeine and 300 mg of acetaminophen.
[f] Calculated using analysis of variance.
[g] One patient in each group had imputed NRS data.

Table 3. Between-Group Difference in Mean Change in Numerical Rating Scale (NRS) Pain Scores

Comparison	Between-Group Difference in Mean Change in NRS Pain Score (99.2% CI)[a]	
	From Baseline to 1 h	From Baseline to 2 h
Ibuprofen and acetaminophen vs oxycodone and acetaminophen	−0.2 (−1.0 to 0.6)	−0.1 (−1.0 to 0.8)
Ibuprofen and acetaminophen vs hydrocodone and acetaminophen	0.5 (−0.3 to 1.3)	0.8 (−0.2 to 1.7)
Ibuprofen and acetaminophen vs codeine and acetaminophen	0.2 (−0.6 to 1.0)	0.4 (−0.6 to 1.3)
Oxycodone and acetaminophen vs hydrocodone and acetaminophen	0.7 (−0.1 to 1.5)	0.9 (−0.1 to 1.8)
Oxycodone and acetaminophen vs codeine and acetaminophen	0.4 (−0.4 to 1.2)	0.5 (−0.4 to 1.4)
Hydrocodone and acetaminophen vs codeine and acetaminophen	−0.3 (−1.1 to 0.5)	−0.4 (−1.3 to 0.6)

[a] Indicates mean change in pain of first analgesic minus mean change in pain from second analgesic. Pain intensity was assessed using an 11-point NRS in which a score of 0 indicates no pain and a score of 10 indicates the worst possible pain.

Table 4. Rescue Analgesic and Total Morphine Equivalent Units Received Within 2 Hours

	Ibuprofen and Acetaminophen	Oxycodone and Acetaminophen	Hydrocodone and Acetaminophen	Codeine and Acetaminophen	*P* Value
No. of patients	101	104	103	103	
Received rescue analgesic, No. (%)	18 (17.8)	14 (13.5)	18 (17.5)	23 (22.3)	.42
Type of rescue analgesic received, No. (%)					
Oxycodone	17 (16.8)	13 (12.5)	17 (16.5)	22 (21.4)	
Morphine	1 (1.0)	0	0	1 (1.0)	.55
Tramadol	0	1 (1.0)	1 (1.0)	0	
Analgesic dose in morphine equivalent units, mean (SD)[a]					
Initial	0 (0)	7.5 (0)	5.0 (0)	4.5 (0)	NA[b]
Rescue	1.6 (3.5)	1.1 (2.7)	1.7 (3.2)	2.0 (3.4)	.27
Total	1.6 (3.5)	8.6 (2.7)	6.7 (3.2)	6.5 (3.4)	<.001

[a] Calculated based on the US Centers for Medicare & Medicaid Services Opioid Oral Morphine Milligram Equivalent conversion factor table: 1.5 for oxycodone; 1.0 for hydrocodone; 0.15 for codeine; 0.1 for tramadol; and 3.0 for intravenous morphine.
[b] Statistical test cannot be calculated.

patients who received rescue analgesics were nearly identical to the analysis without imputation (eTable 1 and eTable 2 in Supplement 2). There were no clinically important or statistically significant differences in efficacy when these post hoc analyses were performed.

The amount of rescue analgesia received in morphine equivalent units was not significantly different across groups (Table 4). The total amount of opioid was significantly associated with treatment group. One patient in the ibuprofen and acetaminophen group received 6 mg of intravenous morphine and 1 patient in the codeine and acetaminophen group received 4 mg of intravenous morphine.

We conducted a post hoc subset analysis to assess whether any analgesic was more effective for severe pain among patients who either (1) rated their initial pain as a score of 10 on the NRS or (2) had a documented fracture on radiological imaging. The results were similar to those from the entire sample. There were no statistically significant or clinically important between-group differences (eTable 3 in Supplement 2).

Discussion

Among patients presenting to the ED with acute extremity pain, none of 4 different combination analgesics, 1 of which was opioid-free, resulted in greater pain relief after 2 hours. The largest difference in decline in mean NRS pain score between any 2 treatments was 0.9 at the 2-hour time point, a difference that

was not statistically significant and was less than 1.3, which is a commonly used criterion to define minimal clinically important difference in pain. The findings support the inference that there are no clinically meaningful differences between the analgesic effects of these 4 analgesics and suggest that a combination of ibuprofen and acetaminophen represents an alternative to oral opioid analgesics for the treatment of acute extremity pain in the ED.

Relatively few studies have made direct comparison of commonly used oral opioid analgesics for the treatment of acute pain.[3-7,19-22] These studies are difficult to compare because they used varying doses, had different outcomes, and had methodological limitations, including small sample sizes and substantial loss to follow-up. However, the results generally support the inference that opioid analgesics have similar efficacy.

The combination of nonopioids makes clinical sense because of the potential to increase analgesic efficacy through different modes of action.[23] However, there are relatively few studies of the relative efficacy of combination nonopioid oral analgesics vs oral opioids[9-12]; all were postoperative or dental studies that compared a combination of ibuprofen and acetaminophen vs codeine and acetaminophen. None found any dose of codeine (30 mg or 60 mg) to be superior to the combination of 400 mg of ibuprofen and acetaminophen in doses ranging from 325 mg to 1000 mg. One ED-based study compared a combination nonopioid vs oxycodone. All patients received ibuprofen and acetaminophen. There were 3 groups in the study (group 1 received 1000 mg of acetaminophen, 400 mg of ibuprofen, and 200 mg of thiamine; group 2 received 1000 mg of acetaminophen, 400 mg of ibuprofen, and 60 mg of codeine; and group 3 received 1000 mg of acetaminophen, 400 mg of ibuprofen, and 10 mg of oxycodone). At 30 minutes, there was no difference in analgesic efficacy among the groups.[24] The evidence from these studies suggests that the lack of greater pain reduction with opioid analgesics over the combination of ibuprofen and acetaminophen found in the current study may generalize beyond the treatment of acute extremity pain. In contrast to earlier research, the current study offered a direct comparison of the most commonly prescribed oral opioids used in the ED and a nonopioid combination.

The idea that nonopioid analgesics have less analgesic efficacy and that there are differences between the opioids can be found in the World Health Organization pain ladder that has guided clinicians in the treatment of cancer and noncancer pain since 1986.[25] Depending on the intensity of pain, nonopioids (eg, ibuprofen, acetaminophen) are prescribed first, and then, as necessary, mild opioids (eg, codeine), followed by strong opioids (eg, hydrocodone, oxycodone). The findings of the current study coupled with the existing literature do not support these distinctions among the oral analgesics for the treatment of acute extremity pain.

In light of the substantial increase in prescription opioid-related overdoses and deaths, the widespread use of oral opioids has been questioned.[26] Overuse and misuse of opioid analgesics in the community is an important contributor to the opioid epidemic; however, the current study only focused on treatment in the ED. If a nonopioid combination analgesic provides comparable pain relief to that obtained by oral opioids commonly used in the ED, it is possible that physicians may be more likely to discharge patients and prescribe the same nonopioid combination analgesics. In addition, patients might be more accepting of that analgesic so long as it provides ample pain relief when used in the ED. This change in prescribing habit could potentially help mitigate the ongoing opioid epidemic by reducing the number of people initially exposed to opioids and the subsequent risk of addiction, as shown in a recent study[13] that found long-term opioid use was significantly higher among patients treated by high-intensity ED opioid prescribers than among patients treated by low-intensity ED opioid prescribers.

Limitations

This study has several limitations. First, the follow-up time was limited to 2 hours. Although a more prolonged follow-up would have provided additional information, the goal was to determine if a single dose of an analgesic would provide superior pain relief for patients while in the ED. In addition, the enrolled patient population included those generally seen in a fast-track setting, in which patients are discharged quickly with minimal or no testing. Whether the duration of analgesia differs among the analgesics is unknown, although the half-lives are similar and range from approximately 3 hours to 4 hours.

Second, the oral opioids used in this study may be dispensed as 1 or 2 tablets at a time. We chose to administer the equivalent of 1 tablet. There are no nationally representative data sets that allow estimation of usual analgesic dose in the ED setting. For example, the National Hospital Ambulatory Care Survey[2] has medication and route information but not dose information. The dosage used in this study represents common practice among physicians from a variety of training programs and institutions. The dose of opioid chosen also reflects prior studies,[3-5] which have shown effective pain relief at the identical dosages used in the current study. In addition, there was concern that many physicians would not refer patients for enrollment if it meant administering higher doses of opioids because most patients were expected to be discharged quickly and the rescue analgesic was predefined to be 5 mg of oxycodone.

Third, approximately 18% of patients received rescue analgesia, and this may have driven results toward the null. However, additional analyses imputing NRS pain score for patients who received rescue analgesics also showed no clinically important or statistically significant difference.

Fourth, adverse effect information was not collected. Such information could influence the choice of analgesic prescribed, especially if one group had significantly more adverse effects than another group. Significant adverse effects were not expected to occur during the 2-hour follow-up of this study. However, a similar ED-based study lasting 90 minutes had an incidence of adverse events of 1.6% in the codeine group, 3.3% in the nonopioid group, and 16.9% in the oxycodone group, with lightheadedness accounting for 70% of adverse events in the oxycodone group. In that study, the amount

of oxycodone and codeine administered was double the dose used in the current study and thus is not directly comparable.[24]

Fifth, the nonopioid combination analgesic used requires 2 separate analgesics (ibuprofen and acetaminophen) and this could represent a barrier because there is no single tablet available in the United States that combines these 2 drugs. A combination product of ibuprofen and acetaminophen (paracetamol) in a single tablet is available for patients in Australia and New Zealand, though in smaller dosages than were used in this study.

Conclusions

For patients presenting to the ED with acute extremity pain, there were no statistically significant or clinically important differences in pain reduction at 2 hours among single-dose treatment with ibuprofen and acetaminophen or with 3 different opioid and acetaminophen combination analgesics. Further research to assess adverse events and other dosing may be warranted.

ARTICLE INFORMATION

Accepted for Publication: October 4, 2017.

Author Contribution: Drs Chang and Bijur had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.
Concept and design: Chang, Bijur, Esses, Baer.
Acquisition, analysis, or interpretation of data: All authors.
Drafting of the manuscript: Chang, Bijur, Esses.
Critical revision of the manuscript for important intellectual content: Chang, Bijur, Barnaby, Baer.
Statistical analysis: Chang, Bijur.
Administrative, technical, or material support: Esses, Barnaby, Baer.
Supervision: Chang, Esses, Baer.

Conflict of Interest Disclosures: The authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and none were reported.

Funding/Support: Dr Chang is funded by award 7K23AG033100-07 from the National Institute on Aging, National Institutes of Health.

Role of the Funder/Sponsor: The National Institute on Aging had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

Previous Presentation: This study was presented as an oral abstract at the annual Society for Academic Emergency Medicine meeting; May 17, 2017; Orlando, Florida.

Additional Contributions: We thank Ashar Ata, PhD (Albany Medical College), for help with revisions to the statistical analysis including imputation calculations and Clyde Schechter, MD (Albert Einstein College of Medicine), for review of the methods, analysis, and presentation of the results. Neither Dr Ata nor Dr Schechter received compensation for their assistance.

REFERENCES

1. Burke DS. Forecasting the opioid epidemic. *Science*. 2016;354(6312):529.

2. Kea B, Fu R, Lowe RA, Sun BC. Interpreting the National Hospital Ambulatory Medical Care Survey: United States emergency department opioid prescribing, 2006-2010. *Acad Emerg Med*. 2016;23(2):159-165.

3. Chang AK, Bijur PE, Holden L, Gallagher EJ. Comparative analgesic efficacy of oxycodone/acetaminophen versus hydrocodone/acetaminophen for short-term pain management in adults following ED discharge. *Acad Emerg Med*. 2015;22(11):1254-1260.

4. Chang AK, Bijur PE, Lupow JB, Gallagher EJ. Comparative analgesic efficacy of oxycodone/acetaminophen vs codeine/acetaminophen for short-term pain management following ED discharge. *Pain Med*. 2015;16(12):2397-2404.

5. Chang AK, Bijur PE, Munjal KG, Gallagher EJ. Randomized clinical trial of hydrocodone/acetaminophen versus codeine/acetaminophen in the treatment of acute extremity pain after emergency department discharge. *Acad Emerg Med*. 2014;21(3):227-235.

6. Marco CA, Plewa MC, Buderer N, Black C, Roberts A. Comparison of oxycodone and hydrocodone for the treatment of acute pain associated with fractures: a double-blind, randomized, controlled trial. *Acad Emerg Med*. 2005;12(4):282-288.

7. Turturro MA, Paris PM, Yealy DM, Menegazzi JJ. Hydrocodone versus codeine in acute musculoskeletal pain. *Ann Emerg Med*. 1991;20(10):1100-1103.

8. Friedman BW, Dym AA, Davitt M, et al. Naproxen with cyclobenzaprine, oxycodone/acetaminophen, or placebo for treating acute low back pain: a randomized clinical trial. *JAMA*. 2015;314(15):1572-1580.

9. Sniezek PJ, Brodland DG, Zitelli JA. A randomized controlled trial comparing acetaminophen, acetaminophen and ibuprofen, and acetaminophen and codeine for postoperative pain relief after Mohs surgery and cutaneous reconstruction. *Dermatol Surg*. 2011;37(7):1007-1013.

10. Daniels SE, Goulder MA, Aspley S, Reader S. A randomised, five-parallel-group, placebo-controlled trial comparing the efficacy and tolerability of analgesic combinations including a novel single-tablet combination of ibuprofen/paracetamol for postoperative dental pain. *Pain*. 2011;152(3):632-642.

11. Mitchell A, van Zanten SV, Inglis K, Porter G. A randomized controlled trial comparing acetaminophen plus ibuprofen versus acetaminophen plus codeine plus caffeine after outpatient general surgery. *J Am Coll Surg*. 2008;206(3):472-479.

12. Mitchell A, McCrea P, Inglis K, Porter G. A randomized, controlled trial comparing acetaminophen plus ibuprofen versus acetaminophen plus codeine plus caffeine (Tylenol 3) after outpatient breast surgery. *Ann Surg Oncol*. 2012;19(12):3792-3800.

13. Barnett ML, Olenski AR, Jena AB. Opioid-prescribing patterns of emergency physicians and risk of long-term use. *N Engl J Med*. 2017;376(7):663-673.

14. Butler MM, Ancona RM, Beauchamp GA, et al. Emergency department prescription opioids as an initial exposure preceding addiction. *Ann Emerg Med*. 2016;68(2):202-208.

15. Bijur PE, Latimer CT, Gallagher EJ. Validation of a verbally administered numerical rating scale of acute pain for use in the emergency department. *Acad Emerg Med*. 2003;10(4):390-392.

16. Holdgate A, Asha S, Craig J, Thompson J. Comparison of a verbal numeric rating scale with the visual analogue scale for the measurement of acute pain. *Emerg Med (Fremantle)*. 2003;15(5-6):441-446.

17. Todd KH. Clinical versus statistical significance in the assessment of pain relief. *Ann Emerg Med*. 1996;27(4):439-441.

18. Sedgwick P. Multiple hypothesis testing and Bonferroni's correction. *BMJ*. 2014;349:g6284.

19. Forbes JA, Bates JA, Edquist IA, et al. Evaluation of two opioid-acetaminophen combinations and placebo in postoperative oral surgery pain. *Pharmacotherapy*. 1994;14(2):139-146.

20. Litkowski LJ, Christensen SE, Adamson DN, Van Dyke T, Han SH, Newman KB. Analgesic efficacy and tolerability of oxycodone 5 mg/ibuprofen 400 mg compared with those of oxycodone 5 mg/acetaminophen 325 mg and hydrocodone 7.5 mg/acetaminophen 500 mg in patients with moderate to severe postoperative pain: a randomized, double-blind, placebo-controlled, single-dose, parallel-group study in a dental pain model. *Clin Ther*. 2005;27(4):418-429.

21. Palangio M, Morris E, Doyle RT Jr, Dornseif BE, Valente TJ. Combination hydrocodone and ibuprofen versus combination oxycodone and acetaminophen in the treatment of moderate or severe acute low back pain. *Clin Ther*. 2002;24(1):87-99.

22. Palangio M, Wideman GL, Keffer M, et al. Combination hydrocodone and ibuprofen versus combination oxycodone and acetaminophen in the treatment of postoperative obstetric or gynecologic pain. *Clin Ther*. 2000;22(5):600-612.

23. Raffa RB. Pharmacology of oral combination analgesics: rational therapy for pain. *J Clin Pharm Ther*. 2001;26(4):257-264.

24. Graudins A, Meek R, Parkinson J, Egerton-Warburton D, Meyer A. A randomised controlled trial of paracetamol and ibuprofen with or without codeine or oxycodone as initial analgesia for adults with moderate pain from limb injury. *Emerg Med Australas*. 2016;28(6):666-672.

25. Carlson CL. Effectiveness of the World Health Organization cancer pain relief guidelines: an integrative review. *J Pain Res*. 2016;9:515-534.

26. Gostin LO, Hodge JG Jr, Noe SA. Reframing the opioid epidemic as a national emergency. *JAMA*. doi:10.1001/jama.2017.13358

Alaska Dispatch News

Alaska News

Alaska governor declares opioid abuse public health disaster

Author: **Michelle Theriault Boots** Updated: December 2, 2017 Published February 15, 2017

Gov. Bill Walker issued an order Tuesday officially declaring the state's opioid crisis a public health disaster.

The disaster declaration was designed to create a legal basis for the state to issue a medical "standing order" that allows community groups, law enforcement and members of the public to dispense and administer naloxone, an anti-overdose medication, said Dr. Jay Butler, Alaska's chief medical officer.

Alaska used a $5 million federal grant on naloxone kits it is now distributing through a program run by the state Division of Public Health. The medical standing order was issued Tuesday, Butler said.

"It seems like a bit of an unorthodox approach, but other states have used similar mechanisms," said Butler.

Butler, who has a background in infectious disease, said he thought it was the first time the state had used a disaster declaration to respond to a public health crisis.

The opioid order is the 11th disaster declaration Walker has issued. Others include a December storm in Western Alaska, landslides in Sitka, flooding on the Dalton Highway and a washateria fire in Alatna.

Declaring opioid abuse a public health disaster usually reserved for events like floods, earthquakes and fires holds extra rhetorical weight, said Butler.

"It's a great way to begin framing the response to this epidemic."

[Whether you become a long-term opioid user may depend on which ER doctor you see]

The disaster declaration shouldn't cost the state any additional money, according to supporting materials released with the declaration.

Butler, an infectious disease specialist, said he is cautious about using the term "epidemic." But he says it's appropriate in talking about opioid abuse in Alaska.

Nationally, heroin abuse began to rise about 15 years ago, according to Butler. Prescription painkiller deaths increased in Alaska about a decade ago. Heroin hit hard starting five or six years ago: The declaration says the number of heroin-associated deaths in Alaska quadrupled between 2009 and 2015.

The epidemic has changed, but the wave hasn't crested yet. In the past two years, treacherous painkillers like fentanyl have become more prominent in the state, he said. And most recently, novel lab-made forms of synthetic opioids have appeared.

The declaration "comes in response to the growing number of overdoses attributed to opioid abuse and the evidence that highly dangerous synthetic opioids have made their way into Alaska."

"It's hard to know what's going to come next," he said.

A letter to legislators signed by Walker says emergency responders in communities from Juneau to Fairbanks have been "overwhelmed" with opioid overdoses.

Alaska is not the only state to declare opioid abuse a disaster.

In November, Virginia's governor issued a similar declaration.

Butler said the disaster declaration is only a temporary solution to getting anti-overdose drugs to the public.

"This is a short period of time. If we continue for a longer period, we'll probably have to work with the Legislature," Butler said.

[Volunteers assemble 'rescue kits' in hopes of preventing overdose deaths]

Clearly, getting anti-overdose drugs to more people is only one part of responding to opioid abuse, Butler said.

More Alaskans still die of alcohol-related diseases than opioid abuse.

"We need to move beyond molecule-specific responses to look more broadly at how we treat addictions."

About this Author

Michelle Theriault Boots

Michelle Theriault Boots is a reporter for Alaska Dispatch News.

Alaska Dispatch News

Rural Alaska

Alaska's heroin problem brings together state, local and federal leaders in search of a solution

Author: **Lisa Demer** Updated: September 20, 2016 Published September 20, 2016

Jerry Evan, an investigator with Alaska State Troopers; Marlin Ritzman, FBI special agent in charge; and Andrea Hattan, assistant U.S. Attorney, listen to residents Monday at a community meeting on heroin in Bethel. (Lisa Demer / Alaska Dispatch News)

BETHEL — Alaska's heroin problem is significant, growing and, authorities say, in need of attention from all quarters to get under control.

That was the message Monday at school and community meetings in Bethel that included Alaska's top FBI agent and a federal prosecutor, local police and a state trooper, a pharmacist and a counselor, public health nurses and Native hospital leaders.

A team is touring rural Alaska this month to put attention on the damage heroin and other opioid drugs already are inflicting across the state. The Obama administration has declared a nationwide "week of action." The hope, say leaders, is to prevent young people from falling under the grip and to steer those already addicted toward help.

Some wonder whether the national anti-opioid agenda is the right strategy for the Yukon-Kuskokwim Delta, where alcohol causes so many more problems.

The destruction of the addictive drugs showed itself in the Southwestern Alaska village of Quinhagak last month when a 19-year-old just out of high school died and three others overdosed on heroin supercharged with the painkiller fentanyl.

[After a young woman's death from a heroin overdose, an Alaska village looks inward]

A team that includes Marlin Ritzman, the Anchorage-based FBI special agent in charge, and Andrea Hattan, an assistant U.S. attorney, already traveled to Kotzebue, Barrow and Bethel and were in Ketchikan on Tuesday. Nome, Kodiak and Petersburg are scheduled for visits, too.

Community meetings and school assemblies on heroin and other opioids are anchored by a film produced by the FBI and the Drug Enforcement Administration called "Chasing the Dragon: The Life of an Opiate Addict" that features disturbing first-person accounts by drug users and their family members.

One mother, Trish, tells of helping to put her daughter — once a bubbly honor-roll student — in jail as a way to get her clean. Six days after getting out, Trish found her daughter in her room, dead of a heroin overdose.

"Still calling her, still calling her. It's that powerful that you could spend seven months clean, clean and being educated on nothing but how to beat it, how bad it is for you," Trish says in the film. "And you last six days."

Addicts talked about injecting with heroin cut with meat tenderizer, which then ate away at their flesh. They just kept doing it. A woman said maggots multiplied in an infected leg wound from where she had stuck the needle in. One time, she ended up in the hospital and walked out to buy heroin, still in her hospital gown. She used the IV line to shoot up.

Cory, a young man, talked about growing up in a good family, camping, becoming an Eagle Scout. Then, he said, his fixation on drugs turned him into a monster. He lost years in his addiction fog.

Similar stories unfold right in Bethel, Teri Forst, a counselor at Bethel Family Clinic, told students at the Bethel Regional High School morning assembly.

"A lot of you may be thinking they just show the scariest, the worst, the most dangerous, the worst-case scenarios," said Forst, who grew up and went through school in Bethel. "I can tell you I've seen dozens of clients in my office with that exact same story that are from this town that you each of may know and love. So that's for real."

Kids often fidget and squirm their way through school assemblies. For Bethel's assembly on heroin, hundreds of students sat quietly, watching and listening.

"Please, please, please take this movie seriously," Forst urged.

Later, an overflow crowd packed the Bethel City Council chambers at City Hall for a similar showing and panel discussion.

Alaska's rate of death from heroin is 50 percent higher than the national average and from prescription opioids, double it, Hattan, the federal prosecutor, told the high school and community groups. And the numbers are growing, she said.

[Alaska's heroin death rate spikes, but prescription opioids take more lives]

Both the high school students and the community residents asked pointed questions. Why do doctors prescribe painkillers if they are so addictive — and lead some to heroin? What are police doing? What can residents do with unused pain pills? What help is available?

Michael Stamper, a pharmacist with Yukon-Kuskokwim Health Corp., said painkillers have a place in medicine, but must be carefully controlled.

"As low a dose as possible for as short a time as possible," he said.

Patients are put on pain management contracts, and a committee that includes medical providers, behavioral health clinicians and pharmacists reviews them monthly.

Law enforcement needs the public's help, said Bethel Police Chief Andre Achee. If you see something, call and keep calling, he said. If something suspicious is happening right then, stress that to the dispatcher, the chief said.

Jerry Evan, an investigator with Alaska State Troopers' Western Alaska Alcohol and Narcotics Team who is originally from the Kuskokwim River village of Napaskiak, told the community anonymous tips may not be enough to get a search warrant. Drug cases are complex, not cut and dried like drunken-driving offenses, he said. The Western Alaska team is down to two investigators, when it used to have three and a clerk, he said.

As to unused prescription pain pills, residents can mix them with coffee grounds or kitty litter, and put them in the trash, Stamper said. People also can bring them to troopers, or ask troopers to pick them up, Evan said. Don't flush them down the toilet, Hattan said. Drugs can end up in water sources and waterways, including the Kuskokwim River.

Some elements of the local response are in flux. Officials with Yukon-Kuskokwim Health Corp. last week said the antidote naloxone would be provided to users and their families over the counter, without a prescription. It can revive people near death from a heroin overdose.

Asked about naloxone or Narcan, the brand name, at Bethel's community meeting, YKHC pharmacist Stamper said a prescription would be needed.

After the meeting, Dan Winkelman, chief executive of the Alaska Native-run health corporation, said he had been told the facility would provide it over the counter, "and if we can't, that will be changed immediately."

Community members also were told YKHC will begin offering treatment specifically for heroin addiction this fall but were told first it would be outpatient, then it would be residential.

The new program is designed as intensive outpatient but some patients who need residential treatment will be able to get it, based on an assessment, Jim Sweeney, YKHC vice president, explained after the meeting.

The spotlight on heroin and opioid abuse is welcome. Yet alcohol leads to far more deaths, injuries and arrests, Leif Albertson, a Bethel City Council member and a paramedic with the Bethel Fire Department, noted after the meeting.

"As a volunteer on the ambulance, I have seen the same thing; call after call for alcohol-related injury, incapacitation or death," Albertson said in an email. "In the fight against substance abuse, we need to remember that alcohol has a near-monopoly on the suffering we see in our region. If we're serious about addiction in our community, we need to be honest about that fact."

That's a fair point, Jay Butler, the state's chief medical officer, said Tuesday. Alcohol has not received the same focused public health response as heroin and prescription opioids, Butler said, even though it is a more pervasive problem.

The recent rise in deaths from heroin and opioids and the availability of an antidote for someone who has stopped breathing from heroin are among the reasons those drugs get such attention, he said.

"In some ways the opioid epidemic suggests it may have more opportunities for intervention and to reverse the current trends of what we are seeing in deaths," he said.

Still, as for heroin, alcohol abuse materializes as a public health problem as well as a problem for individuals, he said. More attention is needed for alcohol as well, he said.

About this Author

Lisa Demer

Lisa Demer has been a reporter about 35 years, mostly in Alaska and mostly of the last three in Bethel covering Western Alaska. She is currently back in Anchorage covering general assignments. Phone 907-257-4345.

Dr. John DeGarmo, Contributor
Leading Expert in Parenting and Foster Care

How The Heroin Crisis Is Straining Foster Care

The foster care system is struggling to care for thousands of children left behind as victims.

04/11/2017 12:58 pm ET | **Updated** Apr 11, 2017

Heroin is unraveling families across the nation, and it is our children who are left as innocent victims of this drug and opioid epidemic.

Make no mistake; the heroin crisis in America is destroying our families. From 2000 to 2015 more than half a million people died from drug overdoses. Shockingly, 91 people in America die from an opioid overdose each day. The governor of Maryland Larry Hogan, declared a state of emergency in March of 2017, with plans of 50 million in new funding over the next five years, to combat the increasing problem. "We need to

continuing threat increasing at such an alarming rate, we must allow for rapid coordination with our state and local emergency management teams."

As more and more parents become addicted to heroin, and other opioids, thousands of more children are being placed into a foster care system throughout the nation; a system that is struggling to properly assist these children due to lack of resources, foster parents, and funding. "The heroin epidemic is forcing more kids into foster care, but in most states, funding can't keep up with the need," according to Lana Freeman and the National Foster Parent Association. "The states need more foster families, the workers need more resources, and parents need more services."

With the increase in children being placed into foster care, the foster care system is struggling to keep up. With roughly 450,000 children in foster care across the nation, there are not enough foster homes, as foster care agencies face the challenge of recruitment and retention of foster parents. The end result is simply that there are not enough homes for children in need to be placed in, or a child is moved from one home to another.

"Recruiting new foster parents is always challenging, as most people foster for a season of their lives, rather than a lifetime," said Kim Phagan-Hansel, editor of Fostering Families Today. "As an increasing number of children have entered the foster care system in recent years due to escalating drug use across the country, some states have struggled to recruit foster parents to keep pace with that demand. I think what you'll see is that in some areas of the country they're really struggling to address this latest drug epidemic and its impact on children and families."

One of the reasons children are placed into foster care is due to parental drug abuse. According to the book Helping Foster Children in School: A Guide for Foster Parents, Social Workers, and Teachers, "those parents who abuse drugs and/or alcohol place their children in danger. This danger may result in neglect, physical abuse, or domestic violence." Indeed, the larger number of children being placed into foster care, nationwide, is due much in part of an increase in parental drug usage and substance abuse, with Heroin use being the chief drug increasing among parents. Other substance abuse among parents include meth, cocaine and prescription medication abuse.

In Alaska, the heroin crisis is troubling. Chris Scott, the director of Royal Family Kids Camp in Anchorage , has seen the problem increase and become widespread in Alaska. "The number of kids in foster care has increased by 1000 kids in a year in the state of Alaska. It is believed that nearly all of them are in care because of substance abuse and the drug of choice being heroin. Heroin has no boundaries whether it is the big city of Anchorage or the little village of Eek. It is killing families."

Yes, it is killing families.

And the foster care system is struggling to care for these thousands of children left behind as victims.

Dr. John DeGarmo is an international expert on foster care. He has been a foster parent for 15 years, now, and he and his wife have had over 50 children come through their home. He is a consultant to foster care agencies, child welfare organizations, and legal firms, as well as a speaker and trainer on many topics about the foster care system. He is the author of several foster care books, including The Foster Parenting Manual: A Practical Guide to Creating a Loving, Safe, and Stable Home, and writes for several publications. He can be contacted at drjohndegarmo@gmail.com, through his Facebook page, Dr. John DeGarmo, or at The Foster Care Institute.

THE NEW YORKER

THE FAMILY THAT BUILT AN EMPIRE OF PAIN

The Sackler dynasty's ruthless marketing of painkillers has generated billions of dollars—and millions of addicts.

By Patrick Radden Keefe

The north wing of the Metropolitan Museum of Art is a vast, airy enclosure featuring a banked wall of glass and the Temple of Dendur, a sandstone monument that was constructed beside the Nile two millennia ago and transported to the Met, brick by brick, as a gift from the Egyptian government. The space, which opened in 1978 and is known as the Sackler Wing, is also itself a monument, to one of America's great philanthropic dynasties. The Brooklyn-born brothers Arthur, Mortimer, and Raymond Sackler, all physicians, donated lavishly during their lifetimes to an astounding range of institutions, many of which today bear the family name: the Sackler Gallery, in Washington; the Sackler Museum, at Harvard; the Sackler Center for Arts Education, at the Guggenheim; the Sackler Wing at the Louvre; and Sackler institutes and facilities at Columbia, Oxford, and a dozen other universities. The Sacklers have endowed professorships and underwritten medical research. The art scholar Thomas Lawton once likened the eldest brother, Arthur, to "a modern Medici." Before Arthur's death, in 1987, he advised his children, "Leave the world a better place than when you entered it."

Mortimer died in 2010, and Raymond died earlier this year. The brothers bequeathed to their heirs a laudable tradition of benevolence, and an immense fortune with which to indulge it. Arthur's daughter Elizabeth is on the board of the Brooklyn Museum, where she endowed the Elizabeth A. Sackler Center for Feminist Art. Raymond's sons, Richard and Jonathan, established a professorship at Yale Cancer Center. "My father raised Jon and me to believe that philanthropy is an important part of how we should fill our lives," Richard has said. Marissa Sackler, the thirty-six-year-old daughter of Mortimer and his third wife, Theresa Rowling, founded Beespace, a nonprofit "incubator" that supports organizations like the Malala Fund. Sackler recently told *W* that she finds the word "philanthropy" old-fashioned. She considers herself a "social entrepreneur."

When the Met was originally built, in 1880, one of its trustees, the lawyer Joseph Choate, gave a speech to Gilded Age industrialists who had gathered to celebrate its dedication,

and, in a bid for their support, offered the sly observation that what philanthropy really buys is immortality: "Think of it, ye millionaires of many markets, what glory may yet be yours, if you only listen to our advice, to convert pork into porcelain, grain and produce into priceless pottery, the rude ores of commerce into sculptured marble." Through such transubstantiation, many fortunes have passed into enduring civic institutions. Over time, the origins of a clan's largesse are largely forgotten, and we recall only the philanthropic legacy, prompted by the name on the building. According to *Forbes*, the Sacklers are now one of America's richest families, with a collective net worth of thirteen billion dollars—more than the Rockefellers or the Mellons. The bulk of the Sacklers' fortune has been accumulated only in recent decades, yet the source of their wealth is to most people as obscure as that of the robber barons. While the Sacklers are interviewed regularly on the subject of their generosity, they almost never speak publicly about the family business, Purdue Pharma—a privately held company, based in Stamford, Connecticut, that developed the prescription painkiller OxyContin. Upon its release, in 1995, OxyContin was hailed as a medical breakthrough, a long-lasting narcotic that could help patients suffering from moderate to severe pain. The drug became a blockbuster, and has reportedly generated some thirty-five billion dollars in revenue for Purdue.

But OxyContin is a controversial drug. Its sole active ingredient is oxycodone, a chemical cousin of heroin which is up to twice as powerful as morphine. In the past, doctors had been reluctant to prescribe strong opioids—as synthetic drugs derived from opium are known—except for acute cancer pain and end-of-life palliative care, because of a long-standing, and well-founded, fear about the addictive properties of these drugs. "Few drugs are as dangerous as the opioids," David Kessler, the former commissioner of the Food and Drug Administration, told me.

Purdue launched OxyContin with a marketing campaign that attempted to counter this attitude and change the prescribing habits of doctors. The company funded research and paid doctors to make the case that concerns about opioid addiction were overblown, and that OxyContin could safely treat an ever-wider range of maladies. Sales representatives marketed OxyContin as a product "to start with and to stay with." Millions of patients found the drug to be a vital salve for excruciating pain. But many others grew so hooked on it that, between doses, they experienced debilitating withdrawal.

Since 1999, two hundred thousand Americans have died from overdoses related to OxyContin and other prescription opioids. Many addicts, finding prescription painkillers too expensive or too difficult to obtain, have turned to heroin. According to the American

Society of Addiction Medicine, four out of five people who try heroin today started with prescription painkillers. The most recent figures from the Centers for Disease Control and Prevention suggest that a hundred and forty-five Americans now die every day from opioid overdoses.

Andrew Kolodny, the co-director of the Opioid Policy Research Collaborative, at Brandeis University, has worked with hundreds of patients addicted to opioids. He told me that, though many fatal overdoses have resulted from opioids other than OxyContin, the crisis was initially precipitated by a shift in the culture of prescribing—a shift carefully engineered by Purdue. "If you look at the prescribing trends for all the different opioids, it's in 1996 that prescribing really takes off," Kolodny said. "It's not a coincidence. That was the year Purdue launched a multifaceted campaign that misinformed the medical community about the risks." When I asked Kolodny how much of the blame Purdue bears for the current public-health crisis, he responded, "The lion's share."

Although the Sackler name can be found on dozens of buildings, Purdue's Web site scarcely mentions the family, and a list of the company's board of directors fails to include eight family members, from three generations, who serve in that capacity. "I don't know how many rooms in different parts of the world I've given talks in that were named after the Sacklers," Allen Frances, the former chair of psychiatry at Duke University School of Medicine, told me. "Their name has been pushed forward as the epitome of good works and of the fruits of the capitalist system. But, when it comes down to it, they've earned this fortune at the expense of millions of people who are addicted. It's shocking how they have gotten away with it."

"Dr. Sackler considered himself and was considered to be the patriarch of the Sackler family," a lawyer representing Arthur Sackler's children once observed. Arthur was a gap-toothed, commanding polymath who trained under the Dutch psychoanalyst Johan H. W. van Ophuijsen, whom Sackler proudly described as "Freud's favorite disciple." Arthur and his brothers, the children of Jewish immigrants from Galicia and Poland, grew up in Brooklyn during the Depression. All three attended medical school, and worked together at the Creedmoor Psychiatric Center, in Queens, collectively publishing some hundred and fifty scholarly papers. Arthur became fascinated, he later explained, by the ways that "nature and disease can reveal their secrets." The Sacklers were especially interested in the biological aspects of psychiatric disorders, and in pharmaceutical alternatives to mid-century methods such as electroshock therapy and psychoanalysis.

But the brothers made their fortunes in commerce, rather than from medical practice. They shared an entrepreneurial bent. As a teen-ager, Mortimer became the advertising manager of his high-school newspaper, and after persuading Chesterfield to place a cigarette ad he got a five-dollar commission—a lot of money at a time when, he later said, "even doctors were selling apples in the streets." In 1942, Arthur helped pay his medical-school tuition by taking a copywriting job at William Douglas McAdams, a small ad agency that specialized in the medical field. He proved so adept at this work that he eventually bought the agency —and revolutionized the industry. Until then, pharmaceutical companies had not availed themselves of Madison Avenue pizzazz and trickery. As both a doctor and an adman, Arthur displayed a Don Draper-style intuition for the alchemy of marketing. He recognized that selling new drugs requires a seduction of not just the patient but the doctor who writes the prescription.

Sackler saw doctors as unimpeachable stewards of public health. "I would rather place myself and my family at the judgment and mercy of a fellow-physician than that of the state," he liked to say. So in selling new drugs he devised campaigns that appealed directly to clinicians, placing splashy ads in medical journals and distributing literature to doctors' offices. Seeing that physicians were most heavily influenced by their own peers, he enlisted prominent ones to endorse his products, and cited scientific studies (which were often underwritten by the pharmaceutical companies themselves). John Kallir, who worked under Sackler for ten years at McAdams, recalled, "Sackler's ads had a very serious, clinical look—a physician talking to a physician. But it was advertising." In 1997, Arthur was posthumously inducted into the Medical Advertising Hall of Fame, and a citation praised his achievement in "bringing the full power of advertising and promotion to pharmaceutical marketing." Allen Frances put it differently: "Most of the questionable practices that propelled the pharmaceutical industry into the scourge it is today can be attributed to Arthur Sackler."

Advertising has always entailed some degree of persuasive license, and Arthur's techniques were sometimes blatantly deceptive. In the nineteen-fifties, he produced an ad for a new Pfizer antibiotic, Sigmamycin: an array of doctors' business cards, alongside the words "More and more physicians find Sigmamycin the antibiotic therapy of choice." It was the medical equivalent of putting Mickey Mantle on a box of Wheaties. In 1959, an investigative reporter for *The Saturday Review* tried to contact some of the doctors whose names were on the cards. They did not exist.

During the sixties, Arthur got rich marketing the tranquillizers Librium and Valium. One Librium ad depicted a young woman carrying an armload of books, and suggested that even the quotidian anxiety a college freshman feels upon leaving home might be best handled with tranquillizers. Such students "may be afflicted by a sense of lost identity," the copy read, adding that university life presented "a whole new world . . . of anxiety." The ad ran in a medical journal. Sackler promoted Valium for such a wide range of uses that, in 1965, a physician writing in the journal *Psychosomatics* asked, "When do we *not* use this drug?" One campaign encouraged doctors to prescribe Valium to people with no psychiatric symptoms whatsoever: "For this kind of patient—with no demonstrable pathology—consider the usefulness of Valium." Roche, the maker of Valium, had conducted no studies of its addictive potential. Win Gerson, who worked with Sackler at the agency, told the journalist Sam Quinones years later that the Valium campaign was a great success, in part because the drug was so effective. "It kind of made junkies of people, but that drug worked," Gerson said. By 1973, American doctors were writing more than a hundred million tranquillizer prescriptions a year, and countless patients became hooked. The Senate held hearings on what Edward Kennedy called "a nightmare of dependence and addiction."

While running his advertising company, Arthur Sackler became a publisher, starting a biweekly newspaper, the *Medical Tribune*, which eventually reached six hundred thousand physicians. He scoffed at suggestions that there was a conflict of interest between his roles as the head of a pharmaceutical-advertising company and the publisher of a periodical for doctors. But in 1959 it emerged that a company he owned, MD Publications, had paid the chief of the antibiotics division of the F.D.A., Henry Welch, nearly three hundred thousand dollars in exchange for Welch's help in promoting certain drugs. Sometimes, when Welch was giving a speech, he inserted a drug's advertising slogan into his remarks. (After the payments were discovered, he resigned.) When I asked John Kallir about the Welch scandal, he chuckled, and said, "He got co-opted by Artie."

In 1952, the Sackler brothers bought a small patent-medicine company, Purdue Frederick, which was based in Greenwich Village and made such unglamorous staples as laxatives and earwax remover. According to court documents, each brother would control a third of the company, but Arthur, who was occupied with his publishing and advertising ventures, would play a passive role. The journalist Barry Meier, in his 2003 book, "Pain Killer: A 'Wonder' Drug's Trail of Addiction and Death," remarks that Arthur treated his brothers "not as siblings but more like his progeny and understudies." Now Raymond and Mortimer, who became joint C.E.O.s, had a company of their own.

In the early sixties, Estes Kefauver, a Tennessee senator, chaired a subcommittee that looked into the pharmaceutical industry, which was growing rapidly. Kefauver, who had previously investigated the Mafia, was especially intrigued by the Sackler brothers. A memo prepared by Kefauver's staff noted, "The Sackler empire is a completely integrated operation in that it can devise a new drug in its drug development enterprise, have the drug clinically tested and secure favorable reports on the drug from the various hospitals with which they have connections, conceive the advertising approach and prepare the actual advertising copy with which to promote the drug, have the clinical articles as well as advertising copy published in their own medical journals, [and] prepare and plant articles in newspapers and magazines." In January, 1962, Arthur travelled to Washington to testify before Kefauver's subcommittee. A panel of senators assailed him with pointed questions, but he was a formidable interlocutor—slippery, aloof, and impeccably prepared—and no senator landed a blow. At one point, Sackler caught Kefauver in an error and said, "If you personally had taken the training that a physician requires to get a degree, you would never have made that mistake." Quizzed about his promotion of a cholesterol drug that had many side effects, including hair loss, Sackler deadpanned, "I would prefer to have thin hair to thick coronaries."

As the Sacklers grew wealthy, they became patrons of the arts. In 1974, the brothers gave the Met three and a half million dollars, enabling the construction of the wing housing the Temple of Dendur. Mortimer used the space for a lavish birthday party. The cake was in the shape of the Great Sphinx, but its face had been replaced with Mortimer's.

In April, 1987, when Arthur Sackler was seventy-three, he demanded that his third wife, Gillian, account for all their household expenditures. He dictated a terse memo: "I am determined to take command of all situations for which I personally and my estate bear the ultimate obligation." A month later, he had a heart attack, and died. The family gathered for a fond memorial service at the Met, but Arthur's children fought bitterly with Gillian, and sparred with Mortimer and Raymond, over the estate. They accused Gillian of trying to steal their inheritance, and of being "inspired variously by greed, malice, or vindictiveness toward her stepchildren." According to the minutes of a family meeting, Arthur's daughter Elizabeth suggested that he had hidden the true worth of some family investments, "because he didn't want Morty and Ray to think they were more valuable." A family lawyer told the children, "There were no absolutely white lilies here on either side."

Arthur's descendants still owned a third of Purdue Frederick, and Mortimer and Raymond were interested in buying the stake. The company, which had moved to Connecticut and

would eventually change its name to Purdue Pharma, had made a great deal of money under their stewardship. But such riches were about to seem paltry. By the time the brothers made their bid, Purdue was already developing a new drug: OxyContin.

Humans have cultivated the opium poppy for five thousand years. The father of medicine, Hippocrates, recognized the therapeutic properties of the plant. But even in the ancient world people understood that the benevolent powers of this narcotic were offset by the perils of addiction. In his 1996 book, "Opium: A History," Martin Booth notes that, for the Romans, the poppy was a symbol of both sleep and death. During the nineteen-eighties, Raymond and Mortimer Sackler had a great success at Purdue with an innovative painkiller called MS Contin, a morphine pill with a patented "controlled release" formula: the drug dissolved gradually into the bloodstream over several hours. ("Contin" was short for "continuous.") MS Contin became the biggest seller in Purdue's history. But, by the late eighties, its patent was about to expire, and Purdue executives started looking for a drug to replace it.

One executive who was centrally involved in this effort was Raymond's son Richard, an enigmatic, slightly awkward man who, in the family tradition, had trained as a doctor. Richard had joined Purdue in 1971 as an assistant to his father, and worked his way up. His name appears on numerous medical patents. In the summer of 1990, a Purdue scientist sent a memo to Richard and several other colleagues, pointing out that MS Contin could "face such serious generic competition that other controlled-release opioids must be considered." The memo described ongoing efforts to create a product containing oxycodone, an opioid that had been developed by German scientists in 1916.

Oxycodone, which was inexpensive to produce, was already used in other drugs, such as Percodan (in which it is blended with aspirin) and Percocet (in which it is blended with Tylenol). Purdue developed a pill of pure oxycodone, with a time-release formula similar to that of MS Contin. The company decided to produce doses as low as ten milligrams, but also jumbo pills—eighty milligrams and a hundred and sixty milligrams—whose potency far exceeded that of any prescription opioid on the market. As Barry Meier writes, in "Pain Killer," "In terms of narcotic firepower, OxyContin was a nuclear weapon."

Before releasing OxyContin, Purdue conducted focus groups with doctors and learned that the "biggest negative" that might prevent widespread use of the drug was ingrained concern regarding the "abuse potential" of opioids. But, fortuitously, while the company was developing OxyContin, some physicians began arguing that American medicine should

reëxamine this bias. Highly regarded doctors, like Russell Portenoy, then a pain specialist at Memorial Sloan Kettering Cancer Center, in New York, spoke out about the problem of untreated chronic pain—and the wisdom of using opioids to treat it. "There is a growing literature showing that these drugs can be used for a long time, with few side effects," Portenoy told the *Times*, in 1993. Describing opioids as a "gift from nature," he said that they needed to be destigmatized. Portenoy, who received funding from Purdue, decried the reticence among clinicians to administer such narcotics for chronic pain, claiming that it was indicative of "opiophobia," and suggesting that concerns about addiction and abuse amounted to a "medical myth." In 1997, the American Academy of Pain Medicine and the American Pain Society published a statement regarding the use of opioids to treat chronic pain. The statement was written by a committee chaired by Dr. J. David Haddox, a paid speaker for Purdue.

Richard Sackler worked tirelessly to make OxyContin a blockbuster, telling colleagues how devoted he was to the drug's success. The F.D.A. approved OxyContin in 1995, for use in treating moderate to severe pain. Purdue had conducted no clinical studies on how addictive or prone to abuse the drug might be. But the F.D.A., in an unusual step, approved a package insert for OxyContin which announced that the drug was *safer* than rival painkillers, because the patented delayed-absorption mechanism "is believed to reduce the abuse liability." David Kessler, who ran the F.D.A. at the time, told me that he was "not involved in the approval." The F.D.A. examiner who oversaw the process, Dr. Curtis Wright, left the agency shortly afterward. Within two years, he had taken a job at Purdue.

Mortimer, Raymond, and Richard Sackler launched OxyContin with one of the biggest pharmaceutical marketing campaigns in history, deploying many persuasive techniques pioneered by Arthur. Steven May, who joined Purdue as an OxyContin sales representative in 1999, recalled, "At the time, we felt like we were doing a righteous thing." He used to tell himself, "There's millions of people in pain, and we have the solution." (May is no longer working for Purdue.) The company assembled a sales force of as many as a thousand representatives and armed them with charts showing OxyContin's benefits. May attended a three-week training session at Purdue's headquarters. At a celebratory dinner following the training, he was seated at a table with Richard Sackler. "I was blown away," he recalled. "My first impression of him was 'This is the dude that made it happen. He has a company that his family owns. I want to *be* him one day.' "

A major thrust of the sales campaign was that OxyContin should be prescribed not merely for the kind of severe short-term pain associated with surgery or cancer but also for less

acute, longer-lasting pain: arthritis, back pain, sports injuries, fibromyalgia. The number of conditions that OxyContin could treat seemed almost unlimited. According to internal documents, Purdue officials discovered that many doctors wrongly assumed that oxycodone was *less* potent than morphine—a misconception that the company exploited.

A 1995 memo sent to the launch team emphasized that the company did "not want to niche" OxyContin just for cancer pain. A primary objective in Purdue's 2002 budget plan was to "broaden" the use of OxyContin for pain management. As May put it, "What Purdue did really well was target physicians, like general practitioners, who were not pain specialists." In its internal literature, Purdue similarly spoke of reaching patients who were "opioid naïve." Because OxyContin was so powerful and potentially addictive, David Kessler told me, from a public-health standpoint "the goal should have been to sell the least dose of the drug to the smallest number of patients." But this approach was at odds with the competitive imperatives of a pharmaceutical company, he continued. So Purdue set out to do exactly the opposite.

Sales reps, May told me, received training in "overcoming objections" from clinicians. If a doctor inquired about addiction, May had a talking point ready. " 'The delivery system is believed to reduce the abuse liability of the drug,' " he recited to me, with a rueful laugh. "Those were the specific words. I can still remember, all these years later." He went on, "I found out pretty fast that it wasn't true." In 2002, a sales manager from the company, William Gergely, told a state investigator in Florida that Purdue executives "told us to say things like it is 'virtually' non-addicting."

May didn't ask doctors simply to take his word on OxyContin; he presented them with studies and literature provided by other physicians. Purdue had a speakers' bureau, and it paid several thousand clinicians to attend medical conferences and deliver presentations about the merits of the drug. Doctors were offered all-expenses-paid trips to pain-management seminars in places like Boca Raton. Such spending was worth the investment: internal Purdue records indicate that doctors who attended these seminars in 1996 wrote OxyContin prescriptions more than twice as often as those who didn't. The company advertised in medical journals, sponsored Web sites about chronic pain, and distributed a dizzying variety of OxyContin swag: fishing hats, plush toys, luggage tags. Purdue also produced promotional videos featuring satisfied patients—like a construction worker who talked about how OxyContin had eased his chronic back pain, allowing him to return to work. The videos, which also included testimonials from pain specialists, were sent to tens of thousands of doctors. The marketing of OxyContin relied on an empirical circularity:

the company convinced doctors of the drug's safety with literature that had been produced by doctors who were paid, or funded, by the company.

David Juurlink, who runs the division of clinical pharmacology and toxicology at the University of Toronto, told me that OxyContin's success can be attributed partly to the fact that so many doctors wanted to believe in the therapeutic benefits of opioids. "The primary goal of medical practice is the relief of suffering, and one of the most common types that doctors see is pain," he said. "You've got a patient in pain, you've got a doctor who genuinely wants to help, and now suddenly you have an intervention that—we are told—is safe and effective."

Keith Humphreys, a professor of psychiatry at Stanford, who served as a drug-policy adviser to the Obama Administration, said, "That's the real Greek tragedy of this—that so many well-meaning doctors got co-opted. The level of influence is just mind-boggling. Purdue gave money to continuing medical education, to state medical boards, to faux grassroots organizations." According to training materials, Purdue instructed sales representatives to assure doctors—repeatedly and without evidence—that "fewer than one per cent" of patients who took OxyContin became addicted. (In 1999, a Purdue-funded study of patients who used OxyContin for headaches found that the addiction rate was thirteen per cent.)

Within five years of its introduction, OxyContin was generating a billion dollars a year. "There is no sign of it slowing down," Richard Sackler told a team of company representatives in 2000. The sales force was heavily incentivized to push the drug. In a memo, a sales manager in Tennessee wrote, "$$$$$$$$$$$$ It's Bonus Time in the Neighborhood!" May, who was assigned to the Virginia area, was astonished to learn that especially skillful colleagues were earning hundreds of thousands of dollars in commissions. One year, May's own sales were so brisk that Purdue rewarded him with a trip to Hawaii. As prescriptions multiplied, Purdue executives—and the Sackler family members on the company's board—appeared happy to fund such blandishments. Internal budget plans described the company's sales force as its "most valuable resource." In 2001, Purdue Pharma paid forty million dollars in bonuses.

One day, May drove with a colleague to Lewisburg, a small city in West Virginia. They were there to visit a doctor who had been one of May's top prescribers. When they arrived, the doctor was ashen. A relative had just died, she explained. The girl had overdosed on OxyContin.

Arthur and Mortimer Sackler each married three times, and Raymond married once. There are fifteen Sackler children in the second generation, most of whom have children of their own. The Sackler clan has pursued a variety of causes and interests. In 2011, Mortimer's widow, Theresa, who sits on the board of Purdue, was awarded the Prince of Wales Medal for Art Philanthropy. When the medal was conferred, Ian Dejardin, the Sackler Director of the Dulwich Picture Gallery, remarked, "It's going to be difficult not to make her sound utterly saintly." Theresa's daughter, Sophie, is married to the English cricket player Jamie Dalrymple, and lives in a forty-million-dollar house in London. Raymond's thirty-seven-year-old grandson, David Sackler, runs a family investment fund, and is the only member of the third generation who sits on Purdue's board. The fact that Purdue is privately held is a major reason that the Sacklers' connection to OxyContin has remained obscure. A publicly traded company makes periodic disclosures to its shareholders. But Purdue, Barry Meier writes, "was the Sackler family's private domain."

On occasion, press accounts about OxyContin note that profits from the drug flow to the Sacklers, but these stories tend to depict the family as a monolith. As with any large clan, however, there are fissures of discord. In the eighties, Mortimer sued his ex-wife Gertraud, claiming that she had illegally taken possession of an apartment that he owned on Fifth Avenue and had loaned it out to a contingent of models and photographers. None of Arthur's descendants sit on the company's board. At a courthouse in Long Island, in files stemming from the family fight over Arthur's fortune, I came across a document indicating that, after a "protracted negotiation," Arthur's estate "sold its one third interest in Purdue" to Raymond and Mortimer.

"I have never owned any shares in Purdue," Michael Sackler-Berner, a Brooklyn-based singer-songwriter who is a grandson of Arthur Sackler, told me, in an e-mail. "None of the descendants of Arthur M. Sackler have ever had anything to do with, or benefited from, the sale of OxyContin." Sackler-Berner made no mention of Librium, Valium, or MS Contin, but he added, "Given the current controversy surrounding OxyContin, I appreciate your clarifying the matter."

Even though Mortimer Sackler had a large stake in the company, he was only an occasional presence at the Connecticut headquarters. He renounced his U.S. citizenship in 1974, reportedly for tax reasons, and lived a flamboyant life in Europe, shuttling among residences in England, the Swiss Alps, and Cap d'Antibes. (In 1999, Queen Elizabeth conferred an honorary knighthood on him, in recognition of his philanthropy.) Raymond

Sackler, who lived in Connecticut, had a more modest temperament and came to his office at Purdue—where he was respectfully known as Dr. Raymond—every day. John Kallir, Arthur's former advertising colleague, recalled, "Ray was quiet, reasonably honest, always married to the same woman. The least interesting of the three brothers."

Almost immediately after OxyContin's release, there were signs that people were abusing it in rural areas like Maine and Appalachia. If you ground the pills up and snorted them, or dissolved them in liquid and injected them, you could override the time-release mechanism and deliver a huge narcotic payload all at once. Perversely, users could learn about such methods by reading a warning label that came with each prescription, which said, "Taking broken, chewed or crushed OxyContin tablets could lead to the rapid release and absorption of a potentially toxic dose." As more and more doctors prescribed OxyContin for an ever-greater range of symptoms, some patients began selling their pills on the black market, where the street price was a dollar a milligram. Doctors who were easily manipulated by their patients—or corrupted by the money in play—set up so-called pill mills, pain clinics that thrived on a wholesale business of issuing OxyContin prescriptions.

The company did not pull the drug from shelves, however, or acknowledge that it was addictive. Instead, Purdue insisted that the only problem was that recreational drug users were not taking OxyContin as directed. "Their rap has always been that a bunch of junkies ruined their product," Keith Humphreys, the Stanford professor, said. In 2001, Michael Friedman, Purdue's executive vice-president, testified before a congressional hearing convened to look into the alarming increase in opioid abuse. The marketing of OxyContin had been "conservative by any standard," he maintained. "Virtually all of these reports involve people who are abusing the medication, not patients with legitimate medical needs."

In 2002, a twenty-nine-year-old woman from New Jersey, Jill Skolek, was prescribed OxyContin for a back injury. One night, after four months on the drug, she died in her sleep, from respiratory arrest, leaving behind a six-year-old son. Her mother, Marianne Skolek Perez, was a nurse. Distraught and bewildered, she became convinced that OxyContin was dangerous. Perez wrote to F.D.A. officials, urging them to append to OxyContin packaging a warning about the risk of addiction.

The following year, Perez attended a conference on addiction at Columbia University. A sandy-haired man named Robin Hogen, wearing a pin-striped suit and a bow tie, was

there, too. He was a communications specialist for Purdue, and had launched a vigorous campaign to defend the drug, warning newspapers to be careful about their coverage. "We're going to be watching them," he had promised. He had also enlisted Rudolph Giuliani, the former mayor of New York, and his associate Bernard Kerik to preëmpt any government crackdown. "We have to be politically Machiavellian, often, to win the day," Hogen once said. At the Columbia event, he was asked about Perez's daughter. He cautioned that one should not read into the tragedy any liability on Purdue's part. The real problem, he said, was Jill Skolek: "We think she abused drugs." (Hogen subsequently apologized for his remark. He no longer works for Purdue.)

Another speaker at the event was Purdue's senior medical adviser, J. David Haddox, who insisted that OxyContin was not addictive. He once likened the drug to a vegetable, saying, "If I gave you a stalk of celery and you ate that, it would be healthy. But if you put it in a blender and tried to shoot it into your veins, it would not be good." When Haddox was walking out of the event, Perez, who is petite and rail thin, deliberately bumped into him. Caught off guard, Haddox staggered backward and fell, with a clatter, into a row of folding chairs. "It was one of those Kodak moments," Perez recalled. "It was probably the wrong thing to do. But I loved it."

Arthur Sackler once wrote that "all health problems devolve upon the individual," and it was Purdue's position that OxyContin overdoses were a matter of individual responsibility, rather than the drug's addictive properties. In addition to people like Hogen and Haddox, the company put forward several top executives to mount a defense, including Howard Udell, Purdue's general counsel, who had been a longtime legal adviser to the Sacklers. Udell "was like Tom Hagen in 'The Godfather,' " an attorney who dealt with him told me. "*Very* loyal to the family." Udell was clearly aware, however, of the abuse potential of OxyContin. According to court documents, his own secretary became addicted to the drug, and was subsequently fired by Purdue.

By 2003, the Drug Enforcement Administration had found that Purdue's "aggressive methods" had "very much exacerbated OxyContin's widespread abuse." Rogelio Guevara, a senior official at the D.E.A., concluded that Purdue had "deliberately minimized" the risks associated with the drug. But the company continued shifting the blame to drug abusers, creating a public-service announcement that showed a teen-ager raiding his parents' medicine cabinet.

In a phone interview, Hogen told me that, for Purdue and the Sacklers, "there was a sense almost of betrayal—how could people put the availability of that product in jeopardy by abusing it for pleasure?" Hogen said that the company received many letters from grateful pain patients, thanking Purdue for "giving them their lives back." Asked about his reticence to acknowledge that OxyContin might be addictive, Hogen said, "Today, addiction is broadly seen as a disease. Then, it was not. I think our understanding of addiction has grown enormously in the last fifteen years."

People have known for thousands of years that opium derivatives are addictive, I said.

"You really need to talk to a clinician," Hogen replied. "I'm not a doctor."

J. David Haddox is a doctor. In 2001, he told an Associated Press reporter, "A lot of these people say, 'Well, I was taking the medicine like my doctor told me to,' and then they start taking more and more and more." He added, "I don't see where that's my problem." (Haddox, who still works for Purdue, declined to comment.)

The truth was that the dangers of OxyContin were intrinsic to the drug—and Purdue knew it. The time-release formula meant that, in principle, patients could safely ingest one giant dose every twelve hours. They could sleep through the night—a crucial improvement over conventional painkillers, such as morphine, which require more frequent dosing. One of Purdue's initial advertising campaigns featured a photograph of two little dosage cups, one marked "8 A.M." and the other "8 P.M.," and the words "Remember, Effective Relief Just Takes Two." But internal Purdue documents, which have emerged through litigation, show that even before the company received F.D.A. approval it was aware that not all patients who took OxyContin were achieving twelve-hour relief. A recent exposé by the Los Angeles *Times* revealed that the first patients to use OxyContin, in a study conducted by Purdue, were ninety women recovering from surgery in Puerto Rico. Roughly half the women required more medication before the twelve-hour mark. The study was never published. For Purdue, the business reason for obscuring such results was clear: the claim of twelve-hour relief was an invaluable marketing tool. But prescribing a pill on a twelve-hour schedule when, for many patients, it works for only eight is a recipe for withdrawal, addiction, and abuse. Notwithstanding Purdue's claims, many people who were not drug abusers—and who took OxyContin exactly as their doctors instructed—began experiencing withdrawal symptoms between doses. In March, 2001, a Purdue employee e-mailed a supervisor, describing some internal data on withdrawal and wondering whether

or not to write up the results, even though doing so would only "add to the current negative press." The supervisor responded, "I would not write it up at this point."

Doctors who prescribed OxyContin were beginning to report that patients were coming to them with symptoms of withdrawal (itching, nausea, the shakes) and asking for more medication. Haddox had an answer. In a 1989 paper, he had coined the term "pseudo-addiction." As a pain-management pamphlet distributed by Purdue explained, pseudo-addiction "seems similar to addiction, but is due to unrelieved pain." The pamphlet continued, "Misunderstanding of this phenomenon may lead the clinician to inappropriately stigmatize the patient with the label 'addict.' " Pseudo-addiction generally stopped once the pain was relieved—"often through an increase in opioid dose."

"When you promote these very massive doses of opioids, the more of it that is out there the more abuse there will be," David Kessler said. "It's almost linear." U.S. sales of OxyContin soon exceeded those of Viagra. Everywhere the drug spread, addiction followed. To Steven May, the sales representative in Virginia, it seemed as if the problems associated with OxyContin were metastasizing, "like a cancer."

According to Robin Hogen, the members of the Sackler family "were unified in their shock that this was happening to a product they were very proud of." The Sacklers did not have an arm's-length relationship with Purdue, Hogen said: "This was an active family and an active board." In 1999, Richard Sackler became Purdue's president. As the head of a privately held company, however, he felt no pressure to be the public face of the business, and he never appeared at forums where people like Haddox defended Purdue. Indeed, though Sackler presided over the tremendously successful launch of OxyContin, he has never given an on-the-record interview about the drug. "I've had a lot of experience with Purdue over the years, in different settings, but I've never even *seen* Richard Sackler," the addiction specialist Andrew Kolodny, who is a frequent Purdue critic, told me. "I don't think I'd know him if he was standing in front of me."

Even after it became clear that OxyContin was being widely abused, Purdue refused to concede that it posed risks. Company leaders worried mainly that attempts to stem overdoses might deprive pain patients of access to the drug. "They said, 'We need to make sure that these products are available for patients,' " Hogen said. "That was their sole focus." According to Steven May, the sales force was instructed to ride out the controversy, ignore abuse reports, and "sell through it." As late as 2003, the F.D.A. sent Purdue a

warning letter about ads that "grossly overstate the safety profile of OxyContin by not referring in the body of the advertisements to serious, potentially fatal risks."

In his congressional testimony, Michael Friedman, Richard Sackler's deputy, said that Purdue first became aware of problems with OxyContin only in April, 2000, after a series of press reports about people abusing it recreationally in Maine. But Purdue didn't need the media's help to know that something was seriously off with the distribution of OxyContin. For years, it had maintained a contract with I.M.S., a little-known company, co-founded by Arthur Sackler, that furnished its clients with fine-grained information about the prescribing habits of individual doctors. Purdue's sales representatives used the data to figure out which doctors to target.

Such data could also be used to track patterns of abuse. "They know *exactly* what people are prescribing," Kolodny said. "They know when a doctor is running a pill mill." At the 2001 hearing, James Greenwood, a Pennsylvania congressman, asked Friedman whether Purdue would take any action if, say, I.M.S. data revealed that a rural osteopath was writing thousands of prescriptions.

Friedman replied that it was not up to Purdue to assess "how well a physician practices medicine."

"Why do you want that information, then?" Greenwood pressed, before answering his own question: "To see how successful your marketing techniques are."

Greenwood then observed that, in a recent case involving a Pennsylvania doctor, Richard Paolino, who was wantonly overprescribing OxyContin, a local pharmacist had alerted the authorities. "He looked at this data and he said, 'Holy God, there is some guy in Bensalem called Paolino, and he's writing prescriptions out the wazoo,' " Greenwood said. "Now, he had that data and he blew the whistle. And you had that data. What did *you* do?"

Purdue had not alerted the authorities. Clinicians like Paolino were breaking the law—he was sentenced to a minimum of thirty years in prison. But overprescribing generated tremendous revenue for the company. According to four people I spoke with, at Purdue such prescribers were given a name that Las Vegas casinos reserve for their most prized gamblers: whales.

In July, 2001, Richard Blumenthal, who was then the attorney general of Connecticut, wrote to Richard Sackler. "I have been increasingly dismayed and alarmed about the

problems and escalating abuse of OxyContin," he began, citing overdose deaths, addiction, pharmacy robberies, and "the astonishing growth in state funding" that was being used to pay for OxyContin prescriptions through Medicaid and Medicare. Blumenthal acknowledged that other prescription drugs were also abused. "But OxyContin is different," he wrote. "It is more powerful, more addictive, more widely sold, more illicitly available, and more publicized." He urged Purdue to "overhaul and reform" its marketing of OxyContin.

The Sacklers disregarded his recommendation, and so in 2004 Blumenthal filed a complaint against Purdue, on behalf of the State of Connecticut. It cited data indicating that a fifth of OxyContin prescriptions were now for dosing intervals shorter than twelve hours. In fact, Blumenthal obtained Purdue records indicating that company officials knew by 1998 that prescriptions for eight-hour intervals were becoming more and more frequent. In one document, a Purdue employee called the numbers "very scary."

Such alarm over off-label dosing may have been prompted less by concern about public health than by considerations of profit. If OxyContin was being widely prescribed at intervals of fewer than twelve hours, the company might lose its "two pills a day" marketplace advantage against cheaper alternatives, like generic morphine, and insurers could start refusing to cover the costs. As early as 1997, some benefit plans had begun citing abuse of OxyContin as an excuse not to pay. In a 1997 e-mail, Richard Sackler urged colleagues to counter this resistance, warning that, for insurance companies, " 'addiction' may be a convenient way to just say 'NO.' "

Purdue has been sued thousands of times over OxyContin since its release. (Steven May, the sales rep, initiated a whistle-blower suit years after leaving the company; it was dismissed, on procedural grounds.) In 2002, Howard Udell said that the firm would defend itself "to the hilt." The next year, a New York trial lawyer named Paul Hanly assembled a lawsuit, signing up five thousand patients who said that they'd become addicted to OxyContin after receiving a doctor's prescription. In discovery, Hanly obtained thousands of documents. "They demonstrated that this company had set out to perpetrate a fraud on the entire medical community," he told me. "These pronouncements about how safe the drug was emanated from the marketing department, not the scientific department. It was pretty shocking. They just made this stuff up."

In 2006, Purdue settled with Hanly's clients, for seventy-five million dollars. Shortly afterward, the company pleaded guilty, in a case brought by federal prosecutors in Virginia,

to criminal charges of misbranding, and acknowledged that Purdue had marketed OxyContin "with the intent to defraud or mislead." (Rudolph Giuliani had tried, on Purdue's behalf, to get the lead prosecutor to scuttle the case.) Michael Friedman, the executive vice-president, pleaded guilty to a criminal misdemeanor, as did Howard Udell and the company's chief medical officer, Paul Goldenheim.

Marianne Perez attended the sentencing, in Virginia. "I was on cloud nine," she recalled. She had been working with the prosecution, and doing everything she could to inform the public about the dangers of OxyContin. Before the sentence was handed down, Perez delivered a victim-impact statement. "I want to know why the Sackler brothers have not been held accountable," she said. (Richard Sackler, despite his leadership role at Purdue, had not been charged.)

During a break in the proceedings, Perez looked over at Friedman, Goldenheim, and Udell, and told herself, "I could reach over, at ninety-eight pounds, and smack one of them." This time, she restrained herself. Instead, she told them, "You are sheer evil. You are bastards." The executives reddened, but said nothing. They all received probation, and were ordered, collectively, to pay nearly thirty-five million dollars in fines. Purdue agreed to pay an additional six hundred million. Given the billions of dollars that the Sacklers and Purdue had reaped from OxyContin, some observers felt that the company had got off easy. Arlen Specter, the Republican senator from Pennsylvania, remarked that such fines amounted to "expensive licenses for criminal misconduct."

Arthur Sackler wrote a regular column for the *Medical Tribune*, and one of his fixations was the unethical behavior of tobacco companies. In 1979, he critiqued the "weasel-worded warning" on cigarette packages as insufficient, arguing that the "hazard to health should be more specific." He also condemned newspapers and magazines for accepting "misleading" advertising about cigarettes, and contended that the publishers must "square with their own consciences their contribution to our national mortality."

In 1998, the tobacco industry, which had been sued by dozens of states, entered into the largest civil-litigation settlement in history, agreeing to pay two hundred and forty-six billion dollars. Tobacco and opioids are different in significant ways. The F.D.A. approved OxyContin as a medicine, and, whereas tobacco can kill you even when used as directed, Purdue would argue that this isn't the case with OxyContin. Mike Moore, who, as Mississippi's attorney general, played a key role in the tobacco litigation, noted another difference: the tobacco companies had more money to spare than Purdue does. "To resolve

the opioid problem, you're going to need billions," he said. "Treatment alone could be fifty billion dollars or more. And you need prevention and education programs on top of that."

Moore is now working with Paul Hanly and other attorneys to bring a fresh wave of lawsuits against Purdue and other pharmaceutical companies. Ten states have filed suits, and private attorneys are working in partnership with dozens of cities and counties to bring others. Many public officials are furious at the makers of powerful painkillers. Prescriptions are expensive, and taxpayers often foot the bill, through programs like Medicaid. Then, as the ruinous consequences of opioid addiction take hold, the public must pay again—this time for emergency services, addiction treatment, and the like. Moore feels that the Sackler family, as the initial author and a prime beneficiary of the epidemic, should be publicly shamed. "I don't call it Purdue. I call it the Sackler Company," he said. "They are the main culprit. They duped the F.D.A., saying it lasted twelve hours. They lied about the addictive properties. And they did all this to grow the opioid market, to make it O.K. to jump in the water. Then some of these other companies, they saw that the water was warm, and they said, 'O.K., we can jump in, too.' " There may be significant legal distinctions between a tobacco company and an opioid producer, but to Moore the ethical parallel is unmistakable: "They're both profiting by killing people."

One day in August, 2015, a plane landed in Louisville, Kentucky, and Richard Sackler stepped out, surrounded by attorneys. Eight years earlier, the State of Kentucky had sued Purdue, charging the company with deceptive marketing. Greg Stumbo, the state attorney general at the time, initiated the suit; the son of a cousin of his had fatally overdosed on OxyContin. Purdue fought the suit with its customary rigor, pushing to move the proceedings elsewhere, on the ground that the company could not get a fair trial in Pike County, Kentucky—the rural stretch of coal country where the state intended to try the case. In support of this motion, the company commissioned a demographic study of Pike County and submitted it to the court, as an illustration of potential bias in the jury pool. The report was revealing in ways that Purdue may not have intended: according to the filing, twenty-nine per cent of the county's residents said that they or their family members knew someone who had died from using OxyContin. Seven out of ten respondents described OxyContin's effect on their community as "devastating."

A judge ruled that Purdue could not shift the venue for the trial, and so Richard Sackler flew to Louisville. He gave a deposition at a law firm. Four lawyers questioned him about his role in the development and the marketing of OxyContin. Tyler Thompson, the lead attorney, told me that Sackler's demeanor during the session reminded him of Jeremy

Irons's portrayal of Claus von Bülow, the aristocrat accused of murdering his wife, in the 1990 bio-pic "Reversal of Fortune." "A smirk and a so-what attitude—an absolute lack of remorse," Thompson said. "It reminded me of these mining companies that come in here and do mountaintop removal, and leave a mess and just move on: 'It's not my back yard, so I don't care.' " Mitchel Denham, a former litigator in the Kentucky attorney general's office, also attended the deposition. "It was surreal," he recalled. "We were face to face with the guy whose company had helped to create the opioid epidemic." Denham told me that, in preparing for trial, he discovered a photograph of the 1997 Pikeville High School football team. "Nearly half the players had died of overdoses, or were addicted," he said. "It was going to be a pretty good visual."

But Denham never presented the photograph to a jury, because before the case could go to trial Purdue settled, for twenty-four million dollars. This was a coup for the Sacklers. The settlement was more than Purdue's original offer—half a million dollars—but still totally incommensurate with Pike County's needs; Purdue admitted no liability; and, in settling, the company sealed from public view both Richard Sackler's deposition and internal documents obtained through discovery. Purdue has sometimes claimed to have never "lost a case" related to OxyContin, but it's more accurate to say that the company has never allowed a case to go to trial, often settling rather than litigating the culpability of the company—and the Sacklers—in open court. "That's the main reason these folks don't go to trial," Denham said. "Because all these documents could end up in the public record." The Kentucky prosecutors were required to destroy millions of documents, or return them to Purdue. The medical-news Web site STAT subsequently sued to unseal Richard Sackler's deposition. A state judge ruled in its favor, but Purdue appealed. I spent several months trying to obtain a copy of the deposition, but, because it remains under a protective order while Purdue appeals the matter, no lawyer would share it with me. Mike Moore said, "The idea that they're fighting so hard to keep this deposition hidden should tell you something."

Richard Sackler stepped down as Purdue's president in 2003, but stayed on as co-chairman of the company's board. After spending several years as an adjunct professor of genetics at Rockefeller University, he moved to Austin, Texas, in 2013. He lives in a modern hilltop mansion on the outskirts of the city, in an area favored by tech entrepreneurs. According to tax disclosures from his personal foundation, he has continued giving money to Yale, but his largest donation in 2015 was a hundred-thousand-dollar gift to a neoconservative think tank, the Foundation for Defense of Democracies. Through a representative, Sackler declined to speak with me. I contacted a dozen other members of the Sackler family, but

none of them would answer questions about OxyContin. Jo Sheldon, a London-based media adviser, called me, and said that she works with some of the Sacklers. (She would not identify which ones.) When I told her that I had questions for the Sacklers, she said that my inquiries would be better directed to Purdue. She said of the Sacklers, "Some of them are still quite involved in Purdue, but some have absolutely nothing to do with it," apart from depositing checks.

Given the sometimes fractious nature of the Sackler family, it was striking that they were united in their silence on the subject of OxyContin. These were urbane, expensively educated, presumably well-informed people. Could they conceivably be unaware of the accumulated evidence about the tainted origins of their fortune? Did they simply put it out of mind? "Greed can get people to rationalize pretty bad behavior," Andrew Kolodny had told me. Someone who knows Mortimer, Jr., socially told me, "I think for him, most of the time, he's just saying, 'Wow, we're really rich. It's fucking cool. I don't really want to think that much about the other side of things.' "

Paul Hanly, the lawyer, said that the Sacklers' steadfast refusal to address the legacy of OxyContin may just be a legal tactic—and a shrewd one. "The more interviews you give, the more targets you create for lawyers like me, and for government investigators," he said. I wondered whether philanthropy might represent, for at least some of the Sacklers, a form of atonement. But, when you consider the breadth of the family's donations, one field is conspicuously lacking: addiction treatment, or any other measures that might serve to counter the opioid epidemic.

In August, 2010, Purdue quietly replaced OxyContin with a drug that was subtly different. The company had been granted patents for a reformulated version of OxyContin. If you crushed these new pills, they became not a fine, dissolvable powder but an unwieldy gummy substance. Purdue had received F.D.A. approval for the reformulation, in part, by touting the ostensible safety of the new product. The F.D.A. had approved a label, the first of its kind, that included a claim about the drug's "abuse deterrent" properties.

In an interview, Craig Landau, Purdue's C.E.O., told me, "A very large proportion of Purdue's R. & D. efforts post-2001 was dedicated toward addressing the specific vulnerability of the original OxyContin product." To a casual observer, it might have seemed that the makers of OxyContin, after years of obstructing efforts to curb the disastrous impacts of their painkiller, had finally seen the error of their ways. But Purdue

was almost certainly motivated by another consideration: it needed to block competition from generic drugs. Arthur Sackler had often used the pages of the *Medical Tribune* to criticize generics. In 1985, the paper had published a story, "Schizophrenics 'Wild' on Weak Generic," describing how "all hell broke loose" at a veterans' hospital after the psychiatric unit switched from a brand-name antipsychotic to a generic. (According to the *Times*, the F.D.A. investigated and found that the story was bogus, because "the generic had been introduced six months before the purported problems began.") I spoke with a leading patent lawyer who frequently represents manufacturers of generic drugs, and she said that companies often make a minor tweak to a branded product shortly before the patent expires, in order to obtain a new patent and reset the clock on their exclusive right to produce the drug. The patent for the original OxyContin was set to expire in 2013.

Purdue had long denied that the original OxyContin was especially prone to abuse. But, upon receiving its patents for the reformulated drug, the company filed papers with the F.D.A., asking the agency to refuse to accept generic versions of the original formulation—because they were unsafe. The F.D.A., ever obliging, agreed, blocking any low-cost generic competition for Purdue. For more than a year, Purdue continued to sell the original formulation of OxyContin in Canada. According to a recent study, OxyContin sales in Windsor, Ontario—just across the border from Detroit—suddenly quadrupled, a clear indication that the pills were being purchased for the U.S. black market. Through I.M.S. tracking data, Purdue would have been able to monitor the Canadian surge, and to deduce the reason for it. (The company acknowledges that it was aware of the spike in sales, and maintains that it alerted authorities, but will not say when it did so.)

By the time Purdue reformulated OxyContin, the country was in the middle of a full-blown epidemic. Andrew Kolodny, the addiction specialist, told me that many older people remain addicted to the reformulated OxyContin, and continue to obtain the drug through prescriptions. These people purchase the drug legally, and swallow the pills whole, as instructed. "That's Purdue's market now," Kolodny said. Younger people, who can less readily secure prescriptions for pain—and for whom OxyContin may be too expensive—have increasingly turned to black-market substitutes, including heroin. As Sam Quinones details in his 2015 book, "Dreamland: The True Tale of America's Opiate Epidemic," heroin dealers from Mexico fanned out across the U.S. to supply a burgeoning market of people who had been primed by pill addiction. This is one dreadful paradox of the history of OxyContin: the original formulation created a generation addicted to pills; the reformulation, by forcing younger users off the drug, helped create a generation addicted to heroin. A recent paper by a team of economists, citing a dramatic uptick in heroin

overdoses since 2010, is titled "How the Reformulation of OxyContin Ignited the Heroin Epidemic." A survey of two hundred and forty-four people who entered treatment for OxyContin abuse after the reformulation found that a third had switched to other drugs. Seventy per cent of that group had turned to heroin.

Perhaps the most surprising aspect of Quinones's investigation is the similarities he finds between the tactics of the unassuming, business-minded Mexican heroin peddlers, the so-called Xalisco boys, and the slick corporate sales force of Purdue. When the Xalisco boys arrived in a new town, they identified their market by seeking out the local methadone clinic. Purdue, using I.M.S. data, similarly targeted populations that were susceptible to its product. Mitchel Denham, the Kentucky lawyer, told me that Purdue pinpointed "communities where there is a lot of poverty and a lack of education and opportunity," adding, "They were looking at numbers that showed these people have work-related injuries, they go to the doctor more often, they get treatment for pain." The Xalisco boys offered potential customers free samples of their product. So did Purdue. When it first introduced OxyContin, the company created a program that encouraged doctors to issue coupons for a free initial prescription. By the time Purdue discontinued the program, four years later, thirty-four thousand coupons had been redeemed.

Purdue Pharma now acknowledges that there is an opioid crisis, but maintains that it has taken every available step to address it, from sponsoring "prescription monitoring" programs in some states to underwriting drug-abuse education. Craig Landau, the C.E.O., told me, "If the Holy Grail is a pain medicine that is safe and effective for patients with severe pain but carries no abuse risk, we haven't found it yet." He added that the company has been trying to develop "non-opioid pain products." Purdue likes to emphasize that there are many other powerful painkillers, and that OxyContin never had more than two per cent of the market for opioids. This is true in terms of the number of prescriptions. But most painkillers are prescribed for very short periods—following surgery, for instance—and in relatively small doses, whereas OxyContin's sales have been driven by long-term, high-dose prescriptions. If one measured market share by the actual volume of narcotics administered, OxyContin's would be considerably higher. Some doctors I spoke with estimated that it could be as high as thirty per cent.

The United States accounts for roughly a third of the global market for opioid painkillers. But, as politicians and journalists have raised alarms over the addiction crisis, many American doctors have grown leery, again, of prescribing these drugs. In a statement, Purdue acknowledged that even patients "who take OxyContin in accordance with its

F.D.A.-approved labeling instructions will likely develop physical dependence." The company maintains that physical dependence is different from addiction, but Jane Ballantyne, the president of Physicians for Responsible Opioid Prescribing, said that, for patients, this can be a meaningless distinction: if they find themselves unable to stop taking a drug, for fear of crippling withdrawal, "at a certain point that might as well be addiction." The drugstore chain CVS, which has been accused of profiteering from opioids, recently announced that it plans to limit prescriptions for powerful doses to one week's worth, a change that could have a major impact on the abuse of these drugs. It may also be that OxyContin has achieved market saturation. In recent years, American clinicians have issued about a quarter of a billion opioid prescriptions annually. Last year, in Ohio, a state particularly hard hit by the epidemic, 2.3 million residents—roughly one in five people in the state—received a prescription for opioids. In 2012, the Milwaukee *Journal Sentinel* published a story about pain patients who had offered testimonials about the wonders of OxyContin in Purdue promotional videos. Johnny Sullivan, the construction worker who had talked about OxyContin easing his back pain, became addicted to the drug. In 2008, while driving home from a hunting trip, he apparently blacked out; he flipped his truck, and died instantly. In a Purdue brochure, Sullivan is quoted as saying that OxyContin pills "don't put me in a stupor or make me groggy."

David Juurlink, the Toronto doctor, told me that opioids are problematic even for users who don't succumb to addiction. "Opioids really do afford pain relief—initially," he said. "But that relief tends to diminish over time. That's, in part, why people increase the dose. They are chasing pain relief from a drug that has failed. I see all these people who are convinced they are one of the 'legitimate' pain patients. They're on a massive dose of opioids, and they're telling me they need this medication, which is clearly doing them *harm*. For many of them, the primary benefit of therapy, at this point, is not going into withdrawal."

Even Russell Portenoy, the Purdue-funded doctor who advocated for wider long-term use of opioids, has reassessed his views. "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation?" he said to the *Wall Street Journal* in 2012. "I guess I did." (In a statement, Portenoy told me that he has "refocussed" his approach to pain management, adding, "No funder has had any undue influence over my thinking.")

In his defense, Portenoy has pointed out that, two decades ago, doctors did not know what they know now about opioids and addiction. The Sackler family and Purdue Pharma could

have taken responsibility in a similar spirit: apologizing for their role in unleashing a national catastrophe while noting that, during the nineties, they had relied on a series of mistaken assumptions about the safety of OxyContin. But Purdue has continued to fight aggressively against any measures that might limit the distribution of OxyContin, in a way that calls to mind the gun lobby's resistance to firearm regulations. Confronted with the prospect of modest, commonsense measures that might in any way impinge on the prescribing of painkillers, Purdue and its various allies have responded with alarm, suggesting that such steps will deny law-abiding pain patients access to medicine they desperately need. Mark Sullivan, a psychiatrist at the University of Washington, distilled the argument of Purdue: "Our product isn't dangerous—it's *people* who are dangerous."

Last year, the C.D.C., which formally declared an opioid epidemic in 2011, introduced the first set of guidelines to help reduce the prescribing of strong painkillers like OxyContin. "Opioids should not be considered first-line or routine therapy for chronic pain," the guidelines said, recommending that doctors first consider "non-pharmacologic" approaches, such as physical therapy, and "non-opioid pharmacologic" treatments.

Purdue and other pharmaceutical companies have long funded ostensibly neutral nonprofit groups that advocate for pain patients. The C.D.C. guidelines were nonbinding, yet many of these organizations fought to prevent the agency from releasing them. This kind of obstruction is typical at both the state and the federal level. A recent series by the Associated Press and the Center for Public Integrity revealed that, after Purdue made its guilty plea, in 2007, it assembled an army of lobbyists to fight any legislative actions that might encroach on its business. Between 2006 and 2015, Purdue and other painkiller producers, along with their associated nonprofits, spent nearly nine hundred million dollars on lobbying and political contributions—eight times what the gun lobby spent during that period.

Since Purdue made it more difficult to grind OxyContin pills, prescriptions have reportedly plummeted by forty per cent. This suggests that nearly half of the original drug's consumers may have been crushing it to get high. As David Juurlink pointed out to me, it is a misnomer to call the reformulation an "abuse deterrent." It can still be abused—and is, widely, by people who become addicted by swallowing the pills, just as the bottle instructs. But Purdue, facing a shrinking market and rising opprobrium, has not given up the search for new users. In August, 2015, over objections from critics, the company received F.D.A. approval to market OxyContin to children as young as eleven.

Forbes estimates that the Sacklers continue to receive some seven hundred million dollars a year from the family companies, and, as the Sacklers are surely aware, the real future of OxyContin may be global. Many big companies, once their sales plateau in America, look abroad. After introducing OxyContin in the U.S., Purdue moved into Canada and England. At the University of Toronto, the company sponsored a class on pain management for medical and dental students. The instructor was a member of Purdue's speakers' bureau. Students received a complimentary textbook, produced by Purdue, that described oxycodone as a "moderate" opioid. The course was discontinued after students and doctors criticized it; one of the critics was Rick Glazier, a physician at the university, whose son, Daniel, had fatally overdosed on OxyContin in 2009.

As OxyContin spread outside the U.S., the pattern of dysfunction repeated itself: to map the geographic distribution of the drug was also to map a rash of addiction, abuse, and death. But the Sackler family has only increased its efforts abroad, and is now pushing the drug, through a Purdue-related company called Mundipharma, into Asia, Latin America, and the Middle East. Part of Purdue's strategy from the beginning has been to create a market for OxyContin—to instill a perceived need by making bold claims about the existence of large numbers of people suffering from untreated chronic pain. As Purdue moves into countries like China and Brazil, where opioids may still retain the kind of stigma that the company so assiduously broke down in the United States, its marketing approach has not changed. According to a Los Angeles *Times* report from 2016—well after the Sacklers' playbook for OxyContin had been repudiated by the medical establishment as possibly the main driver of the opioid epidemic—Mundipharma commissioned studies showing that millions of people in these countries suffered from chronic pain. The company has organized junkets, and paid doctors to give presentations extolling OxyContin's virtues. In fact, certain doctors who are currently flogging OxyContin abroad—"pain ambassadors," they are called—used to be on Purdue's payroll as advocates for the drug in the U.S.

The *Times* report described Joseph Pergolizzi, Jr.—a Florida doctor who runs a pain-management clinic and hawks a pain-relieving cream of his own invention on cable TV—giving paid talks in places like Brazil about the merits of OxyContin. In Mexico, Mundipharma has asserted that twenty-eight million people—a quarter of the population—suffer from chronic pain. In China, the company has distributed cartoon videos about using opioids for pain relief; other promotional literature cites the erroneous claim that rates of addiction are negligible. In a 2014 interview, Raman Singh, a Mundipharma executive, said, "Every single patient that is in emerging markets should have access to our

medicines." The term "opiophobia" has largely fallen into disuse in America, for obvious reasons. Mundipharma executives still use it abroad.

"It's a parallel to what the tobacco industry did," Mike Moore told me. "They got caught in America, they saw their market share decline, so they export it to places with even fewer regulations than we have." He added, "You know what's going to happen. You're going to see lots and lots of death." In May, several members of Congress wrote to the World Health Organization, urging it to help stop the spread of OxyContin, and mentioning the Sackler family by name. "The international health community has a rare opportunity to see the future," they wrote. "Do not allow Purdue to walk away from the tragedy they have inflicted on countless American families simply to find new markets and new victims elsewhere." David Kessler, the former F.D.A. commissioner, believes that the destigmatization of opioids in the U.S. represents one of the "great mistakes" of modern medicine. When I asked for his thoughts on Mundipharma's efforts to market OxyContin abroad, he said, "It gives me a sick feeling. It makes me ill."

Earlier this year, Peter Salovey, the president of Yale, announced that the university will rename a residential college that was named for John C. Calhoun, because Calhoun's "legacy as a white supremacist and a national leader who passionately promoted slavery as a 'positive good' fundamentally conflicts with Yale's mission and values." This move, which was not without its critics, was emblematic of a broader trend to look back skeptically at individuals who were venerated in earlier epochs, and ask how they should be judged by the moral standards of today. At Oxford, a Rhodes Scholar from South Africa recently led a campaign to take down a statue of Cecil Rhodes.

One great fortune—and reputation—that has evaded such scrutiny is that of the Sacklers, a family whose dubious business practices are not an artifact of previous centuries but an ongoing reality. If present statistics are any indication, in the time it likely took you to read this article six Americans have fatally overdosed on opioids. Yet Yale appears to be in no hurry to rename its Raymond and Beverly Sackler Institute for Biological, Physical and Engineering Sciences, or its Richard Sackler and Jonathan Sackler Professorship of Internal Medicine. Perhaps it's because the Sacklers, unlike the Calhoun family, still have a fortune to give away.

"It's amazing how they are left out of the debate about causation, but also about solutions," Allen Frances, the Duke psychiatrist, said of the Sacklers. "A truly philanthropic family, looking at the last twenty years, would say, 'You know, there's several million Americans

who are addicted, directly or indirectly, because of us.' Real philanthropy would be to contribute money to taking care of them. At this point, adding their name to a building—it rings hollow. It's not philanthropy. It's just a glorification of the Sackler family." According to the American Society of Addiction Medicine, more than two and a half million Americans have an opioid-use disorder. Frances continued, "If the Sacklers wanted to clear their name, they could take a very substantial fraction of that fortune and create a mechanism for providing free treatment for everyone who's become addicted." Alfred Nobel, the inventor of dynamite, created the Nobel Peace Prize. In recent years, several philanthropic organizations run by the descendants of John D. Rockefeller have devoted resources to addressing climate change and critiquing the environmental record of the oil company he founded, now called ExxonMobil. Last year, Valerie Rockefeller Wayne told CBS, "Because the source of the family wealth is fossil fuels, we feel an enormous moral responsibility."

Mike Moore, the former Mississippi attorney general, believes that the Sacklers will feel no pressure to emulate this gesture until more of the public becomes aware that their fortune is derived from the opioid crisis. Moore recalled his initial settlement conference with tobacco-company C.E.O.s: "We asked them, 'What do you want?' And they said, 'We want to be able to go to cocktail parties and not have people come up and ask us why we're killing people.' That's an exact quote." Moore is puzzled that museums and universities are able to continue accepting money from the Sacklers without questions or controversy. He wondered, "What would happen if some of these foundations, medical schools, and hospitals started to say, 'How many babies have become addicted to opioids?' " An addicted baby is now born every half hour. In places like Huntington, West Virginia, ten per cent of newborns are dependent on opioids. A district attorney in eastern Tennessee recently filed a lawsuit against Purdue, and other companies, on behalf of "Baby Doe"—an infant addict.

Purdue executives won't be able to settle every case against them, Moore believes. "There's going to be a jury somewhere, someplace, that's going to hit them with the largest judgment in the nation's history," he said. Paul Hanly noted that, in the face of a crippling judgment, Purdue may have to declare bankruptcy. "But I'm certainly not going to walk away if they do," he said. "At that point, I would start looking closely at individual liability on the part of the Sacklers."

Robin Hogen, the former Purdue communications executive, said, "I don't want to be portrayed as an apologist for what is clearly a public-health crisis. But I wanted to make sure you spoke to someone who had very high regard for the Sackler family. The Sacklers

were first class in everything they did." I asked him what he would say to the doctors and the public-health officials who believe that the heirs of Raymond and Mortimer Sackler bear some moral responsibility for the epidemic. "I'm not a doctor," Hogen demurred. "I really can't comment."

The Sacklers have always excelled at the confidence game of marketing, and it struck me that the greatest trick they ever pulled was to write the family out of the history of the family business. I was reminded of Arthur Sackler's admonition that you should endeavor to leave the world a better place than it was when you came into it, and I wondered about the moral arithmetic of the Sacklers' deeds. But the family, through a Purdue representative, declined to comment.

I recently went to Amagansett, on Long Island, to meet a man I'll call Jeff. At a restaurant, he told me about his struggles with addiction. A decade ago, when he was a teen-ager, he started abusing opioids. They were "everywhere," he recalled. He particularly liked OxyContin, for the "clean high" it provided. After sucking the pill's red coating off, he crushed the rest with the edge of a cigarette lighter, then snorted it. He didn't inject it. "When I was growing up, I always told myself, 'I'll never stick a needle in my arm,' " he said.

In a soft, unflinching tone, Jeff recounted the next decade of his life: he kept abusing painkillers, met a woman, fell in love, and introduced her to opioids. One day, his dealer was out of pills and said, "I'll sell you a bag of heroin for twenty bucks." Jeff was reluctant, but when withdrawal set in he acquiesced. At first, he and his girlfriend snorted heroin. "But you build up a tolerance, just like with the pills," he said, and eventually they started injecting it. They were high when they got married. Jeff's wife gave birth to a boy, who was addicted to opioids. "The doctors weaned him off with droplets of morphine," he said.

After a long stretch in rehab, Jeff has been sober for more than a year. His baby is healthy, and his wife is clean, too. Looking back, he said, he feels that an impulsive youthful decision to snort pills set him on a path from which he could not deviate. "It was all about the drug," he said. "I just created a hurricane of destruction."

We left the restaurant and strolled along a leafy side street flanked by grand houses. During the worst years of his addiction, Jeff worked as a tradesman in the area. I had asked him to show me a property that he had serviced, and we stopped outside a sprawling estate that was mostly hidden behind dense shrubbery. It was the home of Mortimer Sackler, Jr.

Jeff, who knew about the family, appreciated the irony. "I couldn't tell you how many times I was on that property, sitting in a work truck, snorting a pill," he said.

We reached an ornamental wooden gate, beyond which was a yard dominated by a stately weeping willow. As I was admiring the tree, Jeff said that, for the people who maintained the grounds, it was "a pain in the ass." Whenever the wind picks up, he explained, branches break and scatter all over the lawn. "But the place has to be flawless," he said. "There can't be a leaf on the ground." So a crew comes by regularly, to clear away the mess. ♦

This article appears in the print edition of the October 30, 2017, issue, with the headline "Empire of Pain."

Patrick Radden Keefe, a staff writer, has been contributing to The New Yorker since 2006. *Read more »*

Video

National Institute on Drug Abuse
Advancing Addiction Science

What is the Federal Government Doing to Combat the Opioid Abuse Epidemic?

May 01, 2015
presented by Nora D. Volkow, Director, National Institute on Drug Abuse
House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations

#SubOversight Continues Hearing Series to Review Prescription Drug & Opioid Abuse (Energy and Commerce Committee)

Good Morning, Mr. Chairman, Ranking Member DeGette, and Members of the Subcommittee. Thank you for inviting the National Institute on Drug Abuse (NIDA), a component of the National Institutes of Health (NIH), to participate in this important hearing and provide an overview of what science tells us about the growing and intertwined problems of non-medical use of prescription pain medicines and use of heroin in our Nation.

Background

The misuse of and addiction to opioids such as heroin, morphine, and other prescription pain medicines is a serious national problem that affects public health as well as social and economic welfare. An estimated 1.9 million people in the United States suffered from substance use disorders related to prescription opioid pain medicines in 2013 and 517,000 suffered from a heroin use disorder. [1] This issue has become a public health epidemic with devastating consequences including not just opioid use disorders and related overdoses, but also the rising incidence of newborns who experience neonatal abstinence syndrome because their mothers used these substances during pregnancy; and increased spread of infectious diseases including HIV and hepatitis C (HCV).

Existing evidence based prevention and treatment strategies are highly underutilized across the United States. The recently announced initiative of the Secretary of Health and Human Services to address the complex problem of prescription opioid and heroin abuse in this country emphasizes the implementation of these evidence based prevention and treatment strategies which include not only better prescription practices but also deployment of medication to combat overdoses and medication-assisted treatment (MAT) to treat opioid use disorders. NIDA is an active partner in this

initiative and will focus on supporting research and disseminating findings to improve opioid prescribing practices, to expand the use of the opioid overdose reversal drug naloxone, to improve the integration of pharmacotherapies into treatment services in specialty care and primary care, and to develop pain treatments with reduced potential for misuse and diversion.

The Effects of Opioids on the Brain and Body

Both prescription opioid drugs (such as oxycodone and hydrocodone) and heroin work through the same mechanism of action. Opioids reduce the perception of pain by binding to opioid receptors, which are found on nerve cells in the brain and periphery (as well as in other organs in the body). The binding of these drugs to opioid receptors in reward regions in the brain produces a sense of well-being, while stimulation of opioid receptors in deeper brain regions results in drowsiness and that can lead to respiratory depression, which can lead to overdose deaths. Presence of opioid receptors in other tissues is responsible for side effects such as constipation and cardiac arrhythmias. The effects of opioids are typically mediated by specific subtypes of opioid receptors (mu, delta, and kappa) that are activated by the body's own (endogenous) opioid chemicals (endorphins, enkephalins). With repeated administration of opioid drugs (prescription or heroin) the production of endogenous opioids decreases , which accounts in part for the discomfort that ensues when the drugs are discontinued (*i.e.,* withdrawal).

People who use opioids non-medically may seek to intensify their experience by taking the drug in ways that deliver the drug more rapidly to their brain. For example, extended-release oxycodone is designed to release slowly and steadily into the bloodstream when taken orally, which minimizes its euphoric effects. People who use pills for their mood elevating effects may crush them to snort or inject the drug, which not only increases the euphoria but also increases the risk for serious medical complications, such as respiratory arrest, coma, and substance use disorder. When people tamper with long-acting or extended-release medicines, which typically contain higher doses because they are intended for release over long periods, the results can be particularly dangerous, as all of the medicine can be released at once. Taking opioids through nasal, smoked, or intravenous routes enhances risks both because of the higher than manufacturer intended dose and the quicker onset.

Another important property of opioid drugs is their tendency, when used repeatedly over time, to induce tolerance. Tolerance occurs when the person no longer responds to the drug as strongly as he or she initially did, thus necessitating a higher dose to achieve the same effect. The establishment of tolerance results from the ability of opioids to desensitize the brain's own natural opioid system, making it less responsive over time.[2] This tolerance contributes to the high risk of overdose during a relapse to opioid use after a period of abstinence whether it is intentional, for example when a person tries to quit using or whether it is situational, for example if a user cannot obtain opioid drugs while incarcerated or hospitalized. Users who do not realize they have lost their tolerance during periods of abstinence may initially take the high dosages that they previously had used before quitting, thus producing overdoses. Another contributing factor to the risk of opioid-related morbidity and mortality is the combined use of benzodiazepines (BZDs) or other central nervous system (CNS) depressants like some sleeping pills, even if these agents are used for the correction indication. Thus, patients with

chronic pain who use opioid analgesics along with BZDs are at higher risk for overdose. Similar risks are observed when opioids are combined with alcohol.[3] Indeed, the label for these drugs often state, for example, that they should not be used in combination with alcohol and that they should be started at lower doses when used in combination with sedatives. Also, existing and model clinical guidance on opioid prescribing often suggest opioids should not be used with other BZDs.[4] Unfortunately in many cases practitioners fail to heed practice guidelines and recommendations with respect to co-use.[6],[7]

The public-health consequences of opioid misuse are broad and worrisome. For example, use of opioids by pregnant women can result in a withdrawal syndrome in newborns, referred to as neonatal abstinence syndrome, which increased by almost 300 percent in the United States between 2000 and 2009.[8] This increase was driven in part by the high rate of opioid prescriptions being given to pregnant women. An estimated 14.4 percent of pregnant women in the United States are prescribed an opioid during their pregnancy.[9] Despite producing neonatal abstinence syndrome, methadone has been the acknowledged gold standard for use during pregnancy and there is a growing literature on the use of buprenorphine in pregnant women. These treatments, in combination with behavioral treatment (*e.g.*, MAT), remain highly underused and present the best opportunities to treat opioid use disorder in pregnancy.

Another concern is the transmission of infectious diseases such as HIV and HCV due to injection of heroin or prescription opioids, which has risen along with the increases in individuals injecting opioids. The high prevalence of opioid use also impacts public safety; from 1999-2010, there was a six-fold increase in positive opioid tests among drivers who died within one hour of a crash.[10]

Research on National Efforts to Curb the Prescription Opioid Epidemic

Significant efforts have been undertaken across the United States to reduce diversion and misuse of prescription opioids and to reduce opioid overdoses and related deaths. NIDA supports research to understand the impact of these policy changes on rates of opioid misuse, use disorders, and related public health outcomes. This research has demonstrated the efficacy of multiple types of interventions including:

- Educational initiatives delivered in school and community settings (primary prevention)[11]
- Supporting consistent use of prescription drug monitoring programs (PDMPs)[12]
- Implementation of overdose education and naloxone distribution programs to issue naloxone directly to opioid users and potential bystanders[13]
- Aggressive law enforcement efforts to address doctor shopping and pill mills[14]
- Diverting individuals with substance use disorders to Drug Courts[15]
- Expansion of access to MAT[16]

- Abuse-deterrent formulations for opioid analgesics [17]

In states with the most comprehensive initiatives to reduce opioid overprescribing, the results have been encouraging. Washington State's implementation of evidence-based dosing and best-practice guidelines and enhanced funding for the state's PDMP helped reduce opioid deaths by 27 percent between 2008 and 2012. [18] In Florida, new restrictions were imposed on pain clinics, new policies were implemented requiring more consistent use of the state PDMP, and the Drug Enforcement Administration worked with state law enforcement to conduct widespread raids on pill mills, which resulted in a dramatic decrease in overdose deaths between 2010 and 2012. [19] These examples show that state and Federal policies can reduce the availability of prescription opioids and overdose deaths.

Relationship between Prescription Opioids and Heroin Abuse

While the initiatives discussed above are beginning to show successes in the form of decreasing availability of prescription opioid drugs and a decline in overdose deaths in states with the most aggressive policies, since 2010, overdose deaths related to heroin have started to increase (as detailed in the testimony from CDC). There is some concern that the increase in heroin-related overdoses may be an unintended consequence of reducing the availability of prescription opioids. Research has shown that prescription opioid use is a risk factor for heroin use. The incidence of heroin initiation is 19 times higher among those who report prior non-medical pain-reliever use than among those who do not (0.39 percent vs. 0.02 percent). [20] However, heroin use is rare in prescription drug users. According to the National Survey on Drug Use and Health, less than four percent of people who had used prescription painkillers non-medically started using heroin within five years of their initiation of non-medical use of pain medication. [18]

Heroin and prescription opioid pain relievers belong to a single class of drugs—but each are associated with distinct risks. The risk of overdose and negative consequences is even greater with heroin due to the lack of control over the purity of the drug and its possible contamination with other drugs (such as fentanyl, originally a potent prescription opioid but now variants of which are often produced in clandestine labs). All of these factors increase the risk for overdose since users have no way of assessing the potency of the drug before taking it and because in the case of fentanyl contamination, users typically have no opportunity to become tolerant.

There also has been a shift in the demographic of opioid users over the last few decades. In the 1960s, more than 80 percent of people who began using opioids initiated with heroin; in the 2000s, 75 percent of opioid users reported that their first regular opioid was a prescription pain reliever. [xxii] It also has been reported that current heroin users are more likely to be white, middle-class, and live in more suburban and rural areas; this is consistent with the population of people who report the largest increases in non-medical use of opioid pain relievers over the last decade. [21]

The transition from misusing prescription opioids to using heroin may be part of the natural progression of disease in a subset of users. Evidence from interviews with individuals with heroin use disorder suggest that market forces, including the accessibility, cost, and high potency of heroin are driving increased use of and transition from prescription opioids.[22],[23] Some individuals who have developed dependence on prescription opioids, when faced with the increasing difficulty in obtaining these medications through their providers and the cost of obtaining them illegally, have initiated heroin use, which is cheaper and in some communities easier to obtain than prescription opioids.

In aggregate, these data suggest that preventing the initiation of prescription opioid misuse is a crucial component of efforts to prevent heroin use.

NIDA Efforts to Stem the Tide of Prescription Opioid and Heroin Abuse

NIDA first launched its prescription drug abuse public health initiative in 2001 using evidence-based strategies to (1) enhance our understanding of pain and its management; (2) prevent overdose deaths; and (3) effectively treat opioid use disorders.

Research on Pain and Next Generation Analgesics

Although opioid medications have a legitimate role in the treatment of acute pain and some chronic pain conditions, it is clear that they often are overprescribed or are prescribed without adequate safeguards and monitoring and that their misuse can have devastating effects. This presents a dilemma for healthcare providers who seek to relieve suffering while preventing drug abuse and addiction. As summarized in a recent report from the NIH Pain Consortium,[24] there is a pressing need for more research on the effectiveness and safety of using opioids to treat chronic pain as well as on optimal management and risk mitigation strategies. As noted, there are some patients for whom opioids are the best treatment for their chronic pain (*e.g.*, cancer-related pain). However, many other chronic pain patients are inappropriately prescribed opioid medications that may be ineffective or even harmful, often due to lack of adequate clinician education on pain management and screening for substance use disorder risk. This is partially the result of inadequate research on the best approaches to treat various types of pain, but it also is because clinicians may find prescribing opioids to be the easiest and least expensive course for addressing pain. The challenge is to identify the patients for whom opioids are the most appropriate treatment, to identify the best alternative treatments for those who are unlikely to benefit from opioids, and to define the best approach to ensuring that every patient's individual needs are met by a patient-centered health care system.

To better understand these issues, NIDA launched a research initiative on "Prescription Opioid Use and Abuse in the Treatment of Pain." This initiative encourages a multidisciplinary approach using both human and animal studies to examine factors that predispose or protect against opioid abuse and addiction. Funded grants cover clinical neurobiology, genetics, molecular biology, prevention,

treatment, and services research. This type of information will help develop screening and diagnostic tools that physicians can use to assess the potential for prescription drug misuse in their patients.

Another important initiative pertains to the development of new approaches to treat pain. NIDA has initiated multiple strategic partnerships to advance development of medications for pain, leveraging NIDA funds with the strengths and resources of outside organizations, including academic institutions, pharmaceutical and biotechnology companies, private and public foundations, and small businesses. This includes research to identify new pain medicines with reduced abuse, tolerance, and dependence risk, as well as devising alternative delivery systems and formulations for existing drugs that minimize diversion and non-medical use (*e.g.,* by preventing tampering) and reduce the risk of overdose deaths. For example, a partnership with Signature Therapeutics is working to develop an abuse deterrent formulation of oxycodone that uses prodrug technology—attaching an extension to the opioid molecule that renders it inactive if injected, snorted, or smoked; instead it must pass through the digestive system to begin the process of releasing the opioid. Early phase trials have supported safety, dose proportionality, and a clinically beneficial extended release profile.

In addition, new compounds are being developed that exhibit novel properties as a result of their combined activity on two different opioid receptors (*i.e.*, mu and delta). Preclinical studies show that these compounds can induce strong analgesia without producing tolerance or dependence.[25] Researchers are also getting closer to developing a new generation of non–opioid-based medications for severe pain that would circumvent the brain reward pathways, thereby greatly reducing abuse potential. This includes compounds that work through a type of cannabinoid receptor found primarily in the peripheral nervous system.

Education is another critical component of any effort to curb the abuse of prescription medications and must target every segment of society, including healthcare providers (doctors, nurses, dentists, pharmacists). NIDA is advancing addiction awareness, prevention, and treatment in primary care practices through four Centers of Excellence for Physician Information. Intended to serve as national models, these Centers target physicians-in-training, including medical students and resident physicians in primary care specialties (*e.g.* internal medicine, family practice, and pediatrics). NIDA also has developed, in partnership with the Office of National Drug Control Policy, two online continuing medical education courses on safe prescribing for pain and managing patients who abuse prescription opioids. To date, these courses have been completed by over 100,000 clinicians combined.

Developing More Effective Means for Preventing Overdose Deaths

The opioid overdose-reversal drug naloxone can rapidly restore normal respiration to a person who has stopped breathing as a result of overdose from heroin or prescription opioids. Naloxone is widely used by emergency medical personnel and some first responders. Beyond first responders, some communities have established overdose education and naloxone distribution programs that issue naloxone directly to opioid users and their friends or loved ones, or other potential bystanders, along

with brief training in how to use these emergency kits. Such programs have been shown to be effective, as well as cost-effective, ways of saving lives. CDC reported that, as of 2010, lay-distributed naloxone had resulted in more than 10,000 overdose reversals nationwide since 1996.[26]

For many years, naloxone was available only in an injectable formulation that was generally carried only by medical emergency personnel. However, FDA recently approved a new hand-held auto-injector of naloxone to reverse opioid overdose that is specifically designed to be given by family members or caregivers. NIDA and other agencies are working with the FDA and drug manufacturers to support the development and approval of a user-friendly intranasal formulation that would match the pharmacokinetics (*i.e.,* how much and how rapidly the drug gets into the body) of the injectable version. More market competition is expected to help bring down the cost of naloxone products.

Research on the Treatment of Opioid Addiction

There are a number of medications available for the treatment of opioid use disorders, both for patients in acute withdrawal and to support long term recovery. Medications have become an essential component of an ongoing treatment plan, enabling opioid-addicted persons to regain control of their health and their lives. Agonist medications developed to treat opioid addiction work through opioid receptors but are safer and less likely to produce the harmful behaviors that characterize addiction, because the rate at which they enter and leave the brain is slower. The three classes that have been developed to date include (1) agonists, *e.g.* methadone (Dolophine or Methadose), which activate opioid receptors; (2) partial agonists, *e.g.* buprenorphine (Subutex, Suboxone, Zubsolve), which also activate opioid receptors but produce a diminished response; and (3) antagonists, *e.g.* naltrexone (Vivitrol), which block the receptor and interfere with the rewarding effects of opioids. Physicians can select from these options on the basis of a patient's specific medical needs. The evidence strongly demonstrates that methadone, buprenorphine, and injectable naltrexone (*e.g.,* Vivitrol), when administered in the context of an addiction treatment program, all effectively help maintain abstinence from other opioids, reduce opioid use disorder-related symptoms, and reduce the risk of infectious disease and crime.[27] Two comprehensive Cochrane reviews, one analyzing data from 11 randomized clinical trials that compared the effectiveness of methadone to placebo and another analyzing data from 31 trials comparing buprenorphine or methadone treatment to placebo,[28],[29] found that:

- Patients on methadone were over four times more likely to stay in treatment and had 33 percent fewer opioid-positive drug tests compared to patients treated with placebo;
- Methadone treatment significantly improves treatment outcomes alone and when added to counseling; long-term (beyond six months) outcomes are better for patients receiving methadone, regardless of counseling received;
- Buprenorphine treatment significantly decreased the number of opioid-positive drug tests, multiple studies found a 75-80 percent reduction in the number of patients testing positive for opioid use;

- Methadone and buprenorphine are equally effective at reducing opioid use; no differences were found in opioid-positive drug tests or self-reported heroin use when treating with these medications.

To be clear, the evidence supports long term maintenance with these medicines in the context of behavioral treatment and recovery support, not short term detoxification programs aimed at abstinence.[30] Abstinence from all medicines may be a particular patient's goal and that goal should be discussed between patients and providers. However the scientific evidence suggests the relapse rates are high when tapering off of these medications and treatment programs with an abstinence focus generally do not facilitate patients' long term, stable recovery. It is often the case that patients with good long-term outcomes are the ones who engaged in MAT although cycling in and out of treatment is not unusual in the path to a stable recovery.[31] Maintenance treatments have also been shown to be protective against injecting and overdose.[32], [33]

Ongoing NIDA research is working to develop improved strategies for the implementation of these evidence-based interventions. This includes research to better understand the role environment—be it social, familial, structural, or geographic—plays in preventing opioid use and in the success of prevention and treatment interventions; and how to tailor prevention and treatment interventions to individuals with unique needs, including those in the criminal justice system or with HIV.

Conclusion

NIDA will continue its close collaborations with other Federal Agencies and community partners with a strong interest in preserving public health to address the ongoing challenge posed by abuse of prescription and non-prescription opioids in this country. We commend the Subcommittee for recognizing the serious and growing challenge associated with this exceedingly complex issue. Indeed, prescription opioids, like other prescribed medications, do present health risks but they are also powerful clinical tools for the treatment of pain. It is imperative that we strive to achieve a balanced approach to ensure that people suffering from pain can get the relief they need while minimizing the potential for negative consequences. We support the development and implementation of multipronged, evidence-based strategies that minimize the intrinsic risks of opioid medications and make effective, long term treatments more widely available.

References

[1] Substance Abuse and Mental Health Services Administration. Results from the 2013 National Survey on Drug Use and Health: Summary of National Findings. (2014)

[2] Williams, J. T. *et al.* Regulation of μ-opioid receptors: desensitization, phosphorylation, internalization, and tolerance. *Pharmacol. Rev.* **65,** 223–254 (2013).

[3] Jones, C. M. et al. Alcohol involvement in opioid pain reliever and benzodiazepine drug abuse-related emergency department visits and drug-related deaths - United States, 2010. MMWR. 2014 Oct 10;63(40):881-5.

[4] Federation of State Medical Boards Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain. Available at http://www.fsmb.org/Media/Default/PDF/FSMB/Advocacy/pain_policy_july2013.pdf

[6]Gaither JR1, Goulet JL2, Becker WC3, Crystal S4, Edelman EJ5, Gordon K6, Kerns RD2, Rimland D7, Skanderson M8, Weisberg DF9, Justice AC10, Fiellin DA1. Guideline-concordant management of opioid therapy among human immunodeficiency virus (HIV)-infected and uninfected veterans. J Pain. 2014 Nov;15(11):1130-40. doi: 10.1016/j.jpain.2014.08.004. Epub 2014 Aug 23.

[7] Office of Healthcare Inspections. Report No-14-00895-163 Healthcare Inspection-VA Patterns of Dispensing Take-Home Opioids and Monitoring Patients on Opioid Therapy. Available at http://www.va.gov/oig/pubs/VAOIG-14-00895-163.pdf linked to on 4-23-2015

[8] Patrick, S. W. *et al.* Neonatal abstinence syndrome and associated health care expenditures: United States, 2000-2009. *JAMA* **307,** 1934–1940 (2012)

[9] Bateman, B. T. *et al.* Patterns of opioid utilization in pregnancy in a large cohort of commercial insurance beneficiaries in the United States. *Anesthesiology* **120,** 1216–1224 (2014).

[10] Rudisill, T. M., Zhao, S., Abate, M. A., Coben, J. H. & Zhu, M. Trends in drug use among drivers killed in U.S. traffic crashes, 1999-2010. *Accid. Anal. Prev.* **70,** 178–187 (2014).

[11] Spoth, R. *et al.* Longitudinal effects of universal preventive intervention on prescription drug misuse: three randomized controlled trials with late adolescents and young adults. *Am. J. Public Health* **103,** 665–672 (2013).

[12] Haegerich, T. M., Paulozzi, L. J., Manns, B. J. & Jones, C. M. What we know, and don't know, about the impact of state policy and systems-level interventions on prescription drug overdose. *Drug Alcohol Depend.* **145,** 34–47 (2014).

[13] Walley, A. Y. *et al.* Opioid overdose rates and implementation of overdose education and nasal naloxone distribution in Massachusetts: interrupted time series analysis. *BMJ* **346,** f174–f174 (2013).

[14] Johnson, H. *et al.* Decline in drug overdose deaths after state policy changes - Florida, 2010-2012. *MMWR Morb. Mortal. Wkly. Rep.* **63,** 569–574 (2014).

[15] Mitchell, O., Wilson, D. B., Eggers, A. & MacKenzie, D. L. Assessing the effectiveness of drug courts on recidivism: A meta-analytic review of traditional and non-traditional drug courts. *J. Crim. Justice* **40,** 60–71 (2012).

[16] Schwartz, R. P. *et al.* Opioid agonist treatments and heroin overdose deaths in Baltimore, Maryland, 1995-2009. *Am. J. Public Health* **103,** 917–922 (2013).

[17] Havens J.R. et al. The impact of a reformulation of extended-release oxycodone designed to deter abuse in a sample of prescription opioid abusers. Drug Alcohol Depend. 2014 Jun 1;139:9-17.

[18] Franklin, G. *et al.* A Comprehensive Approach to Address the Prescription Opioid Epidemic in Washington State: Milestones and Lessons Learned. *Am. J. Public Health* **105,** 463–469 (2015).

[19] Johnson, H. *et al.* Decline in drug overdose deaths after state policy changes - Florida, 2010-2012. *MMWR Morb. Mortal. Wkly. Rep.* **63,** 569–574 (2014).

[20] Muhuri PK, Gfroerer JC & Davies MC. Associations of nonmedical pain reliever use and initiation of heroin use in the United States. (2013).

[21] Cicero, T. J., Ellis, M. S., Surratt, H. L. & Kurtz, S. P. The Changing Face of Heroin Use in the United States: A Retrospective Analysis of the Past 50 Years. *JAMA Psychiatry* **71,** 821 (2014).

[22] Cicero TJ, Ellis MS, Surratt HL, Kurtz SP. The changing face of heroin use in the United States: a retrospective analysis of the past 50 years. JAMA Psychiatry. 2014 Jul 1;71(7):821-6. doi: 0.1001/jamapsychiatry.2014.366.

[23] Mars SG, Bourgois P, Karandinos G, Montero F, Ciccarone D. "Every 'never' I ever said came true": transitions from opioid pills to heroin injecting. Int J Drug Policy. 2014 Mar;25(2):257-66.

[24] Reuben, D. B. et al. National Institutes of Health Pathways to Prevention Workshop: the role of opioids in the treatment of chronic pain. Ann. Intern. Med. 162, 295–300 (2015).

[25] Podolsky, A. T. *et al.* Novel fentanyl-based dual μ/δ-opioid agonists for the treatment of acute and chronic pain. *Life Sci.* **93,** 1010–1016 (2013).

[26] Centers for Disease Control and Prevention (CDC). Community-based opioid overdose prevention programs providing naloxone - United States, 2010. *MMWR Morb. Mortal. Wkly. Rep.* **61,** 101–105 (2012).

[27] Mattick, R. P., Breen, C., Kimber, J. & Davoli, M. Buprenorphine maintenance versus placebo or methadone maintenance for opioid dependence. Cochrane Database Syst. Rev. 2, CD002207 (2014).

[28] Mattick, R.P., Breen, C., Kimber, J., and Davoli, M. (2009). Methadone maintenance therapy versus no opioid replacement therapy for opioid dependence. In Cochrane Database of Systematic Reviews, The Cochrane Collaboration, ed. (Chichester, UK: John Wiley & Sons, Ltd).

[29] Mattick, R.P., Breen, C., Kimber, J., and Davoli, M. (2014). Buprenorphine maintenance versus placebo or methadone maintenance for opioid dependence. Cochrane Database Syst. Rev. *2*, CD002207.

[30] Nosyk B1, Sun H, Evans E, Marsh DC, Anglin MD, Hser YI, Anis AH.Addiction. Defining dosing pattern characteristics of successful tapers following methadone maintenance treatment: results from a population-based retrospective cohort study. 2012 Sep;107(9):1621-9. doi: 10.1111/j.1360-0443.2012.03870.x. Epub 2012 May 8.

[31] Weiss RD, Potter JS, Griffin ML, Provost SE, Fitzmaurice GM, McDermott KA, Srisarajivakul EN, Dodd DR, Dreifuss JA, McHugh RK, Carroll KM. Long-term outcomes from the National Drug Abuse Treatment Clinical Trials Network Prescription Opioid Addiction Treatment Study. Drug Alcohol Depend. 2015 May 1;150:112-9. doi: 10.1016/j.drugalcdep.2015.02.030. Epub 2015 Mar 6. PMID: 25818060

[32] Woody GE1, Bruce D, Korthuis PT, Chhatre S, Poole S, Hillhouse M, Jacobs P, Sorensen J, Saxon AJ, Metzger D, Ling W.J. HIV risk reduction with buprenorphine-naloxone or methadone: findings from

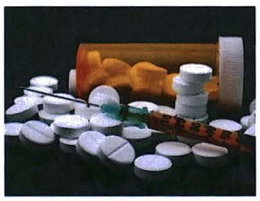
a randomized trial. Acquir Immune Defic Syndr. 2014 Jul 1;66(3):288-93. doi: 10.1097/QAI.0000000000000165.

[33] Schwartz RP, Gryczynski J, O'Grady KE, Sharfstein JM, Warren G, Olsen Y, Mitchell SG, Jaffe JH. Opioid agonist treatments and heroin overdose deaths in Baltimore, Maryland, 1995-2009. Am J Public Health. 2013 May;103(5):917-22. doi: 10.2105/AJPH.2012.301049. Epub 2013 Mar 14.

Article from The Star Press Online: http://www.thestarpress.com/story/opinion/contributors/2017/12/30/hidden-victims-opioid-use-sends-more-kids-foster-care/987266001/

Hidden victims: Opioid use sends more kids to foster care

Tami Silverman Published 4:00 p.m. ET Dec. 30, 2017



(Photo: Moussa81, Getty Images/iStockphoto)

The news offers daily reminders of the complex challenges our communities, state and country face in the opioid crisis. Governor Eric Holcomb made attacking the drug epidemic a pillar of his inaugural policy agenda. Indiana University has announced its Grand Challenge to respond to the addictions crisis, committing $50 million to finding solutions.

Indiana's social service, emergency service, criminal justice, health care, and public health providers are working to respond to the relentless array of ongoing, interconnected needs arising from the crisis. Collaborations among local, state and federal agencies are developing new cross-cutting partnerships and interventions. At the Indiana Youth Institute, we are concentrating on identifying and addressing the short- and long-term consequences of the opioid crisis on Hoosier children.

For the past three years the number of children in Indiana's foster care system has increased steadily. Experts, including Mary Beth Bonaventura, the former director of the Indiana Department of Child services, agree these increases are directly linked to the opioid problem.

Tami Silverman *(Photo: Submitted)*

"We have more children in care than we've ever had in history, nationwide and in Indiana, Bonventura said. "With all cases counted, (we have) close to 29,000 kids in care in some way shape or form."

In 2016, 52 percent of children DCS removed from a home were removed due to parental substance abuse. When substance abuse is included as a secondary cause, that rate rises to nearly 80 percent.

Who cares for the kids caught in this crisis? In Delaware County, 2.1 percent of children live with foster parents, and 8.3 percent of children live with their grandparents. Bonaventura states in Indiana nearly 51 percent of all DCS foster care placements are with relatives. A September 2017 Pew Charitable Trusts study shows parents of adult children who either struggle with substance use disorder, or have died from an overdose, are raising an increasing number of their grandchildren.

Child placements with relatives, also called kinship care, can be a formal placement from the state or an informal arrangement between the parents and the relative caregivers. In fact, the Pew research estimates that for every foster child formally placed with a relative as a primary caregiver, there are 20 more in informal kinship arrangements. Tina Cloer, president and CEO of Children's Bureau Inc., says "I get calls all the time from people all over the city and state who have now inherited their nieces and nephews, their grandchildren, their friends' kids, because they're struggling with addiction."

About 39 percent of grandparents caring for grandchildren are older than 60, 21 percent live below the poverty line and 26 percent have a disability. Like all children in care, children in kinship care have been found to lack adequate access to primary care, immunization, vision, hearing and dental care services. Despite these challenges, the American Academy of Pediatrics stresses the benefits of kinship care, including increased stability and well-being, reduced trauma, and an increased likelihood that siblings will stay together.

We can help grandparents and family members caring for these young victims of our state's addiction crisis. Kinship care is often unexpected and unplanned. Many families are unaware of available help. For instance, grandparents and families who become licensed foster families can access services and financial supports. Organizations such as Grandfamilies.org (http://grandfamilies.org/) provide valuable information on applicable laws and resources. Cloer works with many faith-based and community groups that are reaching out to grandparents caring for their grandchildren with basic needs items such as diapers, formula and clothing. As employers, we can offer flexible schedules for those suddenly faced with caring for these children. Schools and youth organizations also need to be sensitive to kinship care arrangements.

Any comprehensive solution to Indiana's opioid crisis must include the impacted children and family members. Most child welfare experts agree that an increased focus on the impacts on the youngest victims is warranted. While we look for policy and systems change at the state level, at the local level we can immediately step in to help families providing kinship care. Actions taken now can help prevent this crisis from lasting into the next generation.

For more information on the impact of opioids on children, see IYI's Issue Brief at www.iyi.org (http://www.iyi.org).

Tami Silverman is the president and CEO of the Indiana Youth Institute. She may be reached at iyi@iyi.org or on Twitter at @Tami_IYI.

Vox

New Jersey just passed one of the most aggressive laws to combat the opioid epidemic

Opioid abuse is one of the few public health issues Republicans and Democrats agree on.

By Sarah Frostenson | @sfrostenson | sarah.frostenson@vox.com | Feb 15, 2017, 4:30pm EST

New Jersey Governor Chris Christie, a strong proponent of opioid reform, called for sweeping legislation in his State of the State address on January 10, 2017. (AP Photo/Mel Evans) | Mel Evans/AP

New Jersey just passed one of the nation's most **comprehensive laws** to combat the growing opioid and heroin crisis.

The **law** will reduce the supply of drugs that patients getting their first opioid prescription can get from 30 days to five days. It also will require doctors to talk to patients about how addictive the drugs are. For addicts whose doctors have recommended treatment, the law also mandates that insurers offer 180 days of coverage without preauthorization.

"We're starting to treat substance abuse like the chronic disease that it is," said Cynthia Reilly, the director of Pew Charitable Trusts' substance use prevention and treatment program, about the law. "We don't treat someone for diabetes for a few weeks and then expect them to be cured and stop treatment."

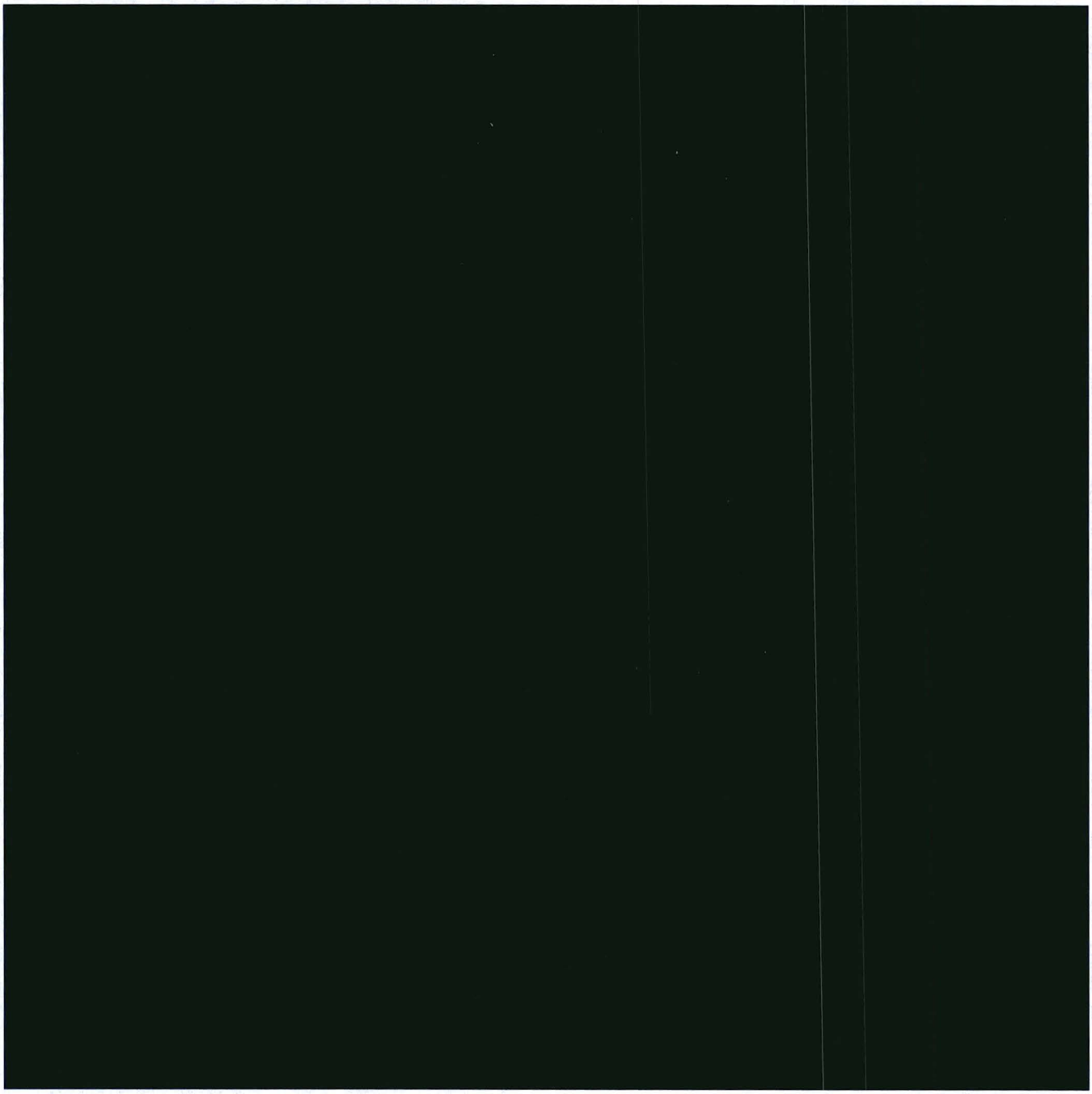
The **bill** received unanimous, bipartisan support in the Senate with a 33-0 vote on Monday and overwhelming support in the House today with a 64-1 vote (there were five abstentions). New Jersey Gov. Chris Christie **signed the bill** into law after calling for the **legislation** in his State of the State address in January.

New Jersey's legislation is part of a larger national trend of states getting tougher on opioid prescriptions

The **Centers for Disease Control and Prevention** estimates that since 1999, 165,000 people have died from overdoses linked to prescription opioid abuse and that as many as 40 Americans die each day.

And since much of the problem is due to too many opioids being prescribed and sold, the agency issued a set of **guidelines** last March that recommended prescribers limit initial opioid prescriptions to seven days or less. **Massachusetts** became the first state to enact the CDC's guidelines, passing a law that restricted opioid prescriptions to a seven-day supply.

Eight other states in the Northeast (including New Jersey) have followed suit and passed their own legislation, as you can see in the map below. In Arizona, Gov. Doug Ducey (R) mandated a seven-day restriction on opioid prescriptions through **executive order**.



Normally, public health is politically polarizing. But Republicans and Democrats are united on curtailing opioid abuse.

Of the 10 states with prescription limits, six are led by a Republican governor and four by a Democratic governor. What's more, in a state like Massachusetts, where the governor is Republican and the state legislature is majority Democrat, they achieved not just consensus but ***unanimous* consensus**.

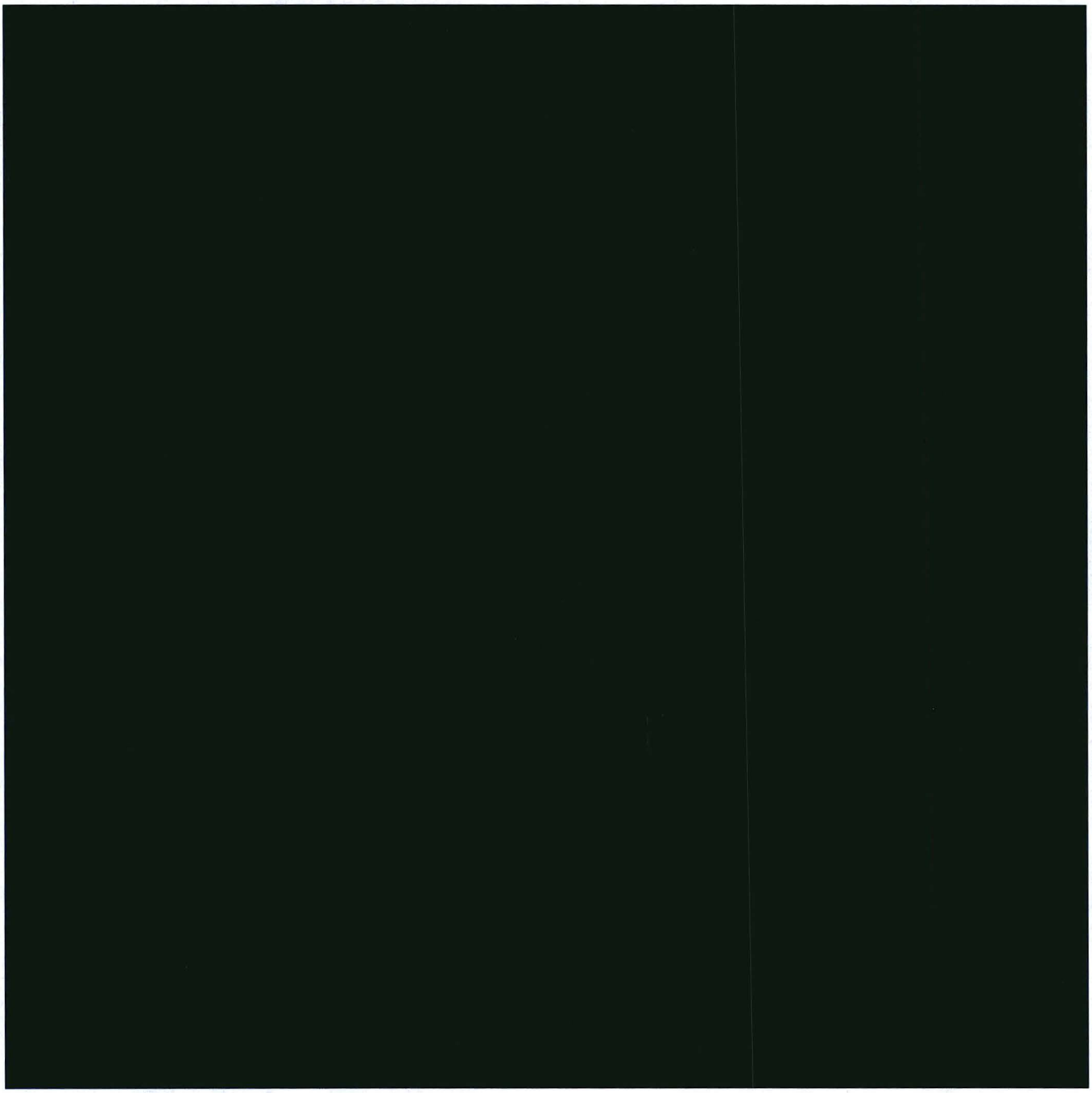
This kind of widespread bipartisanship support isn't a given **in public health**. But the opioid problem has emerged as one of the very few health issues members of both parties

are rallying around these days.

In early 2014, researchers polled US adults on their thoughts about opioid abuse. They wanted to know if Americans thought it was a serious issue and which, if any, policy solutions they supported to combat it.

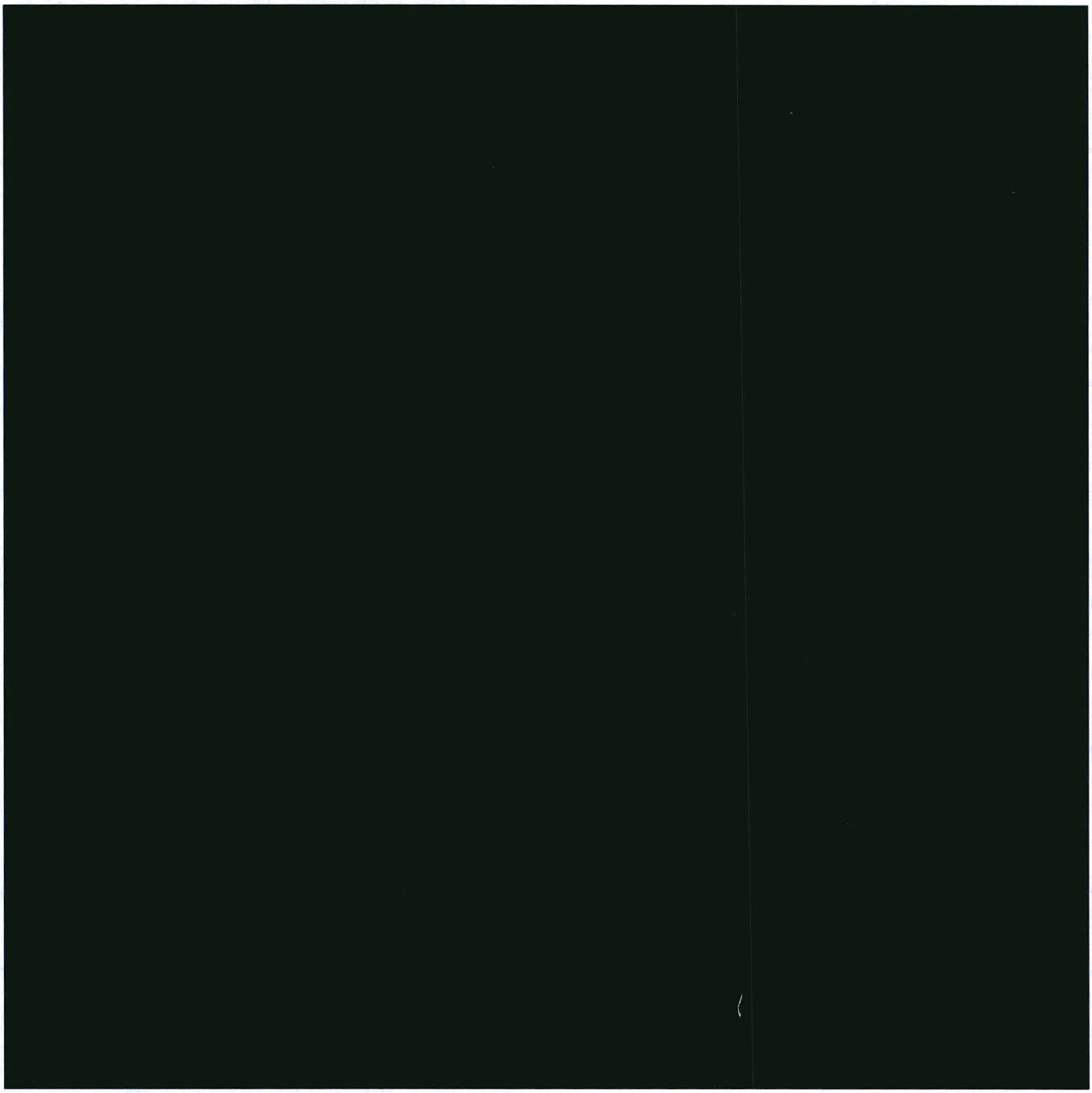
It turned out that Americans on both sides of the political aisle thought opioid abuse was a serious problem, and of **16 possible policy solutions** — ranging from stricter regulation of pharmaceutical companies to expanded Medicaid benefits — there was bipartisan support for all but two proposals.

The reason? People from both parties are **equally likely** to have known someone who has abused prescription painkillers.



The sobering reality, according to **Robert Blendon**, a professor at Harvard's School of Public Health who has studied public opinion around opioids, is that the opioid epidemic is so widespread in the US that it cuts across demographics, class divisions, and even political parties.

And even though certain areas of the country are harder hit than others (as you can see in the map below), researchers found that Democrats and Republicans are equally likely to consider opioid addiction to be a **serious problem in their state**.



People living in rural areas of the US are **more likely** to have known someone who abused opioids than people in urban areas. But "there is a high incidence of death from opioids in both white, rural Republican areas and low-income areas in cities," said Blendon. And so urban Americans are **just as likely** as rural Americans to think that opioid addiction in the US is a serious problem.

What's more, Blendon argues that the type of proposed government intervention around opioid abuse is particularly conducive to bipartisan support because it is limited in reach —

no federally managed oversight, just policy solutions focused on bolstering existing state-run programs.

The **Comprehensive Addiction and Recovery Act (CARA)**, which authorized $181 million annually to fight the opioid epidemic, passed in the summer of 2016 with almost unanimous support (94-1 in the Senate and 400-5 in the House).

"It's a matter of both who's affected by it and the nature of the government intervention," Blendon said. "We're not talking about 20 new federal laws, but rather state laws that will limit the ability of physicians to make certain types of prescriptions. It's not the federal government running the opioid response."

But researchers warn that if opioid addiction becomes politicized, or strongly associated with one of the two political parties, policy adoption will become more challenging.

"If this becomes an issue where politicians are competing for the best way to deal with opioids, we will see polarization emerge," said Sarah Gollust, a professor of health policy at the University of Minnesota who studies how public opinion shapes public health. "But [the opioid epidemic] is also different in a lot of ways. It's more common among white Americans, and that changes the questions about deservingness and groups."

Watch: America's painkiller epidemic, explained

Was this article helpful?

IN THIS STORYSTREAM

The opioid epidemic: America's deadliest drug overdose crisis

A member of Trump's opioid commission calls its work "a charade"

New Jersey just passed one of the most aggressive laws to combat the opioid epidemic

A drug company hiked the price of a lifesaving opioid overdose antidote by 500 percent

VIEW ALL 159 STORIES

Checklist for prescribing opioids for chronic pain

For primary care providers treating adults (18+) with chronic pain ≥3 months, excluding cancer, palliative, and end-of-life care

CHECKLIST

When CONSIDERING long-term opioid therapy

- ☐ Set realistic goals for pain and function based on diagnosis (eg, walk around the block).
- ☐ Check that non-opioid therapies tried and optimized.
- ☐ Discuss benefits and risks (eg, addiction, overdose) with patient.
- ☐ Evaluate risk of harm or misuse.
  - Discuss risk factors with patient.
  - Check prescription drug monitoring program (PDMP) data.
  - Check urine drug screen.
- ☐ Set criteria for stopping or continuing opioids.
- ☐ Assess baseline pain and function (eg, PEG scale).
- ☐ Schedule initial reassessment within 1–4 weeks.
- ☐ Prescribe short-acting opioids using lowest dosage on product labeling; match duration to scheduled reassessment.

If RENEWING without patient visit

- ☐ Check that return visit is scheduled ≤3 months from last visit.

When REASSESSING at return visit

Continue opioids only after confirming clinically meaningful improvements in pain and function without significant risks or harm.

- ☐ Assess pain and function (eg, PEG); compare results to baseline.
- ☐ Evaluate risk of harm or misuse:
  - Observe patient for signs of over-sedation or overdose risk.
    - If yes: Taper dose.
  - Check PDMP.
  - Check for opioid use disorder if indicated (eg, difficulty controlling use).
    - If yes: Refer for treatment.
- ☐ Check that non-opioid therapies optimized.
- ☐ Determine whether to continue, adjust, taper, or stop opioids.
- ☐ Calculate opioid dosage morphine milligram equivalent (MME).
  - If ≥50 MME/day total (≥50 mg hydrocodone; ≥33 mg oxycodone), increase frequency of follow-up; consider offering naloxone.
  - Avoid ≥90 MME/day total (≥90 mg hydrocodone; ≥60 mg oxycodone), or carefully justify; consider specialist referral.
- ☐ Schedule reassessment at regular intervals (≤3 months).

REFERENCE

EVIDENCE ABOUT OPIOID THERAPY

- *Benefits of long-term opioid therapy for chronic pain not well supported by evidence.*
- *Short-term benefits small to moderate for pain; inconsistent for function.*
- *Insufficient evidence for long-term benefits in low back pain, headache, and fibromyalgia.*

NON-OPIOID THERAPIES

Use alone or combined with opioids, as indicated:

- Non-opioid medications (eg, NSAIDs, TCAs, SNRIs, anti-convulsants).
- Physical treatments (eg, exercise therapy, weight loss).
- Behavioral treatment (eg, CBT).
- Procedures (eg, intra-articular corticosteroids).

EVALUATING RISK OF HARM OR MISUSE

Known risk factors include:

- Illegal drug use; prescription drug use for nonmedical reasons.
- History of substance use disorder or overdose.
- Mental health conditions (eg, depression, anxiety).
- Sleep-disordered breathing.
- Concurrent benzodiazepine use.

Urine drug testing: Check to confirm presence of prescribed substances and for undisclosed prescription drug or illicit substance use.

Prescription drug monitoring program (PDMP): Check for opioids or benzodiazepines from other sources.

ASSESSING PAIN & FUNCTION USING PEG SCALE

PEG score = average 3 individual question scores
(30% improvement from baseline is clinically meaningful)

Q1: *What number from 0–10 best describes your **pain** in the past week?*
0="no pain", 10="worst you can imagine"

Q2: *What number from 0–10 describes how, during the past week, pain has interfered with your **enjoyment of life**?*
0="not at all", 10="complete interference"

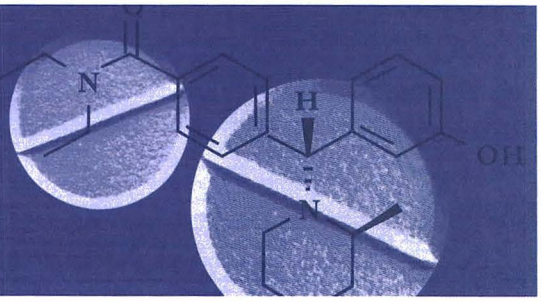
Q3: *What number from 0–10 describes how, during the past week, pain has interfered with your **general activity**?*
0="not at all", 10="complete interference"

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

TO LEARN MORE
WWW.CDC.GOV/DRUGOVERDOSE/PRESCRIBING/GUIDELINE

March 2016

PRESCRIPTION OPIOIDS: WHAT YOU NEED TO KNOW



Prescription opioids can be used to help relieve moderate-to-severe pain and are often prescribed following a surgery or injury, or for certain health conditions. These medications can be an important part of treatment but also come with serious risks. It is important to work with your health care provider to make sure you are getting the safest, most effective care.

WHAT ARE THE RISKS AND SIDE EFFECTS OF OPIOID USE?

Prescription opioids carry serious risks of addiction and overdose, especially with prolonged use. An opioid overdose, often marked by slowed breathing, can cause sudden death. The use of prescription opioids can have a number of side effects as well, even when taken as directed:

- Tolerance—meaning you might need to take more of a medication for the same pain relief
- Physical dependence—meaning you have symptoms of withdrawal when a medication is stopped
- Increased sensitivity to pain
- Constipation
- Nausea, vomiting, and dry mouth
- Sleepiness and dizziness
- Confusion
- Depression
- Low levels of testosterone that can result in lower sex drive, energy, and strength
- Itching and sweating

As many as **1 in 4** PEOPLE*

receiving prescription opioids long term in a primary care setting struggles with addiction.

* Findings from one study

RISKS ARE GREATER WITH:

- History of drug misuse, substance use disorder, or overdose
- Mental health conditions (such as depression or anxiety)
- Sleep apnea
- Older age (65 years or older)
- Pregnancy

Avoid alcohol while taking prescription opioids. Also, unless specifically advised by your health care provider, medications to avoid include:

- Benzodiazepines (such as Xanax or Valium)
- Muscle relaxants (such as Soma or Flexeril)
- Hypnotics (such as Ambien or Lunesta)
- Other prescription opioids

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

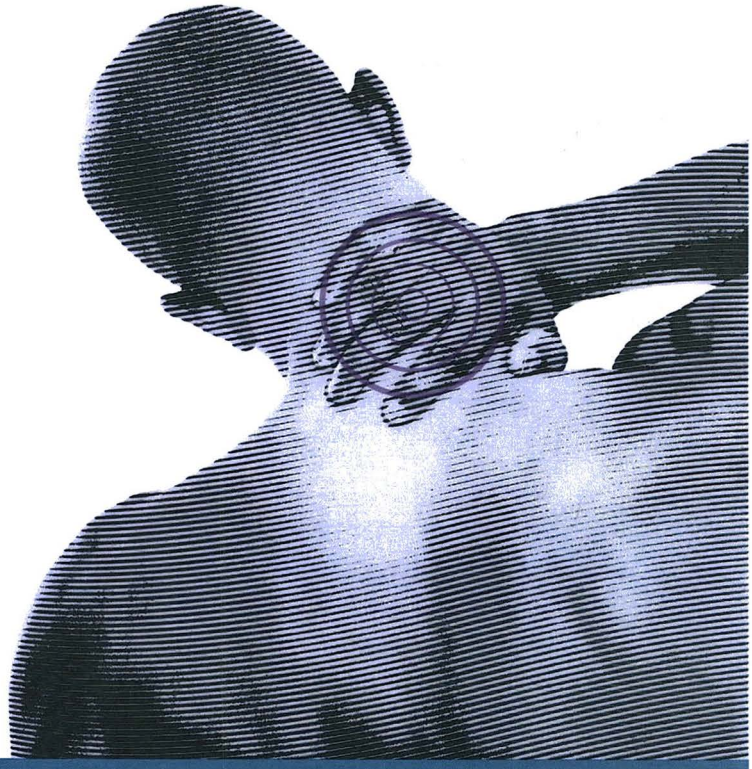
American Hospital Association®

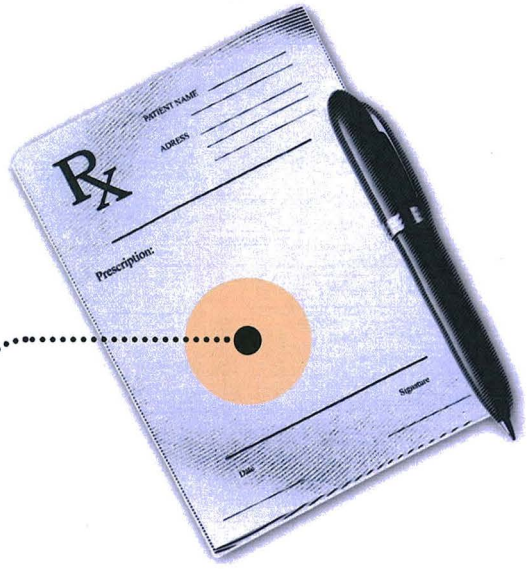
CS264107C May 9, 2016

KNOW YOUR OPTIONS

Talk to your health care provider about ways to manage your pain that don't involve prescription opioids. Some of these options **may actually work better** and have fewer risks and side effects. Options may include:

- ☐ Pain relievers such as acetaminophen, ibuprofen, and naproxen
- ☐ Some medications that are also used for depression or seizures
- ☐ Physical therapy and exercise
- ☐ Cognitive behavioral therapy, a psychological, goal-directed approach, in which patients learn how to modify physical, behavioral, and emotional triggers of pain and stress.





Be Informed!

Make sure you know the name of your medication, how much and how often to take it, and its potential risks & side effects.

IF YOU ARE PRESCRIBED OPIOIDS FOR PAIN:

- ☐ Never take opioids in greater amounts or more often than prescribed.
- ☐ Follow up with your primary health care provider within ___ days.
  - – Work together to create a plan on how to manage your pain.
  - – Talk about ways to help manage your pain that don't involve prescription opioids.
  - – Talk about any and all concerns and side effects.
- ☐ Help prevent misuse and abuse.
  - – Never sell or share prescription opioids.
  - – Never use another person's prescription opioids.
- ☐ Store prescription opioids in a secure place and out of reach of others (this may include visitors, children, friends, and family).
- ☐ Safely dispose of unused prescription opioids: Find your community drug take-back program or your pharmacy mail-back program, or flush them down the toilet, following guidance from the Food and Drug Administration (www.fda.gov/Drugs/ResourcesForYou).
- ☐ Visit www.cdc.gov/drugoverdose to learn about the risks of opioid abuse and overdose.
- ☐ If you believe you may be struggling with addiction, tell your health care provider and ask for guidance or call SAMHSA's National Helpline at 1-800-662-HELP.

LEARN MORE | www.cdc.gov/drugoverdose/prescribing/guideline.html

24:21-15.2 Limitation on amount of opiod initially prescribed under certain circumstances.

11 a. A practitioner shall not issue an initial prescription for an opioid drug which is a prescription drug as defined in section 2 of P.L.2003, c.280 (C.45:14-41) in a quantity exceeding a five-day supply for treatment of **acute pain** . Any prescription for **acute pain** pursuant to this subsection shall be for the lowest effective dose of immediate-release opioid drug.

b. Prior to issuing an initial prescription of a Schedule II controlled dangerous substance or any other opioid drug which is a prescription drug as defined in section 2 of P.L.2003, c.280 (C.45:14-41) in a course of treatment for **acute** or chronic **pain** , a practitioner shall:

(1) take and document the results of a thorough medical history, including the patient's experience with non-opioid medication and non-pharmacological **pain** management approaches and substance abuse history;

(2) conduct, as appropriate, and document the results of a physical examination;

(3) develop a treatment plan, with particular attention focused on determining the cause of the patient's **pain** ;

(4) access relevant prescription monitoring information under the Prescription Monitoring Program pursuant to section 8 of P.L.2015, c.74 (C. 45:1-46.1); and

(5) limit the supply of any opioid drug prescribed for **acute pain** to a duration of no more than five days as determined by the directed dosage and frequency of dosage.

c. No less than four days after issuing the initial prescription pursuant to subsection a. of this subsection, the practitioner, after consultation with the patient, may issue a subsequent prescription for the drug to the patient in any quantity that complies with applicable State and federal laws, provided that:

(1) the subsequent prescription would not be deemed an initial prescription under this section;

(2) the practitioner determines the prescription is necessary and appropriate to the patient's treatment needs and documents the rationale for the issuance of the subsequent prescription; and

(3) the practitioner determines that issuance of the subsequent prescription does not present an undue risk of abuse, addiction, or diversion and documents that determination.

d. Prior to issuing the initial prescription of a Schedule II controlled dangerous substance or any other opioid drug which is a prescription drug as defined in section 2 of P.L.2003, c.280 (C.45:14-41) in a course of treatment for **acute** or chronic **pain** and again prior to issuing the third prescription of the course of treatment, a practitioner shall discuss with the patient, or the patient's parent or guardian if the patient is under 18 years of age and is not an emancipated minor, the risks associated with the drugs being prescribed, including but not limited to:

(1) the risks of addiction and overdose associated with opioid drugs and the dangers of taking opioid drugs with alcohol, benzodiazepines and other central nervous system depressants;

(2) the reasons why the prescription is necessary;

(3) alternative treatments that may be available; and

(4) risks associated with the use of the drugs being prescribed, specifically that opioids are highly addictive, even when taken as prescribed, that there is a risk of developing a physical or psychological dependence on the controlled dangerous substance, and that the risks of taking more opioids than prescribed, or mixing sedatives, benzodiazepines or alcohol with opioids, can result in fatal respiratory depression.

The practitioner shall include a note in the patient's medical record that the patient or the patient's parent or guardian, as applicable, has discussed with the practitioner the risks of developing a physical or psychological dependence on the controlled dangerous substance and alternative treatments that may be available. The Division of Consumer Affairs shall develop and make available to practitioners guidelines for the discussion required pursuant to this subsection.

e. At the time of the issuance of the third prescription for a prescription opioid drug, the practitioner shall enter into a **pain** management agreement with the patient.

f. When a Schedule II controlled dangerous substance or any other prescription opioid drug is continuously prescribed for three months or more for chronic **pain** , the practitioner shall:

(1) review, at a minimum of every three months, the course of treatment, any new information about the etiology of the **pain** , and the patient's progress toward treatment objectives and document the results of that review;

(2) assess the patient prior to every renewal to determine whether the patient is experiencing problems associated with physical and psychological dependence and document the results of that assessment;

(3) periodically make reasonable efforts, unless clinically contraindicated, to either stop the use of the controlled substance, decrease the dosage, try other drugs or treatment modalities in an effort to reduce the potential for abuse or the development of physical or psychological dependence and document with specificity the efforts undertaken;

(4) review the Prescription Drug Monitoring information in accordance with section 8 of P.L.2015, c.74 (C. 45:1-46.1); and

(5) monitor compliance with the **pain** management agreement and any recommendations that the patient seek a referral.

g. As used in this section:

"**Acute pain**" means **pain** , whether resulting from disease, accidental or intentional trauma, or other cause, that the practitioner reasonably expects to last only a short period of time. "**Acute pain**" does not include chronic **pain** , **pain** being treated as part of cancer care, hospice or other end of life care, or **pain** being treated as part of palliative care.

"Initial prescription" means a prescription issued to a patient who:

(1) has never previously been issued a prescription for the drug or its pharmaceutical equivalent; or

(2) was previously issued a prescription for the drug or its pharmaceutical equivalent, but the date on which the current prescription is being issued is more than one year after the date the patient last used or was administered the drug or its equivalent.

When determining whether a patient was previously issued a prescription for a drug or its pharmaceutical equivalent, the practitioner shall consult with the patient and review the patient's medical record and prescription monitoring information.

"**Pain** management agreement" means a written contract or agreement that is executed between a practitioner and a patient, prior to the commencement of treatment for chronic **pain** using a Schedule II controlled dangerous substance or any other opioid drug which is a prescription drug as defined in section 2 of P.L.2003, c.280 (C.45:14-41), as a means to:

(1) prevent the possible development of physical or psychological dependence in the patient;

(2) document the understanding of both the practitioner and the patient regarding the patient's **pain** management plan;

(3) establish the patient's rights in association with treatment, and the patient's obligations in relation to the responsible use, discontinuation of use, and storage of Schedule II controlled dangerous substances, including any restrictions on the refill of prescriptions or the acceptance of Schedule II prescriptions from practitioners;

(4) identify the specific medications and other modes of treatment, including physical therapy or exercise, relaxation, or psychological counseling, that are included as a part of the **pain** management plan;

(5) specify the measures the practitioner may employ to monitor the patient's compliance, including but not limited to random specimen screens and pill counts; and

(6) delineate the process for terminating the agreement, including the consequences if the practitioner has reason to believe that the patient is not complying with the terms of the agreement.

"Practitioner" means a medical doctor, doctor of osteopathy, dentist, optometrist, podiatrist, physician assistant, certified nurse midwife, or advanced practice nurse, acting within the scope of practice of their professional license pursuant to Title 45 of the Revised Statutes.

h. This section shall not apply to a prescription for a patient who is currently in active treatment for cancer, receiving hospice care from a licensed hospice or palliative care, or is a resident of a long term care facility, or to any medications that are being prescribed for use in the treatment of substance abuse or opioid dependence.

i. Every policy, contract or plan delivered, issued, executed or renewed in this State, or approved for issuance or renewal in this State by the Commissioner of Banking and Insurance,

and every contract purchased by the School Employees' Health Benefits Commission or State Health Benefits Commission, on or after the effective date of this act, that provides coverage for prescription drugs subject to a co-payment, coinsurance or deductible shall charge a co-payment, coinsurance or deductible for an initial prescription of an opioid drug prescribed pursuant to this section that is either:

(1) proportional between the cost sharing for a 30-day supply and the amount of drugs the patient was prescribed; or

(2) equivalent to the cost sharing for a full 30-day supply of the opioid drug, provided that no additional cost sharing may be charged for any additional prescriptions for the remainder of the 30-day supply.

L.2017, c.28, s.11

45:1-46.1 Proper time to access prescription monitoring information; restrictions in dispensing Schedule II controlled dangerous substance; exceptions.

8. a. (1) Except as provided in subsection b. of this section, a practitioner or other person who is authorized by a practitioner to access prescription monitoring information pursuant to subsection h. of section 26 of P.L.2007, c.244 (C.45:1-46) shall access prescription monitoring information the first time the practitioner or other person prescribes a Schedule II controlled dangerous substance to a new patient for **acute** or chronic **pain** . In addition, for any prescription of a Schedule II controlled dangerous substance for a new or current patient for **acute** or chronic **pain** which is written on or after the effective date of P.L.2015, c.74 (C.45:1-46.1 et al.) a practitioner or other authorized person shall access prescription monitoring information on a quarterly basis during the period of time the patient continues to receive such prescriptions.

(2) (a) A pharmacist shall not dispense a Schedule II controlled dangerous substance to any person without first accessing the prescription monitoring information, as authorized pursuant to subsection h. of section 26 of P.L.2007, c.244 (C.45:1-46), to determine if the person has received other prescriptions that indicate misuse, abuse, or diversion, if the pharmacist has a reasonable belief that the person may be seeking a controlled dangerous substance, in whole or in part, for any purpose other than the treatment of an existing medical condition, such as for purposes of misuse, abuse, or diversion.

(b) A pharmacist shall not dispense a prescription to a person other than the patient for whom the prescription is intended, unless the person picking up the prescription provides personal identification to the pharmacist, and the pharmacist, as required by subsection b. of section 25 of P.L.2007, c.244 (C.45:1-45), inputs that identifying information into the Prescription Monitoring Program if the pharmacist has a reasonable belief that the person may be seeking a controlled dangerous substance, in whole or in part, for any reason other than delivering the substance to the patient for the treatment of an existing medical condition. The provisions of this subparagraph shall not take effect until the director determines that the Prescription Monitoring Program has the technical capacity to accept such information.

b. The provisions of subsection a. of this section shall not apply to:

(1) a veterinarian;

(2) a practitioner or the practitioner's agent administering methadone, or another controlled dangerous substance designated by the director as appropriate for treatment of a patient with a substance abuse disorder, as interim treatment for a patient on a waiting list for admission to an authorized substance abuse treatment program;

(3) a practitioner administering a controlled dangerous substance directly to a patient;

(4) a practitioner prescribing a controlled dangerous substance to be dispensed by an institutional pharmacy, as defined in N.J.A.C.13:39-9.2;

(5) a practitioner prescribing a controlled dangerous substance in the emergency department of a general hospital, provided that the quantity prescribed does not exceed a five-day supply of the substance;

(6) a practitioner prescribing a controlled dangerous substance to a patient under the care of a hospice;

(7) a situation in which it is not reasonably possible for the practitioner or pharmacist to access the Prescription Monitoring Program in a timely manner, no other individual authorized to access the Prescription Monitoring Program is reasonably available, and the quantity of controlled dangerous substance prescribed or dispensed does not exceed a five-day supply of the substance;

(8) a practitioner or pharmacist acting in compliance with regulations promulgated by the director as to circumstances under which consultation of the Prescription Monitoring Program would result in a patient's inability to obtain a prescription in a timely manner, thereby adversely impacting the medical condition of the patient;

(9) a situation in which the Prescription Monitoring Program is not operational as determined by the division or where it cannot be accessed by the practitioner due to a temporary technological or electrical failure, as set forth in regulation;

(10) a practitioner or pharmacist who has been granted a waiver due to technological limitations that are not reasonably within the control of the practitioner or pharmacist, or other exceptional circumstances demonstrated by the practitioner or pharmacist, pursuant to a process established in regulation, and in the discretion of the director; or

(11) a practitioner who is prescribing a controlled dangerous substance to a patient immediately after the patient has undergone an operation, procedure, or treatment for **acute** trauma, when less than a 30-day supply is prescribed.

L.2015, c.74, s.8.

24:21-15.1 Prescriber to discuss risks of dependence on certain drugs with certain patients.

1. a. A health care professional authorized to issue prescriptions shall, prior to issuing a prescription for an opioid drug which is a Schedule II controlled dangerous substance, discuss with a **patient** who is under 18 years of age and is an emancipated minor, or with the patient's parent or guardian if the **patient** is under 18 years of age and is not an emancipated minor, the risks of developing a physical or psychological dependence on the opioid drug and, if the prescriber deems it appropriate, such alternative treatments as may be available.

b. A prescriber who engages in a **discussion** required pursuant to subsection a. of this section shall include a note in the patient's medical record indicating that the **discussion** took place.

c. The **discussion** required under subsection a. of this section shall not be required prior to issuing a prescription to any **patient** who is currently receiving hospice care from a licensed hospice.

L.2017, c.8, s.1.

NEW PRESCRIBING LAW FOR TREATMENT OF ACUTE AND CHRONIC PAIN

NEW LAW

WHAT YOU NEED TO KNOW ABOUT

NEW PRESCRIBING LAW FOR TREATMENT OF ACUTE AND CHRONIC PAIN

WHAT PROVIDERS DOES THIS NEW LAW APPLY TO?

Physicians, dentists, optometrists, podiatrists, physician assistants, certified nurse midwives, or advanced practice nurses authorized to prescribe controlled substances.

WHICH PATIENTS ARE EXEMPT FROM THIS NEW LAW?

The law does not apply to a prescription for a patient who is currently in active treatment for cancer, receiving hospice care from a licensed hospice or palliative care, or is a resident of a long term care facility, or to any medications that prescribed in the treatment of substance abuse or opioid dependence (medication assisted treatment).

PRIOR TO ISSUING AN INTIAL PRESCRIPTION FOR ACUTE OR CHRONIC PAIN

In cases of acute or chronic pain a practitioner is required to:

- take and document the results of a thorough medical history, including the patient's experience with non-opioid medication and non-pharmacological pain management approaches and substance abuse history;
- develop a treatment plan, with particular attention focused on determining the cause of the patient's pain; and
- access relevant prescription monitoring information under the Prescription Monitoring Program;

ISSUING AN INITIAL PRESCRIPTION FOR ACUTE PAIN

No authorized prescriber can issue an ***initial*** prescription for a Schedule II controlled dangerous substance or any opioid drug, which is a prescription drug, in a quantity

exceeding a ***five-day supply for treatment of acute pain***. There are no exceptions to this rule, not even for post-operative pain. The law does NOT address what constitutes a 5-day supply; however it does provide that any prescription for ***acute pain*** shall be the lowest effective dose of immediate-release opioid drug.

An initial prescription means that the patient has not had a prescription for that medication (or pharmaceutical equivalent) in the last year. Talking to the patient, looking at their medical record and checking the PMP is necessary to determine whether your prescription would be the patient's "initial" prescription.

ISSUING SUBSEQUENT PRESCRIPTIONS FOR ACUTE PAIN

No less than four days after the initial 5-day prescription, an authorized prescribers may issue a prescription for no more than a 30 day-supply, if necessary.

There are several options available to issue a subsequent prescription after the initial 5-day supply. The regulations require you to assess the patient prior to issuing any subsequent prescriptions, but this does not require a physical exam or office visit:

1. The patient comes into the office to pick up the physical script with or without a physical exam;

2. You can electronically prescribe the Scheduled II CDS or opioid prescription if your system is set up to e-prescribe CDS – REMEMBER e-prescribing is authorized by the feds and state; or

3. If the patient is unable to come to the office and you are not able to e-prescribe, current NJ regulations authorize you to call in an emergency oral prescription for pharmacies to dispense a Schedule II controlled substance in an amount not to exceed a 72 hour quantity necessary to treat the patient during an emergency. However, a written prescription with "Authorization for Emergency Dispensing" and the date of the oral order must be written on it and sent within seven days to the dispensing pharmacist in person or by mail/postmarked within the seven day period. See N.J.A.C. 13:45H-7.8

http://www.njconsumeraffairs.gov/regulations/Chapter-45H-Controlled-Dangerous-Substances.pdf

DISCUSSIONS WITH PATIENTS AND NOTATIONS IN PATIENT'S RECORD

Whether prescribing opioids for acute or chronic pain, you are now required to include a note in the patient's medical record that there was a discussion with the patient or the patient's parent or guardian, as applicable, about the risks of developing a physical or psychological dependence on the controlled dangerous substance and alternative treatments that may be available. This discussion must occur prior to the ***initial prescription and prior to issuing the third prescription.*** Once you are treating a patient for chronic pain (defined by the state has 3 consecutive months of treatment) you will be documenting this

discussion as part of the mandatory pain agreement you will enter with the patient, which is outlined further below in this notice.

Until we resolve some confusion with language of the law related to "third script" and "three months" (which is the definition of chronic pain treatment): **WE ARE ADVISING THAT YOU HAVE THESE DISCUSSIONS AT EVERY SCRIPT WRITTEN FOR A SCHEDULED II CDS OR OPIOID PRESCRIBED FOR THE TREATMENT OF PAIN.**

THE DISCUSSION: Prior to issuing the initial prescription of a Schedule II controlled dangerous substance for the treatment of pain or any other opioid drug which is a prescription drug for acute or chronic pain and again prior to issuing the third prescription of the course of treatment, a practitioner shall discuss with the patient, or the patient's parent or guardian if the patient is under 18 years of age and is not an emancipated minor, the risks associated with the drugs being prescribed, including but not limited to:

(1) the risks of addiction and overdose associated with opioid drugs and the dangers of taking opioid drugs with alcohol, benzodiazepines and other central nervous system depressants;

(2) the reasons why the prescription is necessary;

(3) alternative treatments that may be available; and

(4) risks associated with the use of the drugs being prescribed, specifically that opioids are highly addictive, even when taken as prescribed, that there is a risk of developing a physical or psychological dependence on the controlled dangerous substance, and that the risks of taking more opioids than prescribed, or mixing sedatives, benzodiazepines or alcohol with opioids, can result in fatal respiratory depression.

The Division of Consumer Affairs shall develop and make available to practitioners guidelines for the discussion required. These guidelines are in the works, but will not be much different than our guidance above.

FINANCIAL IMPACT OF 5-DAY SUPPLY LIMIT ON PATIENTS

The law allows insurers to pro rate the patient cost for an opioid when less than a 30-day supply is prescribed. But, the law also allows the insurers to collect payment for the full 30 day supply up front, so patients will not likely see any cost reductions if they only obtain an initial 5-day supply.

PAIN AGREEMENTS NOW REQUIRED FOR TREATMENT OF CHRONIC PAIN

While the use of pain contracts for chronic pain patients (treatment 3 months or longer) has been a BME guideline in current regulation, this new law codifies that regulation and makes the use of pain management agreements mandatory when treating chronic pain, defined as the continuous treatment for pain for three months or more. This part is not necessarily new to physicians treating chronic paint patients. The law provides:

At the time of the issuance of the **third** prescription for a prescription opioid drug, the practitioner shall enter into a pain management agreement with the patient. **The way this is written the third prescription for a chronic pain patient COULD BE SOONER THAN the 3rd month of prescribing. This is one of the conflicts in the law that we are addressing.**

When a Schedule II controlled dangerous substance or any other prescription opioid drug is continuously prescribed for chronic pain, the practitioner shall:

(1) review, at a minimum of every three months, the course of treatment, any new information about the etiology of the pain, and the patient's progress toward treatment objectives and document the results of that review;

(2) assess the patient prior to every renewal to determine whether the patient is experiencing problems associated with physical and psychological dependence and document the results of that assessment;

(3) periodically make reasonable efforts, unless clinically contraindicated, to either stop the use of the controlled substance, decrease the dosage, try other drugs or treatment modalities in an effort to reduce the potential for abuse or the development of physical or psychological dependence and document with specificity the efforts undertaken;

(4) review the Prescription Drug Monitoring information; and

(5) monitor compliance with the pain management agreement and any recommendations that the patient seek a referral.

The state is not prescribing a particular agreement or form, however they are in the process of creating a one page template to assist prescribers. The intent of the pain management agreement is to cover the following concerns:

"Pain management agreement" means a written contract or agreement that is executed between a practitioner and a patient, prior to the commencement of treatment for chronic pain using a Schedule II controlled dangerous substance or any other opioid drug which is a prescription drug, as a means to:

(1) prevent the possible development of physical or psychological dependence in the patient;

(2) document the understanding of both the practitioner and the patient regarding the patient's pain management plan;

(3) establish the patient's rights in association with treatment, and the patient's obligations in relation to the responsible use, discontinuation of use, and storage of Schedule II controlled dangerous substances, including any restrictions on the refill of prescriptions or the acceptance of Schedule II prescriptions from practitioners;

(4) identify the specific medications and other modes of treatment, including physical therapy or exercise, relaxation, or psychological counseling, that are included as part of the pain management plan;

(5) specify the measures the practitioner may employ to monitor the patient's compliance, including but not limited to random specimen screens and pill counts; and

(6) delineate the process for terminating the agreement, including the consequences if the practitioner has reason to believe that the patient is not complying with the terms of the agreement.

CHANGES IN INSURANCE COVERAGE FOR ADDICTION TREATMENT

The law increases addiction treatment insurance coverage by requiring insurers to provided unlimited benefits for inpatient or outpatient treatment. The law guarantees coverage for 6 months without any prior authorization or other prospective utilization management requirements. The law also states that the benefits for outpatient visits shall not be subject to concurrent or retrospective review of medical necessity or any other utilization management review. Remember, this insurance mandate will ONLY impact state regulated health plans, not ERISA/self-funded health plans, Medicare or Medicaid.

MANDATORY CME

And, finally, the state is now requiring that you take one credit of educational programs or topics concerning prescription opioid drugs, including responsible prescribing practices, alternatives to opioids for managing and treating pain, and the risks and signs of opioid abuse, addiction, and diversion. This one credit is part of your existing 100 hours for your biennial license renewal. **This will be effective for your 2017-2019 biennial license renewal.**

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Weekly / Vol. 66 / No. 10
March 17, 2017

Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use — United States, 2006–2015

Anuj Shah[1]; Corey J. Hayes, PharmD[1,2]; Bradley C. Martin, PharmD, PhD[1]

Because long-term opioid use often begins with treatment of acute pain (*1*), in March 2016, the CDC Guideline for Prescribing Opioids for Chronic Pain included recommendations for the duration of opioid therapy for acute pain and the type of opioid to select when therapy is initiated (*2*). However, data quantifying the transition from acute to chronic opioid use are lacking. Patient records from the IMS Lifelink+ database were analyzed to characterize the first episode of opioid use among commercially insured, opioid-naïve, cancer-free adults and quantify the increase in probability of long-term use of opioids with each additional day supplied, day of therapy, or incremental increase in cumulative dose. The largest increments in probability of continued use were observed after the fifth and thirty-first days on therapy; the second prescription; 700 morphine milligram equivalents cumulative dose; and first prescriptions with 10- and 30-day supplies. By providing quantitative evidence on risk for long-term use based on initial prescribing characteristics, these findings might inform opioid prescribing practices.

A random 10% sample of patient records during 2006–2015 was drawn from the IMS Lifelink+ database, which includes commercial health plan information from a large number of managed care plans and is representative of the U.S. commercially insured population (*3*). The data are provided in a deidentified format and the institutional review board at the authors' institution deemed the study was not human subject research. Records were selected of patients aged ≥18 years who had at least one opioid prescription during June 1, 2006–September 1, 2015, and ≥6 months of continuous enrollment without an opioid prescription before their first opioid prescription. Patients excluded were those who had any cancer (other than nonmelanoma skin cancer) or a substance abuse disorder diagnosis in the 6 months preceding their first opioid prescription, or whose first prescription was for any buprenorphine formulation indicated for treatment of substance abuse.

Patients were followed from the date of their first prescription until loss of enrollment, study end date, or discontinuation of opioids, which was defined as ≥180 days without opioid use. The duration of use and number of prescriptions and cumulative dose (expressed in morphine milligram equivalents*) for the first episode of opioid use (defined as continuous use of opioids with a gap of no greater than 30 days) were calculated. The number of days' supply and average daily dose in morphine milligram equivalents for the first prescription were also calculated. The first opioid prescription was categorized

*Morphine milligram equivalents is a conversion factor to convert different opioids into an equivalent dose of morphine. http://www.pdmpassist.org/pdf/BJA_performance_measure_aid_MME_conversion.pdf.

INSIDE

Continuing Education examination available at https://www.cdc.gov/mmwr/cme/conted_info.html#weekly.

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

into six mutually exclusive categories: long-acting; oxycodone short-acting; hydrocodone short-acting; other Schedule II short-acting; Schedule III–IV and nalbuphine; and tramadol.[†]

The Kaplan-Meier statistic was used to estimate median time to discontinuation of opioid use; probability of continued opioid use at 1 year and 3 years for different treatment duration thresholds (daily for 1–40 days and weekly for 1–26 weeks); number of prescriptions (1–15); and cumulative dose of the first episode of opioid use (50–2000 morphine milligram equivalents). Similarly, the relationship between the number of days' supply, choice of first opioid prescription, and probability of continued opioid use at 1 and 3 years was also examined. Sensitivity analyses were conducted by modifying the discontinuation definition from ≥180 opioid-free days to ≥90 opioid-free days, changing the allowable gap in the first episode of opioid use from 30 days to 7 days, and excluding patients whose average daily dose of the first prescription exceeded 90 morphine milligram equivalents.

A total of 1,294,247 patients met the inclusion criteria, including 33,548 (2.6%) who continued opioid therapy for ≥1 year. Patients who continued opioid therapy for ≥1 year were more likely to be older, female, have a pain diagnosis before opioid initiation, initiated on higher doses of opioids, and publically or self-insured, compared with patients who discontinued opioid use in <365 days (Table). Among persons prescribed at least 1 day of opioids, the probability of continued opioid use at 1 year was 6.0% and at 3 years was 2.9% (supplemental figure 1; https://stacks.cdc.gov/view/cdc/44182) (supplemental figure 2; https://stacks.cdc.gov/view/cdc/44550) with a median time to discontinuation of 7 days (supplemental figure 3; https://stacks.cdc.gov/view/cdc/44551). Approximately 70% of patients have an initial duration of opioids of ≤7 days and 7.3% were initially prescribed opioids for ≥31 days. The largest incremental increases in the probability of continued opioid pain reliever use were observed when the first prescription supply exceeded 10 or 30 days (Figure 1), when a patient received a third prescription (Figure 2), or when the cumulative dose was ≥700 morphine milligram equivalents (supplemental figure 4; https://stacks.cdc.gov/view/cdc/44552). Substantial increases in probabilities of continued opioid use occurred when the initial duration reached 6 and 31 days (supplemental figure 2; https://stacks.cdc.gov/view/cdc/44550); the findings of the sensitivity analyses were similar (supplemental figures 5–10; https://stacks.cdc.gov/view/cdc/44183).

The highest probabilities of continued opioid use at 1 and 3 years were observed among patients who initiated treatment with a long-acting opioid (27.3% at 1 year; 20.5% at 3 years), followed by those whose initial treatment was with tramadol

[†] The six mutually exclusive categories are 1) long-acting: buprenorphine, fentanyl, morphine, oxycodone, oxymorphone, and tapentadol; 2) other Schedule II short-acting: fentanyl, hydromorphone, levorphanol, meperidine, methadone, morphine, oxymorphone and tapentadol; 3) oxycodone short-acting; 4) hydrocodone short-acting; 5) Schedule III–IV and nalbuphine: codeine, dihydrocodeine, butorphanol, nalbuphine, pentazocine and propoxyphene; 6) tramadol.

The *MMWR* series of publications is published by the Center for Surveillance, Epidemiology, and Laboratory Services, Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services, Atlanta, GA 30329-4027.

Suggested citation: [Author names; first three, then et al., if more than six.] [Report title]. MMWR Morb Mortal Wkly Rep 2017;66:[inclusive page numbers].

TABLE. Characteristics of incident opioid users and patients who continued opioid use for ≥365 days (1 year) and ≥1,095 days (3 years) — United States, 2006–2015

Characteristic	All incident opioid users (N = 1,294,247)		Patients who continued opioid therapy for ≥365 days (n = 33,548)		Patients who continued opioid therapy for ≥1,095 days (n = 6,441)	
	Mean (SD)	95% CI	Mean (SD)	95% CI	Mean (SD)	95% CI
Duration of first episode of opioid use	14.81 (65.00)	14.70–14.92	183.28 (343.27)	179.61–186.96	362.40 (593.26)	347.91–376.90
Enrollment duration (yrs)	2.48 (2.04)	2.47–2.48	3.30 (1.83)	2.47–2.48	4.98 (1.48)	4.94–5.02
Age (yrs)	44.52 (14.56)	44.50–44.54	49.58 (13.45)	49.44–49.72	50.52 (12.68)	50.21–50.83
	No. (%)	95% CI	No. (%)	95% CI	No. (%)	95% CI
Female	698,950 (54.00)	53.92–54.09	18,768 (55.94)	55.41–56.47	3,500 (54.34)	53.12–55.55
Treatment indication						
Back pain	226,681 (17.51)	17.45–17.58	10,396 (30.99)	30.50–31.49	2,137 (33.18)	32.04–34.34
Neck pain	90,352 (6.98)	6.94–7.03	3,824 (11.40)	11.06–11.74	775 (12.03)	11.26–12.85
Head pain	30,123 (2.33)	2.30–2.35	1,495 (4.46)	4.24–4.68	306 (4.75)	4.26–5.30
Joint pain	389,700 (30.11)	30.03–30.19	14,862 (44.30)	43.77–44.83	2,968 (46.08)	44.87–47.30
Patient region						
South	476,565 (36.74)	36.64–36.83	13,437 (40.05)	39.53–40.53	2,449 (38.02)	36.84–39.21
Midwest	376,520 (29.09)	29.01–29.17	9,566 (28.51)	28.03–29.00	1,973 (30.63)	29.52–31.77
East	279,595 (21.60)	21.53–21.67	6,153 (18.34)	17.93–18.76	1,234 (19.16)	18.22–20.14
West	142,698 (11.03)	10.97–11.08	3,640 (10.85)	10.52–11.19	574 (8.91)	8.24–9.63
Missing/Other	19,869 (1.54)	1.51–1.56	752 (2.24)	2.09–2.41	211 (3.28)	2.87–3.74
Payer type						
Commercial	866,815 (66.97)	66.89–67.06	20,920 (62.36)	61.84–62.88	3,910 (60.70)	38.11–40.49
Medicaid/State CHIP	14,855 (1.15)	1.13–1.17	864 (2.58)	2.42–2.76	154 (2.39)	2.05–2.79
Medicare	16,951 (1.31)	1.29–1.33	1,160 (3.46)	3.27–3.66	257 (3.96)	3.52–4.48
Self-insured	387,122 (29.91)	29.83–29.99	10,471 (31.21)	30.72–31.71	2,089 (32.43)	31.30–33.59
RX only/Unknown	8,504 (0.66)	0.64–0.67	130 (0.39)	0.33–0.46	32 (0.50)	0.35–0.70
Prescription characteristic						
First prescription ≥90 MME*	89,438 (6.91)	6.87–6.95	2,613 (7.79)	7.51–8.08	545 (8.46)	7.81–9.17
First prescription ≥120 MME*	22,895 (1.77)	1.75–1.79	1,075 (3.20)	3.02–3.40	244 (3.79)	3.35–4.28
First long-acting opioid prescription†	6,588 (0.51)	0.50–0.52	905 (2.70)	2.53–2.88	226 (3.51)	3.09–3.99

Abbreviations: CHIP = Children's Health Insurance Plan; CI = confidence interval; MME = morphine milligram equivalents; RX = prescription; SD = standard deviation.

* Average daily dose was calculated as total strength of the prescription expressed in MME divided by the days' supply of the first prescription. If a patient had multiple prescriptions on the first day, the daily dose in MME for all the prescriptions on the index date were summed and divided by the days' supply of the longest lasting prescription.

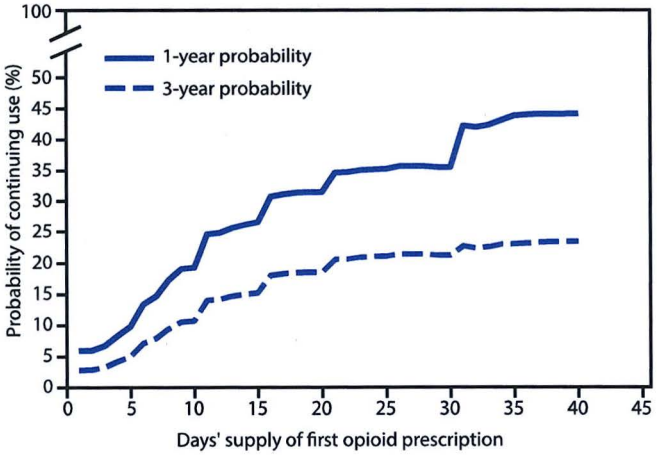
† The first prescription was categorized into six mutually exclusive categories and, in case of multiple prescriptions, on the index date using the following hierarchy to assign category: 1) long-acting; 2) other Schedule II short-acting; 3) Oxycodone short-acting; 4) Hydrocodone short-acting; 5) Schedule III-IV and Nalbuphine; or 6) tramadol.

(13.7% at 1 year; 6.8% at 3 years) or a Schedule II short-acting opioid other than hydrocodone or oxycodone (8.9% at 1 year; 5.3% at 3 years) (supplemental table; https://stacks.cdc.gov/view/cdc/44181). The probabilities of continued opioid use at 1 and 3 years for persons starting on hydrocodone short acting (5.1% at 1 year; 2.4% at 3 years), oxycodone short-acting (4.7% at 1 year; 2.3% at 3 years), or Schedule III–IV (5.0% at 1 year; 2.2% at 3 years) opioids were similar (supplemental table; https://stacks.cdc.gov/view/cdc/44181).

Discussion

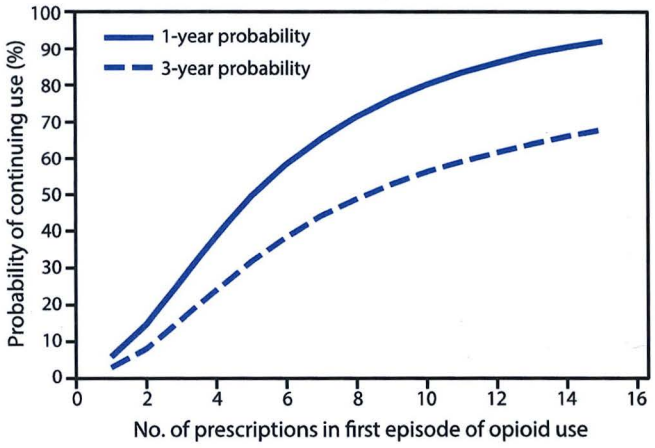
The probability of long-term opioid use increases most sharply in the first days of therapy, particularly after 5 days or 1 month of opioids have been prescribed, and levels off after approximately 12 weeks of therapy. The rate of long-term use was relatively low (6.0% on opioids 1 year later) for persons with at least 1 day of opioid therapy, but increased to 13.5% for persons whose first episode of use was for ≥8 days and to 29.9% when the first episode of use was for ≥31 days. Although ≥31 days of initial opioid prescriptions are not common, approximately 7% do exceed a 1-month supply. Discussions with patients about the long-term use of opioids to manage pain should occur early in the opioid prescribing process, perhaps as early as the first refill, because approximately 1 in 7 persons who received a refill or had a second opioid prescription authorized were on opioids 1 year later. As expected, patients initiated on long-acting opioids had the highest probabilities of long-term use. However, the finding that patients initiated with tramadol had the next highest probability of long-term use was unexpected; because of tramadol's minimal affinity for the μ-opioid receptor, it is deemed a relatively safe opioid agonist with lower abuse potential than other opioids (*4*). However, a report by the Substance Abuse and Mental Health Services Administration determined that emergency department visits associated with tramadol-related adverse events increased by 145% during 2005–2011 (*5*). Long-term

FIGURE 1. One- and 3-year probabilities of continued opioid use among opioid-naïve patients, by number of days' supply* of the first opioid prescription — United States, 2006–2015



* Days' supply of the first prescription is expressed in days (1–40) in 1-day increments. If a patient had multiple prescriptions on the first day, the prescription with the longest days' supply was considered the first prescription.

FIGURE 2. One- and 3-year probabilities of continued opioid use among opioid-naïve patients, by number of prescriptions* in the first episode of opioid use — United States, 2006–2015



* Number of prescriptions is expressed as 1–15, in increments of one prescription.

data on tramadol for pain management are sparse, with only one trial exceeding 12 weeks in duration (*6*). Despite this, among patients initiated with tramadol, >64% of patients who continued opioid use beyond 1 year were still on tramadol, suggesting that tramadol might be prescribed intentionally for chronic pain management. A 2016 study in Oregon (*7*), which did not include tramadol (a predictor of long-term use according to current data), reported similar findings: opioid naïve patients aged <45 years who received two prescription fills (versus one) or a cumulative dose of 400–799 (versus <120) morphine milligram equivalents in their first month of therapy were 2.3 and 3.0 times as likely to be chronic opioid users, respectively. However, that analysis only examined opioid use in the first month after initiation of opioid therapy to characterize risks for long-term use and did not account for the actual duration of therapy.

The findings in this report are subject to at least five limitations. First, although the cumulative dose of the first episode of opioid use is described, the likelihood of long-term use when the prescriber was titrating the dose was not determined. Rather, the total cumulative dose was calculated, which might have been increasing or decreasing over time. Second, the extent to which chronic opioid use was intentional versus the outgrowth of acute use is not known. Less than 1% of patients in this analysis were prescribed Schedule II long-acting opioids at the outset, so intentional chronic opioid prescribing might be uncommon; however, approximately 10% of patients were prescribed tramadol, which might indicate intentional chronic opioid prescribing. Third, information on pain intensity or duration were not available, and the etiology of pain, which might influence the duration of opioid use, was not considered in the analysis. Fourth, the frequency of prescriptions having certain days' supplied (e.g., prescriptions with a 7-day supply would be more frequently observed than those with an 11- or 13-day supply) was not considered. The variability in the relationships between days' supply, the cumulative dose, and duration of first episode and the probability of long-term use could be affected. Finally, prescriptions that were either paid for out-of-pocket or obtained illicitly were not included in the analysis.

Transitions from acute to long-term therapy can begin to occur quickly: the chances of chronic use begin to increase after the third day supplied and rise rapidly thereafter. Consistent with CDC guidelines, treatment of acute pain with opioids should be for the shortest durations possible. Prescribing <7 days (ideally ≤3 days) of medication when initiating opioids could mitigate the chances of unintentional chronic use. When initiating opioids, caution should be exercised when prescribing >1 week of opioids or when authorizing a refill or a second opioid prescription because these actions approximately double the chances of use 1 year later. In addition, prescribers should discuss the long-term plan for pain management with patients for whom they are prescribing either Schedule II long-acting opioids or tramadol.

[1]Division of Pharmaceutical Evaluation and Policy, College of Pharmacy, University of Arkansas for Medical Sciences; [2]Division of Health Services Research, College of Medicine, University of Arkansas for Medical Services.

Corresponding author: Bradley C. Martin, bmartin@uams.edu, 501-603-1992.

Summary

What is already known about this topic?

Based on the CDC Guideline for Prescribing Opioids for Chronic Pain, literature supporting long-term opioid therapy for pain is limited; research suggests an increased risk for harms with long-term opioid use. Early opioid prescribing patterns for opioid-naïve patients have been found to be associated with the likelihood of long-term use.

What is added by this report?

In a representative sample of opioid naïve, cancer-free adults who received a prescription for opioid pain relievers, the likelihood of chronic opioid use increased with each additional day of medication supplied starting with the third day, with the sharpest increases in chronic opioid use observed after the fifth and thirty-first day on therapy, a second prescription or refill, 700 morphine milligram equivalents cumulative dose, and an initial 10- or 30-day supply. The highest probability of continued opioid use at 1 and 3 years was observed among patients who started on a long-acting opioid followed by patients who started on tramadol.

What are the implications for public health practice?

Awareness among prescribers, pharmacists, and persons managing pharmacy benefits that authorization of a second opioid prescription doubles the risk for opioid use 1 year later might deter overprescribing of opioids. Knowledge that the risks for chronic opioid use increase with each additional day supplied might help clinicians evaluate their initial opioid prescribing decisions and potentially reduce the risk for long-term opioid use. Discussions with patients about the long-term use of opioids to manage pain should occur early in the opioid prescribing process.

References

1. Edlund MJ, Martin BC, Russo JE, DeVries A, Braden JB, Sullivan MD. The role of opioid prescription in incident opioid abuse and dependence among individuals with chronic noncancer pain: the role of opioid prescription. Clin J Pain 2014;30:557–64.
2. Dowell D, Haegerich TM, Chou R. CDC Guideline for prescribing opioids for chronic pain—United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1). https://doi.org/10.15585/mmwr.rr6501e1
3. Patil PR, Wolfe J, Said Q, Thomas J, Martin BC. Opioid use in the management of diabetic peripheral neuropathy (DPN) in a large commercially insured population. Clin J Pain 2015;31:414–24. https://doi.org/10.1097/AJP.0000000000000124
4. Babalonis S, Lofwall MR, Nuzzo PA, Siegel AJ, Walsh SL. Abuse liability and reinforcing efficacy of oral tramadol in humans. Drug Alcohol Depend 2013;129:116–24. https://doi.org/10.1016/j.drugalcdep.2012.09.018
5. Bush DM. The CBHSQ report: emergency department visits for adverse reactions involving the pain medication tramadol. Rockville, MD: US Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality; 2015.
6. Karlsson M, Berggren A-C. Efficacy and safety of low-dose transdermal buprenorphine patches (5, 10, and 20 microg/h) versus prolonged-release tramadol tablets (75, 100, 150, and 200 mg) in patients with chronic osteoarthritis pain: a 12-week, randomized, open-label, controlled, parallel-group noninferiority study. Clin Ther 2009;31:503–13. https://doi.org/10.1016/j.clinthera.2009.03.001
7. Deyo RA, Hallvik SE, Hildebran C, et al. Association between initial opioid prescribing patterns and subsequent long-term use among opioid-naïve patients: a statewide retrospective cohort study. J Gen Intern Med 2017;32:21–7. https://doi.org/10.1007/s11606-016-3810-3

New Zealand researchers developing non-addictive relief for severe pain

HANNAH MARTIN
Last updated 19:51, December 13 2017

Professor Jamie Sleigh is among New Zealand researchers working on a new non-addictive form of pain relief and anaesthesia.

New Zealand researchers have received an $8 million funding boost for a programme developing treatments for moderate to severe pain as an alternative to opioids.

Opioids such as morphine, codeine and ketamine are highly effective at treating pain, but are also highly addictive - killing 91 people a day in the United States.

The Medical Research Commercialisation Fund (MRCF) announced an $8m funding injection on Wednesday to help early-stage pharmaceutical company Kea Therapeutics develop a "much needed non-opioid approach" to pain management.

Ketamine is commonly used in anaesthesia and pain relief, but can cause confusion and hallucinations. (File)

Kea Therapeutics is a spin-off of the Auckland Cancer Society Research Centre and the Faculty of Medical and Health Sciences Waikato Clinical Campus at the University of Auckland.

The number of prescriptions for pain medication in New Zealand increased from 6.15 million in 2011 to 7.18 million in 2016, Pharmac figures obtained under the Official Information Act showed.

During the same period, the number of scripts for opioid painkillers rose from 1.56 million to 1.85 million.

The Kea Therapeutics compounds would be a new class of pain medications, used intravenously to treat acute pain during operations, in immediate recovery from surgery and in emergency settings.

Anaesthetist Professor Jamie Sleigh from Waikato Clinical Campus' Faculty of Medical and Health Sciences recognised the need for non-opioid pain relief alternatives.

Sleigh and medicinal chemist Distinguished Professor Bill Denny started a programme to develop a new drug which retained the positive, pain-relieving and anaesthetic qualities of ketamine, while removing its significant side effects.

Medical Research Commercialisation Fund investment manager Duncan Mackintosh said the development of non-opioid pain relief could bring "world-class" New Zealand research to the global market.

Opioids have a range of unwanted side effects and are causing a global epidemic of dependency, he said.

"[Opioids] aren't a problem in themselves but they aren't the right drug all the time - we need some alternatives.

"If we get that right we can make a real difference for patients and save some lives along the way."

The drug had been tested on rats with success, and clinical trials were expected to begin within the next 18 to 24 months.

The MRCF is the largest life sciences fund in Australasia, with $480m (AUD) up for investment in the development and commercialisation of early-stage biomedical discoveries.

The early development of the drug was funded by the University of Auckland, Auckland UniServices Ltd and the Ministry of Business Innovation and Employment's (MBIE) Pre-Seed Accelerator Fund.

Fiscal Note

State of Alaska
2018 Legislative Session

Bill Version: HB 268
Fiscal Note Number:
() Publish Date:

Identifier: HB268SS-DCCED-CBPL-01-26-18
Title: OPIOID PRESCRIPTION WARNINGS
Sponsor: GARA
Requester: (H) Health & Social Services

Department: Department of Commerce, Community and Economic Development
Appropriation: Corporations, Business and Professional Licensing
Allocation: Corporations, Business and Professional Licensing
OMB Component Number: 2360

Expenditures/Revenues

Note: Amounts do not include inflation unless otherwise noted below. (Thousands of Dollars)

	FY2019 Appropriation Requested	Included in Governor's FY2019 Request	Out-Year Cost Estimates				
OPERATING EXPENDITURES	**FY 2019**	**FY 2019**	**FY 2020**	**FY 2021**	**FY 2022**	**FY 2023**	**FY 2024**
Personal Services							
Travel							
Services	15.5						
Commodities							
Capital Outlay							
Grants & Benefits							
Miscellaneous							
Total Operating	**15.5**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Fund Source (Operating Only)							
1156 Rcpt Svcs (DGF)	15.5						
Total	**15.5**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Positions							
Full-time							
Part-time							
Temporary							
Change in Revenues							
1156 Rcpt Svcs (DGF)	15.5						
Total	**15.5**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**

Estimated SUPPLEMENTAL (FY2018) cost: 0.0 *(separate supplemental appropriation required)*
(discuss reasons and fund source(s) in analysis section)

Estimated CAPITAL (FY2019) cost: 0.0 *(separate capital appropriation required)*
(discuss reasons and fund source(s) in analysis section)

ASSOCIATED REGULATIONS

Does the bill direct, or will the bill result in, regulation changes adopted by your agency? Yes
If yes, by what date are the regulations to be adopted, amended or repealed? 07/01/19

Why this fiscal note differs from previous version/comments:

Not applicable, initial version.

Prepared By: Janey McCullough, Director — Phone: (907)465-2538
Division: Corporations, Business and Professional Licensing — Date: 01/26/2018
Approved By: Catherine Reardon, Director — Date: 01/26/18
Agency: Division of Administrative Services, DCCED

FISCAL NOTE ANALYSIS

STATE OF ALASKA
2018 LEGISLATIVE SESSION

BILL NO. SS HB 268

Analysis

HB268 requires licensed healthcare providers to provide oral and written information on opioids under AS 08.68.710 before prescribing an opioid to a patient.

This legislation requires the prescriber to orally inform the patient the reason for prescribing the opioid, any non-opioid alternatives to the prescription, any advantages or disadvantages of using a prescription for a shorter period, and a warning that the prescription may lead to opioid addiction.

HB268 will require a written statement prepared by the department of Health and Social services that provides appropriate information conveying the potential addictive and health danger of opioids.

This bill also permits the board to impose disciplinary sanctions against the licensee for repeatedly and without good cause failing to provide oral and written information on opioids under AS 08.72.277 before prescribing.

If the bill passes the following expenses will be incurred:
Services: $15.5 (regulations project)

Professional licensing programs within the Division of Corporations, Business and Professional Licensing are funded by Receipt Supported Services, fund source 1156 Rcpt Svcs (DGF). Licensing fees for each occupation are set per AS 08.01.065 so the total amount of revenue collected approximately equals the occupation's actual regulatory costs.

30-LS1081\R
Radford
2/9/18

CS FOR SPONSOR SUBSTITUTE FOR HOUSE BILL NO. 268( )

IN THE LEGISLATURE OF THE STATE OF ALASKA

THIRTIETH LEGISLATURE - SECOND SESSION

BY

Offered:
Referred:

Sponsor(s): REPRESENTATIVES GARA, Tuck

A BILL

FOR AN ACT ENTITLED

"An Act relating to the prescription of opioids; relating to the Department of Health and Social Services; relating to the practice of dentistry; relating to the practice of medicine; relating to the practice of podiatry; relating to the practice of osteopathy; relating to the practice of nursing; and relating to the practice of optometry."

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF ALASKA:

*** Section 1.** The uncodified law of the State of Alaska is amended by adding a new section to read:

SHORT TITLE. This Act may be known as the Consumer Advisory on Potential Heroin Addiction from Opioid Use Act.

*** Sec. 2.** The uncodified law of the State of Alaska is amended by adding a new section to read:

OPIOID ADDICTION: LEGISLATIVE FINDINGS. The legislature finds that

(1) the state has a considerable moral, public health, and financial interest in reducing opioid and heroin addiction in the state;

(2) it is medically documented that opioid prescription drugs are addictive and that opioid addiction is harmful and expensive to address;

(3) as of 2017, accepted evidence shows that a significant percentage of people who become addicted to heroin were initially addicted to opioid prescription drugs;

(4) opioid prescription drug and heroin addiction interferes with an addict's ability to work and provide for a stable and healthy family;

(5) the state's opioid epidemic damages the health of families and children and affects the chances that a child will receive a healthy upbringing;

(6) the opioid epidemic increases crime in the state, and the presence of heroin dealers in the state poses a public safety threat;

(7) the opioid epidemic costs the state and other entities excessive amounts of money, which is especially problematic in lean budget times;

(8) policies that reduce the number of people who become addicted to opioids and heroin will better serve citizens of the state and foster healthier families;

(9) patients are not always advised of the addictive effects of opioid prescription drug use or that opioid prescription drug use may lead to opioid prescription drug and heroin addiction; and

(10) requiring medical providers to inform patients of the risks associated with opioid prescription drug use can help to reduce opioid prescription drug and heroin addictions in the state.

*** Sec. 3.** AS 08.36.315 is amended to read:

Sec. 08.36.315. Grounds for discipline, suspension, or revocation of license. The board may revoke or suspend the license of a dentist, or may reprimand, censure, or discipline a dentist, or both, if the board finds, after a hearing, that the dentist

(1) used or knowingly cooperated in deceit, fraud, or intentional misrepresentation to obtain a license;

(2) engaged in deceit, fraud, or intentional misrepresentation in the course of providing or billing for professional dental services or engaging in professional activities;

(3) advertised professional dental services in a false or misleading manner;

(4) received compensation for referring a person to another dentist or dental practice;

(5) has been convicted of a felony or other crime that affects the dentist's ability to continue to practice dentistry competently and safely;

(6) engaged in the performance of patient care, or permitted the performance of patient care by persons under the dentist's supervision, regardless of whether actual injury to the patient occurred,

(A) that did not conform to minimum professional standards of dentistry; or

(B) when the dentist, or a person under the supervision of the dentist, did not have the permit, registration, or certificate required under AS 08.32 or this chapter;

(7) failed to comply with this chapter, with a regulation adopted under this chapter, or with an order of the board;

(8) continued to practice after becoming unfit due to

(A) professional incompetence;

(B) addiction or dependence on alcohol or other drugs that impair the dentist's ability to practice safely;

(C) physical or mental disability;

(9) engaged in lewd or immoral conduct in connection with the delivery of professional service to patients;

(10) permitted a dental hygienist or dental assistant who is employed by the dentist or working under the dentist's supervision to perform a dental procedure in violation of AS 08.32.110 or AS 08.36.346;

(11) failed to report to the board a death that occurred on the premises used for the practice of dentistry within 48 hours;

(12) falsified or destroyed patient or facility records or failed to maintain a patient or facility record for at least seven years after the date the record was created;

(13) prescribed or dispensed an opioid in excess of the maximum dosage authorized under AS 08.36.355; [OR]

(14) procured, sold, prescribed, or dispensed drugs in violation of a law, regardless of whether there has been a criminal action or harm to the patient**; or**

(15) habitually and without good cause failed to provide oral and written information on opioids under AS 08.36.357 before prescribing an outpatient supply of an opioid to a patient.

*** Sec. 4.** AS 08.36 is amended by adding a new section to read:

Sec. 08.36.357. Opioid prescription information; relationship to causes of action. (a) Before a licensee prescribes an outpatient supply of an opioid to a patient, the licensee or an agent of the licensee shall provide to the patient or the person authorized to make health care decisions for the patient

(1) an oral statement which, in the licensee's or agent's own words, includes

(A) the licensee's reasons for prescribing the opioid;

(B) any reasonable non-opioid alternatives to the prescription;

(C) information that

(i) the prescription could potentially lead to opioid addiction;

(ii) the danger of opioid addiction can begin to increase if a prescription is extended over longer periods of time; and

(iii) opioid addiction may pose potentially life-threatening health risks; and

(2) a written statement, which may include graphics, prepared by the Department of Health and Social Services that provides appropriate information conveying the potential addictive and health risks of opioids.

(b) The requirements under (a) of this section do not apply to a patient receiving

(1) hospice care from a licensed provider or facility; and

(2) substance abuse or opioid dependence treatment.

(c) The Department of Health and Social Services shall provide access on the department's Internet website to a printable version of the written statement a licensee is required to distribute under (a)(2) of this section.

(d) Nothing in this section creates a new cause of action or affects an existing cause of action.

*** Sec. 5.** AS 08.64.326(a) is amended to read:

(a) The board may impose a sanction if the board finds after a hearing that a licensee

(1) secured a license through deceit, fraud, or intentional misrepresentation;

(2) engaged in deceit, fraud, or intentional misrepresentation while providing professional services or engaging in professional activities;

(3) advertised professional services in a false or misleading manner;

(4) has been convicted, including conviction based on a guilty plea or plea of nolo contendere, of

(A) a class A or unclassified felony or a crime in another jurisdiction with elements similar to a class A or unclassified felony in this jurisdiction;

(B) a class B or class C felony or a crime in another jurisdiction with elements similar to a class B or class C felony in this jurisdiction if the felony or other crime is substantially related to the qualifications, functions, or duties of the licensee; or

(C) a crime involving the unlawful procurement, sale, prescription, or dispensing of drugs;

(5) has procured, sold, prescribed, or dispensed drugs in violation of a law regardless of whether there has been a criminal action or harm to the patient;

(6) intentionally or negligently permitted the performance of patient care by persons under the licensee's supervision that does not conform to minimum professional standards even if the patient was not injured;

(7) failed to comply with this chapter, a regulation adopted under this chapter, or an order of the board;

(8) has demonstrated

(A) professional incompetence, gross negligence, or repeated negligent conduct; the board may not base a finding of professional

incompetence solely on the basis that a licensee's practice is unconventional or experimental in the absence of demonstrable physical harm to a patient;

(B) addiction to, severe dependency on, or habitual overuse of alcohol or other drugs that impairs the licensee's ability to practice safely;

(C) unfitness because of physical or mental disability;

(9) engaged in unprofessional conduct, in sexual misconduct, or in lewd or immoral conduct in connection with the delivery of professional services to patients; in this paragraph, "sexual misconduct" includes sexual contact, as defined by the board in regulations adopted under this chapter, or attempted sexual contact with a patient outside the scope of generally accepted methods of examination or treatment of the patient, regardless of the patient's consent or lack of consent, during the term of the physician-patient relationship, as defined by the board in regulations adopted under this chapter, unless the patient was the licensee's spouse at the time of the contact or, immediately preceding the physician-patient relationship, was in a dating, courtship, or engagement relationship with the licensee;

(10) has violated AS 18.16.010;

(11) has violated any code of ethics adopted by regulation by the board;

(12) has denied care or treatment to a patient or person seeking assistance from the physician if the only reason for the denial is the failure or refusal of the patient to agree to arbitrate as provided in AS 09.55.535(a);

(13) has had a license or certificate to practice medicine in another state or territory of the United States, or a province or territory of Canada, denied, suspended, revoked, surrendered while under investigation for an alleged violation, restricted, limited, conditioned, or placed on probation unless the denial, suspension, revocation, or other action was caused by the failure of the licensee to pay fees to that state, territory, or province; [OR]

(14) prescribed or dispensed an opioid in excess of the maximum dosage authorized under AS 08.64.363**; or**

(15) habitually and without good cause failed to provide oral and written information on opioids under AS 08.64.371 before prescribing an

outpatient supply of an opioid to a patient.

*** Sec. 6.** AS 08.64 is amended by adding a new section to read:

Sec. 08.64.371. Opioid prescription information; relationship to causes of action. (a) Before a licensee prescribes an outpatient supply of an opioid to a patient, the licensee or an agent of the licensee shall provide to the patient or the person authorized to make health care decisions for the patient

(1) an oral statement which, in the licensee's or agent's own words, includes

(A) the licensee's reasons for prescribing the opioid;

(B) any reasonable non-opioid alternatives to the prescription; and

(C) information that

(i) the prescription could potentially lead to opioid addiction;

(ii) the danger of opioid addiction can begin to increase if a prescription is extended over longer periods of time;

(iii) opioid addiction may pose potentially life-threatening health risks; and

(2) a written statement, which may include graphics, prepared by the Department of Health and Social Services that provides appropriate information conveying the potential addictive and health risks of opioids.

(b) The requirements under (a) of this section do not apply to a patient receiving

(1) hospice care from a licensed provider or facility; and

(2) substance abuse or opioid dependence treatment.

(c) The Department of Health and Social Services shall provide access on the department's Internet website to a printable version of the written statement a licensee is required to distribute under (a)(2) of this section.

(d) Nothing in this section creates a new cause of action or affects an existing cause of action.

*** Sec. 7.** AS 08.68.270 is amended to read:

Sec. 08.68.270. Grounds for denial, suspension, or revocation. The board may deny, suspend, or revoke the license of a person who

(1) has obtained or attempted to obtain a license to practice nursing by fraud or deceit;

(2) has been convicted of a felony or other crime if the felony or other crime is substantially related to the qualifications, functions, or duties of the licensee;

(3) habitually abuses alcoholic beverages, or illegally uses controlled substances;

(4) has impersonated a registered, advanced practice registered, or practical nurse;

(5) has intentionally or negligently engaged in conduct that has resulted in a significant risk to the health or safety of a client or in injury to a client;

(6) practices or attempts to practice nursing while afflicted with physical or mental illness, deterioration, or disability that interferes with the individual's performance of nursing functions;

(7) is guilty of unprofessional conduct as defined by regulations adopted by the board;

(8) has wilfully or repeatedly violated a provision of this chapter or regulations adopted under this chapter or AS 08.01;

(9) is professionally incompetent;

(10) denies care or treatment to a patient or person seeking assistance if the sole reason for the denial is the failure or refusal of the patient or person seeking assistance to agree to arbitrate as provided in AS 09.55.535(a);

(11) has prescribed or dispensed an opioid in excess of the maximum dosage authorized under AS 08.68.705; [OR]

(12) has procured, sold, prescribed, or dispensed drugs in violation of a law, regardless of whether there has been a criminal action or harm to the patient**; or**

(13) has habitually and without good cause failed to provide oral and written information on opioids under AS 08.68.710 before prescribing an outpatient supply of an opioid to a patient.

*** Sec. 8.** AS 08.68 is amended by adding a new section to article 6 to read:

Sec. 08.68.710. Opioid prescription information; relationship to causes of action. (a) Before an advanced practice registered nurse prescribes an outpatient supply of an opioid to a patient, the advanced practice registered nurse or an agent of the advanced practice registered nurse shall provide to the patient or the person authorized to make health care decisions for the patient

(1) an oral statement which, in the advanced practice registered nurse's or agent's own words, includes

(A) the advanced practice registered nurse's reasons for prescribing the opioid;

(B) any reasonable non-opioid alternatives to the prescription; and

(C) information that

(i) the prescription could potentially lead to opioid addiction;

(ii) the danger of opioid addiction can begin to increase if a prescription is extended over longer periods of time;

(iii) opioid addiction may pose potentially life-threatening health risks; and

(2) a written statement, which may include graphics, prepared by the Department of Health and Social Services that provides appropriate information conveying the potential addictive and health risks of opioids.

(b) The requirements under (a) of this section do not apply to a patient receiving

(1) hospice care from a licensed provider or facility; and

(2) substance abuse or opioid dependence treatment.

(c) The Department of Health and Social Services shall provide access on the department's Internet website to a printable version of the written statement an advanced practice registered nurse is required to distribute under (a)(2) of this section.

(d) Nothing in this section creates a new cause of action or affects an existing cause of action.

*** Sec. 9.** AS 08.72.240 is amended to read:

Sec. 08.72.240. Grounds for imposition of disciplinary sanctions. The board may impose disciplinary sanctions when the board finds after a hearing that a licensee

(1) secured a license through deceit, fraud, or intentional misrepresentation;

(2) engaged in deceit, fraud, or intentional misrepresentation in the course of providing professional services or engaging in professional activities;

(3) advertised professional services in a false or misleading manner;

(4) has been convicted of a felony or other crime that affects the licensee's ability to continue to practice competently and safely;

(5) intentionally or negligently engaged in or permitted the performance of patient care by persons under the licensee's supervision that does not conform to minimum professional standards regardless of whether actual injury to the patient occurred;

(6) failed to comply with this chapter, with a regulation adopted under this chapter, or with an order of the board;

(7) continued to practice after becoming unfit due to

(A) professional incompetence;

(B) failure to keep informed of or use current professional theories or practices;

(C) addiction or severe dependency on alcohol or other drugs that impairs the licensee's ability to practice safely;

(D) physical or mental disability;

(8) engaged in lewd or immoral conduct in connection with the delivery of professional service to patients;

(9) failed to refer a patient to a physician after ascertaining the presence of ocular or systemic conditions requiring management by a physician;

(10) prescribed or dispensed an opioid in excess of the maximum dosage authorized under AS 08.72.276;

(11) procured, sold, prescribed, or dispensed drugs in violation of a law, regardless of whether there has been a criminal action or harm to the patient**; or**

(12) habitually and without good cause failed to provide oral and

written information on opioids under AS 08.72.277 before prescribing an outpatient supply of an opioid to a patient.

*** Sec. 10.** AS 08.72 is amended by adding a new section to read:

Sec. 08.72.277. Opioid prescription information; relationship to causes of action. (a) Before a licensee prescribes an outpatient supply of an opioid to a patient, the licensee or an agent of the licensee shall provide to the patient or the person authorized to make health care decisions for the patient

(1) an oral statement which, in the licensee's or agent's own words, includes

(A) the licensee's reasons for prescribing the opioid;

(B) any reasonable non-opioid alternatives to the prescription; and

(C) information that

(i) the prescription could potentially lead to opioid addiction;

(ii) the danger of opioid addiction can begin to increase if a prescription is extended over longer periods of time;

(iii) opioid addiction may pose potentially life-threatening health risks; and

(2) a written statement, which may include graphics, prepared by the Department of Health and Social Services that provides appropriate information conveying the potential addictive and health risks of opioids.

(b) The requirements under (a) of this section do not apply to a patient receiving

(1) hospice care from a licensed provider or facility; and

(2) substance abuse or opioid dependence treatment.

(c) The Department of Health and Social Services shall provide access on the department's Internet website to a printable version of the written statement a licensee is required to distribute under (a)(2) of this section.

(d) Nothing in this section creates a new cause of action or affects an existing cause of action.

*** Sec. 11.** The uncodified law of the State of Alaska is amended by adding a new section to read:

TRANSITION: REGULATIONS. The Department of Health and Social Services may adopt regulations necessary to implement the changes made by secs. 4, 6, 8, and 10 of this Act. The regulations take effect under AS 44.62 (Administrative Procedure Act), but not before the effective date of the relevant provision of this Act implemented by the regulation.

ALASKA STATE LEGISLATURE

REPRESENTATIVE LES GARA

Memorandum

Explanation of Changes: CS SS HB 268
(Version O to Version R)

SS HB 268: An Act relating to the prescription of opioids; relating to the Department of Health and Social Services; relating to the practice of dentistry; relating to the practice of medicine; relating to the practice of podiatry; relating to the practice of osteopathy; relating to the practice of nursing; and relating to the practice of optometry.

Section 3. (15) Line 5: Clarified the bill applies to outpatient prescriptions only. Added the term "outpatient supply" before "of an opioid to a patient." in order to further define situations in which a prescriber must provide patient information about opioid medication. The term "outpatient supply" is used in law currently.

- Concurring changes for all prescribing professions follow in:
  - Section 4 (a) Line 8
  - Section 5 (15) Line 1
  - Section 6 (a) Line 4
  - Section 7 (13) Line 30
  - Section 8 (a) Line 2
  - Section 9 (12) Line 2
  - Section 10 (a) Line 5

Section 4 (C)(iii). Lines 20-21: Language removed requiring prescriber information to a patient on heroin addiction and the connection between opioid prescription drug addiction and heroin use. Changed "health danger" to "health risks". Now reads that a prescriber must provide information on how "opioid addiction may pose potentially life threatening health risks".

- Concurring changes for all prescribing professions follow in:
  - Section 6, C, iii, Line 17-18
  - Section 8, C, iii, Line 17-18
  - Section 10, C, iii,Lines 18-19

January-May: State Capitol • Juneau, AK 99801-1182 • (907) 465-2647 • Fax (907) 465-3518
June-December: 1500 W. Benson Blvd. • Anchorage, AK 99503 • (907) 269-0106 • Fax (907) 269-0109
Rep.Les.Gara@akleg.gov

FROM THE DESK OF

ANNE ZINK

February 21, 2018

To the Honorable Representatives through the chair,

I appreciate your time and considering this testimony for HB 268, Opioid Prescription Writing on behalf of Alaska ACEP (American College of Emergency Physicians) a local group representing more than 80% of the emergency medicine physicians in Alaska.

I am a full time practicing Emergency Physicians at Mat-Su Regional Hospital in Palmer Alaska and have spoken before on the need to better address the opioid epidemic facing our great state.

In the Emergency Department we see both the best and worst of opioids. When a tragic accident leaves a patient mutilated and in agony, or an elder suffering from the intense pain of metastatic cancer and its resultant fractures, opioids play a critical role. Opioids ability to provide relief from pain and suffering remain important. We also see the destruction that opioids wreak on patients lives, the overdoses, and the violent threats for opioids if they are not delivered on demand. We see a generation that expects (and demands) a pain free life. As physicians, we have been inappropriately incentivized to both make our patients "satisfied" and "do everything possible to alleviate pain". The combination of these factors, along with aggressive marketing by the pharmaceutical industry, have contributed to the nightmare of the opioid epidemic we see today.

As Emergency Physicians, we recognize the critical role that physicians and the broader medical system play in both addressing the opioid epidemic that exists today, as well as preventing Alaskans from becoming embroiled in the opioid epidemic in the future. We have worked with DHSS to create guidelines for how opioids should be prescribed in the Emergency Department. We are implementing IT fixes across the state so we can more easily identify patients at risk for opioid addiction and overdose sooner. In conjunction with DHSS, we are finalizing an opioid education handout that discusses many of the aspects of pain and opioid use and abuse called for in HB 268. Statewide, we now have a CME requirement related to opioids. Our state chapter of ACEP, National ACEP, and the broader house of medicine have all recognized the tragedy of medical opioid use and the link to opioid addiction.

In general, as physicians, we are concerned when legislation inserts itself into the the conversations and relationships we have with our patients. We are concerned by moves in other states where key issues regarding health of patients were legislatively prohibited from being discussed. We see the patient / physician relationship as a special and very personal space that we fight hard to protect.

HB 268 appears to be legislating something that we believe physicians should be doing for their patients. As emergency physicians we fully embrace the importance of the risk-benefit- alternative discussion between provider and patient any time a potentially hazardous test or treatment is being considered. The decision to use opioids or not certainly falls into this category. Our hope is that with all the attention being paid to opioids by both the house of medicine and society in general, these conversations are already happening.

We all play a role in creating a happy and healthy society. We need our medical system to be better stewards of the opioids they prescribe and administer, we need physicians to not be graded on "ending pain", we need better patient education about the risk and alternatives for these medication, we need better information systems that let providers know what treatment a patient has received else where, and we need treatment options available for patients seeking recovery. HB 268 may help encourage a conversation we believe in and is in line with many other steps this body and others have taken end this epidemic. If this bill does pass, we would suggest the addition of a sunset clause to ensure limited health care resources are being devoted to the most appropriate location.

Thank you for your time and consideration and accepting this written testimony. Please feel free to reach out with any questions or concerns.

Sincerely,

Anne Zink, MD, FACEP

annezink@gmail.com

907-315-5991

LEGAL SERVICES

DIVISION OF LEGAL AND RESEARCH SERVICES
LEGISLATIVE AFFAIRS AGENCY
STATE OF ALASKA

(907) 465-3867 or 465-2450
FAX (907) 465-2029
Mail Stop 3101

State Capitol
Juneau, Alaska 99801-1182
Deliveries to: 129 6th St., Rm. 329

MEMORANDUM February 5, 2018

SUBJECT: Statutory interpretation
(CSSSHB 268( ); Work Order No. 30-LS1081\U)

TO: Representative Les Gara
Attn: Representative Gara

FROM: Claire Radford
Legislative Counsel

The term "outpatient supply" is not currently defined in statute or regulation and has not arisen in litigation. Generally, the most reliable guide to the meaning of a statute is the words of the statute construed in accordance with their common usage. However, even where the statutory language considered alone seems to reasonably leave room for only one meaning, the legislative history and the rules of statutory construction may be consulted, as sometimes language that seems clear in the abstract takes on a different meaning when viewed in context. In such cases, the legislative history and rules of construction must present a compelling case that the literal meaning of the language of the statute is not what the legislature intended.[1]

"Outpatient supply" could be defined by the respective boards under these statutes. A court would then look to a board's definition when interpreting the meaning and give deference to the board's definition, as long as the term falls within the board's specialized subject area. It's possible that each of the relevant boards may, however, define the supply amounts differently.

"Outpatient supply" was used in the Governor's opioid bill, HB 159 (enrolled as Chapter 2 SSSLA 17) and was not defined in that statute. This phrase would therefore be construed in accordance with its common usage. Each of the two words used have commonly understood meanings and since this phrase was not defined in HB 159, I do not believe that it is necessary to define the phrase in this bill. Construing this phrase as it appears in CSSSHB 268 in accordance with its common usage is sufficient.

If I may be of further assistance, please advise.

CER:dls
18-037.dls

Attachment

---

[1] *Homer Elec. Ass'n v. Towsley*, 841 P.2d 1042, 1043 - 1044 (Alaska 1992) (internal citations omitted).

LEGAL SERVICES

DIVISION OF LEGAL AND RESEARCH SERVICES
LEGISLATIVE AFFAIRS AGENCY
STATE OF ALASKA

(907) 465-3867 or 465-2450
FAX (907) 465-2029
Mail Stop 3101

State Capitol
Juneau, Alaska 99801-1182
Deliveries to: 129 6th St., Rm. 329

MEMORANDUM February 21, 2018

SUBJECT: Statutory interpretation (CSSSHB 268( );
Work Order No. 30-LS1081\R)

TO: Representative Les Gara
Attn: Claire Gross

FROM: Claire E. Radford
Legislative Counsel

You asked about the meaning of "habitually and without good cause" and what the meaning of this phrase would be since it is not otherwise defined in this bill. The phrase "habitually and without good cause" is not currently defined in statute or regulation. The terms "habitually" and "without good cause" are also not defined in statute or regulation but are used several times in statute.[1]

As previously advised, generally the most reliable guide to the meaning of a statute is the words of the statute construed in accordance with their common usage. If the word is clear and unmistakable without definition, it is superfluous and confusing to define it. A word that is not defined in a statute will probably be given its common law meaning by a court construing the statute.[2] A statute is interpreted according to reason, practicality, and common sense, considering the meaning of its language, its legislative history, and its purpose. Alaska courts may also consider how courts have interpreted the words in other cases or statutes, or how administrative agencies have used the words.[3]

"Habitually and without good cause" could be defined by the respective boards under these statutes. A court would then look to a board's definition when interpreting the meaning and give deference to the board's definition, as long as the term falls within the board's specialized subject area.

---

[1] *See, e.g.* AS 22.30.011, AS 28.15.221, and AS 47.10.011 (uses of "habitually"); AS 08.87.200, AS 12.50.010, AS 18.07.081 (uses of "without good cause").

[2] *Manual of Legislative Drafting* (2017), p. 51. (*See Hugo v. City of Fairbanks*, 658 P.2d 155 (Alaska App. 1983)).

[3] *Wilson v. State, Dept. of Corrections*, 127 P.3d 826 (Alaska 2006).

If this phrase was not defined, this phrase would be construed in accordance with its common usage. The words have commonly understood meanings and I do not believe it is necessary to define these words or this phrase in this bill. On occasion, the Supreme Court of Alaska does reference the dictionary meanings when the meaning of a word is essential in litigation. I do not think this would be necessary for "habitual" or "without good cause" since these terms are commonly used and understood and they will be applied to a set of facts. However, for your reference, Black's Law Dictionary defines "habitual" as customary; usual, and as recidivist[4] and "good cause" is defined as a "legally sufficient reason."[5]

The legislature can also make a record of their intent in using a particular word or phrase that the court will refer to when interpreting a statute. This legislative history can have an important role in statutory interpretation since the plain meaning of a statute does not always control its interpretation, as the Alaska Supreme Court has recognized that legislative history can sometimes alter a statute's literal terms. However, under Alaska's sliding-scale approach to statutory interpretation, "the plainer the language of the statute, the more convincing contrary legislative history must be."[6] In such cases the legislative history and rules of construction must present a compelling case that the literal meaning of the language of the statute is not what the legislature intended.

If I may be of further assistance, please advise.

CER:dls
18-075.dls

---

[4] Black's Law Dictionary (10th ed. 2014), habitual.

[5] Black's Law Dictionary (10th ed. 2014), cause, 2. good cause.

[6] *Alaskans For Efficient Gov't Inc. v. Knowles*, 91 P.3d 273, 275 (Alaska 2004) (*quoting Ganz v. Alaska Airlines, Inc.*, 963 P.2d 1015, 1019 (Alaska 1998)).

THE STATE of ALASKA
GOVERNOR BILL WALKER

Department of Health and Social Services

ALASKA MENTAL HEALTH BOARD
ADVISORY BOARD ON ALCOHOLISM AND DRUG ABUSE

431 North Franklin Street, Suite 200
Juneau, Alaska 99801
Main: 907.465.8920
Fax: 907.465.4410

February 7, 2018

The Honorable Representative Les Gara
State Capitol Room 511
Juneau AK, 99801

RE: House Bill 268- At Act Relating to the Prescription of Opioids

Dear Representative Gara;

The Advisory Board on Alcoholism and Drug Abuse (ABADA) and the Alaska Mental Health Board (AMHB) are the state agencies charged with planning and coordinating behavioral health services funded by the State of Alaska. The joint mission of ABADA/AMHB is to advocate for programs and services that promote healthy, independent, productive Alaskans.

We believe opioid prescribers should talk to their patients about the potential addictive qualities of opioids and discuss other treatment options while following the state prescribing guidelines. We are aware that the Department of Health and Social Services is developing patient information brochures and we fully support the distribution of these materials when prescribing opioids. Taken together, patients will be able to make informed choices about their healthcare.

We also believe that patient education is one piece of the puzzle to preventing and managing opioid addiction. ABADA/AMHB staff and Board were key stakeholders in the development of the Alaska Opioid Policy Taskforce and the formation of their statewide policy recommendations. As noted in that taskforce report the Alaska State Medical and Dental Boards, Board of Pharmacy, Board of Nursing, Board of Optometry, and Division of Professional Licensing adopted the State of Washington's "Interagency Guidelines for Prescribing Opioids for Pain' for Alaska in 2015. We strongly believe health care professionals in Alaska need additional training and supports about these prescribing guidelines to understand the science of addiction and how their overall prescribing practices can help mitigate the risk of prescription opioid misuse.

We appreciate your hope to keep the requirements flexible and as non-burdensome as possible. Working with the licensing boards to offer providers training and support on the interagency prescribing guidelines and encouraging providers to educate their patients will help turn the tide on opioid addiction.

Thank you for this opportunity to support and comment on HB 268 and please contact me if you need additional information.

Sincerely,

Alison L. Kulas, MSPH
Executive Director

Alaska
DENTAL SOCIETY

January 25, 2018

The Honorable Les Gara
Alaska House of Representatives
State Capitol Room 511
Juneau, AK 99801

Dear Representative Gara:

The Alaska Dental Society (ADS) supports HB268.

As the opioid public health crisis in Alaska continues, we have the opportunity to serve a key role in educating our communities and our patients about the devastation of opioids, through timely discussions with our patients and by distributing written material during the course of prescribing pain control agents.

Increasing patient awareness of non-opioid alternatives benefits both patients and providers. Increasing patient education of alternatives will be necessary to overcome years of patient expectations to receive opioids, frequently in large doses, after even minor surgical procedures. We look forward to working with the State HSS Department to transition patient and provider expectations to reasonable pain control appropriate for the level of surgery received.

There is a documented epidemic of opioid and heroin abuse in Alaska. The ADS has recognized the need for the responsible use and prescribing of prescription opiates by Alaskan dentists. The ADS is committed to informing our members of the latest research and keeping dentists abreast of the latest findings on the efficacy of pain control agents and responsible dosing.

As ethical providers of healthcare, we have an obligation to educate ourselves about safe prescribing, about how to have a frank discussion with patients and, in the case of minors, their parents or caregivers, as well as how to identify possible abuse and recommend help. The Alaska Dental Society has developed guidelines for its members to aid in the proper prescribing of opioids and alternative pain control methods. We welcome other prescribers to utilize the guide where appropriate.

Sincerely,

David Logan, DDS
Executive Director, Alaska Dental Society

1407 W. 31st. Avenue., Ste. 304 Anchorage, AK 99503
Phone: (907) 563-3003 • Fax: (907) 563-3009 • Website: akdental.org • E-mail: info@akdental.org

THE STATE of ALASKA
GOVERNOR BILL WALKER

Department of Health and Social Services
OFFICE OF THE COMMISSIONER

Anchorage
3601 C Street, Suite 902
Anchorage, Alaska 99503-5923
Main: 907.269.7800
Fax: 907.269.0060

Juneau
350 Main Street, Suite 404
Juneau, Alaska 99801-1149
Main: 907.465.3030
Fax: 907.465.3068

January 29, 2018

The Honorable Les Gara
Alaska House of Representatives
Room 511
Alaska State Capitol
Juneau AK, 99801 .

Dear Representative Gara,

Thank you for your ongoing work to address the opioid crisis facing our nation and Alaska. I support the intent of HB 268 to encourage providers to have critical conversations with patients when opioid pain-relievers are prescribed and to ensure that important information on the risks of addiction and methods of proper disposal of unused pills are communicated. While the risk of subsequent opioid misuse and addiction associated with a single prescription is low, the public health impact of opioid misuse is significant in view of how commonly opioid pain relievers have been prescribed in recent years. According to the Substance Abuse and Mental Health Services Administration and the National Institute for Drug Abuse, 3.6% of persons using prescription opioids for non-medical purposes initiate heroin use within the following 5 years, and 23% of persons who try heroin, will become addicted. Among people who become addicted to heroin, the majority report using prescription opioids for non-medical purposes prior to first use of heroin.

Anecdotal reports suggest that conversations about the risks associated with opioid pain relievers often do not occur when an opioid is prescribed or dispensed. This may be in part because providers have not been aware of the potential risk until recently. HB 159, passed during the first session of the 30th Legislature and signed into law by Governor Walker, requires a portion of the continuing medical education credits required for healthcare provider licensure be committed to training in pain management and the basics of addiction medicine. Additionally, the Department of Health and Social Services is working with professional organizations, such as the Alaska chapter of the American College of Emergency Physicians and the Alaska Dental Society to

develop and implement tools that will help communicate the risks associated with prescription opioid use, non-opioid pain management options, and proper disposal of unused medications.

Additionally, the Department continues to provide drug disposal bags to all Alaskans through the Public Health Centers and in partnership with other organizations to reduce the amount of opioids available for misuse in our homes and communities.

I hope that this information will be helpful to you as HB 268 moves through the legislative process.

Sincerely,

Jay C. Butler, MD, FAAP, MACP, FIDSA
Chief Medical Officer, and
Director, Division of Public Health

Turning Point Counseling Services
Building Recovery Foundations Together

Honorable Representative Les Gara, February 14, 2018

My name is Gunnar Ebbesson. I am a licensed professional counselor supervisor, master addiction counselor and a chemical dependency counselor supervisor working in the field of mental health and addiction since 2002. During that time I have served on the Governor's Advisory Board for Alcoholism and Drug Abuse (chair in 2016), and co-chaired the Alaska Opioid Policy Task force. I am co-founder and clinical director of Turning Point Counseling Services in Fairbanks and have been engaged in that endeavor since 2009. I have been deeply entrenched in the opioid epidemic as a therapist and an advocate where I started to see young, bright 18 to 24 year old youth, deeply addicted to Oxycontin beginning in around 2010. These were youth who came from upper middle class families with what seemed to be good upbringing and bright futures. The addictions they had to Oxycontin were severe and intractable; I have had the sad experience of losing friends, clients to overdose, and currently one of my children is homeless and addicted on the streets of California. His addiction to heroin started with prescription pain medication he procured on the street. As a person in long term recovery (20 years) I have had the experience of doctors who have treated me, not understand addiction and the danger of opioids and other drugs related to addiction. On one occasion some years ago, I informed an emergency department physician of the fact that I was in recovery and that I could not take narcotic pain medication or benzodiazepines after I had broken my ankle, only to have her come back to the exam room with a prescription for Percocet and valium. When I explained again, that I could not take these, the physician huffed out of the room saying "Fine! Go home and take aspirin!" I reported her to the hospital, but am not sure of any censure for that behavior.

I believe that many physicians have come a long way in understanding the impact of opioids on the epidemic, and that longer exposure to opioids increases the likelihood of dependence and addiction, and that in general physicians have the best intentions when treating their patients. However, this understanding is far from ubiquitous, my 80 year old father was just treated for back pain with Percocet, became physically dependent on it over the course of his back pain treatment, and required withdrawal management from a PA friend of mine who does that work. I asked him if his doctor had warned him of the possible impacts of his taking Percocet, he said that he had not gotten any information like that. This made me think of all of the elderly people who are unwittingly being exposed to these issues.

I am in full support of House Bill 268, which requires physicians to inform their patients on the risks of taking opioids. I am aware that taking that kind of time with their patients is an added burden to their often-overwhelming workload, however, it falls on deaf ears with me. I see what happens, and what happened in my community and family and have to think that it is a moral and ethical mandate for physicians to be educated on addiction and to then educate their patients on risks associated with taking opioids.

With deep respect and thanks,

Gunnar Ebbesson, LPCS MAC CDCS
Clinical Director/Turning Point Counseling Services
315 5th Ave
Fairbanks, AK 99701
Phone: (907) 978-5367

Partners For Progress
417 Barrow St.
Anchorage
Alaska 99501
Ph: (907) 272-1192
Fax: (907) 272-1194

PARTNERS FOR PROGRESS
Supporting Justice that Protects and Heals

www.partnersforprogressak.org

February 2, 2018

Representative Les Gara
State Capitol Room 511
Juneau AK, 99801

Representative Gara,

Partners for Progress, Inc., Board of Directors strongly supports HB268. Through our work in Reentry and Therapeutic Court Support, we see the devastation of opioid addiction every day. In 1998 when Alaska developed our first Therapeutic Court, the focus was on alcohol. Today, the number of participants in Therapeutic Courts and Reentry Programs in Alaska who are addicted to opiates has drastically increased. We hear the same story over and over, "It started with pain killers".

Partners Reentry Center Director, Cathleen McLaughlin has this story from an experience last week, *"Just today I did an intake of an individual who got hooked on opioids after receiving an over-abundance of pain management medication after a fairly standard surgery. When the prescriptions ran out, she sought heroin as her drug of choice. It was cheaper. After losing her home and kids, she is clawing her way back up to normal. I continue to wonder – what if the Dr. had prescribed a non-addictive pain management medication? Would she have lost her bearings?*

Individuals, like the woman who entered our program today, are the reason I am committed to addressing the opioid crisis. She did not choose to be an opioid addict. She became one because of the lack of awareness of the impact a prescribed drug had on her. She had addictive tendencies, which she disclosed prior to the surgery. It was easier for the medical profession to go with the easiest, for them, to address the pain and to prescribe". Cathleen McLaughlin, J.D./M.B.A.

In March, our Therapeutic Court Peer Support Group will be in Juneau to support this Bill and advocate on behalf of recovery from addiction. Please call on us if we can support you further.

Sincerely,

Doreen Schenkenberger
Executive Director