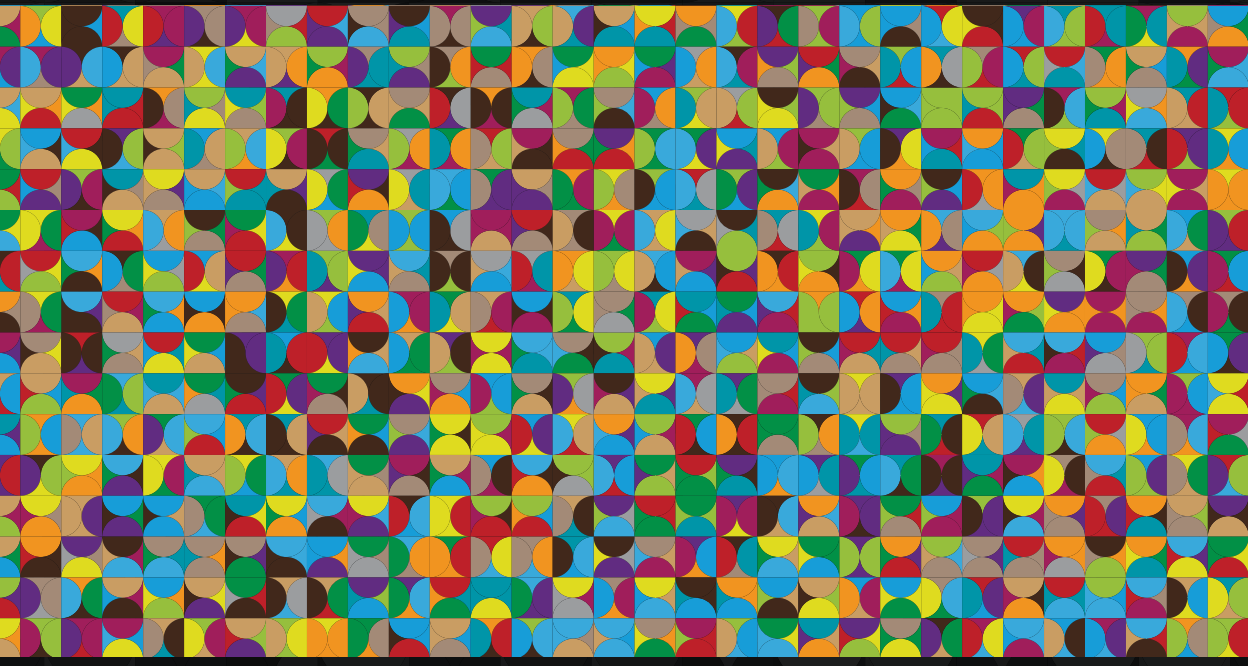
CONFRONTING OUR NATION'S OPIOID CRISIS

A Report of the Aspen Health Strategy Group



THE ASPEN INSTITUTE HEALTH STRATEGY GROUP

Foreword by Kathleen Sebelius and Tommy G. Thompson

Edited by Alan R. Weil and Rachel Dolan

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funding for this report provided by:

Robert Wood Johnson Foundation

The mission of the **Aspen Health Strategy Group** is to promote improvements in policy and practice by providing leadership on important and complex health issues. The group is comprised of 24 senior leaders across influential sectors such as health, business, media, and technology and is part of the Health, Medicine and Society Program at the Aspen Institute. Co-chaired by Kathleen Sebelius and Tommy G. Thompson, both former governors and former U.S. Secretaries of Health and Human Services, the Aspen Health Strategy Group tackles one health issue annually through a year-long, in-depth study. This book is a collection of papers on the group's second subject: confronting the nation's opioid crisis. The papers address topics related to the health care system, financing, and the law's response to the opioid epidemic and include a final consensus report based on the group's work.

The Aspen Institute
2300 N Street, NW
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Washington, DC 20037

Published in the United States of America in 2017 by The Aspen Institute

Printed in the United States of America
Wye Publication Number: 17/019

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THE ASPEN INSTITUTE

December 2017

It is my great pleasure to introduce the second annual report of the Aspen Health Strategy Group (AHSG). Now a highly respected and increasingly impactful initiative of our Health, Medicine and Society Program, the Aspen Health Strategy Group is co-chaired by former U.S. Secretaries of Health and Human Services (HHS) and governors, Kathleen Sebelius and Tommy G. Thompson. The group is comprised of two dozen CEOS and other senior leaders from all areas of influence – industry, academia, health systems, media, publishing, and elsewhere. Six of the seven other living former HHS secretaries also serve in an ex officio capacity; we believe AHSG is the only organization that includes this prestigious group of individuals.

Each year, AHSG chooses a single health policy and practice issue for comprehensive, in-depth study. This year's topic was the U.S. opioid epidemic, a national crisis with staggering consequences for our health care system and, of course, for the families, friends, neighbors, and workplace colleagues of people with opioid use disorder. The group's consensus recommendations on how to tackle this pressing problem are the subject of this publication.

Throughout its work, the Aspen Health Strategy Group has carried on the Aspen Institute's tradition of a nonpartisan, evidence-based approach to address society's most vexing challenges and to identify opportunities to have an impact. This report, including the group's "Big Ideas" for confronting opioid addiction, reflects that approach, as well as the members' talent, wisdom, and experience for getting hard stuff done and making a difference. We are honored they have joined in this latest AHSG effort and are most grateful for their time, thoughts, and commitment.

All best,

Walter Isaacson

Walter Isaacson
President & CEO
The Aspen Institute

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Foreword

Kathleen Sebelius
AHSG Co-Chair

Tommy G. Thompson
AHSG Co-Chair

Our nation is in the midst of an opioid crisis. The U.S. Centers for Disease Control and Prevention (CDC) reports that 33,000 people died from opioid overdoses in 2015. About half of those were due to prescription opioids, with the rest attributed to heroin and synthetic opioids, such as fentanyl. An estimated two million Americans are abusing prescription pain relievers and an additional 591,000 are addicted to heroin. The crisis shows no signs of abating on its own.

In our second year as co-chairs of the Aspen Health Strategy Group, we continue our efforts to promote improvements in policy and practice by providing leadership on important and complex health issues. This year we selected the opioid crisis as our topic. In June 2017, the Aspen Health Strategy Group met for three days and took on hard questions related to this complicated and critical issue.

We are pleased to present the final report from our work, based upon our group's rich discussion. In the tradition of the thought-provoking conversations and dialogue on how to address challenging societal issues -- the hallmark of the Aspen Institute -- the report includes five Big Ideas to address our nation's opioid epidemic. In our discussions, we relied heavily upon four background papers, prepared in advance of our June meeting. Those papers are included in this compendium as well.

Each background paper was written by a subject matter expert. Harold Pincus and Carlos Blanco provided an overview on the opioid crisis in the United States. Richard Frank and Carrie Fry summarized how we pay for treating substance use disorders and how those policies affect access, quality and cost. Keith Humphreys provided a portrait of the fragmented systems we rely upon to treat substance use disorders. Amanda Pustilnik described the legal and ethical issues related to the epidemic. We were fortunate to have five of the authors present for the discussion in Aspen, in addition to Mollyann Brodie from the Henry J. Kaiser Foundation who again this year, provided valuable data about Americans' views on this issue. We also heard from Vivek Murthy, the 19th U.S. Surgeon General; Dr. Murthy produced a major report on addiction during his time in office.

Before our meeting, we issued a broad call to the public for their ideas on how to address the opioid crisis. We benefited from all of the ideas, but we particularly want to acknowledge the following individuals and organizations for submitting ideas that made their way, often with modification, into the final set of big ideas adopted by the group: Mark Bertolini, Aetna; Jim Hood, Greg Williams, and Ivana Grahovac, Facing Addiction; Andrew Kolodny, Brandeis University; Victoria Maizes, University of Arizona Center for Integrative Medicine; Keith Martin, Consortium of Universities for Global Health; Kathryn Martucci, Advisory Board; Eugenia Middleton, The Aspen Institute; Susan Thompson, Ottawa Public Health; Valory Wangler, Physicians for Social Responsibility; and Michael White, Community Medical Services.

We are also grateful to the three organizations that provided funding to make this year's work possible. We received generous financial support from the Robert Wood Johnson Foundation, the Laura and John Arnold Foundation, and the Laurie M. Tisch Illumination Fund. The perspectives expressed in this report are those of the authors and do not necessarily reflect the views of any of these organizations. On behalf of the Aspen Health Strategy Group and everyone associated with the 2017 opioid project, we thank them for their support and continued commitment to this effort.

ASPEN HEALTH STRATEGY GROUP REPORT

Five Big Ideas to Confront Our Nation's Opioid Crisis

Part 1

"The Aspen Health Strategy Group, with its bipartisan and multi-sector membership, has developed these ideas to address the opioid crisis in America. It has never been more important for all parties to come together, examine the evidence, and make strides against this deadly problem."

– THE ASPEN HEALTH STRATEGY GROUP

Five Big Ideas to Confront Our Nation's Opioid Crisis

Introduction

The U.S. Centers for Disease Control and Prevention (CDC) reports that 33,000 people died from opioid overdoses in 2015. About half of those were due to prescription opioids, with the rest due to heroin and synthetic opioids, such as fentanyl. These deaths were an avoidable and unnecessary tragedy. Early CDC estimates for 2016 tally more than 64,000 overdose deaths from all drugs, a 21% increase from 2015. An estimated two million Americans are abusing prescription pain relievers and an additional 591,000 are addicted to heroin. The growing use and misuse of opioids is a national crisis.

The Aspen Health Strategy Group selected the opioid crisis as its topic for discussion in 2017, its second year. This group of leaders in and outside health care spent three days considering the topic with the assistance of subject matter experts who prepared four background papers to frame the conversation. The group emerged with five big ideas to confront the opioid crisis.

The Aspen Health Strategy Group's goal is to promote improvements in policy and practice by providing leadership on important and complex health issues. Co-chaired by Kathleen Sebelius and Tommy Thompson, both former governors and former U.S. Secretaries of Health and Human Services, the group is composed of 24 senior leaders across sectors including health, business, media, and technology. More information about the Aspen Health Strategy Group can be found on the Aspen Institute website. This report captures the deliberations of the group, but no specific proposal or statement in the report should be considered to represent the opinion of any individual member of the group.

Background

Harold Pincus and Carlos Blanco trace the growing problem of opioid abuse and its consequences in "The Opioid Crisis in America: An Overview." They describe the multiple narratives that have been suggested as propelling the growth in opioid use, including a steady increase in the rate of opioid prescriptions and a decrease in the price of heroin and synthetic opioids.

Opioid prescriptions grew following the movement toward increased pain treatment in the 1990s intended to help the many patients who had unrelieved pain. Approximately one-third of U.S. adults are estimated to suffer from chronic pain. While there is strong evidence for the efficacy of opioids for acute pain, they have not been systematically studied for treatment of chronic pain, and there is substantial evidence that they can be harmful when used long-term. Despite this, clinicians routinely prescribe opioids for chronic pain and, at least until recent years, were often cavalier regarding the duration of the prescriptions they wrote for opioids. It is estimated that more than 15 billion opioid tablets were dispensed per year in retail pharmacies in the U.S. in 2013 and 2014, far more per capita than in any other nation. From 1991 to 2013, the prevalence of non-medical use of prescription opioids nearly tripled, from 1.5% to 4.1% of the population, and the prevalence of addiction to prescription opioids tripled, from 0.3% to 0.9% of the population.

Increased accessibility and purity of heroin coupled with reduced price appear to be major drivers of the recent increases in rates of heroin use. Between 2001-2002 and 2012-2013, the prevalence of lifetime heroin use and lifetime heroin addiction (i.e. use or addiction at least once in the person's lifetime) in the U.S. both increased dramatically. Lifetime heroin use increased from 0.33% to 1.6% and the lifetime prevalence of heroin addiction increased from 0.21% to 0.69%. While there is certainly a relationship between legal opioid prescribing and use of illegal opioids, Pincus and Blanco point out that "the available data suggest

that nonmedical prescription-opioid use is neither necessary nor sufficient for the initiation of heroin use and that other factors are contributing to the increase in the rate of heroin use and related mortality."

The public health consequences of the crisis are staggering. Overdose deaths nearly quadrupled between 2000 and 2014 and most of these overdoses were accidental. Increased risk of HIV and hepatitis C infection are also consequences of opioid addiction; approximately 6% of new HIV diagnoses are due to injectable drug use. The crisis places a tremendous burden on the children, other family members, friends, neighbors and workplace colleagues of people with opioid use disorder.

"Spending for substance use disorder (SUD) treatment in the United States has increased dramatically in recent years and can be expected to continue its rapid expansion," note Richard Frank and Carrie Fry in "Financing Care for Opioid Use Disorders." From 2004 to 2014, spending on treatment for substance use disorders grew from $15.3 billion in 2004 to $44.9 billion in 2014, faster than the rate of national health expenditures over the same period.

Payment arrangements for substance use disorder treatment have shifted from primarily grant-based funding of specialty substance use disorder providers to one that relies more heavily on insurance and more closely resembles other elements of the modern U.S. health care system. The prior system of financing relied mostly upon fixed-budget funding of state agencies that directly paid service providers through grants. The role of insurance-based financing, including private insurance, Medicare and Medicaid has expanded.

Two pieces of legislation have significantly altered the financing landscape for opioid use disorder and other substance use disorders. The *Mental Health Parity and Addiction Equity Act (MHPAEA)*, sponsored by U.S. Senators Paul Wellstone and Pete Domenici, requires group health insurance plans that provide mental health and substance use disorder benefits to offer them at parity with medical and surgical benefits. The *Affordable Care Act (ACA)* extends the reach of the *MHPAEA* beyond employer-sponsored insurance. The *ACA* defines mental health and substance use disorder treatments as essential health benefits and extends *MHPAEA's* provisions to all plans in the individual and small group markets as well as to those newly eligible for Medicaid. The net effect of these changes is to increase substance use disorder coverage for over 170 million Americans.

Data from the National Household Survey on Drug Use and Health for 2015 indicate that 34% of people with opioid use disorder were covered by Medicaid and 42% by private insurance. Coverage of services does not always lead people

to access them. In 2015, only one-quarter of individuals with opioid use disorder received treatment in the prior 12 months, with the two most likely stated reasons being inability to afford treatment and a lack of readiness to seek treatment.

In combination, the requirements of *MHPAEA* and the *ACA* have dramatically changed the funding and financing mechanism of opioid use disorder treatment in the United States. These financing changes are reshaping the treatment of opioid use disorder in the U.S. toward evidence-based practices and value.

While the evolution of financing for substance use disorder is driving changes in care delivery, much work remains to provide integrated and high quality care to those with opioid use disorders. "Historically most opioid specialty treatment services have existed largely independent of the health care system," notes Keith Humphreys in "The Opioid Epidemic and the U.S. Health Care System." For those with opioid use disorder, the care system is fragmented and uncoordinated. There is little to no role for primary care screening or treatment; most patients are referred to specialists. This leads to delays in care and increased severity of the opioid use disorder by the time the problem is identified and treated. This lack of coordination produces lower quality care and increases patient suffering.

More effective would be to treat those with opioid use disorders similarly to those with other chronic conditions and to appropriately manage their care. The treatment of opioid addiction did not emerge from the health care system and that has resulted in its being poorly integrated with the rest of health care, less generously resourced, less staffed by medically-trained personnel, and less subject to the quality improvement mechanisms that are built into the rest of the health care system. People with opioid use disorders have a range of needs, some specific to their substance use and some not. These needs have historically not been well met by the health care system. While use of quality, evidence-based care such as medication-assisted treatments is increasing, there are still significant barriers to access for many. As noted above, only a fraction of those with opioid use disorder are receiving treatment for it.

One major recent shift has been viewing addiction through a medical and public health lens as opposed to a viewing it exclusively as a criminal justice problem. "[U]ntil recently, criminal policy and enforcement practices have relied nearly exclusively upon arrest and incarceration for achieving drug control," says Amanda Pustilnik in "Legal Issues Related to the Opioid Crisis," where she outlines the complicated legal and regulatory infrastructure surrounding the opioid crisis. The opioid epidemic is a cross-cutting criminal drug and pharmaceutical problem which involves lawmaking, policy-setting, and anti-drug enforcement.

About 1.5 million people are arrested annually for a drug-related offense; 85% of these are for individual drug possession. Mass arrests for drug possession have led to mass incarceration with dire consequences for communities, families, and tremendous cost to taxpayers. This approach has done little to reduce the supply of illegal drugs or rates of addiction. Decades of drug-related mass arrests and mass incarceration have disrupted the lives of individuals, families, and communities; kept people in poverty; and widened inequality.

Federal and state governments are increasingly recognizing the failure of incarceration as a response to illegal drug use and its potential harms and, are moving to alternative criminal processes and penalties. Major initiatives such as prescription drug monitoring programs, expanded access to naloxone, harm reduction and drug courts, (at both the federal and state levels) illustrate this shift in response. These nascent efforts and experiments are relatively recent in comparison to the institutionalized approach of incarceration and will require wider application and time to produce long-term results.

Framing the Issue

Five themes emerged in the group's discussions that helped guide the development of this year's big ideas. The themes are:

- **The opioid crisis has complex origins**

  The opioid crisis emerged from a complex constellation of personal despair, the neuroscience of addiction, and treated and untreated pain. There is no single path to opioid addiction. Some begin using legally-prescribed opioids, become addicted, and transition to illegal sources of either prescription opioids or illicit drugs. Some begin with diverted legal opioids while others begin using illegal opioids, such as heroin. For some, acute or chronic physical pain is the reason for first use, while for others there is a desire for escape from emotional pain. Some people with opioid addiction have other substance use disorders, such as alcohol use disorder, while others do not. Opioid use disorder is a chronic condition, and the course of addiction is highly variable. Some people remain highly functional as their dependence on opioids increase, while others deteriorate more quickly, and may move into illegal activities to support their addiction.

  This complexity means there is no single response that will reverse the opioid crisis. Rather, a comprehensive response is required – one that engages all of the tools available to prevent and treat addiction. A comprehensive

response must include addressing the social malaise that leads people to misuse substances. It must include modifications to how the medical system promotes and prescribes opioids. It must make the best possible treatment available to those who have opioid use disorder. It must engage law enforcement appropriately with respect to drug interdiction and the crimes people commit to support their addiction, but not use the legal system to punish people for their health condition.

- **The medical system is involved in the crisis in multiple ways**

  The rapid growth in opioid prescriptions was largely due to well-intentioned efforts to respond to the realization that patients experience a great deal of untreated pain. The manufacturer of OxyContin promoted the notion, inaccurately, that its product had a low risk of addiction relative to other painkillers in use at the time. Opioid prescription rates in the United States far exceed those of other developed countries, which set the stage for high levels of diversion of opioids to illegal uses. A small subset of clinicians prescribe opioids in large quantities and with little monitoring of patients for effectiveness or potential addiction. Limited availability of opioid treatment is due in large part to the long-standing isolation of addiction services from the mainstream medical system. Medical system reimbursement methods make it easier and more desirable to prescribe opioids than to take other approaches to pain management. The myriad ways the medical system was involved in creating the crisis means the medical system must be at the center of responding to the crisis.

- **Treatment is currently the largest gap in addressing the opioid crisis**

  Medication-assisted treatment -- the combination of drugs to reduce craving for opioids and therapies designed to address the social and emotional context in which addiction occurs -- is highly effective in treating opioid addiction. Like other chronic conditions, opioid addiction requires sustained treatment, often for a lifetime. With only one-quarter of people with opioid use disorder receiving treatment, the need for more treatment is profound. Increasing treatment rates requires increasing the number of providers of evidence-based treatment methods, reducing financial barriers to receiving treatment, and addressing geographic disparities in treatment availability. It also requires better identification of opportunities to intervene in the lives of people with opioid use disorders when they interact with the criminal justice system or social programs. No matter how successful we are in reducing the number of people with new substance use disorders, effective treatment is necessary to reduce the burden of this disease on the approximately two million people who misuse or are dependent on prescription opioids.

- **Knowledge gaps are a barrier to an effective response to the opioid crisis**

  Despite great efforts, there is much we do not know about the nature of the crisis and the best way to respond. Our knowledge gaps begin with poor understanding of the best ways to treat acute and chronic pain and how to reduce the risk of addiction. We need to know more about which variants of medication-assisted treatment are most effective for different populations. The relationship between opioid use and other substance use disorders is not fully understood. While deaths from opioid overdose are fairly well measured, the broader social consequences of opioid misuse are not as well known.

- **Partial successes need to be bolstered and spread**

  Rates of opioid prescribing are beginning to decline. In some localities, cooperation among the health care, criminal justice, and public health sectors are yielding better identification of people in need of services and referral to those services. Sustained progress will be required to convert these signs of success into a comprehensive response to the opioid crisis. Successful strategies in some locales need to spread across the country.

Five Big Ideas to Confront the Opioid Crisis

There is much we can do to address the opioid crisis in the United States. The Aspen Health Strategy Group offers five big ideas that will help catalyze this change.

1. Stop overprescribing

Opioids are easy to prescribe, prescriptions are easy to fill, and most insurance readily covers the cost of the drugs. The United States is a global outlier in the rate of legal opioid prescribing. Sometimes pain can be managed with lower cost treatments that do not carry the risk of addiction, such as over-the-counter medications. Clinicians may avoid alternative methods for treating pain, such as physical therapy, which often involve substantially higher costs to patients and may be subject to significantly more oversight by insurers.

Steps to reduce overprescribing include:

- Engage the full range of clinicians, including primary care, specialty care, and dentistry, in education regarding pain treatment and appropriate opioid prescribing.
- The Food and Drug Administration should increase its oversight of the marketing practices of opioid producers given a documented history of some firms making inaccurate claims regarding their products.
- States should adopt best practices for prescription drug monitoring programs (PDMP), including comprehensive data collection, integration with electronic health record systems, and promotion of their use by clinicians, to make them more effective. States should also work together to share PDMP data across state lines and enable uniform data entry for multi-state providers.
- Encourage continued dialogue regarding voluntary or mandatory limits on the duration of initial and subsequent opioid prescriptions.
- Continue to update clinical guidelines based upon the best available evidence regarding appropriate prescribing of opioids for acute and chronic pain.

2. Treat opioid addiction as the public health crisis that it is

Addiction is a chronic medical condition, not a moral failing. People with the disease need evidence-based treatment, not punishment. The past use of mass incarcerations as a means of drug control has not curbed the epidemic and instead has disrupted lives and caused societal harm.

Taking a public health approach to the crisis means:

- Drug enforcement should focus on reducing the supply of illegal opioids through interdiction, targeting excessive prescribing, and reducing drug diversion.

- Identification of people with opioid use disorder and guiding them to treatment should be the top priority for health, social, educational, and criminal justice systems. Health care providers, particularly those who provide emergency care, should view linking people with opioid use disorder to addiction services as their responsibility.

- Identification of people with opioid use disorder is particularly important within the criminal justice system, where the emphasis should be on providing evidence-based treatment.

- Opioid use disorder is a chronic disease. Treatment of people with opioid use disorder should be undertaken as a life-long endeavor with uncertain results. Relapse is not evidence of failure and should not be punished.

- Program eligibility standards should be clarified to assure that people with opioid use disorder are not denied social supports, such as public housing, solely due to their disorder.

3. Stop the deaths

More than 30,000 people died from an opioid overdose in 2015. Most of these deaths were accidental and almost all were avoidable. Naloxone is an opioid antagonist, meaning it blocks the effect of opioids on the brain. When administered promptly either by injection or nasal spray, naloxone can reverse an opioid overdose and prevent death. It is also available as an auto-injector, allowing people without medical training to administer it readily.

Steps to eliminate unnecessary deaths include:

- Continue the spread of the number of first responders, including police, fire, and emergency medical services, that carry naloxone and are trained in its use.

- Designate public places where naloxone can be available for emergency use, much as has occurred with automated external defibrillators (AEDs).

- Expand the number of states that authorize standing orders that permit the filling of a prescription for naloxone to keep for future use rather than for a specific patient.

- Extend immunity from prosecution for people who call for help or administer naloxone, avoiding the fear that, if they are drug using themselves, they will be subjecting themselves to legal liability.

- Reduce the availability of drugs that can be stolen or misused through improved drug return programs that enable people to easily dispose of excess drugs.

4. Guarantee Access to Treatment

There is strong evidence that medication-assisted therapy -- pharmaceuticals combined with behavioral therapies -- can reduce opioid dependence. Yet, only about one out of every four people with opioid use disorder is receiving treatment.

Achieving higher rates of treatment requires better identification and referral of those with opioid use disorder; overcoming financial barriers to obtaining care; reducing stigma and concerns about criminal and civil exposure that discourage individuals with opioid use disorder to seek care; and expanding the availability of evidence-based treatment.

Specific steps to increase treatment include:

- Retain the Medicaid expansion under the *Affordable Care Act* as a source of coverage for a population disproportionately affected by the opioid epidemic.
- Retain and improve enforcement of mental health parity laws that strengthen private insurance coverage for evidence-based addiction services.
- Increase the number of addiction service providers through reexamination of caseload limits for certain providers and treatment programs and greater use of advance practice nurses and physician assistants.
- Build the costs of addiction, which are borne by individuals, families, employers, communities, and taxpayers, into the price of opioids and dedicate those resources to prevention and treatment.
- Engage clinicians in the use of screening tools that help identify people with opioid use disorders.
- Encourage public and private payers to expand the use of outcome-based payment models that create financial incentives for primary care clinicians and health systems to improve health outcomes, thereby creating strong incentives to identify and treat people with opioid use disorders.
- Change federal law to remove the prohibition against states obtaining federal Medicaid matching funds for treating people with opioid use dis-

orders in residential settings with more than 16 beds (the Institutions for Mental Disease (IMD) exclusion).

- Continue to educate the public about the risks of opioid misuse and the chronic nature of this medical condition to reduce stigma associated with its diagnosis and treatment.
- Invest in the design and testing of additional models of medication-assisted treatment that expand the capacity of the current addiction treatment workforce and bring in additional service providers.

5. Invest in data and knowledge

The opioid crisis emerged in part from poor understanding of how to treat chronic pain. A robust research and data analytics agenda is needed to manage appropriate opioid use, improve pain management, and reduce inappropriate prescribing and diversion of legal opioids.

An appropriate investment would include:

- Link data across states' prescription drug monitoring programs to avoid inappropriate prescribing due to shopping across state lines.
- Harness the separate data silos that exist across insurers, pharmacy benefit managers, and employers, to better understand patterns of prescribing and use.
- Redesign current prohibitions against sharing data between the medical care and mental health care systems that impede identification and treatment of people with opioid use disorder while retaining patient control over the information they choose to share.
- Continue to develop quality standards for opioid use disorder treatment as a means for holding treatment programs accountable and for encouraging resources to flow to high quality programs.
- Continue to build the evidence of the costs and benefits of opioid use.
- Continue to build the evidence regarding medication-assisted treatment to identify the most effective medications, and the most effective types of therapy, for different people with opioid use disorder.
- Study methods for treating pain, both acute and chronic, so prescribers and patients can select options other than opioids.

Moving Forward

We are encouraged by the attention this issue is getting and the progress that has already been made in embracing some of the ideas we put forward here. We especially acknowledge the efforts of the President's Commission on Combating Drug Addiction and the Opioid Crisis and look forward to follow-up actions taken in response to their recommendations.

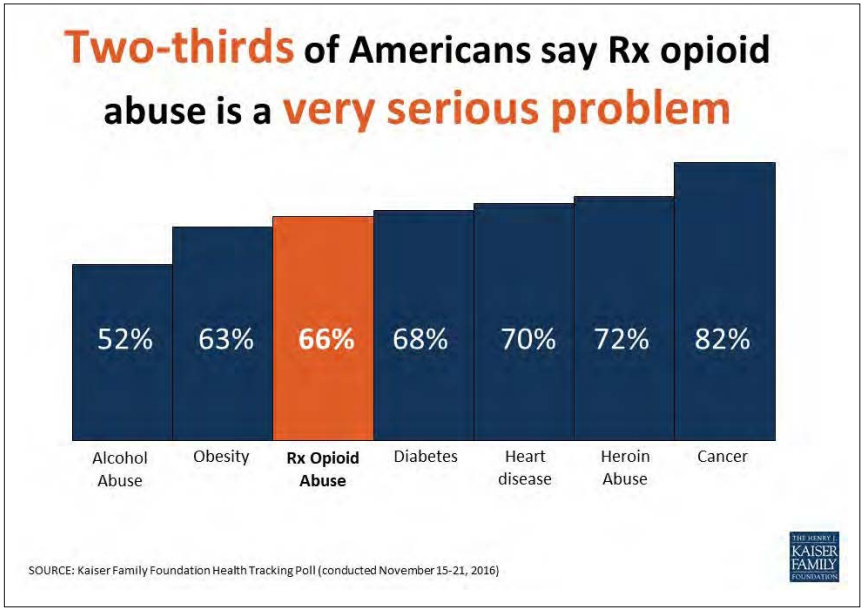
Our nation did not enter into this crisis quickly, and it will not be solved quickly. Even if we are able to dramatically reduce the number of people becoming addicted to opioids, the chronic condition of opioid use disorder will continue to afflict hundreds of thousands of Americans for many years to come. Our commitment to addressing the opioid crisis must be sustained.

Recent policy changes have helped set the stage for confronting this crisis. Mental health parity, the expansion of Medicaid coverage, and efforts across the nation to engage the criminal justice system are among the strongest platforms on which to build solutions. Coverage expansions through the *Affordable Care Act,* and the inclusion of mental health and substance use disorder services as essential benefits, are critical features of the current treatment landscape and they must be preserved. Threats to coverage, whether through the recent lapse of funding for the Children's Health Insurance Program or various efforts to repeal the *ACA* or roll back requirements regarding substance use coverage, must be resisted if we are to make progress on this crisis.

The Aspen Health Strategy Group, with its multi-sector membership, has developed these ideas to address the opioid crisis in America. It has never been more important for all parties to come together, examine the evidence, and make strides against this deadly problem.

The Aspen Health Strategy Group hopes that these big ideas will serve as catalysts for changes in policy and practice. We have a broad array of dissemination activities planned to spread the big ideas contained in this report. The leadership of the group will share this report with officials in the U.S. Department of Health and Human Services, which houses the Centers for Medicare and Medicaid Services, the National Institutes of Health, the Centers for Disease Control and Prevention, the Food and Drug Administration, and other agencies. It has already shared its findings with the President's Commission on Combating Drug Addiction and the Opioid Crisis.

The Aspen Health Strategy Group members have committed to examining steps they can take within their own institutions and organizations. They are also looking for opportunities to share these ideas with others in their own sector. Change of the scale needed to address the opioid crisis will require the effort of many. The Aspen Health Strategy Group has set out to provide leadership and looks forward to working with all who share their goal of addressing the opioid crisis.


Two-thirds of Americans say Rx opioid abuse is a very serious problem
52%
63%
66%
68%
70%
72%
82%
Alcohol Abuse
Obesity
Rx Opioid Abuse
Diabetes
Heart disease
Heroin Abuse
Cancer
SOURCE: Kaiser Family Foundation Health Tracking Poll (conducted November 15-21, 2016)
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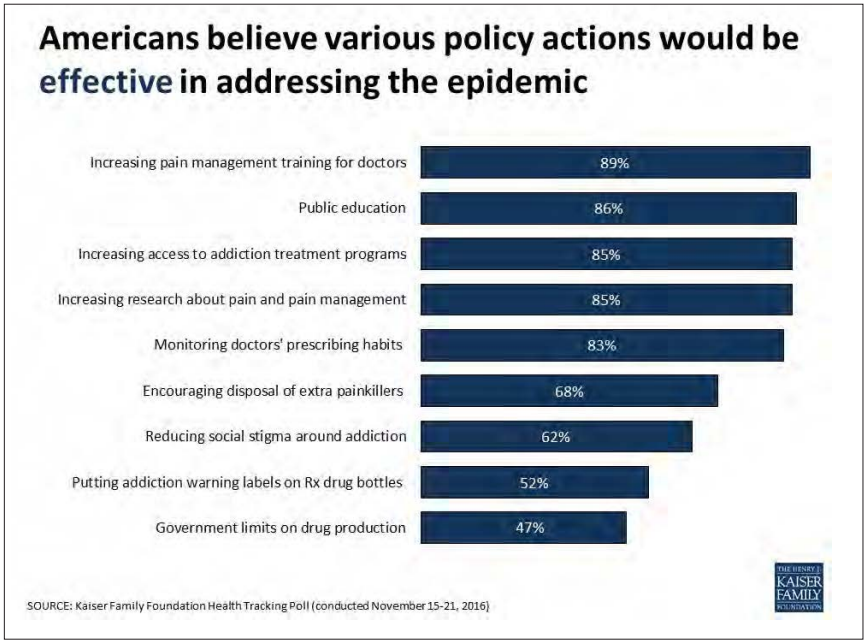
Americans believe various policy actions would be effective in addressing the epidemic
Increasing pain management training for doctors
89%
Public education
86%
Increasing access to addiction treatment programs
85%
Increasing research about pain and pain management
85%
Monitoring doctors' prescribing habits
83%
Encouraging disposal of extra painkillers
68%
Reducing social stigma around addiction
62%
Putting addiction warning labels on Rx drug bottles
52%
Government limits on drug production
47%
SOURCE: Kaiser Family Foundation Health Tracking Poll (conducted November 15-21, 2016)
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BACKGROUND PAPERS

The Opioid Crisis in America: An Overview

Harold Alan Pincus, M.D.
and
Carlos Blanco, M.D., Ph.D., M.S.

The Opioid Epidemic and the U.S. Health Care System

Keith Humphreys, Ph.D.

Part 2

Financing Care for Opioid Use Disorders

Richard G. Frank, Ph.D.
and
Carrie E. Fry, Doctoral Student

The Law's Responses to the Opioid Epidemic: Legal Solutions to a Unique Public Health, Criminal Law, and Market-Related Crisis

Amanda Pustilnik, J.D.

"Although the opioid crisis has multiple causes, two major driving factors have been a steady increase in the rate of opioid prescriptions and a decrease in the price of heroin and synthetic opioids."

– HAROLD ALAN PINCUS, M.D. and
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The Opioid Crisis in America: An Overview

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Introduction and Context

The non-medical use of prescription opioids (i.e., medications not used as prescribed or by people to whom they were not prescribed) is a major public health problem in the United States. Inappropriate use of opioids leads to death and disease, as well as increased family instability, risk of violence, legal problems, unemployment, financial hardship, and decreased social support (Compton et al., 2015).

The problem is growing. A recent national poll by the Harvard T.H. Chan School of Public Health and the *Boston Globe* found that about 40% of respondents personally knew someone who had used prescription opioids non-medically at least once in their lives (Koh, 2015). Large epidemiological studies of nationally representative samples indicate that, from 1991 to 2013, the prevalence of non-medical use of prescription opioids increased almost three-fold, from 1.5% to 4.1%, and the prevalence of addiction to prescription opioids tripled, from 0.3% to 0.9% (Blanco et al., 2007; Saha et al., 2016). Data suggest not only that the prevalence of non-medical use has increased over the last decade, but also the severity of non-medical use, as measured by the frequency of use, has increased among non-medical users (Han et al., 2015).

Origins and Evolution of the Crisis

Although the opioid crisis has multiple causes, two major driving factors have been a steady increase in the rate of opioid prescriptions and a decrease in the price of heroin and synthetic opioids. Increases in the rate of opioid prescribing followed the identification of pain in the 1990s as an insufficiently addressed clinical problem (IOM, 2011). It is estimated that approximately one-third of U.S. adults suffer from chronic pain. Pain constitutes one of the most common symptoms for which patients seek medical attention and is associated with intense

personal suffering, high rates of disability, and an economic burden surpassing one-half of $1 trillion dollars per year due to the cost of medical treatment and productivity losses (IOM, 2011; Gaskin & Richard, 2012). Vigorous efforts to close this gap in treatment were initiated at educational, clinical and policy levels. Such efforts included adding medical student course content, adding pain assessment in hospitals as a "fifth vital sign," and instituting quality metrics and patient surveys to assess pain control (Baker, 2017).

The relationship between pain and opioid addiction is complex. While there is strong evidence for the efficacy of opioids for acute pain (IOM, 2011), opioids have not been systematically studied for treatment of chronic pain, and there is substantial evidence that they can be harmful when used long-term (Dowell et al., 2016). Thus, while use of opioids for acute treatment of pain is often justified, long-term use of opioids for pain is generally less well justified and has likely contributed to overprescription of opioids. Yet, pain itself is an important risk factor for non-medical use and addiction to prescription opioids. Individuals who are in pain are more likely to become addicted to opioids in the future (Blanco et al., 2016).

It is estimated that more than 15 billion opioid tablets (more than 50 per adult) were dispensed per year in retail pharmacies in the U.S. in 2013 and 2014, dwarfing rates of prescriptions in any other country (Jones et al., 2016). There is little question that opioids are sometimes prescribed to individuals who do not need them for their pain. A 2016 Pulitzer prize-winning piece (Eyre, 2016), documenting the trail of prescription medications to areas of West Virginia, suggested that prescription drug wholesalers failed to detect suspicious orders for controlled substances or to report them to the West Virginia Board of Pharmacy. The article raised questions about the role of pharmacists, prescribers, and the agencies charged with overseeing them, in the face of clear outliers in prescribing behavior.

Diversion by patients (i.e., selling or giving prescription drugs to family or friends) is a related problem. The majority of individuals with non-medical use of or addiction to prescription opioids obtain their prescription opioids from a friend or relative who got them from a doctor, rather than from their own physician (Han et al., 2015). To our knowledge, there are no national data on the percentage

of individuals who divert their medications or the percentage of doctors who write prescriptions for individuals whom they know or suspect will divert them or not use them as prescribed. It is also unknown the proportion of addicted individuals who were initially prescribed opioids as opposed to the proportion who always obtained them illegally. This knowledge could be useful in preventing diversion of medication and in determining which strategies might be most effective in reducing non-medical use and addiction.

As awareness and understanding of the crisis has grown (Compton & Volkow, 2006; Blanco et al., 2007), the response has included prescription monitoring programs, restricting prescription of certain products through FDA rescheduling, and limiting the number of pills that can be authorized in each prescription. Initiatives to decrease the use of opioids for chronic pain face the problem that the evidence for the efficacy of other approaches to chronic pain is also limited (Dowell et al., 2016). At present, expert consensus recommends a multimodal (i.e., combination of several types of treatment), integrated and individualized approach for chronic pain, but additional research is needed to empirically support this recommendation (National Pain Strategy, 2016). Furthermore, non-opioid pain treatments such as physical therapy or cognitive-behavioral therapy are often more expensive and more time consuming for clinicians and patients. These alternatives also may not be available, particularly outside large metropolitan areas, and may not be covered by insurance. By contrast, opioids are easy to prescribe, accessible, and have relatively low cost. This imbalance creates a tension between the need to treat pain and efforts to decrease opioid prescriptions.

There has also been a recent increase in the prevalence of heroin use and addiction (Compton et al., 2016). A large epidemiological study indicated that between 2001-2002 and 2012-2013 the prevalence of lifetime heroin use (i.e., use at least once in the person's lifetime) in the U.S. increased from 0.33% to 1.6%, and the lifetime prevalence of heroin addiction increased from 0.21% to 0.69%. Increases were particularly marked among whites and those aged 18-44 (Martins et al., 2017). There is debate regarding the association between efforts to decrease use of prescription opioids and increases in the prevalence of heroin use and addiction. Although studies have consistently documented that individuals who use prescription opioids are more likely than those who don't to use heroin, only 3%-5% of individuals who used prescription drugs non-medically in the previous year also reported using heroin during the same year (Muhuri et al., 2013; Compton et al., 2016). Furthermore, increases in heroin use among non-medical users of prescription opioids preceded the development of policies to address the non-medical use of prescription opioids. Increased accessibility and purity of heroin coupled with reduced price appear to be major drivers of the recent increases in rates of heroin use (Unick et al., 2014; Mars et al., 2015).

A recent authoritative review concluded "the available data suggest that non-medical prescription-opioid use is neither necessary nor sufficient for the initiation of heroin use and that other factors are contributing to the increase in the rate of heroin use and related mortality" (Compton et al., 2016).

A more recent entrant in the opioid crisis has been fentanyl, a synthetic opioid that is medically used as an anesthetic. The low production costs of fentanyl compared to heroin ($3,500 per kilogram versus $65,000) make it an attractive option to mix it with ("lace") heroin (Frank & Pollock, 2017). However, its potency is 50- to 100-fold that of heroin. Heroin users may be inadvertently exposed to much higher doses of opioids than they realize, increasing the risk of overdose. The greater potency of fentanyl decreases the efficacy of naloxone to reverse its effects, further contributing to the lethality of fentanyl or fentanyl-laced heroin. From 2012 through 2014, the number of reported deaths involving fentanyl more than doubled, from 2628 to 5544 (Frank & Pollack, 2017). Frank and Pollack (2017) estimated that 41% of the approximately 7100 heroin-related deaths during this period involved fentanyl. Carfentanyl, a derivative of fentanyl, is an even newer entrant. It is 100 times more potent than fentanyl and 10,000 more potent than heroin, making it even more dangerous.

Medical Consequences of Misuse

The increase in non-medical use of opioids has been accompanied by an increase in associated adverse consequences. Perhaps best known and most troubling has been the increase in deadly overdoses. Between 2000 and 2014, deaths from prescription-opioid overdose nearly quadrupled (from 1.5 to 5.9 deaths per 100,000 individuals) (Compton et al., 2016), higher than the number of deaths from motor vehicle accidents (Williams & Bisaga, 2016). A recent review found that although some overdoses may represent suicidal acts, the majority of overdoses are unintentional (Darke, 2016). Most deaths occur through respiratory depression (Brecher, 1973; Monforte, 1977). Despite time to intervene, responses by witnesses of overdose are often delayed due to factors such as witnesses being impaired themselves, failure to recognize signs of acute respiratory distress, or fear of police involvement (Darke et al., 1996; Darke et al., 2000; Darke & Duflou, 2016; Tobin et al., 2005).

Contrary to what could be expected, the majority of overdose victims are not inexperienced users unaware of variations in purity and the amount consumed, but rather experienced, highly opioid-tolerant users (Darke, 2016). It is likely that individuals develop tolerance for the rewarding effects of opioids faster than for their effects on the respiratory system. As individuals increase their opioid dose to reach the same rewarding effects, they also increase their risk of death due to respiratory depression (White & Irvine, 1999).

Most overdoses involve multiple drugs (Monforte, 1977; White & Irvine, 1999; Darke & Duflou, 2016). In the past, the most common co-occurring drugs were alcohol and barbiturates. Currently, benzodiazepines are probably more common. Alcohol, barbiturates and benzodiazepines act through γ-aminobutyric acid (GABA) receptors to potentiate the inhibitory effect of opioids on the respiratory control system, which explains the increased lethality of their combination (Darke, 2016). In addition to overdoses, there have been substantial increases in emergency department visits and admissions to substance use disorder treatment programs linked to prescription opioids (Compton et al., 2016).

A second major consequence of the increase in opioid addiction is the continued risk of HIV infection. According to the Centers for Diseases Control and Prevention (CDC), 6% of new HIV diagnoses in the United States are attributed to injection drug use and another 3% to male-to-male sexual contact and injection drug use. The proportion of new cases due to injection drug use is even higher among women (13%) (CDC, 2017). HIV management in individuals who inject drugs is typically complex and challenging due to the presence of multiple medical and psychiatric comorbidities (Lopes et al., 2012) as well as social, physical, economic and legal factors that often disrupt the HIV continuum of care (Kay et al., 2016). Following diagnosis, linkage and retention in care is difficult due to mutual distrust between patients and clinicians who often see individuals with addiction as manipulative and undeserving of care (Kamarulzaman & Altice, 2015). An important research and clinical goal is to improve the integration of treatment for opioid addiction and HIV.

The opioid crisis has also led to an increase in hepatitis C virus (HCV) infection. The prevalence of HCV varies across populations of injection drug users with estimates ranging from 15%-90%. Until recently, HCV infection was very high among older injection drug users (≥80% in injection drug users aged ≥50 years), with lower rates among younger injection drug users aged 18-40 years (≤35% in recent years). There is concern that this trend could be reversed soon due to increases in opioid use and subsequent increases in injection drug use. The incidence of HCV infection among injection drug users can be as high as 40 per 100 person-years (Klevens et al., 2012), especially among new injectors (Garfein et al., 1998; Des Jarlais et al., 2005; Hagan et al., 2010). Complicating matters further, many acutely HCV-infected persons are not queried or do not answer questions about risk, delaying diagnosis and treatment and increasing the risk that they will infect additional persons either through sex or by sharing needles (Klevens et al., 2012). Coinciding with the increased prevalence of opioid addiction, there has been a recent increase in new cases of HCV. These new cases are more likely than previous cohorts to be younger, typically aged ≤24 years, white,

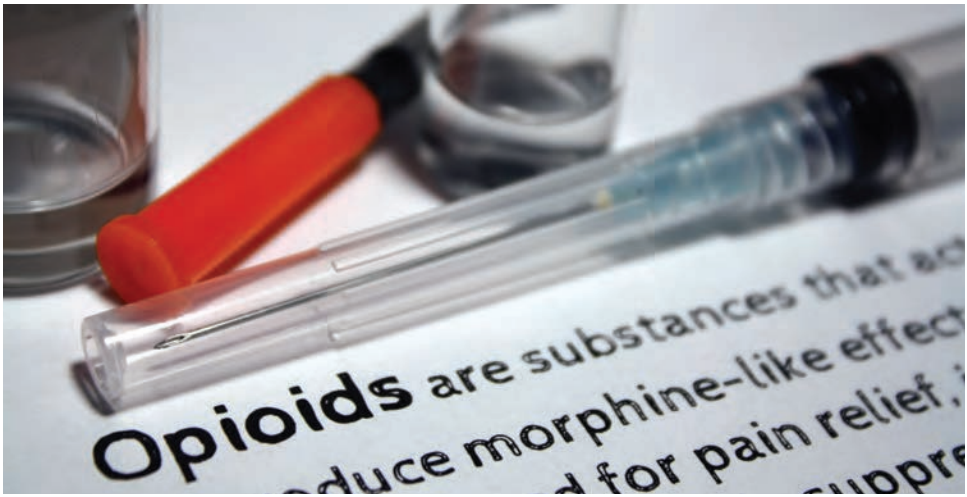
and usually rural (Klevens et al., 2012) and more likely to be co-infected with HIV (Kamarulzaman & Altice, 2015). Effective treatments for hepatitis C exist, and although their cost may be decreasing, they remain very expensive. However, opioid agonist therapy (often referred to as medication-assisted therapy) is substantially cheaper than treatment of HCV and is associated with a lower incidence of HCV infection. Maintenance treatment with methadone or buprenorphine for opioid use disorders may be an important strategy to prevent the spread of HCV infection among young injection drug users (Tsui et al., 2014).

The incidence of neonatal abstinence syndrome, a drug-withdrawal syndrome that most commonly occurs after in utero exposure to opioids, has also increased, coinciding with the increase in the prevalence of opioid addiction. A large study examining data from 299 neonatal intensive care units (NICU) in the U.S. found that, from 2004 through 2013, the rate of admission to the intensive care unit increases almost four-fold, from seven admissions per 1,000 births to 27 admissions per 1,000 births. The total percentage of NICU days nationwide increased from 0.6% to 4%, indicating not only an increase in the number of admissions, but also longer stays among those admitted. Furthermore, particularly in the later years of the study, many of the affected infants were born to mothers who used prescription opioids, rather than heroin or other opioids with no therapeutic indications (Tolia et al., 2015).

There has been a marked increase in hospitalizations associated with opioid addiction. Using discharge data from the Nationwide Inpatient Sample (NIS), the largest publicly available, all-payer, national inpatient database in the United States, a study found that hospitalizations related to opioid use disorders both with and without associated serious infection significantly increased from 2002 to 2012, from 301,707 to 520,275 and from 3,421 to 6,535, respectively. Inpatient charges for both types of hospitalizations almost quadrupled over the same period, reaching almost $15 billion for hospitalizations related to opioid addiction and over $700 million for those related to associated infections in 2012. The most common associated infections were endocarditis, osteomyelitis, and septic arthritis (Ronan & Herzig, 2016).

Who is Affected?

Certain sociodemographic groups are at increased risk for prescription opioid non-medical use and addiction (Blanco et al., 2007; Han et al., 2015; Saha et al., 2016). For example, the prevalence of addiction to prescription opioids is higher among Native Americans (1.4%), blacks (1.0%) and non-Hispanic whites (1.0%) than among Asian Americans (0.2%) and Hispanics (0.7%). The risk of



non-medical use and addiction is greater among individuals aged 18-29 (1.2%) than those age 30-64 (1.0%) or older than 65 (0.4%). It is also greater among those with only a high school diploma (1.2%), less than a high school education (1.5%), or with some college education but no college degree (0.63%). Rates of non-medical use tend to be greater in the West (4.4%) and the Midwest (4.5%) than in the Northeast (3.3%) or the South (4.1%), but rates of addiction tend to be around 0.9% in all four regions, with no significant differences among them. There are some indications that rates of non-medical use are greater among men (4.4%) than women (3.9%), but there are no sex differences in rates of addiction (0.9% for both sexes). Having a history of psychiatric disorders also increases the risk of non-medical use of prescription opioids and addiction. The risk varies by disorder. For example, having a history of addiction to another substance increases the odds of non-medical use of prescription opioids by a factor of four, and the risk of addiction by a factor of three. A history of anxiety disorders increases the odds of non-medical use and addiction by 50%. Although addiction to prescription opioids was more prevalent in rural than in urban communities in 2003-2008, more recent data suggest that prevalence no longer differs by urbanicity (Jones, 2017).

What is It About Opioids that Make Them Addictive?

From a biological perspective, three main factors contribute to non-medical use and addiction to opioids. At the most basic level, opioids have high affinity for the receptors located in reward centers in the brain (Koob & Volkow, 2016). This generates an intense desire to consume them once they have been tried.

This craving is much more intense than the desire to engage in other pleasurable activities, such as hobbies, work, food or sex, which also stimulate the brain reward centers. Simply put, opioids hijack the brain's motivational system (Kalivas & Volkow, 2005). A second reason is the strong relationship between stress and opioids. Opioids can be highly effective at decreasing pain and other forms of subjective stress, which increase their rewarding properties and make them more likely to lead to opioid use disorder (Volkow et al., 2016). Third, the brain structures involved in addiction are involved in other psychiatric disorders (Goodkind et al., 2015). Some abnormalities in brain structures affected in other psychiatric disorders may predispose towards impulsivity, anxiety or low tolerance to stress, which, in turn, will increase the likelihood of difficulties controlling opioid use and predispose a person toward non-medical use and addiction.

The existence of a genetic predisposition to the initiation and continuation of drug use is also now well-established (Kendler et al., 2000; Blanco et al., 2014; Reed et al., 2014). Brain imaging studies have convincingly shown that individuals with addictive disorders, including those addicted to opioids, have abnormalities at the level of brain receptors and brain circuits. Individuals with addictive disorders have fewer dopamine receptors in the reward center of the brain, which may lead them to seek more intense experiences (including use of drugs) than the general population to obtain comparable levels of reward. They also are more likely to have fewer receptors in the prefrontal cortex, an area of the brain related to impulse control (Goldstein & Volkow, 2011). Thus, individuals with addictive disorders are predisposed to have more difficulty resisting cravings for drugs.

There are other neurotransmitters involved in addiction, including serotonin and glutamate. Their role in addiction is an active area of research, as they could give clues for the development of new medications. It is often difficult to disentangle what preceded opioid use and what was a consequence of it. A recently started national study, the Adolescent Brain Cognitive Development (ABCD) Study, will follow 10,000 children for 10 years to investigate what biological and environmental factors predispose individuals to use drugs, including opioids, and to get addicted to them, as well as what are the effects of drugs on brain development (Adolescent Brain Cognitive Development Study, 2017). This study is likely to help clarify what precedes and what is a consequence of drug use.

Multiple Hypothesized Causes

Dear kindly Sergeant Krupke,
You gotta understand,
It's just our bringin' up-ke
That gets us out of hand.

In the musical, "West Side Story," Stephen Sondheim and Leonard Bernstein wrote a song satirizing a hapless police officer, Sergeant Krupke, who, trying to find someone to take responsibility for a "juvenile delinquent," approached a judge, a psychiatrist and a social worker. Like most complex problems (such as juvenile delinquency), the current opioid crisis has multiple roots, each of which suggests different strategies in response. Historically, addiction was considered a moral weakness or a criminal problem and there is still a strong emphasis on criminal justice approaches to opioid addiction. A wealth of evidence accumulated over the last three decades has documented the biological basis of addiction. As a result, there has been increased acceptance of opioid addiction as a medical disorder that has clear causes and treatments directed at specific neurobiological targets. Others point to the social and economic roots of these conditions. The recent rise in opioid prescriptions has also been linked to failures in the delivery of medical services, poor organization of our health system, and its incentive structures and regulatory approaches.

Overmedication

As noted above, in 2011, the Institute of Medicine (IOM) issued an influential report (Relieving Pain in America), identifying chronic pain as a major source of suffering for the U.S. population and a major source of potentially avoidable health care costs (IOM, 2011). The recommendations of the report stimulated a range of clinical and policy responses that are perceived to be a major contributor to the current crisis. While some have argued that the regulatory responses overshot their mark, others have rejoined that clinicians and hospitals over-interpreted or simplistically responded to the regulatory recommendations (Baker, 2017).

In any case, even before the IOM report, the pharmaceutical industry was heavily marketing more powerful but, perhaps, no more effective drugs. Most notably, in 2007, Purdue Pharma pleaded guilty and paid a $600 million fine for misleading regulators, doctors and patients about the risk of addiction for its drug OxyContin (Meier, 2007). Introduced in 1996 and touted as a longer-acting, less

addictive narcotic pain reliever with fewer side effects, the company made billions of dollars while the drug became increasingly popular.

As noted above, the U.S. has by far the highest rate of opioid prescribing in the world. This has led to a kind of expectation, and even normalization, of using these drugs for pain, despite the limited evidence of long-term effectiveness for relieving pain as compared to alternatives. Also witness, for example, the frequent television commercials, not for the opioids themselves, but for medications to treat the gastro-intestinal side effects of the drugs with an attractive woman in a body suit depicting an anthropomorphic version of the intestines.

Some of the prescribing and dispensing of opioids represents criminal activity, where physicians or pharmacists may knowingly dispense opioids to individuals who are using greater doses than prescribed or perhaps diverting the medications. As noted above, Eric Eyre, reporter for the *Charleston Gazette-Mail,* received the Pulitzer Prize "for courageous reporting, performed in the face of powerful opposition, to expose the flood of opioids flowing into depressed West Virginia counties with the highest overdose death rates in the country" (Eyre, 2016).

Others have argued that the expansion of opioid prescriptions is simply indicative of the failure of physicians to spend enough time with their patients. Driven by high pressure productivity expectations and a fee-for-service payment system that emphasizes procedures and volume, the path of least resistance may simply be to prescribe an opioid for chronic pain. Physicians may need to develop a more personalized, comprehensive (and more time-intensive) approach to treating pain within which prescribing opioids is a much smaller part of their armamentarium. Such an approach would take into account the needs of the patient, but also the potential for misuse or diversion. This may lead to prescribing a lower number of pills per visit and educating patients about locking their medications and not sharing them with others. Payment models encouraging more flexibility and use of "interstitial" services, such as care management, patient education and coordination and follow-up activities, would encourage use of non-physician supports as well.

Undertreatment

This view of the problem, not incompatible with the previous one, takes the position that substance use disorders are chronic medical problems and should be treated in the same way as other common chronic conditions such as diabetes, asthma, hypertension, etc. (McLellan, 2000). The wealth of evidence doc-

umenting the biological basis of addiction notwithstanding, effective systems for treatment of opioid addiction have been undermined by four fundamental barriers: (1) failure to achieve agreement on the goals of treatment; (2) failure to align various parts of a fragmented care system; (3) failure to develop accountability and incentive strategies to encourage provision of evidence-based care; and, finally, (4) the relatively low priority given to resourcing systems of care. As Keith Humphreys indicates in his paper, there are multiple effective treatments for opioid addiction. With regard to the goals of treatment, however, approaches may vary in whether they seek primarily to reduce the use of opioids, avoid the harmful effects of opioid use (either at an individual or societal level) or improve overall functioning for the individual patient. Even with regard to the achievement of reduced opioid use there are variations in terms of reducing use of illegal opioids or all opioids, and whether the goal is one of reduction or total abstinence. In any case, the treatment system has significant deficits in delivering care that is accessible, evidence-based, and coordinated, and there are insufficient mechanisms to assure accountability.

Probably most significant, is the lack of access to evidence-based care for many people with substance use disorders. Barriers to access for evidence-based treatments exist at multiple levels. For example, medication-assisted treatment, a topic briefly summarized below and addressed in more detail elsewhere, is a well-established evidence-based treatment for opioid dependence. In 2013, less than one-fourth of adults aged 18 through 64 years who had prescription opioid use disorder received any type of substance use treatment (Han, 2015). In a review of over 35,000 records of individuals hospitalized for opioid abuse or overdose, only 16.7% received any form of medication-assisted treatment within the 30 days following discharge (Naeger et al., 2016).

Because opioid addiction affects disproportionately individuals of low socioeconomic status, public payer coverage of medication-assisted treatment is crucial to ensure access to treatment for those who could not afford it otherwise. At present, most states have policies that cover both buprenorphine and methadone among Medicaid enrollees (Burns et al., 2016). However, some states have

policies, such as prior authorization requirements, which can serve as a barrier to physicians prescribing medications, as well as copayments, which increase the cost to patients of obtaining medications. Other factors that can interfere with (or promote) the adoption and diffusion of medication-assisted treatment include state licensing and regulation of treatment facilities, facility funding sources, and parity laws. Restrictions imposed on pharmacy benefits such as preauthorization, "fail-first," quantity limits, and lifetime limits on duration of therapy intended to support appropriate cost-effective prescribing are barriers for both patients and providers and contribute to reduced uptake of medication-assisted treatment. Requirements for concurrent counseling can also serve as a barrier to opioid agonist therapy if such services are not easily accessible and for patients who prefer not to have these services. There are some indications, though, that the number of physicians with waivers to prescribe buprenorphine is growing, particularly among primary care physicians, and this growth is larger in states that have adopted the provisions of the *Affordable Care Act* (Knudsen et al., 2015; Turner et al., 2015).

Health System Failure

The U.S. health care system is riddled with problems of fragmentation, but the substance use disorder treatment system is an extreme case. Care may be centered in various types of hospitals, specialty substance treatment settings (both residential and outpatient), mental health clinics, primary care, criminal justice settings and social service organizations. Comorbidity of opioid dependence with mental disorders and general medical conditions is common and coercive elements imposed by the legal system are a frequent occurrence. Providers administering care for individuals with substance use disorders are highly diverse with significant variation in training in evidence-based practices. In addition, privacy rules at both federal and state levels often inhibit communication among providers and systems. As such, effective coordination of care is limited and maintaining accountability for quality and performance across the different silos is difficult.

Social Failure

Other commentators have depicted a very different narrative for the evolution of the opioid crisis (Achenbach & Keating, 2017; Donnan, 2017). Building on findings by Case and Deaton (2015) that white Americans with a high school education or less are more likely to die earlier than those who are black or Hispanic, multiple commentators have noted the links among this education gap, unemployment, suicide and deaths due to alcohol and drugs. They also found

that that this trend was unique to the U.S. While this narrative often includes links to the promotion of OxyContin, it also reflects the increased use of heroin by those same demographic groups. While there is some truth to the notion that there is some concentration of opioid addiction in Rust-belt states, contrary to popular belief, recent epidemiologic studies do not show greater prevalence of opioid addiction in rural areas. It is also important to note this relatively sudden attention to the plight of white opioid users has engendered a strong backlash among African Americans who note that the sort of social ills described in these narratives have been present in their community for years, yet have received relatively little attention and few resources in response (McKenzie, 2017).

Legal Failure

Two (somewhat competing) lines of thought support the notion that our approaches to treating opioid use as a criminal issue have contributed to the opioid crisis. First, there has been a failure to stem the supply of opioids that have entered the market for illegal use. Second, the moral opprobrium attached to the criminal use of opioids has limited options for public health interventions and created opposition to (or, at least skepticism of) harm reduction strategies.

The supply of illegally used opioids has three components: (1) those entering from outside the U.S.; (2) those produced illegally in this country; and (3) those that are legally prescribed but diverted to illegal use. Different strategies are required to reduce the supply of opioids at each of the sources. In particular, the availability of cheap sources of heroin and synthetic opioids has had a significant impact in a price sensitive market. Approaches to address these supply lines range from border control and diplomatic initiatives in foreign relations to tracking down the sites of synthetic opioid production to arresting middlemen suppliers to prosecuting prescribers funneling opioids into the system for profit to prosecuting users. Many argue that there are simply not enough resources being put into supply reduction activities.

Yet, the supply of illegally used opioids is more complex. For example, opioids are frequently prescribed to individuals receiving hospice services or a prescription after an ER visit or in a general outpatient setting with no real controls once a prescription is filled. In some proportion of the cases, the pills are diverted by friends, family members, attendants, or others. Caregivers are under tremendous stress, providers want to relieve pain for patients with serious illnesses and we don't really know what works, both from a regulatory or clinical perspective to reduce diversion.

Some argue that the "brain disease" model of drug dependence is an alternative framework to moral and criminal approaches, which turn people away from care and stigmatize them. On the other hand, others argue that sometimes coercive approaches can augment clinical treatment. For example, Sally Satel, a psychiatrist who specializes in substance use disorders treatment and a resident scholar at the American Enterprise Institute has noted: "I speak from long experience when I say that few heavy users can simply take a medication and embark on a path to recovery. It often requires a healthy dose of benign paternalism and, in some cases, involuntary care through civil commitment. Many families see such legal action as the only way to interrupt the self-destructive cycle in which their loved ones are caught" (Satel quoted in Brooks, 2017).

Lessons from Abroad and from the Past

Experience from the past and from other countries can inform potential responses to the current crisis. Based on the 1961 Single Convention on Narcotic Drugs (United Nations Single Convention on Narcotic Drugs, 1961) and the 1998 United Nations General Assembly Special Sessions on Drugs (United Nations General Assembly, 1998), which declared drugs "a grave threat to the health and well-being of all mankind," past approaches have focused on drug prohibition, law enforcement and criminal justice. Although still dominant in certain countries, particularly in Asia and Eastern Europe, a recent review suggested that those approaches are no longer tenable due to their lack of efficacy and their frequent association with violation of human rights, including arrest of people who use drugs; poor access to opioids and other needed medications; ethnic and racial discrimination in drug law enforcement; and even the use of the death penalty for drug offenses. The review found that repressive drug policing contributed to risk of HIV infection and represented an important barrier to medication-assisted treatment and syringe exchange programs (Csete et al., 2016).

More recently, both the UN and the World Health Organization (WHO) have advocated for strategies that move away from law-enforcement-led and abstinence-based approaches and towards approaches that favor prevention and treatment of drug use (including opioid addiction) and harm reduction (United Nations High Commissioner for Human Rights, 2015; United Nations Development Programme, 2015; World Health Organization, 2016). Emerging evidence, especially from some European countries such as Portugal and the Czech Republic, suggests that these approaches can save money and increase public health benefits without significant increases in drug use. Other cases, such as Switzerland and the city of Vancouver, British Columbia, have focused on com-

prehensive harm reduction models, including supervised injection sites and heroin assisted treatment, as well as provision of psychosocial services (Csete et al., 2016).

France has focused on a large expansion of buprenorphine treatment. In the French model, there is no requirement for any specialized training for the physicians; there is also no requirement for urine testing, and it is possible for pharmacies to provide daily, supervised dosing of buprenorphine, if specified by the physician. The French health care system is organized on a pay-per-service basis with universal medical coverage. The social security system acts as a universal medical insurance that covers over 90% of the population, regardless of an individual's economic situation, legal status, or nationality. Because opioid dependence qualifies as a chronic illness in the French health care system, payment is fully covered by social security. This removes an important barrier to care for low-income populations. In addition, there is a dense psychosocial support service funded by local authorities available at no charge to those in need (Auriacombe et al., 2004; Carrieri et al., 2006).

Two experts have recently suggested that lessons from the AIDS epidemic may also help inform effective approaches to the current opioid crisis (Williams & Bisaga, 2016). This would include more intense efforts to train and support clinicians who may be new to the treatment of opioid dependence and addictive disorders more generally, as well as for the treatment of opioid dependence and consultation with experts. They also suggested increased funding for wrap-around social services, similar to those provided through the *Ryan White CARE Act* for people with HIV/AIDS. This funding could support the work of social workers, nurse care managers and outreach workers to help marginalized or hard-to-reach populations. Williams and Bisaga also suggested that, just as regulations were relaxed to allow the FDA to fast-track antiretroviral drug development, there could be regulatory changes to facilitate access to medication-assisted treatment through the use of specialized community pharmacies, telemedicine and hub-and-spoke systems of care. Some of those systems, such as use of community pharmacies or the provision of interim methadone and buprenorphine (i.e., without concomitant counseling) are already being considered or tested in the U.S. and Canada based on empirical support provided by research studies.

Another suggested option would be the hub-and-spoke model used in Vermont, in which substance use disorders treatment programs stabilize patients using medication-assisted treatment and then refer them to local "spokes" such as community health centers or private practitioners. Emergency funding to states to pay for medications, much as it was done for HIV medications, would

also facilitate access to treatment for those most in need. The enactment of the *21st Century Cures Act* which allocated $1.1 billion to states for the treatment of opioid addiction may help implement some of these solutions. On a longer-term basis, Williams and Bisaga suggested that the Centers for Medicare and Medicaid Services, which regulate and administer the largest public insurance programs in the U.S., could make methadone and buprenorphine maintenance treatment a mandated benefit, in accordance with the *Affordable Care Act* requirement that treatment for substance use disorders be considered an essential health benefit. Recent approaches to the Ebola and Zika epidemics, which have killed few Americans compared to almost 250,000 dead from opioids in the past 20 years, may provide other models for how to mount a comprehensive response to a public health crisis.

Options for the U.S.

Better Prescribing

In cases where there is clear overprescribing of opioids, there is a role for state health departments and Medicaid programs (or other regulatory bodies) to monitor unusual patterns of prescribing and dispensing. Additional regulatory and manufacturing approaches and marketing restrictions are described in accompanying papers. There has also been expansion of the systematic use of prescription drug monitoring programs (PDMPs), which electronically track prescriptions of all controlled drugs and can help clinicians be aware of medications prescribed by other doctors. Although laws requiring or authorizing their use vary by state, PDMPs now operate in 49 states (all except Missouri) and in Washington, DC (Schwartz, 2014). A preliminary analysis of mandated PDMP use in Kentucky, Tennessee, and New York showed fewer episodes of patients seeking prescription opioids from multiple providers (Koh, 2015). Nevertheless, many PDMPs still need substantial improvements to reach the ideal in which they are easy to use, offer standardized content, update information in real time, and demonstrate interstate accessibility (Koh, 2015).

Most physicians seek to help their patients and efforts to educate and otherwise influence health professionals are critical. Perhaps the most important progress in this area has been the development of the Centers for Disease Control and Prevention prescribing guidelines for the use of opioids for the treatment of pain (Dowell et al., 2016). There is limited research on the treatment of chronic pain and these guidelines were largely based on consensus expert recommendations. Future research will serve to refine the guidelines and provide stronger empirical support for them. A second important development regarding the education of health professionals is the requirement by some jurisdictions of additional training for individuals who prescribe controlled substances. For example, New York State now requires a completion of a mandatory 3-hour course for all individuals authorized to prescribe controlled substances (e.g., some anti-anxiety medications such as clonazepam) even if they do not prescribe opioids.

Expand Access to Naloxone

To reduce deaths from opioid overdoses, it is crucial to maintain and expand access to naloxone, a short-acting opioid antagonist used for the reversal of opioid overdoses. Every overdose that is not reverted is a life that might have been saved if the overdose had been reverted and the person linked to treatment. Until recently, the use of naloxone was limited by the requirement that health care professionals administer it. The development of user-friendly forms of administration such as the auto-injectable form and particularly the intranasal form, are likely to increase the use of naloxone, particularly by first responders and friends or relatives of individuals with opioid dependence. It is probably still too early to estimate the improved accessibility and effectiveness of these new delivery systems. A new challenge in the use of naloxone has been the increase in the use of fentanyl (and more recently carfentanyl) either in isolation or mixed with heroin. Because fentanyl is 50-100 times more potent and carfentanyl is 10,000 times more potent than heroin, standard doses of naloxone may be insufficient to reverse overdoses due to these compounds. Development of longer-lasting, more potent antagonists might be helpful in reversing overdoses related to fentanyl, carfentanyl or other high-potency opioids.

Improving Treatment

In the course of reforming the U.S. health care system, both before and since the *Affordable Care Act*, multiple policy strategies have been initiated to enhance quality, safety, efficiency and accountability. A series of reports from the Institute of Medicine has played a particular role in identifying problems in these areas,

including, Improving the Quality of Health Care for Mental and Substance-Use Conditions (IOM, 2006). That report identified key barriers in achieving better quality, in particular, the lack of sufficient development of a quality measurement and improvement infrastructure in the substance use disorders treatment field. While there have been some improvements in the development of quality measures, very few have been fully validated, endorsed by key organizations such as the National Quality Forum (NQF) or the National Committee for Quality Assurance (NCQA), or used by public or private payers to hold providers, systems and payers accountable. In addition, the establishment of parity laws and inclusion of substance use disorders treatment services in the required package of insurance benefits play key roles in breaking down barriers to care.

Potential amelioration is on the horizon, however. One billion dollars has been authorized by the *21st Century Cures Act* to be provided to states to expand substance use disorders treatment services. Additional quality measures are making their way through the endorsement process. Nonetheless, there is still a lack of full acceptance of the concept of treating drug addiction as a chronic disease requiring continuing, indeterminate care. Even now, there is continuing debate about the language to be used in referring to addiction and the potential stigma of using terms such as "addict" and "medication-assisted treatments" (Botticelli & Koh, 2016; Calver & Saitz, 2017). However, even the $1 billion may be insufficient to ensure full accessibility to evidence-based care to all in need and the question of continuing resources remains.

Linking Criminal Justice and Public Health

One expanding approach to integrating criminal justice and treatment systems has been the referral of drug-involved offenders to drug courts. These settings provide a way for offenders to avoid incarceration as long as they participate in treatment and avoid using illegal drugs. Similar types of linkages between criminal justice and public health activities have been advocated by Dr. Tom Frieden, the former director of the CDC. He has been quoted as saying: "If law enforcement can substantially interfere with the supply of illicit opioids, it will save a lot of lives" (Frieden quoted in Katz, 2017), suggesting that partnerships with public health professionals would enable elimination of sources of especially deadly drugs and identification of individuals who might benefit from treatment.

Addressing Social Needs

In many communities distress, malaise, unemployment and failed expectations are risk factors, and broader social and economic approaches that link to job

growth and offer vocational training and other social services are an important part of a solution. As David Brooks has noted in the *New York Times*: "This isn't just about painkillers run amok. Instant and slow-motion suicide by alcohol and a range of other drugs are rising at the same time. And these addictions and deaths are happening in the most socially and economically barren parts of the country. An anti-opioid effort won't be effective unless it's part of a broader effort at social and economic reweaving, a set of efforts to either help people move out of rural, blighted communities or to find jobs and social networks while there" (Brooks, 2017).

Conclusion

The opioid crisis has complex causes and manifestations. As we consider solutions, it may be wise to reflect on the words of Dr. Vivek Murthy in the introduction to the his Surgeon General's Report on Alcohol, Drugs and Health: "I recognize there is no single solution. We need more policies and programs that increase access to proven treatment modalities. We need to invest more in expanding the scientific evidence base for prevention, treatment, and recovery. We also need a cultural shift in how we think about addiction. For far too long, too many in our country have viewed addiction as a moral failing. This unfortunate stigma has created an added burden of shame that has made people with substance use disorders less likely to come forward and seek help. It has also made it more challenging to marshal the necessary investments in prevention and treatment. We must help everyone see that addiction is not a character flaw – it is a chronic illness that we must approach with the same skill and compassion with which we approach heart disease, diabetes, and cancer" (U.S. Department of Health and Human Services, 2016).

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The opinions expressed in this manuscript are those of the authors and do not necessarily represent the views of the National Institute on Drug Abuse, the National Institutes of Health or any other agency of the U.S. government.

References

Achenbach, J. & Keating, D. (2017, March 23). New research identifies a 'sea of despair' among white, working-class Americans. *The Washington Post*. Retrieved from: https://www.washingtonpost.com/national/health-science/new-research-identifies-a-sea-of-despair-among-white-working-class-americans/2017/03/22/c777ab6e-0da6-11e7-9b0d-d27c98455440_story.html

Adolescent Brain Cognitive Development Study. (2017, October 21). Retrieved from: https://abcdstudy.org/

Auriacombe, M., Fatséas, M., Dubernet, J., Daulouède, J.P., & Tignol, J. (2004). French field experience with buprenorphine. *The American Journal on Addictions*, 13(Suppl 1), S17-28.

Baker, D.W. (2017). History of The Joint Commission's pain standards: Lessons for today's prescription opioid epidemic. *Journal of the American Medical Association*, 317(11), 1117-1118.

Blanco, C., Alderson, D., Ogburn, E., Grant, B.F., Nunes, E.V., Hatzenbuehler, M.L., & Hasin, D.S. (2007). Changes in the prevalence of non-medical prescription drug use and drug use disorders in the United States: 1991-1992 and 2001-2002. *Drug and Alcohol Dependence*, 90(2-3), 252-260.

Blanco, C., Rafful, C., Wall, M.M., Ridenour, T.A., Wang, S., & Kendler, K.S. (2014). Towards a comprehensive developmental model of cannabis use disorders. *Addiction*, 109(2), 284-294.

Blanco, C., Wall, M.M., Okuda, M., Wang, S., Iza, M., & Olfson, M. (2016). Pain as a predictor of opioid use disorder in a nationally representative sample. *American Journal of Psychiatry*, 173(12), 1189-1195.

Botticelli, M.P. & Koh, H.K. (2016). Changing the language of addiction. *Journal of the American Medical Association*, 16(13), 1361-1362.

Brecher, E.M. (1973). Licit and Illicit Drugs; The Consumers Union Report on Narcotics, Stimulants, Depressants, Inhalants, Hallucinogens, and Marijuana. Boston, MA: Little Brown & Co.

Brooks, D. (2017, April 4). Let's go for a win on opioids. *The New York Times.* Retrieved from: https://www.nytimes.com/2017/04/04/opinion/lets-go-for-a-win-on-opioids.html?_r=1

Burns, R.M., Pacula, R.L., Bauhoff, S., Gordon, A.J., Hendrikson, H., Leslie, D.L., & Stein, B.D. (2016). Policies related to opioid agonist therapy for opioid use disorders: The evolution of state policies from 2004 to 2013. *Substance Abuse*, 37(1), 63-69.

Calver, K.E. & Saitz, R. (2017). Substance use terminology. *Journal of the American Medical Association*, 317(7), 768-769.

Carrieri, M.P., Amass, L., Lucas, G.M., Vlahov, D., Wodak, A., & Woody, G.E. (2006). Buprenorphine use: The international experience. *Clinical Infectious Diseases*, 43(Suppl 4), S197-215.

Case, A. & Deaton, A. (2015). Rising morbidity and mortality in midlife among white non-Hispanic Americans in the 21st century. *Proceedings of the National Academy of Sciences of the United States of America*, 112(49), 15078-15083.

Centers for Disease Control and Prevention (CDC) (2017, October 21). HIV and Injection Drug Use. Retrieved from: https://www.cdc.gov/hiv/risk/idu.html

Compton, W.M., Jones, C.M., & Baldwin, G.T. (2016). Relationship between nonmedical prescription-opioid use and heroin use. *New England Journal of Medicine*, 374(2), 154-163.

Compton, W.M. & Volkow, N.D. (2006). Major increases in opioid analgesic abuse in the United States: Concerns and strategies. *Drug and Alcohol Dependence*, 81(2), 103-107.

Csete, J., Kamarulzaman, A., Kazatchkine, M., Altice, F., Balicki, M., Buxton, J., Cepeda, J., Comfort, M., Goosby, E., Goulão, J., Hart, C., Kerr, T., Lajous, A.M., Lewis, S., Martin, N., Mejía, D., Camacho, A., Mathieson, D., Obot, I., Ogunrombi, A., Sherman, S., Stone, J., Vallath, N., Vickerman, P., Zábranský, T., & Beyrer, C. (2016). Public health and international drug policy. *Lancet*, 387(10026), 1427-1480.

Darke, S. (2016). Heroin overdose. *Addiction*, 111(11), 2060-2063.

Darke, S. & Duflou, J. (2016). The toxicology of heroin-related death: Estimating survival times. *Addiction*, 111(9), 1607–1613.

Darke, S., Ross, J., & Hall, W. (1996). Overdose among heroin users in Sydney, Australia: II. responses to overdose. *Addiction*, 91(3), 413–417.

Darke, S., Ross, J., Zador, D., & Sunjic, S. (2000). Heroin-related deaths in New South Wales, Australia, 1992–1996. *Drug and Alcohol Dependence*, 60(2), 141–150.

Des Jarlais, D.C., Perlis, T., Arasteh, K., Torian, L.V., Hagan, H., Beatrice, S., Smith, L., Wethers, J., Milliken, J., Mildvan, D., Yancovitz, S., & Friedman, S.R. (2005). Reductions in hepatitis C virus and HIV infections among injecting drug users in New York City, 1990–2001. *AIDS*, 19(Suppl 3), S20–25.

Donnan, S. (2017, March 23). 'Deaths of despair' surge among U.S. white working class. *Financial Times*. Retrieved from: https://www.ft.com/content/34637e1a-0f41-11e7-b030-768954394623

Dowell, D., Haegerich, T.M., & Chou, R. (2016). CDC guideline for prescribing opioids for chronic pain — United States, 2016. *MMWR Recommendations and Reports*, 65(No. RR-1), 1–49.

Eyre, E. (2016, December 17). Drug firms poured 780M painkillers into WV amid rise of overdoses. *Charleston Gazette-Mail*. Retrieved from: https://www.wvgazettemail.com/news/health/drug-firms-poured-m-painkillers-into-wv-amid-rise-of/article_78963590-b050-11e7-8186-f7e8c8a1b804.html

Frank, R.G. & Pollack, H.A. (2017). Addressing the fentanyl threat to public health. *New England Journal of Medicine*, 376(7), 605-607.

Garfein, R.S., Doherty, M.C., Monterroso, E.R., Thomas, D.L., Nelson, K.E., & Vlahov, D. (1998). Prevalence and incidence of hepatitis C virus infection among young adult injection drug users. *Journal of Acquired Immune Deficiency Syndrome Human Retrovirus,* 18(Suppl 1), S11–19.

Gaskin, D.J. & Richard, P. (2012). The economic costs of pain in the United States. *The Journal of Pain*, 13(8), 715-724.

Goldstein, R.Z. & Volkow, N.D. (2011). Dysfunction of the prefrontal cortex in addiction: Neuroimaging findings and clinical implications. *Nature Reviews Neuroscience,* 12(11), 652-69.

Goodkind, M., Eickhoff, S.B., Oathes, D.J., Jiang, Y., Chang, A., Jones-Hagata, L.B., Ortega, B.N., Zaiko, Y.V., Roach, E.L., Korgaonkar, M.S., Grieve, S.M., Galatzer-Levy, I., Fox, P.T., & Etkin, A. (2015). Identification of a common neurobiological substrate for mental illness. *JAMA Psychiatry*, 72(4), 305-315.

Greisman, H.C. (2017, March 27). Little hope of a route out of poverty for those who live in the transit desert. *Financial Times*. Retrieved from: https://www.ft.com/content/3c2a0c34-12ea-11e7-80f4-13e067d5072c

Hagan, H., Pouget, E.R., Williams, I.T., Garfein, R.L., Strathdee, S.A., Hudson, S.M., Latka, M.H., & Ouellet, L.J. (2010). Attribution of hepatitis C virus seroconversion risk in young injection drug users in 5 U.S. cities. *The Journal of Infectious Diseases*, 201(3), 378–385.

Han, B., Compton, W.M., Jones, C.M., & Cai, R. (2015). Nonmedical prescription opioid use and use disorders among adults aged 18 through 64 years in the United States, 2003-2013. *Journal of the American Medical Association*, 314(14), 1468-1478.

Hari, J. (2017, January 12). Op-Ed: What's really causing the prescription drug crisis? *Los Angeles Times*. Retrieved from: http://www.latimes.com/opinion/op-ed/la-oe-hari-prescription-drug-crisis-cause-20170112-story.html

Institute of Medicine (IOM) (2006). Improving the Quality of Health Care for Mental and Substance-Use Conditions. Washington, DC: National Academies Press.

Institute of Medicine (IOM) (2011). Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research. Washington, DC: National Academies Press.

Jones, C.M. (2017). The paradox of decreasing nonmedical opioid analgesic use and increasing abuse or dependence – An assessment of demographic and substance use trends, United States, 2003-2014. *Addictive Behaviors*, 65, 229-235.

Jones, C.M., Lurie, P.G., & Throckmorton, D.C. (2016). Effect of U.S. Drug Enforcement Administration's rescheduling of hydrocodone combination analgesic products on opioid analgesic prescribing. *JAMA Internal Medicine,* 176(3), 399-402.

Kalivas, P.W. & Volkow, N.D. (2005). The neural basis of addiction: A pathology of motivation and choice. *American Journal of Psychiatry*, 162(8), 1403-1413.

Kamarulzaman, A. & Altice, F.L. (2015). Challenges in managing HIV in people who use drugs. *Current Opinion in Infectious Disease*, 28(1), 10-16.

Katz, J. (2017, April 14). You draw it: Just how bad is the drug overdose epidemic? *The New York Times*. Retrieved from: https://www.nytimes.com/interactive/2017/04/14/upshot/drug-overdose-epidemic-you-draw-it.html?_r=0

Kay, E.S., Batey, D.S., & Mugavero, M.J. (2016). The HIV treatment cascade and care continuum: Updates, goals, and recommendations for the future. *AIDS Research and Therapy,* 13, 35.

Kendler, K.S., Karkowski, L.M., Neale, M.C., & Prescott, C.A. (2000). Illicit psychoactive substance use, heavy use, abuse, and dependence in a U.S. population-based sample of male twins. *Archives of General Psychiatry*, 57(3), 261-269.

Klevens, R.M., Hu, D.J., Jiles, R., & Holmberg, S.D. (2012). Evolving epidemiology of hepatitis C virus in the United States. *Clinical Infectious Diseases*, 55 (Suppl 1), S3-9.

Knudsen, H.K., Lofwall, M.R., Havens, J.R., & Walsh, S.L. (2015). States' implementation of the Affordable Care Act and the supply of physicians waivered to prescribe buprenorphine for opioid dependence. *Drug and Alcohol Dependence*, 157, 36-43.

Koh, H. (2015). Community approaches to the opioid crisis. *Journal of the American Medical Association*, 314(14), 1437-1438.

Koob, G.F. & Volkow, N.D. (2016). Neurobiology of addiction: A neurocircuitry analysis. *Lancet Psychiatry*, 3(8), 760-773.

Lopes, M., Olfson, M., Rabkin, J., Hasin, D.S., Alegría, A.A., Lin, K.H., Grant, B.F., & Blanco, C. (2012). Gender, HIV status, and psychiatric disorders: Results from the National Epidemiologic Survey on Alcohol and Related Conditions. *Journal of Clinical Psychiatry*, 73(3), 384-391.

Mars, S.G., Fessel, J.N., Bourgois, P., Montero, F., Karandinos, G., & Ciccarone, D. (2015). Heroin related overdose: The unexplored influences of markets, marketing and sourcetypes in the United States. *Social Science and Medicine*, 140, 44-53.

Martins, S.S., Sarvet, A., Santaella-Tenorio, J., Saha, T., Grant, B.F., & Hasin, D.S. (2017). Changes in U.S. lifetime heroin use and heroin use disorder: Prevalence from the 2001-2002 to 2012-2013 National Epidemiologic Survey on Alcohol and Related Conditions. *JAMA Psychiatry*, 74(5), 445-455.

McKenzie, K. (2017, April 1). Largely white opioid epidemic highlights black frustration. *Deseret News/Associated Press*. Retrieved from: http://www.deseretnews.com/article/765693543/Largely-white-opioid-epidemic-highlights-black-frustration.html

McLellan, A.T., Lewis, D.C., O'Brien, C.P., & Kleber, H.D. (2000). Drug dependence, a chronic medical illness: Implications for treatment, insurance, and outcomes evaluation. *Journal of the American Medical Association*, 284(13), 1689-1695.

Meier, B. (2007, May 10). In guilty plea, OxyContin maker to pay $600 million. *The New York Times.* Retrieved from: http://www.nytimes.com/2007/05/10/business/11drug-web.html

Monforte, J.R. (1977). Some observations concerning blood morphine concentrations in narcotic addicts. *Journal of Forensic Science*, 22(4), 718–724.

Muhuri, P.K., Gfroerer, J.C., & Davies, M.C. (2013). Associations of nonmedical pain reliever use and initiation of heroin use in the United States. *CBHSQ Data Review*, 17.

Naeger, S., Mutter, R., Ali, M.M., Mark, T., & Hughey, L. (2016). Post-discharge treatment engagement among patients with an opioid-use disorder. *Journal of Substance Abuse Treatment*, 69, 64-71.

National Pain Strategy. A Comprehensive Population Health-Level Strategy for Pain. (2017, October 21). Retrieved from: https://iprcc.nih.gov/sites/default/files/HHSNational_Pain_Strategy_508C.pdf

Reed, B., Butelman, E.R., Yuferov, V., Randesi, M., & Kreek, M.J. (2014). Genetics of opiate addiction. *Current Psychiatry Reports*, 16(11), 504.

Ronan, M.V. & Herzig, S.J. (2016). Hospitalizations related to opioid abuse/dependence and associated serious infections increased sharply, 2002-12. *Health Affairs*, 35(5):832-837.

Ryan White Comprehensive AIDS Resources Emergency Act, P.L. 101–381, 104 Stat. 576 (1990).

Saha, T.D., Kerridge, B.T., Goldstein, R.B., Chou, S.P., Zhang, H., Jung, J., Pickering, R.P., Ruan, W.J., Smith, S.M., Huang, B., Hasin, D.S., & Grant, B.F. (2016). Nonmedical prescription opioid use and DSM-5 nonmedical prescription opioid use disorder in the United States. *Journal of Clinical Psychiatry,* 77(6), 772-780.

Schwarz, A. (2014, July 20). Missouri alone in resisting prescription drug database. *The New York Times.* Retrieved from: https://www.nytimes.com/2014/07/21/us/missouri-alone-in-resisting-prescription-drug-database.html?_r=1

Tobin, K.E., Davey, M.A., & Latkin, C.A. (2005). Calling emergency medical services during drug overdose: An examination of individual, social and setting correlates. *Addiction*, 100(3), 397–404.

Tolia, V.N., Patrick, S.W., Bennett, M.M., Murthy, K., Sousa, J., Smith, P.B., Clark, R.H., & Spitzer, A.R. (2015). Increasing incidence of the neonatal abstinence syndrome in U.S. neonatal ICUs. *New England Journal of Medicine*, 372(22), 2118-2126.

Tsui, J.I., Evans, J.L., Lum, P.J., Hahn, J.A., & Page, K. (2014). Association of opioid agonist therapy with lower incidence of hepatitis C virus infection in young adult injection drug users. *JAMA Internal Medicine*, 174(12), 1974-1981.

Turner, L., Kruszewski, S.P., & Alexander, G.C. (2015). Trends in the use of buprenorphine by office-based physicians in the United States, 2003-2013. *The American Journal on Addictions*, 24(1), 24-29.

21st Century Cures Act (2015). P.L. 114-255, 130 Stat. 1033.

Unick, G., Rosenblum, D., Mars, S., & Ciccarone, D. (2014). The relationship between U.S. heroin market dynamics and heroin-related overdose, 1992–2008. *Addiction*, 109(11), 1889-1898.

United Nations Commission on Narcotic Drugs (2014). Joint Ministerial Statement of the 2014 High-Level Review by the Commission on Narcotic Drugs of the Implementation by Member States of the Political Declaration and Plan of Action on International Cooperation Towards an Integrated and Balanced Strategy to Counter the World Drug Problem.

United Nations Development Programme (2015). Addressing the Development Dimensions of Drug Policy.

United Nations General Assembly (1998). Political Declaration of the UN General Assembly Special Session on the World Drug Problem.

United Nations High Commissioner for Human Rights (2015). Study on the Impact of the World Drug Problem on the Enjoyment of Human Rights. Human Rights Council, 30th session.

United Nations Single Convention on Narcotic Drugs (1961). 1961 as Amended by the 1972 Protocol Amending the Single Convention on Narcotic Drugs.

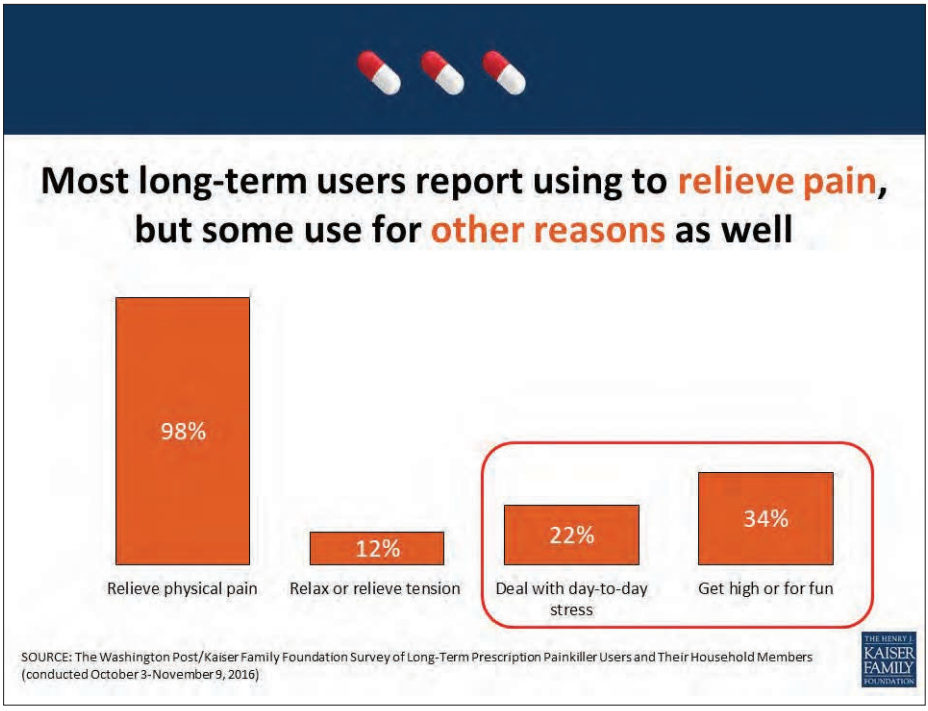
U.S. Department of Health and Human Services (HHS), Office of the Surgeon General (2016). Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health. Washington, DC: HHS.

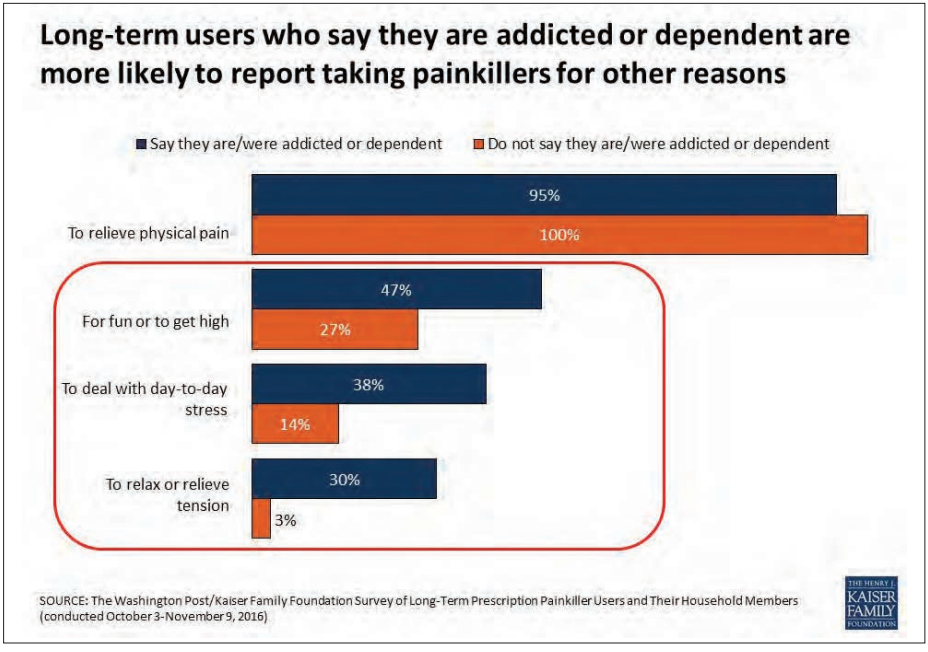
Volkow, N.D., Koob, G.F., & McLellan, A.T. (2016). Neurobiologic advances from the brain disease model of addiction. *New England Journal of Medicine*, 374(4), 363-371.

White, J. & Irvine, R. (1999). Mechanisms of fatal opioid overdose. *Addiction*, 94(7), 961–972.

Williams, A.R. & Bisaga, A. (2016). From AIDS to opioids – how to combat an epidemic. *New England Journal of Medicine*, 375(9), 813-815.

World Health Organization (2016). Public Health Dimension of the World Drug Problem Including in the Context of the Special Session of the United Nations General Assembly on the World Drug Problem, to be held in 2016: Report of the Secretariat. 138th session, doc. EB 138/11.


Most long-term users report using to relieve pain, but some use for other reasons as well
98%
12%
22%
34%
Relieve physical pain
Relax or relieve tension
Deal with day-to-day stress
Get high or for fun
SOURCE: The Washington Post/Kaiser Family Foundation Survey of Long-Term Prescription Painkiller Users and Their Household Members (conducted October 3-November 9, 2016)
THE HENRY J. KAISER FAMILY FOUNDATION


Long-term users who say they are addicted or dependent are more likely to report taking painkillers for other reasons
Say they are/were addicted or dependent
Do not say they are/were addicted or dependent
To relieve physical pain
95%
100%
For fun or to get high
47%
27%
To deal with day-to-day stress
38%
14%
To relax or relieve tension
30%
3%
SOURCE: The Washington Post/Kaiser Family Foundation Survey of Long-Term Prescription Painkiller Users and Their Household Members (conducted October 3-November 9, 2016)
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"There is no need to invent a new, unique or complex model for the health care system to respond to opioid use disorder. Rather, the health of people with opioid use disorders should be managed exactly the way the system manages the health of people with any other chronic condition."

– KEITH HUMPHREYS, PH.D.

The Opioid Epidemic and the U.S. Health Care System

Keith Humphreys, Ph.D.

As the United States grapples with the worst public health crisis since at least the HIV/AIDS epidemic, policymakers' attention naturally turns to the health care system as one important component of a coordinated response (HHS, 2016). This paper describes the nature and effectiveness of the services the health care system can offer people who have opioid use disorder, and, how such services might be organized within the health care system. The paper then briefly describes selected policies that may reduce the number of new cases of opioid use disorder caused by the health care system.

Meeting the Needs of People with Opioid Use Disorder

Determining whether or not the health care system is helping people with opioid use disorder requires understanding the services the population needs, the availability of those services, and how well or badly those services map onto population needs.

What Services Do People with Opioid Use Disorders Need?

People with opioid use disorder typically face challenges that go beyond opioids per se. Polydrug use is the norm among people in addiction treatment, with at least one-third of "opioid overdoses" in reality being due to opioids combined with benzodiazepines, alcohol or both (Darke & Zador, 1996; Sun et al., 2017). Treatment services that don't consider this reality can find that very dangerous substance use patterns persist or become worse even as opioid use itself is lessening. For example, some patients receiving opioid agonist therapy (e.g., methadone maintenance) drink alcohol at dangerous levels, and in some "successful" patients the alcohol problem may actually worsen over time (Hall & Strang, 2017). Heavy smoking of tobacco and cannabis are also common among opioid use disorder treatment patients.

In addition to problems with substances other than opioids, many people with opioid use disorders experience significant challenges in other domains, such as legal, family, financial, medical and psychiatric. At one time it was widely believed that these other problems would naturally abate if drug addiction were successfully treated, but this is not necessarily the case (McLellan et al., 1981), particularly given that (as will be explained later) addiction treatment services are often poorly resourced and therefore, don't typically have the power to transform all aspects of a patient's life. Thus, we should expect that people with opioid disorders will -- like people without such disorders -- need other health care and social services that are not inherently focused on addiction (e.g., primary care, dental care, legal and housing services).

Finally, clinicians and patients may not always know precisely what services are needed. A good example is people who access needle exchange programs, which are intended to reduce the risks associated with injection rather than opioid use per se. Yet, some needle exchange program clients use them as an entry point to abstinence-promoting treatments. Because such moves within care systems are common, service systems that offer a broad range of services with different goals may be accessed by a broader proportion of the opioid-using population than would systems built around a narrow range of services.

What Evidence-Based Health Care Services Are Available for People with Opioid Use Disorder?

The history of addiction treatment is littered with many ineffective treatments that vary from outright quackery to well-intended but non-therapeutic interventions (White, 1998). Obviously, health and social care systems should provide services that have scientific evidence of safety and effectiveness. Table 1 provides highlights of the evidence on different types of evidence-based, specialty services. The text below elaborates on the role each has in the care system.

TABLE 1: EVIDENCE-BASED SERVICES FOR PEOPLE WITH OPIOID USE DISORDER

Type of Service	Nature and Purpose	Advantages	Concerns
Detoxification/ Stabilization	• Generally provided in hospital • Manages acute crisis safely • Removes opioids from body if needed prior to treatment	• Reduces immediate medical risk • Gives opportunity to engage patient in treatment	• Without follow-up treatment, patient at higher risk of overdose due to loss of tolerance
Opioid Agonist Therapy	• Outpatient care in specialty clinic (methadone) or primary care (buprenorphine) • Transitions patient away from more dangerous opioids (e.g., heroin) and use routes (e.g., injection)	• Extremely strong clinical trial evidence of reducing illicit drug use, infectious disease transmission, mortality, and crime • Provides biological stabilization that allows patients to engage in employment or vocational training/ counselling	• Methadone and buprenorphine are opioids with street value and may be diverted for sale/ misuse • Some patients may increase alcohol consumption or other non-opioid drug use • Usually requires additional psycho-social services to be maximally effective
Opioid Antagonist Therapy	• Naltrexone blocks the rewarding effects of opioids	• Injectable, long-acting version has good evidence of reducing illicit drug use and overdose; may also reduce problem drinking • Naltrexone has no street value so diversion not a concern	• Oral version shows poor compliance except with a small minority of patients • Injectable formulation is more costly than any other form of medication-assisted treatment • Patients must be fully detoxified from opioids before beginning treatment
Contingency Management; Behavior Therapy; Cognitive-Behavioral Therapy	• Psychological techniques that incentivize positive behavior change • Teach patients more adaptive ways of thinking and coping	• Very strong evidence of reducing opioid and non-opioid use • Strong evidence of positively changing many other behaviors	• Less effective as a standalone than when combined with medication
12-Step Facilitation Counselling	• Introduces patients to 12-step concepts • Links patients to 12-step fellowships	• Evidence of reducing all forms of drug use • Takes advantage of long-term, cost-free supports for recovery (e.g. Narcotics Anonymous)	• Less effective as a standalone than when combined with medication • Some 12-step group members object to medication-assisted treatment

TABLE 1: EVIDENCE-BASED SERVICES FOR PEOPLE WITH OPIOID USE DISORDER			
Type of Service	**Nature and Purpose**	**Advantages**	**Concerns**
Therapeutic Communities	• Residential communities designed to promote abstinence and eliminate antisocial attitudes/ behaviors • Make extensive use of peer counselling • Often connected to correctional facilities	• Some evidence of reducing substance use and recidivism • May ease transition back to society for addicted prisoners	• Costly and requires long-term absence from any work and family roles • In-prison therapeutic communities without post-prison services may confer little or no benefit
Needle/Syringe Exchange	• Provides sterile injection equipment and education on reducing infectious disease risk	• Evidence of reducing HIV/AIDS transmission • May serve as a gateway to other needed services, including addiction treatment	• Probably has no effect on hepatitis C infection • Siting programs can be challenging due to community resistance • Not relevant for those who only consume opioids without injection
Naloxone	• Antagonist medication that rapidly reverses opioid overdose • Increasingly carried by emergency medical technicians, police officers, fire fighters, homeless shelter workers • Sometimes distributed to drug users and their loved ones	• Low-risk medication that can be safely employed after minimal training • Initial evidence of reducing community overdose rates • Generic formulation is inexpensive	• Does not affect underlying addiction • Without treatment linkage, may simply set stage for next overdose • Can be overpowered by potent fentanyl

References: Detoxification (Strang et al., 2003); Opioid Antagonist Therapy (Amato et al., 2005; Barnett, 1999; Carroll & Weiss, 2017; Fiellin et al., 2004; Gunne & Gronbladh, 1981; Hall & Strang, 2017; Sordo et al., 2017; World Health Organization, 2009); Opioid Antagonist Therapy (Adi et al., 2007; Connery, 2015; Krupitsky et al., 2012; Lee et al., 2016); Contingency Management/Behavior Therapy/Cognitive-Behavioral Therapy (Mayet et al., 2005; Prendergast et al., 2002); 12-Step Facilitation Counselling (Humphreys, 2004; White et al., 2016); Therapeutic Communities (Butzin et al., 2005; Vanderplasschen et al., 2013); Needle Exchange (Groseclose et al., 1995; Heimer, 1998; Pollack, 2001); Naloxone (Baca & Grant, 2005; Darke & Hall, 1997; Humphreys, 2015; McDonald & Strang, 2016; Strang et al., 1996; Walley et al., 2013; Williams, Williams & Strang, 2014).

Detoxification and stabilization services (row 1 of Table 1) are provided in response to emergency overdoses or to voluntary help-seeking by opioid-addicted individuals in crisis. Generally, such services are provided on an inpatient

basis in hospitals. They are not treatment for addiction per se (Humphreys et al., 2017), but can and should be a gateway to treatment. Indeed, detoxification from opioids without follow-on treatment may raise risk of overdose even beyond what it was prior to detoxification (Strang et al., 2003).

Medication-assisted treatments -- or MAT -- (rows 2 and 3 of Table 1) are intended either to eliminate the use of opioids entirely (the opioid agonist naltrexone) or to restrict use to medically provided, safer opioids (i.e., oral opioid agonist therapy with buprenorphine or methadone). They work by invoking a chemical change at the brain receptor which is normally activated by opioids (e.g., heroin), either by blocking opioids from binding there (an "antagonist") or by activating the receptor at a stable, low level (a "substitute agonist") which reduces craving for more dangerous opioids.

Different forms of MAT are subject to different degrees of regulation, which affects treatment availability. For a mixture of political and health-related (e.g., risk of diversion) reasons, methadone has become highly regulated since its introduction, requiring that the medication be dispensed by and in federally-designated "Opioid Treatment Programs." A less tightly regulated form of opioid agonist therapy, buprenorphine (e.g., Suboxone, Bunavail), can be administered in various settings, including physician offices (with restriction), yielding large increases in its accessibility and use. Long-acting naltrexone is not an opioid and hence poses no risk of diversion or overdose. Randomized clinical trials have

found it effective, which is particularly important given that many people with opioid use disorder do not wish to receive opioid agonist therapy. Naltrexone can be administered by a physician who does not have to undergo special licensing or regulatory procedures, which increases the number of potential prescribers. On the other hand, injected naltrexone is expensive and requires the patient to undergo opioid detoxification prior to administration, which reduces the number of people who can gain access to it.

Because medication alone does not address other substance use, mental health, and life problems that patients may have, medication-assisted treatments are best coupled with behavioral/psychological interventions (rows 4-6 of Table 1). Behavioral/psychological interventions can also be provided alone for individuals who refuse medication, but on average, the outcomes of such care are inferior to those of medication-assisted treatments. Such treatments are intended to teach new skills, foster better coping strategies, and enhance motivation and confidence to change behavior. The skills and strategies conveyed are generic, meaning they can be used not only regarding drug use, but also with other problems the patient may experience, such as marital difficulties, psychiatric disorders, and poor employment prospects. Behavioral/psychological interventions are sometimes provided on a residential basis (e.g., in therapeutic communities), but 90% are provided in the form of outpatient counselling.

The last two rows of Table 1 comprise what are sometimes termed "harm reduction" services, namely needle/syringe exchange and the opioid overdose rescue drug naloxone (known to many people as "Narcan"). These services do not aspire to treat the underlying addiction or reduce drug use per se. Instead, they attempt to minimize harms of drug use, for example, contraction of HIV/AIDS from an infected needle or brain damage from an overdose. "Harm reduction" services have been controversial because both their critics and some of their proponents have overdrawn the contrast of these services with treatment (which is putatively about reducing drug use per se). But in practice, people accessing harm reduction services often reduce their drug use and people accessing treatment often reduce their harm, so the contrast is more apparent than real.

The types and elements of specialty care are described independently in the Table for ease of description, but most people will combine types of care either in the same or separate care episodes. For example, a homeless heroin user may initially visit a needle exchange program only to reduce infection risk. But over time, a trusting relationship with a program staff member there may lead to an introduction to opioid agonist therapy and a transition away from injected heroin. Another individual may enter a methadone maintenance clinic and re-

peatedly drop out of care before eventually transitioning to an entirely different model of help, such as 12-step facilitation counselling followed by lifetime involvement in the self-help group Narcotics Anonymous. Yet another individual may complete a 3-month stay in a therapeutic community and participate in ongoing outpatient cognitive-behavioral therapy offered by the program to all its graduates. And yet another individual may be repeatedly revived from overdose with naloxone by police, spend a day or two in a hospital stabilization unit and then storm out against medical advice to resume heroin use immediately. The key point is that because individuals can have extremely diverse pathways through care -- including multiple unsuccessful care-seeking episodes -- a range of care options is desirable to serve the population.

How Should Specialty Addiction Treatment Services Interact with the Rest of the Health Care System?

Table 1 does not include a row that one would expect to see for other medical disorders: the primary care setting. To understand the implications of this gap, consider how most chronic health problems are managed in the U.S. health care system. Most patients have a primary care doctor who provides basic health care and screens for the presence of disorders. For example, virtually every primary care visit involves a check for abnormal blood pressure. If the primary care doctor detects a low-severity condition, such as mid-range hypertension, a precancerous mole, or mild diabetic complications, he or she will manage it within the primary care setting. But if the problem is severe and, therefore, requires particular expertise, the primary care doctor will refer the patient to a specialist, such as a cardiologist or oncologist. The specialist will treat the patient and report back to the primary care physician about the treatment, its outcome and a follow-up plan. The primary care physician will then continue to manage the condition, with the specialist in reserve for back-up.

This sensible system of stepped, team-based care for chronic health problems within a covered population has not been the norm for the treatment of opioid use disorders. Instead, historically, most opioid specialty treatment services have existed largely independent of the health care system (the exception being the small number of primary care providers who provide buprenorphine maintenance to their patients). Primary care doctors do not generally screen for opioid use disorders, and thus, rarely fill their customary role of identifying and managing low-severity cases while referring high-severity cases on to a specialist who backs them up. Instead, people with opioid use disorders generally receive no care until their problem is severe, and then a subset of them finds their way to a specialty care provider (e.g., a methadone maintenance clinic). Typically, the pri-

mary care doctor does not even know about and does not perform any follow-up of the specialty treatment, nor partner with the specialty treatment provider in any way to improve the patient's health. This produces uncoordinated care of mediocre quality and also means that many people suffer needlessly for years because their primary care doctor has not identified their opioid use disorder.

There is no need to invent a new, unique or complex model for the health care system to respond to opioid use disorder. Rather, the health of people with opioid use disorders should be managed exactly the way the system manages the health of people with any other chronic condition (Humphreys et al., in press). But historical, cultural, and policy forces have conspired to prevent this from happening, as explained below.

The drug addiction treatment system has functioned as a free-standing enterprise outside of health care due to historical accidents that subsequently were cemented with laws, policies and habits. Rather than emerging from within the health care system as did specialties like gerontology and anesthesiology, the drug addiction treatment system emerged from the criminal justice system (e.g., the Federal Bureau of prisons "narcotics farms," White, 1998); the social welfare system (e.g., Salvation Army programs, White, 1998); and peer mutual help efforts (e.g., 12-step Narcotics Anonymous groups, Humphreys, 2004). Each of these "three parents" contributed useful things and saved some lives, but they did it outside of the health care system and primarily saw their work as instilling discipline (at times with punishment), promoting character development, and offering moral uplift (White, 1998).

Once the drug addiction treatment system emerged outside of the mainstream health care system, people in both systems contributed for their own reasons to formal policies that helped them stay segregated. Strict confidentiality regulations unlike anything else in medicine prevented, for example, primary care doctors from knowing that their patients were being treated for addiction in a specialty clinic. Funding streams with their own attendant regulations and success criteria -- the federal substance use disorder treatment block grant being a prominent example -- were created outside of mainstream mechanisms like Medicaid, Medicare, and private insurance. Even when some insurers covered addiction treatment, few specialty addiction treatment providers developed the knowledge to bill such public and private payers.

By being separate from health care as a whole, addiction treatment programs were not subject to accountability and quality improvement regulations increasingly found in medicine. Meanwhile, a significant part of the medical establish-

ment was relieved to have a deeply stigmatized disorder be framed as "someone else's problem," allowing the health care system to focus medical education, energy and resources on "real diseases." Despite the prevalence and health damage caused by drug addiction, fewer than 1% of American physicians specialize in addiction.

As long as drug addiction treatment is segregated from the health care system as a whole, services for people with opioid use disorders will suffer from low status, poor coordination of care, chronic shortages of medically-trained personnel, weak quality improvement mechanisms, and a shortage of funds. Salaries within the field are often poor, reducing the morale and quality of staff and leading to high rates of burnout and turnover. The funding limitations have reduced the interest of pharmaceutical companies in developing medications for addiction, as it is not clear who would buy them or who would prescribe them.

Policies to Promote Integration

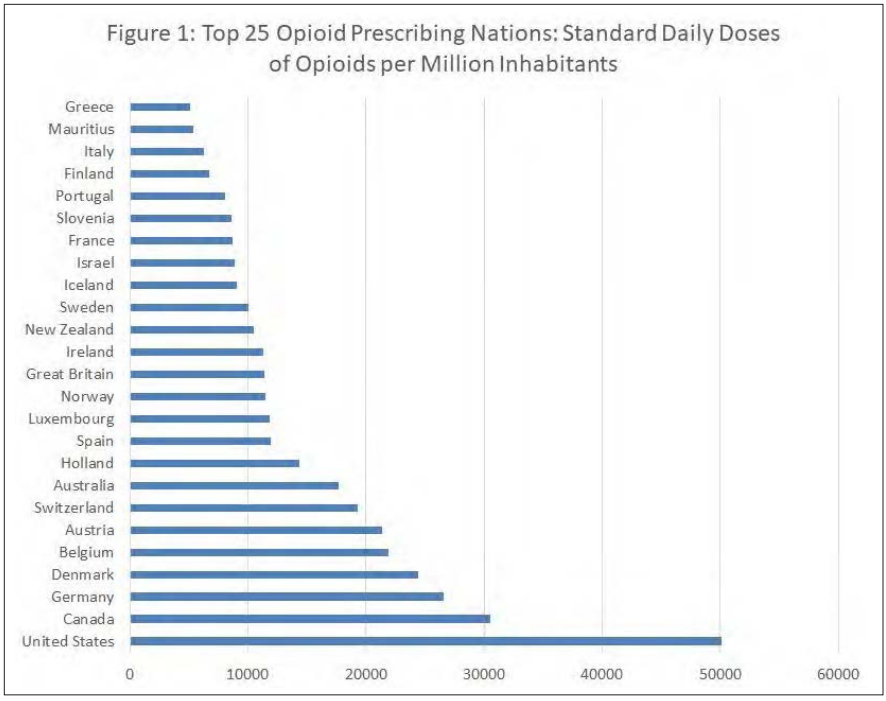
Although many small improvements can be made in services for opioid use disorders, the fundamental change that would make the largest difference is to make it a fully functioning, integrated part of the health care system. How can this be accomplished?

Nothing has promoted integration more effectively and efficiently than mainstreaming addiction treatment into the funding mechanisms that drive the rest of the system. The Congress and the George W. Bush and Obama Administrations made major progress in this regard, most notably by passing the 2008 *Medicare Improvement for Patients and Providers Act* (which, for the first time covered outpatient substance use and mental health disorder services at the same level as services for all other disorders); the 2008 Wellstone-Domenici *Mental Health Parity and Addiction Equity Act* (MHPAEA), which required substance use and mental health insurance benefits offered by large employers to be comparable to benefits for other disorders; and the 2010 *Patient Protection and Affordable Care Act*, which made substance use disorder early intervention and treatment essential health care benefits in Medicaid and health insurance exchange plans and extended MHPAEA protections to small employers and individuals.

Fry and Frank's paper (2017) explains these changes from a fiscal viewpoint. From a health care viewpoint, these major policy shifts incentivized addiction treatment providers and the rest of the health care system to work together; made additional funds available for addiction treatment (which over time will translate into a larger workforce of health care professionals specializing in the field); incentivized primary care providers to screen for substance use disorders as they do all other disorders; and incentivized substance use disorder treatment providers to improve the quality of their services. The fiscal reforms of recent years are recognized by independent analysts as the most transformative positive changes in the U.S. addiction treatment system in at least 40 years (Buck, 2011). Maintaining these reforms -- which as of this writing are under political threat -- is the most consequential step the country could take toward integration of care for substance use disorders with the rest of the health care system.

The second important set of pro-integration policies is less tangible, but still important, as it involves cultural messaging and the legitimation of the health care system's role in helping people with opioid use disorder. For centuries, a common cultural understanding of drug addiction was that it represented moral failure meriting punishment rather than treatment. An enormous number of policy actors both within Washington (e.g., Presidents G.W. Bush and Obama, and White House drug policy director and recovering alcoholic, Michael Botticelli), and outside of it (e.g., recovery activists) have, for the last decade, successfully persuaded much of society that addiction is a legitimate medical disorder that is better resolved through treatment than through incarceration. This makes addicted people more comfortable seeking care, makes addiction treatment a more credible part of the health care system, and helps individuals with drug use disorders avoid the potentially life-destroying effects of incarceration. Legitimizing addiction treatment also helps build the needed workforce to provide specialty care (bright young people like to go into respected rather than disrespected lines of work) and also encourages non-specialty providers (e.g., primary care doctors, nurses) to invest more attention in addressing the substance use problems of their patients.

However, like the Bush/Obama fiscal reforms, the creation of a cultural environment conducive to addiction's being seen as a legitimate disorder worthy of treatment is also currently under political pressure and may not last. The other consequential policy option in this area is, therefore, to preserve the cultural messaging employed by the Bush/Obama Administrations and their allies outside of government to resist a reversion to the concept that drug use disorders deserve incarceration rather than evidence-based treatment.



Preventing Opioid Use Disorder

This paper has thus far focused on what the health care system does for people who already have an opioid use disorder. Before closing, it is worth considering some preventive steps the system takes to reduce the incidence of new cases. These possibilities come about because the modern opioid epidemic (in contrast to the 1960s-1970s heroin epidemic) was largely started by the health care system itself, which drove U.S. consumption to a historically and internationally unprecedented level (Figure 1, Humphreys, 2017).

A range of prevention policies has been put in place and evaluated (e.g., abuse-deterrent prescription opioids, pharmacy interventions with prolific prescribers, clinical practice guideline dissemination), a full review of which is beyond the scope of this paper (see Humphreys & Pollack, in press, for a comprehensive discussion). Here three policies with consistent evidence of benefit are described.

Reimbursement Lock-in

Lock-in programs are designed to prevent "doctor shopping." A significant number of overdoses involve someone who has prescriptions from many doctors filled at many pharmacies (Hall et al., 2008). In lock-in programs, the payer (e.g., Medicaid) restricts the patient to receiving all opioid prescriptions from one provider and filling them at one pharmacy. These programs have evidence of reducing opioid provision (Roberts & Skinner 2014). State lock-in programs in Oklahoma (Katz et al., 2013) and Washington (Franklin et al., 2015) report positive outcomes, including reduced doctor shopping, emergency room visits, and costs.

Restriction of Prescriptions

As a general matter, tightening prescribing of a medication reduces its use, and often increases prescriptions for similar drugs that are not so restricted (see, e.g., Victorri-Vigneau et al., 2003). For example, moving hydrocodone combination products (e.g. Norco, Vicodin, Lortab) from Schedule III to Schedule II status led to substantial drops in prescriptions for these drugs. There was some compensatory uptick in prescriptions for opioid drugs that were scheduled lower (e.g., Tylenol #3 and #4, see Seago et al., 2016), but a national evaluation estimated a net overall decrease of about 15 million opioid prescriptions was produced by rescheduling (Jones et al., 2016). This is the most common though not universal finding, namely that substitution effects are less than the decline in the restricted

drug, meaning that overall prescribing of that class of drug goes down (e.g., Jonasson & Jonasson, 2004).

One way for states to tighten restrictions is through "preferred drug lists," by which certain drugs are allowed and reimbursed without added paperwork or approvals. Putting methadone for pain on the non-preferred list, as some states do, is associated with reduced overdose deaths from methadone (Faul et al., 2017), presumably because prescribers used preferred drugs with better safety profiles.

Prescription Drug Monitoring Programs (PDMPs)

PDMPs allow prescribers, pharmacies, and monitoring agencies to retrieve up-to-date information on prescription patterns. They differ greatly in their oversight, design scope and ease of use, as well as their uptake by prescribers (Furlan et al. 2014; Katz et al., 2008; Pardo, in press). PDMPs generally reduce prescribing of the medications that they monitor, including opioids (Moyo et al., in press). When Ohio implemented an online PDMP, emergency room doctors changed their opioid prescribing for 41% of patients who the system flagged as being potentially of concern (Baehren et al., 2010; see also Dormuth et al., 2012). As with other methods of control, there can be some substitution effects, meaning that prescribers decrease use of medications under the PDMP but increase use of others (Fishman et al. 2004; Gilson et al., 2012). However, the balance favors public health.

States with PDMPs have fewer opioid poisonings and treatment admissions compared to non-PDMP states (Reifler et al., 2012). Implementing a PDMP produces an average reduction of 1.1 opioid-related overdose deaths per 100,000 population in the year after implementation (Patrick et al., 2016; see also Paulozzi et al., 2011). PDMPs differ in their impact on mortality, with states with stronger programs receiving more benefit than those with weaker programs (Pardo, in press). PDMPs operated by law enforcement produce somewhat larger benefits than those operated by other administrative bodies (Pardo, in press).

Summary of Key Points

People with opioid use disorders have a range of needs, some specific to their substance use and some not. Historically, these needs have not been well met by the health care system. The treatment of opioid addiction did not emerge from the health care system and that shapes its nature today, including its being poorly integrated with the rest of health care, less generously resourced, less

staffed by medically-trained personnel, and less subject to the quality improvement mechanisms that are built into the rest of the health care system. Reflecting its history and cultural views of drugs, the addiction treatment system also differs in often being expected to transform the character and life of patients, and to do so with minimal resources. Recent health care reforms by Presidents Bush and Obama and multiple Congresses made major strides toward resolving these problems through integrating the financial mechanisms of addiction treatment with those of the rest health care and spreading the cultural message that addiction treatment is a legitimate response to drug use disorders. These towering accomplishments will need to be protected and expanded if the health care system is to respond effectively to the opioid epidemic.

Efforts to continue the move toward integrated, quality services for people with opioid use disorders must be coupled with efforts to change opioid prescribing in the health care system – otherwise, clinicians are attempting to empty a bathtub with a thimble without first turning off the faucet. Three ways of doing so which have consistent evidence of benefit are reimbursement lock-in programs, restrictions on prescribing, and prescription drug monitoring programs.

How the health care system can most effectively respond to opioid use disorders is neither a mystery nor difficult to understand. Quite simply, opioid use disorders should be handled precisely as are other chronic disorders, namely with primary care coordinated, specialty practitioner supported, team-based, high-quality medical care. By bringing the care of opioid use disorder into the proven care models, quality improvement mechanisms and funding mechanisms of the rest of the health care system, health care professionals can provide care to the millions of Americans who are currently grappling with these debilitating and life-threatening disorders.

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References

Adi, Y., Juarez-Garcia, A., Wang, D., Jowett, S., Frew, E., Day, E., Bayliss S., Roberts T., & Burls, A. (2007). Oral naltrexone as a treatment for relapse prevention in formerly opioid-dependent drug users: A systematic review and economic evaluation. *Health Technology Assessment*, 11(6), 1-85.

Amato, L., Davoli, M., Perucci, C.A., Ferri, M., Faggiano, F., & Mattick, R.P. (2005). An overview of systematic reviews of the effectiveness of opiate maintenance therapies: Available evidence to inform clinical practice and research. *Journal of Substance Abuse Treatment,* 28(4), 321-330.

Baca, C.T. & Grant, K.J. (2005). Take-home naloxone to reduce heroin death. *Addiction*, 100(12), 1823-1831.

Baehren, D.F., Marco, C.A., Droz, D.E., Sinha, S., Callan, E.M., & Akpunonu, P. (2010). A statewide prescription monitoring program affects emergency department prescribing behaviors. *Annals of Emergency Medicine*, 56(1), 19-23.

Barnett, P. (1999). The cost-effectiveness of methadone maintenance as a health care intervention. *Addiction*, 94(4), 479-488.

Buck, J.A. (2011). The looming expansion and transformation of public substance abuse treatment under the Affordable Care Act. *Health Affairs*, 30(8), 1402-1410.

Butzin, C.A., Martin, S.S., & Inciardi, J.A. (2005). Treatment during transition from prison to community and subsequent illicit drug use. *Journal of Substance Abuse Treatment*, 28(4), 351-358.

Carroll, K.M. & Weiss, R.D. (2017). The role of behavioral interventions in buprenorphine maintenance treatment: A review. *American Journal of Psychiatry*, 174(8), 738-747.

Connery, H.S. (2015). Medication-assisted treatment of opioid use disorder: Review of the evidence and future directions. *Harvard Review of Psychiatry*, 23(2), 63-75.

Darke, S. & Hall, W. (1997). The distribution of naloxone to heroin users. *Addiction*, 92(9), 1195-1199.

Darke, S. & Zador, D. (1996). Fatal heroin 'overdose': A review. *Addiction*, 91(12), 1765-1772.

Dormuth, C.R., Miller, T.A., Huang, A., Mamdani, M.M., & Juurlink, D.N. (2012). Effect of a centralized prescription network on inappropriate prescriptions for opioid analgesics and benzodiazepines. *Canadian Medical Association Journal*, 184(16), E852-E856.

Faul, M., Bohm, M., & Alexander, C. (2017). Methadone prescribing and overdose and the association with Medicaid preferred drug list policies – United States, 2007-2014. *Morbidity and Mortality Weekly Report*, 66, 320-323.

Fiellin, D.A., Kleber, H., Trumble-Hejduk, J.G., McLellan, A.T., & Kosten, T.R. (2004). Consensus statement on office-based treatment of opioid dependence using buprenorphine. *Journal of Substance Abuse Treatment,* 27(2), 153-159.

Fishman, S.M., Papazian, J.S., Gonzalez, S., Riches, P.S., & Gilson, A. (2004). Regulating opioid prescribing through prescription monitoring programs: Balancing drug diversion and treatment of pain. *Pain Medicine*, 5(3), 309-324.

Franklin, G., Sabel, J., Jones, C.M., Mai, J., Baumgartner, C., Banta-Green, C.J., Neven D., Tauben, D.J. (2015). A comprehensive approach to address the prescription opioid epidemic in Washington State: Milestones and lessons learned. *American Journal of Public Health*, 105(3), 463-469.

Fry, C.E. & Frank, R.G. (2017). Financing care for opioid use disorders. Aspen, Colorado: Aspen Health Strategy Group.

Furlan, A.D., MacDougall, P., Pellerin, D., Shaw, K., Spitzig, D., Wilson, G., & Wright, J. (2014). Overview of four prescription monitoring/review programs in Canada. *Pain Research & Management*, 19(2), 102-106.

Gilson, A.M., Fishman, S.M., Wilsey, B.L., Casamalhuapa, C., & Baxi, H. (2012). Time series analysis of California's prescription monitoring program: Impact on prescribing and multiple provider episodes. *Journal of Pain*, 13(2), 103-111.

Groseclose, S.L., Weinstein, B., Jones, T.S., Valleroy, L.A., Fehrs, L.J., & Kassler, W.J. (1995). Impact of increased legal access to needles and syringes on practices of injecting-drug users and police officer, Connecticut, 1992-1993. *Journal of Acquired Immune Deficiency Syndrome and Human Retrovirology*, 10(1), 82-89.

Gunne, L.M., & Grönbladh, L. (1981). The Swedish methadone maintenance program: A controlled study. *Drug and Alcohol Dependence*, 7(3), 249-256.

Hall, A.J., Logan, J.E., Toblin, R.L, Kalan, J.A., Kraner, J.C., Bixler, D., Crosby A.E., & Paulozzi, L.J. (2008). Patterns of abuse among unintentional pharmaceutical overdose fatalities. *Journal of the American Medical Association*, 300(22), 2613-2620.

Hall, W.D. & Strang, J.S. (2017). Alcohol problems need more attention in patients receiving long-term opioid substitution therapy. *Lancet Psychiatry*, 4(4), 265-266.

Heimer, R. (1998). Can syringe exchange serve as a conduit to substance abuse treatment? *Journal of Substance Abuse Treatment*, 15(3), 183-191.

Humphreys, K. (2004). Circles of Recovery: Self-Help Organisations for Addictions. Cambridge, UK: Cambridge University Press.

Humphreys, K. (2015). An overdose rescue drug goes mainstream. *Health Affairs*, 34(10), 1624-1627.

Humphreys, K. (2017, March 15). Americans use far more opioids than anyone else in the world. *The Washington Post*, Retrieved from https://www.washingtonpost.com/news/wonk/wp/2017/03/15/americans-use-far-more-opioids-than-anyone-else-in-the-world/?utm_term=.5a8ee2fb612f

Humphreys, K., Malenka, R., Knutson, B., & MacCoun, R. (2017). Brains, environments and policy responses to addiction. *Science*, 356(6344), 1237-1238.

Humphreys, K., McGovern, M., & McLellan, A.T. (in press). Integrated care for substance use disorder. In Miller, S.C., Fiellin, D.A., Rosenthal, R., & Saitz, R. (Eds.), Principles of Addiction Medicine (6th edition). Washington, D.C.: American Society of Addiction Medicine.

Humphreys, K. & Pollack, H.A. (in press). Responding to the public health crisis of opioid addiction and overdose. In Goldman, H.H., Frank, R.G., & Morrisey, J.P. (Eds.), Handbook of U.S. Mental Health Policy: Controversies and Challenges. New York: Palgrave MacMillan.

Jonasson, U. & Jonasson, B. (2004). Restrictions on the Prescribing of Dextropropoxyphene (DXP) - Effects on Sales and Cases of Fatal Poisoning. Stockholm, Sweden: Swedish National Board of Forensic Medicine and Medical Products Agency.

Jones, C.M., Lurie, P.G., & Throckmorton, D.C. (2016). Effect of U.S. Drug Enforcement Administration's rescheduling of hydrocodone combination analgesic products on opioid analgesic prescribing. *JAMA Internal Medicine*, 176(3), 399-402.

Katz, N.P., Birnbaum, H., Brennan, M.J., Freedman, J.D., Gilmore, G.P, Jay, D., Kenna, G.A., Madras, B.K., McElhaney, L., Weiss, R.D., & White, A.G. (2013). Prescription opioid abuse: Challenges and opportunities for payers. *American Journal of Managed Care*, 19(4), 295–302.

Katz, N., Houle, B., Fernandez, K., Kreiner, P., Thomas, C., Kim, M., Carrow, G.M., Audet, A., & Brushwood, D. (2008). Update on prescription monitoring in clinical practice: A survey study of prescription monitoring program administrators. *Pain Medicine*, 9(5), 587-594.

Krupitsky, E., Zvartau, E., Blokhina, E., Verbitskaya, E., Wahlgreen, V., Tsoy-Podosenin, M., Bushara, N., Burakov, A., Masalov, D., Romanova, T., Tyurina, A., Palatkin, V., Slavina, T., Pecoraro, A., & Woody, G.E. (2012). Randomized trial of long-acting sustained-release naltrexone implant vs oral naltrexone or placebo for preventing relapse to opioid dependence. *Archives of General Psychiatry*, 69(9), 973-981.

Lee, J.D., Friedmann, P.D., Kinlock, T.W., Nunes, E.V., Boney, T.Y., Hoskinson, R.A., Wilson, D., McDonald, R., Rotrosen, J., Gourevitch, M.N., Gordon, M., Fishman, M., Chen, D.T., Bonnie, R.J., Cornish, J.W., Murphy, S.M., & O'Brien, C.P. (2016). Extended-release naltrexone to prevent opioid relapse in criminal justice offenders. *New England Journal of Medicine*, 374, 1232-1242.

Mayet, S., Farrell, M., Ferri, M., Amato, L., & Davoli, M. (2005). Psychosocial treament for opiate abuse and dependence. *Cochrane Database Systematic Review*. doi: 10.1002/14651858.CD004330.pub2

McDonald, R. & Strang, J.S. (2016). Are take-home naloxone programmes effective? Systematic review utilizing application of the Bradford Hill criteria. *Addiction*, 111(7), 1177–1187.

McLellan, A.T., Luborsky, L., Woody, G.E., O'Brien, C.P., & Kron, R. (1981). Are the "addiction-related" problems of substance abusers really related? *Journal of Nervous and Mental Disease*, 169(4), 232-239.

Medicare Improvement for Patients and Providers Act of 2008 (2008). P.L. 110-275, 122 Stat. 2494.

Mental Health Parity and Addiction Equity Act (2008). P.L. 110-343, 122 Stat. 3765.

Moyo, P., Simoni-Wastila, L., Griffi, B.A., Harrington, D., Alexander, G.C., & Palumbo, F. (in press). Impact of prescription drug monitoring programs (PDMPs) on opioid utilization among Medicare beneficiaries in 10 U.S. States. *Addiction*.

Pardo, B. (in press). Do more robust prescription drug monitoring programs reduce prescription opioid overdose? *Addiction*. doi: 10.1111/add.13741

Patient Protection and Affordable Care Act (2010). P.L. 111-148 and P.L. 111-152, 124 Stat. 119 et seq.

Patrick, S.W., Fry, C.E., Jones, T.F., & Buntin, M.B. (2016). Implementation of prescription drug monitoring programs associated with reductions in opioid-related death rates. *Health Affairs,* 35(7), 1324-1332.

Paulozzi, L., Kilbourne, E.M., & Desai, H.A. (2011). Prescription drug monitoring programs and death rates from drug overdose. *Pain Medicine*, 12(5), 747-754.

Pollack, H.A. (2001). Cost-effectiveness of harm reduction in preventing hepatitis C among injection drug users. *Medical Decision Making*, 21(5), 357-367.

Prendergast, M.L., Podus, D., Chang, E., & Urada, D. (2002). The effectiveness of drug abuse treatment: A meta-analysis of comparison group studies. *Drug and Alcohol Dependence*, 67(1), 53-73.

Reifler, L.M., Droz, D., Bailey, J.E., Schnoll, S.H., Fant, R., Dart, R.C., & Bucher Bartelson, B. (2012). Do prescription monitoring programs impact state trends in opioid abuse/misuse? *Pain Medicine*, 13(3), 434-442.

Roberts, A.W. & Skinner, A.C. (2014). Assessing the present state and potential of Medicaid controlled substance lock-in programs. *Journal of Managed Care & Specialty Pharmacy,* 20(5), 439-446.

Seago, S., Hayek, A., Pruszynski, J., & Newman, M.G. (2016). Change in prescription habits after federal rescheduling of hydrocodone combination products. *Baylor University Medical Center Proceedings*, 29, 268-270.

Sordo, L., Barrio, G., Bravo, M.J., Indave, B.I., Degenhardt, L., Wiessing, L., Ferri, M., & Pastor-Barriuso, R. (2017). Mortality risk during and after opioid substitution treatment: Systematic review and meta-analysis of cohort studies. *BMJ*, 357, j1550.

Strang, J., Darke, S., Hall, W., Farrell, M., & Ali, R. (1996). Heroin overdose: The case for take-home naloxone. *BMJ*, 312(7044), 1435–1436.

Strang, J., McCambridge, J., Best, D., Beswick, T., Bearn, J., Rees, S., & Gossop, M. (2003). Loss of tolerance and overdose mortality after inpatient opiate detoxification: Follow up study. *BMJ*, 326, 959-960.

Sun, E.C., Dixit, A., Humphreys, K., Darnell, B., Baker, L.C., & Mackey, S. (2017). Association between concurrent use of prescription opioids and benzodiazepine with overdose: A retrospective analysis. *BMJ*, 356, j760.

U.S. Department of Health and Human Services (HHS), Office of the Surgeon General (2016). Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs and Health. Retrieved from https://addiction.surgeongeneral.gov/surgeon-generals-report.pdf

Vanderplasschen, W., Colpaert, K., Autrique, M., Rapp, R.C., Pearce, S., Broekaert, E., & Vandevelde, S. (2013). Therapeutic communities for addictions: A review of their effectiveness from a recovery-oriented perspective. *Scientific World Journal*. doi: 10.1155/2013/427817

Victorri-Vigneau, C., Basset, G., Bourin, M., & Jolliet, P. (2003). Impacts of the new flunitrazepam regulations on the consumption of hypnotics. [Impacts de la nouvelle reglementation du flunitrazepam sur la consommation d'hypnotiques]. *Therapie*, 58(5), 425-430.

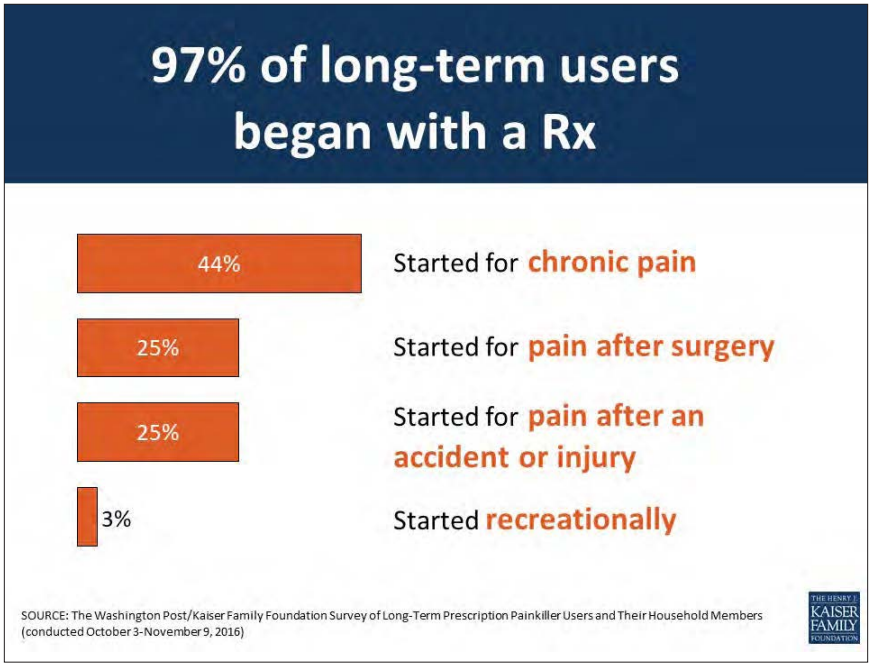
Walley, A.Y., Xuan, Z., Hackman, H.H., Quinn, E., Doe-Simkins, M., Sorenson-Alawad, A., Ruiz, S., Ozonoff, A. (2013). Opioid overdose rates and implementation of overdose education and nasal naloxone distribution in Massachusetts: Interrupted time series analysis. *BMJ*, 346, f174.

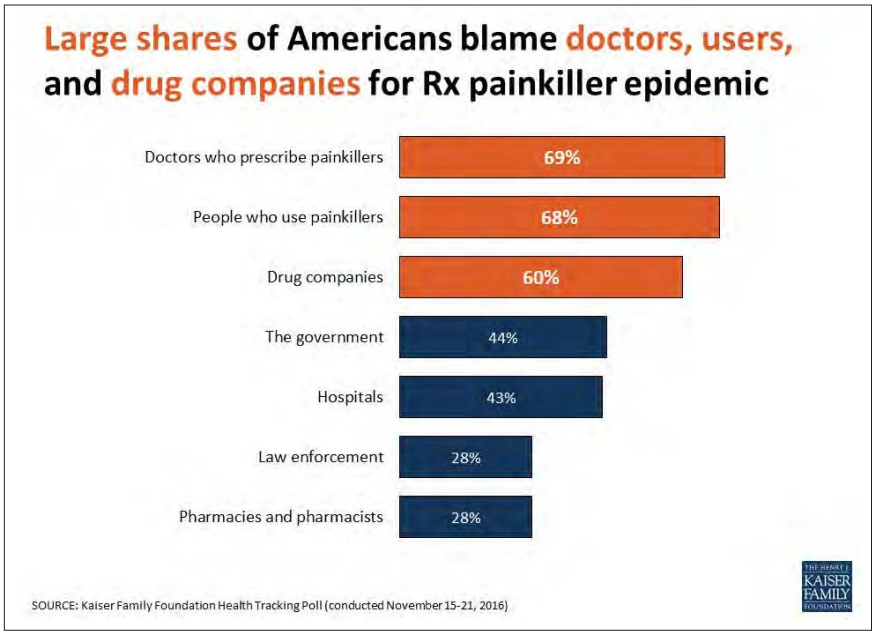
White, W.L. (1998). Slaying the dragon: The History of Addiction Treatment and Recovery in America. Bloomington, IL: Chestnut Health Systems.

White, W., Galanter, M., Humphreys, K., & Kelly, J. (2016). The paucity of attention to Narcotics Anonymous in current public, professional and policy responses to rising opioid addiction. *Alcoholism Treatment Quarterly*, 34(4), 437-462.

Williams, A.V., Marsden, J., & Strang, J. (2014). Training family members to manage heroin overdose and administer naloxone: Randomized trial of effects on knowledge and attitudes. *Addiction*, 109(2), 250-259.

World Health Organization (2009). WHO Guidelines for Psychosocially Assisted Pharmacological Treatment of Persons Dependent on Opioids. Geneva, Switzerland: World Health Organization. Retrieved from http://www.who.int/substance_abuse/publications/opioid_dependence_guidelines.pdf


97% of long-term users began with a Rx
44%
Started for chronic pain
25%
Started for pain after surgery
25%
Started for pain after an accident or injury
3%
Started recreationally
SOURCE: The Washington Post/Kaiser Family Foundation Survey of Long-Term Prescription Painkiller Users and Their Household Members (conducted October 3-November 9, 2016)
THE HENRY J. KAISER FAMILY FOUNDATION


Large shares of Americans blame doctors, users, and drug companies for Rx painkiller epidemic
Doctors who prescribe painkillers
69%
People who use painkillers
68%
Drug companies
60%
The government
44%
Hospitals
43%
Law enforcement
28%
Pharmacies and pharmacists
28%
SOURCE: Kaiser Family Foundation Health Tracking Poll (conducted November 15-21, 2016)
THE HENRY J. KAISER FAMILY FOUNDATION

"The growth in insurance coverage for SUD [substance abuse disorder] treatment has resulted in increased financial access to these services and has changed where and how SUD treatment services are delivered. Despite these changes to the SUD financing structure, many individuals with SUD in general, and OUD [opioid use disorder] specifically, do not engage in treatment for a variety of reasons."

– RICHARD FRANK, PH.D., and CARRIE FRY, DOCTORAL STUDENT

Financing Care for Opioid Use Disorders

Richard G. Frank, Ph.D. and Carrie E. Fry, Doctoral Student

Introduction

Drug overdoses claimed 52,404 lives in the United States in 2015 (Rudd et al., 2016). It is estimated that in 33,091 of those cases, or 63%, opioids were implicated. The number of opioid-related deaths grew 15.5% between 2014 and 2015. Starting in the 1990s, most of the growth in opioid-related mortality was related to the use of prescription opioids, but more recent increases in mortality have been driven by illicit opioids like heroin and fentanyl that are more lethal. There is increasing urgency to engage more people suffering from Opioid Use Disorders (OUD) in treatment. Fortunately, important strides have been made to improve financial access to treatment for OUD.

In this paper, we focus on the financing of Opioid Use Disorder treatment and how financing mechanisms have changed in recent years. We provide data showing a sharp shift in the structure and level of financing for care of Substance Use Disorders (SUDs) generally, and OUDs specifically. We emphasize the structure of financing, and the economic and policy dynamics that drove that structure prior to 2008. We trace the implications that pre-2008 financing mechanisms had for the delivery of treatment for SUDs and OUDs. We then turn to policy changes that have altered the structure of financing and promise to continue to do so in the future. We discuss the ways in which care delivery will change in response to evolving financing arrangements and offer some concluding observations.

Overview

The amount of spending on SUD treatment has increased dramatically over the last 15 years. The growth in insurance coverage for SUD treatment has resulted in increased financial access to these services and has changed where and how SUD treatment services are delivered. Despite these changes to the SUD financ-

ing structure, many individuals with SUD in general, and OUD specifically, do not engage in treatment for a variety of reasons. The challenges facing practitioners and policymakers regarding OUD treatment are not only how to pay for its increasing demand, but also how to remove non-financial barriers to OUD treatment.

Levels and Sources of Payments for SUD Treatment

Spending for substance use disorder treatment in the United States has increased dramatically in recent years and can be expected to continue its rapid expansion. Recent estimates show that spending on treatment for substance use disorders grew from $15.3 billion in 2004 to $44.9 billion in 2014, a factor of nearly three (SAMHSA, 2016a). During the same period, national health expenditures grew by a factor of 1.9 (Martin et al., 2017). Nevertheless, the level of health care spending on substance use disorders has historically been low in both absolute terms and as a share of total health care spending ($220 billion; 7.5% in 2014) (SAMHSA, 2016a).

TABLE 1: SUBSTANCE USE DISORDER EXPENDITURES BY PAYER UNITED STATES; 2004, 2014

	2004		2014	
	$, Millions	**%**	**$, Millions**	**%**
Private		*24*		*31*
Out of Pocket	1,393	7	3,203	9
Private Insurance	2,386	13	6,064	18
Other Private	669	4	1,291	4
Public		*76*		*69*
Medicare	895	5	2,181	6
Medicaid	3,957	21	7,207	21
Other Federal	2,917	16	3,965	12
Other State/Local	6,547	35	9,980	29

Source: SAMHSA Behavioral Health Spending & Use Accounts: 1986-2014

Payment arrangements for substance use disorder treatment have shifted from primarily grant-based funding of specialty SUD providers to one that relies more heavily on insurance and more closely resembles other elements of the modern U.S. health care system. The prior system of financing relied mostly upon fixed-budget funding of state agencies that directly paid service providers through grants. The new system is mostly structured around open-ended insurance arrangements. This evolution is reflected in the shifting level and composition of financing reported in Table 1. From 2004-2014, the role of direct payments to providers from state governments and indirectly from federal block grants has diminished, falling from 51% of spending in 2004 to 41% in 2014[1] (SAMHSA, 2016a). Table 1 also shows that spending growth has largely been driven by the expanding role of insurance-based financing, including private insurance, Medicare and Medicaid. SUD spending in these three insurance arrangements grew by 154%, 144% and 82%, respectively, between 2004 and 2014. This compares to a 47% rise in grant-based financing.

Policy changes have contributed to these trends, but so have changing demographics and treatment needs, partially stemming from the opioid epidemic that dates to the latter part of the 1990s (Rudd et al., 2016). The data in Table 1 mostly pre-date the coverage expansions implemented under the *Affordable Care Act* (*ACA*), which can be expected to further increase the role of private insurance and Medicaid in paying for SUD treatment. This is especially true for the provision of opioid use disorder treatment in Medicaid: The prevalence of OUD is roughly 40% greater among individuals with incomes below 200% of the federal poverty line than for those with incomes above 200% of the federal poverty line (SAMHSA, 2015).[2]

What We Pay For

Overall, SAMHSA estimates that in 2015 there were a total of 14,234 substance use disorder treatment programs in the U.S. Residential or inpatient treatment was offered by about 24% of the programs; outpatient SUD care was offered by 82%. Taken together, these modalities accounted for 89% of the people in treatment (SAMHSA, 2017). About 55% of the treatment programs are owned by private, non-profit organizations; 34% by for-profit entities; and the remainder are owned by some level of government (SAMHSA 2017).

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[1] These figures include prevention funding through the SAMHSA-administered block grant. This is the predominant source of paying for prevention programs. Screening and referral activities are also paid for by most insurance, but those activities are quite limited in scope.

[2] 31 states and the District of Columbia have expanded Medicaid coverage to individuals with incomes below 138% of the federal poverty line under the *Affordable Care Act*.

TABLE 2: SUBSTANCE USE DISORDER EXPENDITURES BY SERVICE MODALITY
UNITED STATES; 2004, 2014

	2004		2014	
	$, Millions	**%**	**$, Millions**	**%**
Hospitals	*5,217*	*30.2*	*10,922*	*37.4*
General Hospitals	4,029	23	8,513	29
Specialty Hospitals	1,187	7	2,409	8.2
Physicians	*852*	*4.9*	*1,828*	*6.2*
Psychiatrists	265	2	399	1.3
Non-Psychiatrist Physicians	586	3.4	1,429	4.9
Other Professionals	*1,687*	*10*	*3,343*	*11.4*
Freestanding Nursing Homes	257	1.5	370	1.3
Freestanding Home Health	69	0.4	240	1
Specialty SUD Centers	7,173	41.5	10,544	36
Specialty Mental Health Centers	2,045	11.8	2,069	7.1

Source: SAMHSA Behavioral Health Spending & Use Accounts: 1986-2014. Only italicized categories should sum to 100%. Remaining delineations are sub-categories as a percent of total. Sub-categories may not sum to main category due to the omission of certain sub-categories.

Since the 1960s, the number of inpatient beds for treatment of substance use disorder has decreased dramatically. Many patients who receive inpatient treatment (dominated by detoxification) for substance use disorder receive this treatment in a psychiatric unit of a general hospital, rather than a specialty hospital. As of 2015, there were 15,415 designated inpatient (non-residential) beds for treatment of substance use disorders and 104,012 residential treatment beds for SUD (SAMHSA, 2017). Even in an era of reduced focus on institutional treatment for SUDs, there was a more than doubling of spending on such care between 2004 and 2014, from $4 billion to nearly $11 billion (Table 2). Thus, nearly 40% of SUD spending continued to purchase costly residential services of some kind that treat relatively small numbers of people (SAMHSA, 2016a). This, in part, reflects remnants of the historical orientation of insurers to limit SUD coverage to institutional detoxification and stabilization (discussed below).

There have been other notable changes in patterns of care delivery for SUDs, including the expanding role of general medical providers, as seen in the increase in expenditures for general hospitals (from 21%–25% over the 2004-2014 period); non-psychiatric physicians (3%–4%); and other medical providers (9%–10%; Table 2) (SAMHSA, 2016a).

The Growing Role of Insurance

Broad coverage of treatment for SUDs by public and private health insurance is a relatively new phenomenon. Prior to the passage of two laws that significantly altered the financing landscape for SUD treatment, the majority of SUD treatment was financed by local and state governments through state budgets and federal block grants. The direct provision of SUD treatment through public funding promoted the notion that private and public health insurance had a small role to play in paying for this care. As a result, private insurance and many Medicaid plans limited insurance coverage for SUD treatment to inpatient detoxification services.[3] In 1986, roughly 45% of substance use disorder spending involved some form of public or private insurance (SAMHSA, 2016a). Today, that figure is close to 60%.

The old system of direct financing resulted in a highly fragmented health care system that lacked incentives for care coordination or high-quality care. The new system of insurance brings about its own complications, most notably the problem of adverse selection. That is, insurers have a strong incentive to avoid covering people with predictably high costs, and people who know they have a given condition have a strong incentive to purchase insurance that covers those costs.

Private Insurance

Competition within health insurance markets has undermined the development of broad coverage for SUD treatment due to concerns about adverse selection. People with SUDs generally, and OUD specifically, not only have the costs related to the treatment of their substance use disorder, but also have elevated health needs related to other health and mental health conditions, making them a relatively high cost population to insure. One recent analysis estimated the surcharge for the drug dependent population in private insurance (Marketplaces) to be $20,450 per year (Berger & Gee, 2017). Because SUDs are typically chronic

[3] For a discussion of some clinical implications of this coverage structure, see the accompanying paper by Humphreys.

recurring conditions, they are persistent and more predictable than many other illnesses (Frank & Glied, 2006; Frank & McGuire, 2000). Together, these characteristics of SUD create incentives for competitive health plans (which are paid a fixed per-enrollee price) to avoid enrolling people with SUD conditions. Insurers can accomplish this by limiting coverage for those conditions, impeding access to SUD services when they are covered, or keeping the quality of those services low.

Advocates for improved insurance coverage for SUDs have long argued their case as a matter of fairness – that health insurance coverage should not "discriminate" against people with substance use disorders. Facing market realities that made SUD coverage rare, some states attempted to address these incentives in the 1980s and 1990s by enacting laws that mandated minimum coverage levels. Eighteen states enacted statutes requiring minimum levels of coverage for drug use disorders like OUDs. These often applied to larger, fully-insured group plans but not the individual, small group or self-insured markets. Consequently, plans in the individual and small group markets excluded or strictly limited coverage for SUD treatment. Among insurers providing coverage in the individual market in 2011, 34% of plans offered did not cover substance use disorder treatment (HHS, Assistant Secretary for Planning and Evaluation, 2011). Similarly, 25%–30% of private group insurance plans did not offer SUD treatment. Among the plans that did offer coverage beyond detoxification, there were strict treatment limits, such as limiting coverage to 20 outpatient visits and 30 inpatient days per year and imposing coinsurance as high as 50%.

Medicaid

State Medicaid programs have also tended to strictly limit coverage of SUD care in general and OUD care specifically. There have been historical concerns from both the federal government and state Medicaid programs that generous coverage of SUD treatment would result in large cost shifts from state-and locally-funded services to the joint state-federal financed Medicaid program. One clear example of this concern is the Institutions of Mental Disease (IMD) provision in the legislation that created the Medicaid program. Medicaid is prohibited from paying for care in 24-hour residential or inpatient facilities with more than 16 beds for patients between the ages of 22 and 64 if more than half of the residents have a severe mental illness (*Social Security Act*, §1905 (a) (B)). These types of institutions are generally run by states, and the inclusion of IMDs in Medicaid would have shifted the cost of these institutions from state and local budgets to the federal government.

Because of differing financing streams, regulatory requirements, and budgetary risk, state Medicaid and substance use agencies have often conflicted over

the role Medicaid should play in financing SUD care. Historically, state governments could control their financial liability simply by setting the budget for the substance abuse agency. These agencies would often limit the number of "slots" for SUD treatment, based on the state budget and per-person expenditures. By contrast, Medicaid eligibility brings with it an entitlement to services, which, when paid on a fee-for-service basis, has no cap on spending. As a result, state Medicaid agencies have sought to restrict costs in other ways, primarily by restricting covered services. For example, methadone was not covered as an optional service in in 11 out of 18 states with a predominantly fee-for-service Medicaid program in 2008. Similarly, five of these same 18 states did not cover outpatient SUD services, and only half (9 of 18) covered short-term residential services (Bouchery et al., 2012).

Medicaid is now playing a significant role in financing Medication-Assisted Treatment (MAT), which is the gold standard of treatment for OUD. MAT combines behavioral therapy (psychotherapy/counseling) and one of three medications: methadone, buprenorphine and long-acting naltrexone. The most recent data show that methadone is available on the Medicaid preferred drug list in 61% of states. Naltrexone is on the preferred drug list of 89% of states and buprenorphine on 100%. While covered, these drugs are typically subject to prior authorization, quantity limits and, in the case of buprenorphine, lifetime limits on utilization (SAMHSA, 2016d).

How Financing Has Guided Delivery

The history of specialty substance use disorder treatment programs' being dependent on grants from states shaped how those programs operated. Prior to recent policy changes that expanded insurance coverage, nearly one-third of programs did not receive any payments from insurance (SAMHSA, 2016d). As a result, they did not resemble health care organizations in the sense that they were not required to meet conditions of participation (for Medicare or Medicaid) or credentialing standards (for private insurers). There was less orientation towards MAT for OUD, which mandates registration and regulatory oversight from the U.S. Drug Enforcement Administration (DEA) and U.S. Department of Health and Human Services (HHS), and state regulatory bodies, where required.

Where insurance has come into play, its design has also affected the delivery of SUD services. Public and private insurers generally contracted with specialized managed care organizations to insure care for mental and substance use disorders. These organizations, known as behavioral health carve-outs, separate the risk and the management of behavioral health services from the rest of the insur-

ance risk. Carve-outs allow an organization with specialized expertise in a provider system that has long been separated from general medical care to manage the care. These carve-outs also segment out the insurance risk most prone to adverse selection, often via a single contract for all behavioral health services for all health insurance subscribers. Overall, behavioral health care carve-outs have reduced the level and the growth in behavioral health spending, especially inpatient care, without reducing quality of care (SAMHSA, 2014). These advantages come with some important negatives. First, the administrative costs of carve-out contracts are high. Additionally, carve-outs tend to maintain the separation of behavioral health and general medical care that impedes coordination of care necessary for many individuals with SUD generally, and OUD specifically.

The Relationship Between Insurance and Treatment

TABLE 3: Health Insurance Coverage for Individuals with OUD

Insurance Type	Population with OUD	Population with SUD	Total Population
Medicare	5.3%	3.3%	8.2%
Medicaid	34.3%	30.4%	22.5%
VA/CHAMPUS/Tricare	2.8%	2.7%	3.8%
Private Insurance	42.6%	47.8%	60.8%
Through Employer	37.1%	42.1%	53.8%
Other	5.5%	5.7%	7.0%
Uninsured	16.6%	15.2%	10.4%

Source: Authors' analysis of 2015 National Survey of Drug Use and Health (NSDUH). Columns may not sum to 100% because respondents may have more than one form of health insurance coverage.

Table 3 presents data on the distribution of people with opioid use disorders and SUDs by insurance status. As noted earlier, these illnesses are considerably more prevalent in low-income populations, whites, and people aged 26-34 years. This has two important implications. First, individuals with OUD have historically been greatly overrepresented in the uninsured population. Even today, the percent of people with OUD that are uninsured is more than 18%; the national uninsured rate for people 18-64 years of age is about 12% (SAMHSA,

2013). Second, Medicaid will have a potentially large and growing role in treatment, as will private insurance with low-income subsidies like plans offered in the Marketplaces. Tabulations from the National Household Survey on Drug Use and Health (NSDUH) for 2015 indicate that 34% of people with OUD were covered by Medicaid and 42% by private insurance (5.5% had Medicare and 2.8% VA and other military coverage; Table 3) (SAMHSA,2015).[4]

In 2015, only-one quarter (25.5%) of individuals with opioid use disorder received treatment in the prior 12 months (authors' analyses of 2015 NSDUH data). What are the reasons for this large gap between apparent need for and receipt of care? The predominant reasons include inability to afford treatment and lack of readiness to seek treatment. For persons with illicit drug use disorders who did not receive treatment, 39% reported that they had no health insurance coverage and could not afford the cost of treatment (authors' analyses of 2015 NSDUH data). An additional 29% reported that they were not ready to stop using substances (authors' analyses of 2015 NSDUH data). Other commonly cited barriers to receiving treatment include the stigma of addiction in the work place and the community, the lack of available providers, and the belief that there isn't a problem that needs care (authors' analyses of 2015 NSDUH data; SAMHSA, 2015).

This treatment gap raises several policy challenges. The first is the need to improve both financial access to treatment through insurance coverage (and associated premium subsidies) and physical access to treatment providers who can

[4] Note the numbers do not add to 100% because of rounding.

deliver evidence-based care for OUD. The second policy challenge involves persuading the set of people who say they do not want to stop using opioids, those who claim not to have a problem, and those who balk at treatment due to the stigma and possible employment and legal consequences, to obtain treatment.

A great deal of recent health policy and SUD policy has focused on expanding financial and physical access. To address the reluctance to seek care, the use of payment arrangements to promote closing the treatment gap is a natural policy impulse. Most payment systems used by public and private insurers pay providers for providing services and in some cases screening for illness. Pay-for-performance schemes or incentive contracts can be put into place that reward outreach activities, including screening. One line of logic would suggest that given the high health costs associated with SUD, health plans responsible for the total cost of care of a population would have a strong incentive to identify and treat those with an SUD, thereby helping to close the treatment gap. A second school of thought posits that because people with OUDs are more costly than other enrollees and because OUDs are chronic recurring conditions, competitive health plans have strong incentives to avoid enrolling these people, especially given the crude risk adjustment methods we have for SUDs (see below). The evidence to date strongly favors the latter type of thinking.

There is some interest in early intervention programs for a variety of chronic diseases. Some recent proposals include a prospective payment system that sets a "per case payment" for each person with an OUD from the relevant population (e.g. Medicaid Managed Care Organization (MCO) enrollees) who is engaged in treatment (Frank & Garfield, 2007). The payment would be based on the cost of outreach and engagement, but would not cover treatment costs; those would be paid separately. This, of course, leaves open the question of whether we currently have effective models of outreach and engagement.

Supply Constraints

The shifting financial arrangements to pay for care for opioid use disorder treatment are occurring in the context of shifts in the types of treatment that are available. The evolving regulatory and medical context affects the supply of providers, which, in turn, affects the degree to which insurance coverage actually translates into care.

Care for opioid use disorders is highly differentiated (Bonhomme et al., 2012). There are important regulations that define the functions that SUD treatment programs can serve. Because methadone and buprenorphine are themselves

opioids and, therefore, potentially drugs of abuse, special regulations define the supply of treatment using these drugs. This is not the case with naltrexone. Some medication-assisted treatment for OUD is delivered by Opioid Treatment Programs (OTPs), which are regulated by the Substance Abuse and Mental Health services Administration (SAMHSA), DEA, and state regulatory authorities (if required by the state). A treatment facility is considered an OTP if it provides medication-assisted treatment, which includes dispensing methadone, buprenorphine, or both.

MAT with methadone is highly-regulated, requiring that the medication be dispensed by an OTP and that the administration of methadone take place at the OTP's physical location. Methadone's risk of abuse, addiction, and diversion has made it more difficult to administer, resulting in smaller increases in the number of individuals with OUD who receive methadone-based MAT. Since 2003, the number of clients who receive methadone treatment from an OTP has increased from 227,003 to 356,843 in 2015 (SAMHSA, 2017). While this is a 57% increase, it is much smaller than the increase for buprenorphine-based treatment. This highlights that even as insurance coverage and public SUD budgets have expanded, the regulatory structure and the stigma associated with OTPs serve to create friction in the further diffusion of this effective treatment.

The reluctance to use methadone in MAT has led to an increased reliance on buprenorphine (e.g., Suboxone, Bunavail), an opioid agonist with lower risks of abuse and diversion. Buprenorphine can be administered in settings that are not accredited as OTPs, including physician offices. However, physicians that provide buprenorphine as treatment for OUD must modify their registration with the DEA, as buprenorphine is considered a Schedule III drug. The *Drug Addiction Treatment Act of 2000 (DATA)* greatly expanded access to buprenorphine-based MAT by lowering the regulatory requirements for physicians who want to prescribe buprenorphine in a manner consistent with FDA approval. However, until recently, physicians who are not a part of a licensed OTP and prescribe buprenorphine could manage a maximum of 100 patients at a time, potentially reducing the supply of physicians who could provide MAT. A 2016 regulation allowed physicians to apply for a waiver to increase this limit to 275 patients per physician, further expanding the supply of physicians that can administer buprenorphine for OUD (SAMHSA, 2016c).

Since the passage of *DATA* and the adoption of the regulatory framework to license OTPs, the number of OTPs and the percent of substance abuse facilities with an OTP has remained relatively stable since 2003. The introduction of buprenorphine, coupled with the regulatory framework of *DATA*, has led to a

large increase in the number of OTPs that provide buprenorphine (644%; from 121 in 2003 to 779 in 2015). A similar, but less dramatic increase in the number of non-OTPs offering buprenorphine-based MAT occurred over this time period (423%; from 620 in 2003 to 2625 in 2015) (SAMHSA, 2016a). However, non-OTPs offering buprenorphine served a greater number of individuals in 2015 than OTPs. This divergence in trend has accelerated over time, suggesting that office-based, non-OTP physicians are an important part of the MAT supply. Buprenorphine regulation is structured so that it fits more comfortably in the health care mainstream and, as a result, is more user-friendly (with respect to availability) and is less stigmatizing (since it does not involve an easily identifiable specialty facility like methadone-based MAT administered at an OTP).

While there are a variety of concerns about MAT in terms of diversion, regulation of supply, and philosophical questions about continued dependence on an opioid, clinical research shows it to be the most effective approach (Prescription Drug Abuse Committee, 2015; Mattick et al., 2009). MAT itself is more costly than other less effective approaches to treatment. For example, data from Vermont show that MAT costs about $5,600 per year, whereas alternative approaches average a cost of $3,700 per year for a similar population. The data also show that some of the $1,900 difference is offset by non-opioid related medical care. The offset has been estimated at $400, making MAT $1,500 more expensive than its less effective counterparts.

Another form of MAT uses long-acting naltrexone, which is not an opioid and can, thus, be administered by a physician who does not have to undergo special licensing or regulatory procedures. Thus, the supply of physicians who can provide naltrexone-based MAT is potentially much larger than the supply of physicians who can administer buprenorphine or methadone-based MAT. Additionally, an injection of long-acting naltrexone provides 30 days of treatment, unlike buprenorphine and methadone, which must be taken at least daily. The increased provider supply and more user-friendly format of MAT with naltrexone make it a potentially promising form of treatment for OUD. However, naltrexone requires a 30-day detoxification from opioids before the first dose can be administered. It is also considerably more expensive than the other medications used for MAT. Moreover, as a physician-administered drug, it is covered under the medical benefit, and the physician must keep an inventory of the drug on hand, which is expensive for physician practices. Thus, naltrexone is often limited to use in criminal justice settings and residential treatment programs.

Recent Policy Changes

In the last decade, two pieces of federal legislation have profoundly changed the coverage for and financial access to opioid use disorder treatment. The first piece of legislation, the *Mental Health Parity and Addiction Equity Act (MHPAEA),* was passed in 2008 and required that group health insurance plans that provide mental health and substance use disorder benefits offer them at parity with medical and surgical benefits. *MHPAEA* required that cost sharing provisions for treatment of mental and substance use disorders, including deductibles and co-payments, be comparable to those for medical and surgical benefits and required that management of care be conducted using comparable processes and evidence (referred to as non-quantitative treatment limits). The *Patient Protection* and *Affordable Care Act (ACA)* extended the reach of *MHPAEA* beyond employer-sponsored insurance. The *ACA* expanded coverage for care of OUD in three ways:

- Mental health and substance use disorder treatment were defined as essential health benefits that must be covered by nearly all health insurance plans.
- MHPAEA's provisions were extended to individual and small group plans.
- The essential health benefits and MHPAEA's provisions were extended to the Medicaid expansion population.

The net effect of these efforts was to increase SUD coverage for over 170 million Americans. In combination, the requirements of *MHPAEA* and the *ACA* have dramatically changed the funding and financing mechanism of OUD treatment in the United States. Those changes are partly reflected in the changes in payment arrangements between 2004 and 2014 displayed in Table 1. However, since the coverage expansions were initiated in 2014, we expect the role of insurance in paying for OUD treatment to continue to expand.

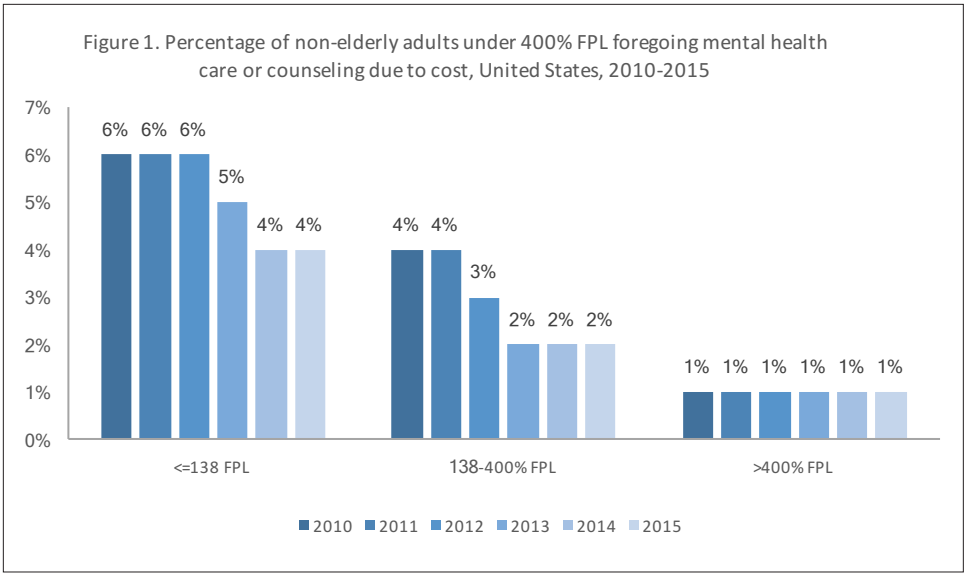
While parity provisions are expanding insurance coverage for people with SUDs, there remain important incentives for insurers to undertake measures to avoid enrolling people with these conditions. This has the potential to impede access through administrative practices that govern the availability and access to care. Recent research by Montz et al. (2016) shows that risk adjustment systems do not compensate for the extra costs of SUDs. Likewise, quality measures remain underdeveloped for these conditions. Together, this implies that there are continued opportunities for health plans to engage in practices aimed at avoiding people with SUDs.

Putting new insurance-based purchasing power in the hands of consumers of OUD care is an important step toward expanding access to OUD treatment. Yet it is also important to consider other financing and regulatory policies that have accompanied those changes. As noted earlier, one consequence of the historical approach to financing is that supply was largely created by funding nonprofit substance use disorder programs through state grants. These effectively created state-sponsored franchises that were disproportionately governed by the state granting agencies. They also limited supply.

The shift toward insurance-based financing has the effect of incorporating providers into health plans' networks (SAMHSA, 2016a). This means meeting conditions of participation of insurers and standards of modern health care organizations. This is especially important given the strong evidence supporting MAT as the treatment of choice for OUD. Medicaid programs, in part due to parity requirements and emerging evidence of the effectiveness of MAT, are beginning to eliminate restrictions on MAT. These efforts are reflected in the fact that some states that have been hard hit by the opioid epidemic, like Ohio and West Virginia, are funding half the MAT care in the state through Medicaid (Martin et al., 2017). These new financing arrangements also begin to pave the way for greater integration of high-quality OUD care with other mental health and general medical services (SAMHSA, 2016a).

Finally, the continued increase in the role played by Medicaid in paying for OUD means that patients with OUD will be more likely to obtain treatment that is evidence-based in coordination with other medical care. Specifically, the adoption of Medicaid Health Homes (a waiver program created by the *Affordable Care Act*) by 21 states puts particular emphasis on coordination of health and human services care for mental and substance use disorders. Additionally, the use of Accountable Care Organizations in both Medicare and Medicaid and the growth of enrollment of dually-eligible beneficiaries in alternate delivery systems offer new possibilities of expanded provision of high-quality OUD treatment using MAT and its accompanying supports.

The net effects of these policies are starting to become visible in treatment utilization data. Figure 1 shows changes in reported access to mental health care, generally; it also shows that there have been significant declines in the number of people reporting failure to obtain treatment due to cost concerns. An analysis of states that expanded Medicaid coverage early showed an 18% reduction in unmet needs for substance use treatment (Rudd et al., 2016; Wen et al., 2015). Recent work on the impact of the larger Medicaid expansion offers a more nuanced view on how the coverage expansions are affecting receipt of care. MacLean and Saloner (2017) find that in comparing Medicaid expansion



Source: Authors' analysis of 2010-2015 National Survey of Drug Use and Health (NSDUH)

versus non-expansion states, individuals receiving specialty OUD care did not grow in the expansion states relative to those not expanding (SAMHSA, 2017). Instead, they estimate that Medicaid had an important effect on increased MAT for OUD. This means that the expanded treatment is being delivered outside the specialty SUD system. Supportive findings of large increases in the growth of buprenorphine use in Medicaid expansion states compared to non-expansion states have been reported in other more recent analyses (Clemans-Cope et al., 2017). This inference is further substantiated by their reporting of an increase in OUD treatment for Medicaid patients in community health centers (Clemans-Cope et al., 2017).

Together, these results support the proposition that there is an expanding role in OUD care for general medical care providers and a shift in financial responsibility for provider payments to Medicaid in expansion states. This is likely to reduce uncompensated care and improve the financial health of OUD providers, while likely improving the quality of care that the consumer receives. More specifically, states that have both expanded Medicaid and faced high levels of OUD and its consequences (e.g., neonatal abstinence syndrome and mortality) have reported improvements in access to care for OUDs (SAMHSA, 2017).

The confluence of the *ACA* and *MHPAEA* means that demand is likely expanding faster than supply. It is for this reason that $100 million in grants to Community

Health Centers for fiscal year 2016 and the appropriation of $1 billion in the *21st Century Cures Act* for addressing the opioid epidemic are important (SAMHSA, 2016b). Those grants to states were targeted at building capacity in areas affected most by the opioid epidemic, where financial and physical access to treatment is low. In one appropriation, the vehicle for increased access to care was Federally Qualified Health Centers; in the other, a broader array of institutions would receive funds to stimulate financial and non-financial barriers to care. The presumption was that, under the *ACA*, consumers had new purchasing power stemming from insurance expansion, but there was insufficient treatment capacity to keep up with demand and too little investment in outreach to stimulate additional demand. In addition, some funds would be directed to provide treatment to low-income populations that remained uninsured.

At the same time, there has been recognition that there were regulatory barriers to the provision of MAT, especially buprenorphine. The limits on the certified number of patients that could be treated with buprenorphine were seen as one important regulatory barrier to the provision of care to a growing number of people. As a result, the U.S. Department of Health and Human Services issued regulations in 2016 to expand the per-physician caseload of patients seeking buprenorphine-based MAT from 100 to 275 at a time (SAMHSA, 2016c).

Concluding Observations

The financing of SUDs in the U.S. is in the midst of a major transformation. The shift from a financing system that relied centrally on grant-based funding of specialty, community-based providers on the one hand with limited insurance that was oriented toward institutional detoxification services on the other, to broad-based insurance that covers the elements of evidence-based practices is forcing fundamental changes in the delivery of care. This transformation is driven by both a large increase in money directed toward SUD treatment and changes in the types of services and the settings in which they are delivered. Evidence also suggests a new trend toward more SUD treatment occurring in mainstream health care settings.

The traditional health insurance payment arrangements that rewarded volume and paid scant attention to performance have become a "bête noir" in health policy circles, but these features have almost surely resulted in improved access to SUD care and expanding treatment capacity as new investment is drawn into the sector. For example, there have been over 170 private equity deals made for behavioral health care providers since 2012 (Duff & Phelps, 2015). The expanding role of mainstream health insurance arrangements is also likely to promote improved quality of care.

Two mechanisms are driving quality of care improvements. First, the requirements of participation and credentialing standards set by private and public insurance programs are pushing SUD providers towards mainstream health care settings and their professional cadres of clinicians. Too often, small, localized treatment programs rely on treatment approaches that lack demonstrated effectiveness and, in fact, are resistant to evidence-based treatments like MAT. The second force for quality is the drive in health care to "pay for value." The shift to value-based purchasing means that there are new pressures to develop performance measures for SUD care, which will be included in performance measure sets.

The expansion of insurance arrangements has clearly expanded treatment for OUD. It is estimated that there are about 220,000 people with OUD who have obtained health insurance through the Medicaid expansion and the health insurance Marketplaces. This accounts for nearly 10% of people with OUD nationally (Frank & Glied, 2017). The ongoing challenge will be to direct treatment capacity so that it follows the continuing epidemic and catches up with policies that are reducing the financial barriers to care. Increasing and directing capacity also means creating incentives for health plans and providers to engage in population health and outreach practices that drive people with OUD into treatment.

Finally, given the improved prospects for addressing the opioid epidemic via *MHPAEA* and the *ACA*, it is important to address the remaining incentives for insurance plans to avoid people with SUDs. Improved risk adjustment and further development of performance measures to be used in accountability systems are areas that can continue the progress that has recently been made in paying for SUD treatment.

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References

Berger, S. & Gee, E. (2017). Premium Increases for Pre-Existing Conditions Under Latest ACA Repeal Plan, by State. Center for American Progress. Retrieved from https://www.americanprogress.org/issues/healthcare/news/2017/04/21/431019/premium-increases-pre-existing-conditions-latest-aca-repeal-plan-state/

Bouchery, E., Harwood, R., Malsberger, R., Caffery, E., Nysenbaum, J., & Hourihan, K. (2012). Medicaid Substance Abuse Treatment Spending: Findings Report. Retrieved from Washington, D.C.: https://aspe.hhs.gov/basic-report/medicaid-substance-abuse-treatment-spending-findings-report - spend

Bonhomme, J., Shim, R., Gooden, R., Tyus, D., & Rust, G. (2012). Opioid addiction and abuse in primary care practice: A comparison of methadone and buprenorphine as treatment options. *Journal of the National Medical Association*, 104(7-8), 342-350.

Clemans-Cope, L., Lynch, V., Epstein, M., & Kenney, J. (2017). Medicaid Coverage of Effective Treatment for Opioid Use Disorder. Urban Institute. Washington, DC. Retrieved from: https://www.urban.org/research/publication/medicaid-coverage-effective-treatment-opioid-use-disorder.

Duff & Phelps, D. (2015). Industry Insights: Behavioral Health. Retrieved from https://www.duffandphelps.com/assets/pdfs/publications/mergers-and-acquisitions/industry-insights/healthcare/duff phelps behavioral health industry insights.pdf

Drug Addiction Treatment Act of 2000 (2000). P.L. 106-310, 114 Stat. 1101.

Frank, R.G. & Garfield, R.L. (2007). Managed behavioral health care carve-outs: Past performance and future prospects. *Annual Review of Public Health*, 28, 303-320. doi:10.1146/annurev.publhealth.28.021406.144029

Frank, R.G. & Glied, S.A. (2006). Better But Not Well. Baltimore, MD: Johns Hopkins University Press.

Frank, R.G. & McGuire, T.G. (2000). Economics and mental health. In J.P. Newhouse & A.J. Culyer (Eds.), Handbook of Health Economics (1 ed., Vol. 1, pp. 893-954). Amsterdam: Elsevier.

Maclean, J.C., & Saloner, B. (2017). Substance use treatment provider behavior and healthcare reform: Evidence from Massachussetts. *Health Economics*. 21 Feb. 2017. [Epub].

Martin, A., Hartman, M., Washington, B., & Catlin, A. (2017). National health spending: Faster growth in 2015 as coverage expands and utilization increases. *Health Affairs*, 36(1), 166-176.

Mattick, R.P., Breen, C., Kimber, J., & Davoli, M. (2009). Methadone maintenance therapy versus no opioid replacement therapy for opioid dependence. *Cochrane Database of Systematic Reviews*, 3, CD002209.

Mental Health Parity and Addiction Equity Act (2008). P.L. 110-343, 122 Stat. 3765.

Montz, E., Layton, T., Busch, A.B., Ellis, R.P., Rose, S., & McGuire, T.G. (2016). Risk-adjustment simulation: Plans may have incentives to distort mental health and substance use coverage. *Health Affairs*, 35(6), 1022-1028.

Patient Protection and Affordable Care Act (2010). P.L. 111-148 and P.L. 111-152, 124 Stat. 119 et seq.

Prescription Drug Abuse Committee. (2015). Addressing Prescription Drug Abuse in the United States: Current Activities and Future Opportunities. Centers for Disease Control and Prevention, Department of Health and Human Services. Washington, DC. Retrieved from: https://www.cdc.gov/drugoverdose/pdf/hhs_prescription_drug_abuse_report_09.2013.pdf

Rudd, R., Seth, P., David, F., & Scholl, L. (2016). Increases in drug and opioid-involved overdose deaths in the United States, 2010-2015. *Morbidity and Mortality Weekly Report*, 65; 1445-1452. doi: 10.15585/mmwr.mm655051e1

Substance Abuse and Mental Health Services Administration (SAMHSA) (2013). Trends in the Use of Methadone and Buprenorphine in Substance Abuse Treatment Facilities: 2003 to 2011. Retrieved from: https://www.samhsa.gov/data/sites/default/files/N-SSATS%20Rprt%20Trnds%20Use%20Methadone%20&%20Buprenorphine%20at%20SA%20Trmt%20Facs%20%2003-11/N-SSATS%20Rprt%20Trnds%20Use%20Methadone%20&%20Buprenorphine%20at%20SA%20Trmt%20Facs%20%2003-11/sr107-NSSATS-Buprenorph.htm

Substance Abuse and Mental Health Services Administration (SAMHSA) (2014). Medicaid Coverage and Financing of Medications to Treat Alcohol and Opioid Use Disorders. Retrieved from: http://store.samhsa.gov/shin/content/SMA14-4854/SMA14-4854.pdf

Substance Abuse and Mental Health Services Administration (SAMHSA) (2015). National Survey on Drug Use and Health (NSDUH). [Dataset]. Substance Abuse and Mental Health Services Administration, Department of Health and Human Services. Rockville, MD.

Substance Abuse and Mental Health Services Administration (SAMHSA) (2016a). Behavioral Health Spending and Use Accounts, 1986-2014. Retrieved from: http://store.samhsa.gov/shin/content/SMA16-4975/SMA16-4975.pdf

Substance Abuse and Mental Health Services Administration (SAMHSA) (2016b). HHS awards $53 million to help address opioid epidemic [Press release]. Retrieved from https://www.samhsa.gov/newsroom/press-announcements/201608310600

Substance Abuse and Mental Health Services Administration (SAMHSA) (2016c). Medication Assisted Treatment for Opioid use Disorders, 81 FR 44711 C.F.R. Substance Abuse and Mental Health Services Administration, Department of Health and Human Services. Rockville, MD.

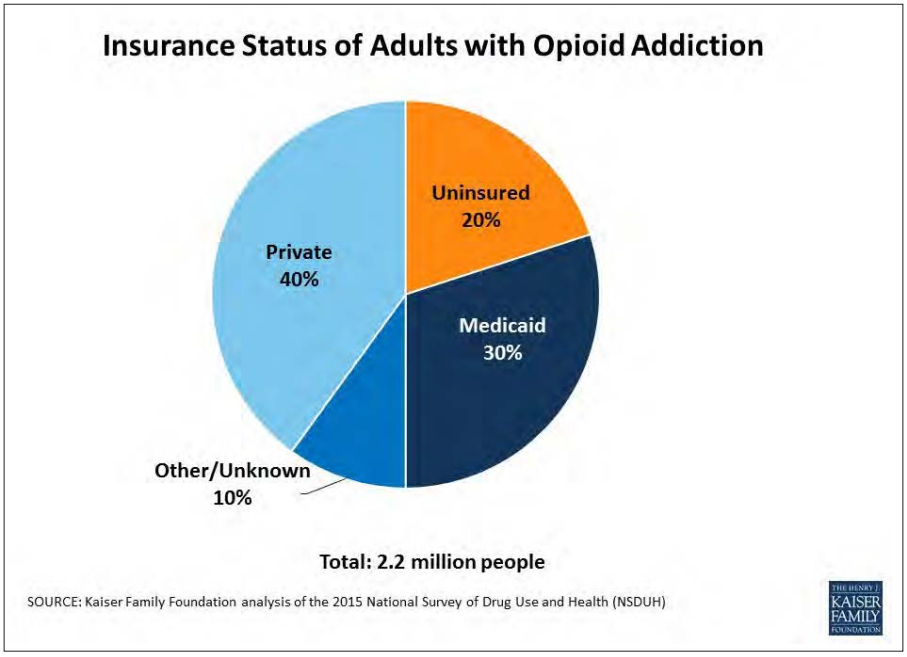
Substance Abuse and Mental Health Services Administration (SAMHSA) (2016d). Medication-Assisted Treatment (MAT). Programs & Campaigns. [Website]. Updated 22 November 2016. Retrieved from: https://www.samhsa.gov/medication-assisted-treatment.

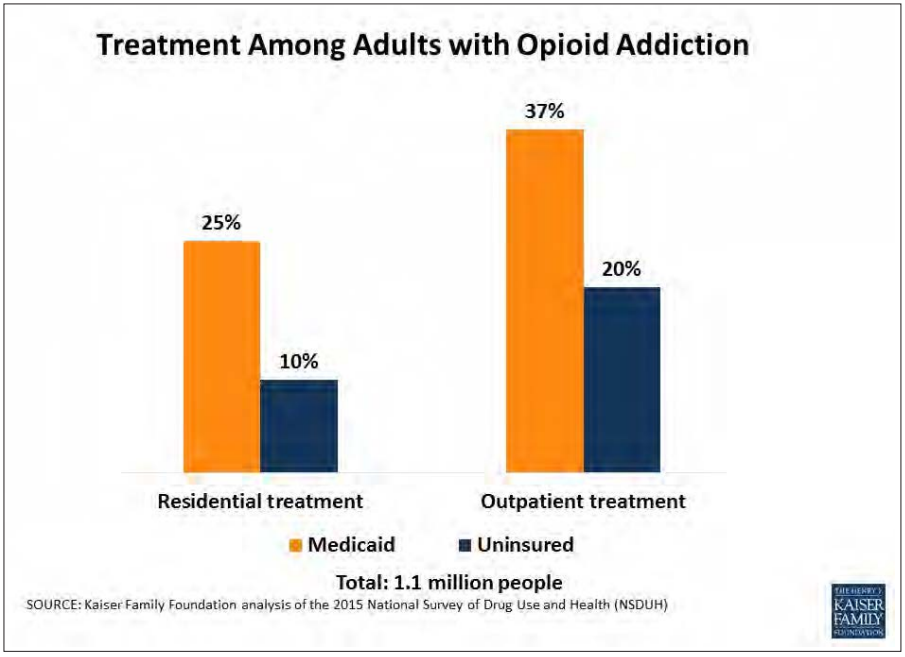
Substance Abuse and Mental Health Services Administration (SAMHSA) (2017). National Survey of Substance Abuse Treatment Services (N-SSATS): 2015. Data on Substance Abuse Treatment Facilities. Retrieved from: https://wwwdasis.samhsa.gov/dasis2/nssats/2015_nssats_rpt.pdf

21st Century Cures Act (2015). P.L. 114-255, 130 Stat. 1033.

U.S. Department of the Health and Human Services (HHS), Assistant Secretary for Planning and Evaluation (2011). Essential Health Benefits: Individual Market Coverage. Retrieved from: https://aspe.hhs.gov/system/files/pdf/76356/ib.pdf

Wen, H., Druss, B.G., & Cummings, J.R. (2015). Effect of Medicaid expansions on health insurance coverage and access to care among low-income adults with behavioral health conditions. *Health Services Research*, 50(6), 1787-1809.


Insurance Status of Adults with Opioid Addiction
Uninsured 20%
Medicaid 30%
Other/Unknown 10%
Private 40%
Total: 2.2 million people
SOURCE: Kaiser Family Foundation analysis of the 2015 National Survey of Drug Use and Health (NSDUH)
THE HENRY J. KAISER FAMILY FOUNDATION


Treatment Among Adults with Opioid Addiction
25%
10%
37%
20%
Residential treatment
Outpatient treatment
Medicaid
Uninsured
Total: 1.1 million people
SOURCE: Kaiser Family Foundation analysis of the 2015 National Survey of Drug Use and Health (NSDUH)
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"This cross-over of lawful and unlawful drugs gives the opioid epidemic a unique legal quality: It is a novel combination of public health and regulatory issues, on the one hand, and criminal drug law and its enforcement on the other. "

– AMANDA PUSTILNIK, J.D.

The Law's Responses to the Opioid Epidemic: Legal Solutions to a Unique Public Health, Criminal Law, and Market-Related Crisis

Amanda Pustilnik, J.D.

Introduction

Unlike drug epidemics the U.S. has known previously, the opioid epidemic presents new legal challenges and opportunities. This epidemic originated with, and continues to involve, an FDA-approved class of drugs promoted through the marketing and distribution arms of major commercial entities. Despite its origins in lawful pharmaceutical products, the majority of opioid abuse and associated mortality now arises from illegal or "street" opioids, particularly street fentanyl. This cross-over of lawful and unlawful drugs gives the opioid epidemic a unique legal quality: It is a novel combination of public health and regulatory issues, on the one hand, and criminal drug law and its enforcement on the other. This suggests the possibility of legal intervention across the spectrum from pharmaceutical regulation to insurance and public benefits law to new strategies in criminal law that include diversion and treatment along with conventional enforcement. These responses will be incomplete, however, if lawmakers do not address the most important factor in creating this epidemic: Pharmaceutical manufacturers are behaving as rational economic actors in maximizing sales of and profits from these products. Apart from sporadic litigation by states against pharmaceutical manufacturers, lawmakers to date have not developed regulatory regimes that would require manufacturers to internalize the foreseeable costs of addiction, and thus align manufacturers' interests with the public interest.

Part I of this paper introduces the criminal and administrative law entities relevant to prescription opioid control and street opioid interdiction. The United States has an extensive public health and health care infrastructure, regulated at the federal and state levels, and an extensive state and federal criminal law infra-

structure dedicated to offenses involving illegal drugs. The opioid epidemic is the first crisis to fully implicate both regimes.

Part II of this paper looks at promising legal innovations emerging from administrative and criminal law, and from their increasing coordination to address the opioid epidemic. Under their public health authority, all states now monitor prescriptions of drugs of potential abuse, using these data both for public health and criminal law interventions. In their capacity as prosecutors, district attorneys and U.S. Attorneys increasingly argue that addiction to opioids and other drugs is a neurological disease that should not be addressed primarily through criminal enforcement. Other notable innovations relate to smarter capture and use of data. Several states now use real-time data systems to predict and identify drug seeking, drug diversion, and drug-related deaths. Additionally, they are using evidence-based criteria to determine the success or failure of drug treatment programs and of alternatives to incarceration, then iterating their approaches based on their findings. Observers ten years in the future who study legal responses to addiction may look back to the opioid epidemic as the decisive factor that shifted U.S. law from its historical criminal enforcement-driven approach and toward a public health approach. Part II then asks why a more treatment-focused approach to addiction is gaining ground now, and whether this move relates to the greater impact that this epidemic is having on white Americans relative to prior drug epidemics. Lawmakers' willingness to move toward treatment presents a tremendous opportunity to limit destructive mass incarceration policies; at the same time, policymakers should be mindful of not creating divergent drug policies that privilege opioid abusers relative to abusers of other, more conventionally "urban" or "street" drugs.

Part III concludes by offering a different conceptual model for legal responses to the opioid epidemic: Although the opioid epidemic presents a unique combination of health law and criminal law challenges, legal efforts to curtail this epidemic and forestall future epidemics should focus on market reform. This drug epidemic is not "iatrogenic," despite the role played by prescribers. Instead, it is more endemic/systemic: The extraordinary oversupply of opioids arises from rational market behavior on the part of manufacturers and distributors. Market structure allows opioid manufacturers and distributors to retain profits while externalizing the foreseeable costs of drug diversion and abuse onto federal and state governments. Tools of law and economics that would re-internalize some of these costs to manufacturers could better align suppliers' interests with the public interest. Tobacco litigation and regulation, products liability law, and environmental protection regulations could help offer models lawmakers could use to develop legal regimes that give manufacturers incentives to mitigate harm, not just maximize sales.

U.S. Criminal and Administrative Health Law Entities Involved in Opioid Management

As a cross-cutting criminal drug and pharmaceutical problem, the opioid epidemic may engage more government agencies and legal regimes than any prior drug-related crisis. The epidemic implicates criminal law in the domains of lawmaking, policy-setting, and anti-drug enforcement. It equally implicates agency-based administrative law and rule-making as to drug regulation and behavioral health. This section briefly introduces relevant criminal laws and enforcement agencies, and administrative regulations and agencies, as a primer for understanding the range of potential legal responses.

The Controlled Substances Act: An Administrative and Criminal Law Framework

Federal administrative regulation and criminal enforcement relating to pharmaceutical and street drugs of abuse, including opioids, both proceed under the *Controlled Substances Act of 1970* (*CSA* or the *Act*). This *Act* is the foundation of U.S. law relative to prohibited drugs, lawful pharmaceuticals, and research chemicals, prohibiting certain substances absolutely and requiring specific conduct as to others. Enforcement of the *Act* primarily resides with the Drug Enforcement Administration (DEA), within the Department of Justice, though numerous other federal agencies play some role. The *Act* also provides a model for states, whose controlled substances laws align with the *Act*.

The *Act* defines five "schedules" of controlled substances, all of which include opioids. Wholly unlawful opioids, like heroin and "street" fentanyl, appear in Schedule I. Schedule I drugs have no known medical benefit and no lawful use. Strong, pharmaceutical opioids, including prescription fentanyl, methadone, morphine, and OxyContin appear in Schedule II. Schedule II drugs have medical use but an unusually high potential for dependency and abuse. Stepping down from Schedule II, Schedule III drugs are those with known medical benefit, moderate potential for dependency and abuse, and high potential for psychological dependency.

Schedule III opioids include drugs with up to 90mg of codeine, like Tylenol 3 and Tylenol 4, and those with less than 15 milligrams of hydrocodone. Schedules IV and V encompass drugs with decreasing potential for abuse, including drugs like Robitussin AC that have low amounts of codeine (DEA, 2006).

A degree of coordination across administrative and criminal law agencies is built into the federal *Controlled Substances Act*, and has occurred since the *Act's* inception. Under the *Act*, FDA determines the classification, or "schedule," of a drug. The *CSA* establishes a "closed system" for transactions involving controlled substances, with heightened requirements for higher-schedule substances (DEA, 2006). To handle and transact in controlled substances, manufacturers, distributors, physicians, pharmacies, and researchers must register with DEA and "maintain strict accounting for all distributions" (DEA, 2006).

Particularly as to Schedule II drugs, like fentanyl, dilaudid, and OxyContin, registrants must comply with specific reporting, prescribing, and refill practices intended to reduce prescription drug "diversion." DEA's Office of Diversion Control (ODC) chiefly has responsibility in this arena. (DEA, Diversion Control, n.d.). "Diversion" includes illegal sales of prescription drugs by or to physicians, patients, or pharmacists; illegal payments to physicians or others for access to drugs or to prescriptions for the drugs; prescription forgery; "doctor shopping;" pharmacy theft; and other prohibited transactions that occur outside of the "closed system" of registrants. Diversion also encompasses transactions that occur within the closed system but lack a medically reasonable basis. DEA has significant authority relative to registrants and may revoke registration for any "conduct which may threaten the public health and safety" (DEA, 2006). Throughout its history, ODC has coordinated with FDA and with state regulators to develop prescribing policies and prescription monitoring systems, as well as leading prosecutions or assisting state authorities in prosecuting registrants and others who violate the *CSA*. ODC has been active since the early days of the opioid crisis, although recent investigative work suggests a degree of industry capture within DEA that significantly slowed ODC's work (Bernstein & Higham, 2016).

Federal and State Criminal Drug Law and Enforcement

Federal drug policy-making and law enforcement is distributed across numerous program agencies, which coordinate with state-level agencies, professional licensing boards, and, to some extent, with industry. This section identifies leading federal players and their role in responding to the opioid epidemic,

although a full description of federal and state drug-law enforcement architecture is beyond its scope.[1] (See Appendix for a list of federal program agencies involved in drug control.)

Anti-drug law and law enforcement are almost wholly the purview of federal and state criminal law. The Office of National Drug Control Policy (ONDCP), established under the *Anti-Drug Abuse Act of 1988*, (as amended in 1996), establishes and coordinates federal drug enforcement priorities and controls budgetary allocations among national drug control program agencies. (*Title VII Office of National Drug Control Policy Reauthorization Act of 1998*, 1998). Implementing these priorities through enforcement of *CSA* rests primarily with DEA.

Although national drug policy emanates from ONDCP, over 80% of the 1.5 million annual drug arrests in the U.S. occur at the state level, under state laws. Drug laws and enforcement priorities can vary dramatically across states, and vary further within states based on local personnel and priorities. This variation can lead to inconsistent adjudication of otherwise-similar cases. The number of different laws and law enforcement priorities across and within states presents challenges for coordination and data sharing, although some framework exists for upward and downward information sharing and collaboration: DEA operates 222 offices throughout the United States, which partner with state and local law enforcement (DEA, 2014). Federal funds to states may be conditioned on their drug enforcement activities (DEA, 2014). The disaggregation of, and diversity in, drug law, policy, and practices across the country has an upside, too: Cities and towns currently are a notable source of innovation in responding to the opioid crisis, discussed below.

Until recently, criminal policy and enforcement practices have relied nearly exclusively upon arrest and incarceration for achieving drug control. About 1.5 million people are arrested annually for a drug-related offense.[2] The overwhelming majority of these arrests -- 1.25 million, or approximately 85% -- are for individual drug possession (FBI, 2015). The other 15% of arrests, about 238,000, relate to sale, distribution, or manufacturing of unlawful drugs (FBI, 2015). Yet even as to these, most arrests are of low-level offenders. According to the Pew Charitable Trusts, most federally incarcerated offenders convicted of drug distribution

[1] These entities are sufficiently numerous, and their relationships sufficiently complex, that the Bureau of Justice Assistance publishes a 100-page handbook and directory to "facilitate collaboration and to provide information on each agency's authority and responsibilities" (Bureau of Justice Assistance, 2015).

[2] Arrests in 2015 totaled 1,488,707 (FBI, 2015).

charges possessed only small quantities of drugs and generally had no record of criminal violence (Pew Research Center, 2014).

Administrative Law Framework: HHS and State Counterparts

Administrative law relating to drug regulation and drug-related public health issues runs largely parallel to the criminal law drug enforcement system. The major administrative entities at the federal level are under the auspices of the Department of Health and Human Services (HHS). HHS oversees the Food and Drug Administration (FDA), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Centers for Disease Control and Prevention (CDC), the National Institutes of Health's National Institute of Drug Abuse (NIDA), and the Interagency Pain Research Coordinating Committee (IPRCC). FDA comprehensively regulates the approval, marketing, distribution, and post-marketing surveillance of prescription drugs. The mission of SAMHSA, established by an act of Congress in 1992, is "to reduce the impact of substance abuse and mental illness on America's communities," which it does by promoting a treatment-first approach to drugs of abuse (SAMHSA, 2017).

FDA has been involved in the opioid epidemic from its inception, as the agency initially approved and continues to regulate OxyContin and other opioid pharmaceuticals. It detected public health problems fairly rapidly after OxyContin's introduction and began to take action in 2000. (A timeline of FDA's efforts to curtail opioid abuse, morbidity, and mortality is available here: https://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM332288.pdf)

Certain serious and knowing violations of administrative law provisions can give rise to criminal penalties. Regulatory-related criminal laws relevant to the opioid epidemic are those relating to fraudulently prescribing, obtaining, or reselling prescription pharmaceuticals (18 U.S.C. §1347; 21 U.S.C. §841(a)). Individuals acting independently or in concert with prescribers may obtain large quantities of opioids that are paid for by government benefits programs, particularly Medicaid, for illegal resale. When they re-sell these free or low-cost drugs at a profit, they are, in effect, stealing from the government, which constitutes criminal fraud under the *False Claims Act* (18 U.S.C. §1347). It also creates a federally-subsidized drug trade in which the government, and taxpayers, are unwitting partners.

Whereas FDA focuses on pharmaceutical compounds and their uses, SAMHSA focuses on person-centered behavioral health (SAMHSA, 2017). It advocates

a "wrap-around" harm-reduction approach that integrates access to treatment with services to promote recovery, including housing, mental health treatment, and employment programs (SAMHSA, 2017). Its resources and recommendations are not law; yet, it influences federal and state approaches, including lawmaking, relating to drug addiction prevention and treatment.

Consistent with its mission, SAMHSA has been active in promoting non-criminal, harm-reduction focused responses to the opioid epidemic. In particular, SAMHSA is active in promoting medically-supervised, medication-assisted treatment (MAT) and the widespread availability of the anti-overdose rescue drug, naloxone. It also has promulgated federal guidelines for opioid treatment programs, certifies such programs (CFR Title 42: Part 8), and maintains a registry of evidence-based treatment practices (SAMHSA, National Registry of Evidence Based Programs and Practices, available at https://www.samhsa.gov/nrepp).

The Centers for Medicare and Medicaid Services (CMS) also play a significant role in addressing opioid prescribing and abuse. CMS administers and oversees Medicare, Medicaid, the Children's Health Insurance Program, and the Health Insurance Marketplace. Collectively, this puts the health of 100 million people under its purview, giving it great power to influence prescribing for acute and chronic pain, and to provide coverage for medication-assisted treatment (MAT). Its actions are particularly relevant, as Medicaid patients have a high rate of opioid abuse (Ghate et al., 2010).

In 2016, CMS issued its strategy document for combatting opioid abuse. Its three pillars, aligned with recommendations promulgated by SAMHSA are to:

- Reduce opioid use disorders and overdose by using evidence-based guidelines in acute and chronic pain management;
- Expand the use and distribution of naloxone; and
- Expand use of medication-assisted treatment for opioid dependent and addicted individuals (CMS, 2016).

This large set of actors, with quite disparate mandates, powers, and policies can create inconsistencies and coordination problems in responding to a national drug epidemic. However, its breadth and diversity provide many potential points of legal innovation and intervention. The next Part describes some of the legal innovation taking place at the state level.

New Federal and State Coordination Across Criminal Law and Health Law: What's Working

Criminal law enforcement and health regulatory agencies have different missions, yet the opioid epidemic is leading to enhanced cooperation among them and, in some cases, to these entities reconceiving their own missions. A major factor driving new legal approaches to opioid abuse is the profound failure of the dominant U.S. approach: Mass arrest for individual drug possession. The outcomes of incarceration are grim. Individuals with substance use disorders who are incarcerated are more likely to reoffend than peers who are not incarcerated; incarcerated individuals lack access to treatment; and they are likely to obtain drugs while incarcerated. Incarcerated individuals also experience disrupted family and employment relationships – yet family and employment are two of the factors most strongly correlated with successful recovery.

Recognizing that incarceration does not mitigate addiction and its harms either at the individual or the societal level, federal and state actors have been experimenting with alternative processes and penalties, with varied success. From 2010 through 2016, President Barack Obama directed executive agencies to expand access to addiction treatment, fund training to help physicians recognize and address abuse, expand first-responder access to the overdose rescue drug naloxone, and promote programs to train physicians in better practices relating to pain management (White House, 2016). These directives, which explicitly rejected possession arrests as the tool of choice, require and contemplate criminal law/health law integration (White House, 2016).

Consistent with the priorities of the last Administration, the Department of Justice (which houses the DEA, as discussed in Part I), recommended prioritizing treatment over arrest, promoting medication-assisted treatment, and supporting pre- and post-booking diversion programs as key responses to opioid abuse (Lynch, 2016). Moving away from historically moral and punitive characterizations of drug abusers, a majority of U.S. Attorneys serving at this time urged that "[p]olicies regarding opioid and heroin use … be grounded in scientific understanding that substance use disorders are a chronic brain disease that can be … treated" (Hickton & Song, 2016).

Some federal law enforcement actions appear contrary to these priorities announced by the Department of Justice. Under 21 U.S.C. §841, an individual who administers a lethal overdose to another, even unwittingly, faces 20 years of incarceration (Harvey, 2016). In a drug-sharing experience in which one partner

dies, the other may be sentenced federally under this statute (Harvey, 2016). Except in cases of knowing conduct, or predatory or exploitative conduct, this seems to punish the sad combination of addiction and bad luck: Where two partners are addicted, and the quality of drugs is unknown, either partner could have administered the lethal dose to the other, or to themselves. While in other areas the law is acknowledging the failure of criminal deterrence as to addicted individuals, federal prosecutors acting pursuant to this statute are doubling down on punishment.

Whether federal policy will continue on this trajectory remains to be seen. The current administration of President Donald J. Trump has convened an opioid epidemic advisory commission, chaired by former New Jersey Governor Chris Christie. Christie has advocated for treatment-based responses to opioid abuse; this issue is addressed in the Commission's final report (President's Commission, 2017). The leadership of U.S. Attorney General Jeff Sessions suggests that the DOJ policy shift away from individual drug possession arrests may have been short-lived, as he has announced intentions to return to maximal enforcement against individuals (White House, 2017).

Data as an Addiction-Prevention Tool: The Case of Prescription Drug Monitoring Programs (PDMPs).

Prescription Drug Monitoring Programs (PDMPs) allow states to identify drug prescription patterns at the state, local, and prescriber level, identifying problem trends, locations, and individuals. Medical providers, too, access PDMPs to determine whether a patient already has a prescription for one or more opioids and may be doctor-shopping.

In 2003, fewer than 20 states operated prescription drug monitoring programs. By 2016, all states had implemented PDMPs (Office of National Drug Control Policy, 2016). The most effective PDMPs operate with real-time data and have architecture that is interoperable with PDMPs of surrounding states (National Alliance for Model State Drug Laws, 2016). CMS, too, is harnessing data to help prescribers limit opioid abuse. The system under development will give providers access to their own prescribing data and patterns, with comparisons to specialty and geographic peers, so they can see their relative performance (CMS, 2016).

CASE STUDY: New York's Real-Time Prescription Management Program

In New York State, any prescriber can see if an individual is pill-seeking and the state itself can see if a prescriber is over-prescribing. Although it had a prescription monitoring program previously, in 2012, New York enacted a law requiring the system to operate with real-time prescribing data and requiring prescribers to check the system before issuing prescriptions for certain drugs (Chapter 447, Laws of New York, 2012). Within three years of enacting the law, New York had cut doctor shopping by 90%; it further began a data-sharing program with New Jersey to stop cross-border doctor shopping (Cuomo, 2017).

CASE STUDY: A Police Chief Uses Data and a Personal Touch

Police Chief, Jody Kasper, of Northampton, Massachusetts, realized that logs of officer contacts with the public hold data gold for identifying the most at-risk and risky drug abusers. She has reoriented her department's response to opioids away from possession arrests and toward training officers to identify and assist high-risk abusers. "People traditionally think of police just working on the enforcement end," Kasper said in an interview, noting that she and other law enforcement leaders have "really been reflecting on" whether possession arrests serve their communities (Newberry, 2016).

Her department started a Drug Abuse Response Team structured around officers who connect high-risk drug abusers with treatment. Officers identify individuals for outreach based on police and overdose logs, find them, and offer them paths to connect with treatment and services. Officers follow up with the individuals, and may engage their family and friends. Additionally, all officers receive training about addiction and treatment, and are equipped with naloxone (Narcan) (Kasper, 2016).

This initiative resembles the most successful model for reducing criminal involvement and hospital admissions for people with severe mental illness, called Assertive Community Treatment (ACT) (Burns et al., 2007). ACT Teams engage mentally ill individuals and support them in following treatment (Burns et al., 2007). The Northampton approach blurs the traditional lines of public health and law enforcement by using police for outreach. This may not be replicable, as it requires intensive officer commitment. As municipalities innovate, new data will emerge about which interventions succeed.

Data mining is used to identify the most at-risk individuals and target state spending efficiently. Beyond PDMPs, many states are using data in novel ways to identify individuals at higher relative risk of opioid addiction and death and, conversely, to determine which populations are the most responsive to treatment and which treatment programs yield the best results. Massachusetts, for example, has determined that individuals newly-released from incarceration are at a 56x relative risk of death from opioid overdose. Targeting these individuals for intervention allows the state to spend its public health dollars most efficiently, while seeing the greatest reductions in mortality (Bharel, 2017).

Using Drugs to Fight Drugs: The Case of Medication-Assisted Treatment

Similar to the 2016 federal executive policy changes discussed above, state governments are increasingly funding and promoting medically-based addiction recovery. This modifies long-standing state and private reliance on abstinence-only, often morally-based, group-support treatment programs. The State of Maryland, for example, has passed legislation establishing poly-morphine-assisted treatment centers for people who have not succeeded with other treatment methods. Medication-assisted treatment, on its own or with group support, has a higher rate of success than conventional, group-support programs on their own.

Reducing Harm from Ongoing Addiction: Safer Opioid Use

Not all addicts will be capable of recovery. In these cases, states can reduce individual and community harm by mitigating the dangers faced by, and posed by, chronic addicts. A significant, proven intervention is the "safe injection facility" (SIF). At SIFs, drug users self-administer drugs, with clean needles, under medical supervision. SIFs mitigate a host of common, drug-related ills, reducing opioid-related transmission of HIV and hepatitis, overdose-related morbidity and mortality, and objectionable street behavior.

Treated as political kryptonite in the United States until recently – and expressly prohibited under the *Anti-Drug Abuse Act of 1988* – SIFs are gaining ground locally. In 2016 and 2017, the first U.S. SIFs opened in Huntington, West Virginia, and Seattle, Washington (Johnson, 2016; Zezima, 2017). New York State legislators are considering SIFs in New York City (Drug Policy Alliance, 2017) and in the hard-hit areas of upstate New York (Butler, 2017). New York has already expanded its safe syringe exchange program and pharmacy-based syringe access programs (New York Public Health Law §3381).

Encouraging Emergency and Ongoing Treatment: "Good Samaritan" and Safe Harbor Laws

When a person overdoses, he or she (if conscious) or other people with the overdose victim may not call for emergency assistance for fear of prosecution for drug possession. To encourage saving lives, many states have passed "Good Samaritan" laws. These laws shield people who call for help for drug overdose or other drug-related medical emergencies from being arrested for drug possession, although not in all circumstances.

Fear of legal jeopardy also can deter individuals from seeking non-emergency treatment. To address this impediment to treatment, several states have passed "safe harbor" laws that allow individuals to request addiction treatment, or receive help finding addiction treatment, from physicians, pharmacists, state social workers, and law enforcement or other first responders. (Becker, D., 2016; Police Executive Research Forum, 2016). Currently, 264 police departments and 300 treatment centers nationally have joined the Police Assisted Addiction and Recovery Initiative (PAARI), which affirmatively encourages people to seek help from police officers to connect to treatment services (Police Executive Research Forum, 2016). This is important because individuals will not seek assistance if it exposes them to prosecution, loss of benefits, or adversely affects important civil rights like child custody.

Creating Opportunities for Treatment Through Expanded Access to Naloxone

People addicted to opioids cannot get treatment if the addiction kills them first. A person saved from overdose has another chance to recover. Naloxone, a non-opioid drug with no abuse potential, saves lives by reversing opioid overdose. The drug, developed in the 1940s, has not been widely available due to regulators' and lawmakers' concerns that its availability would increase irresponsible drug abuse practices.

The staggering number of opioid overdose deaths -- approximately 50,000 per year, for the last several years -- has changed that risk calculus. Federal agencies including ONDCP, NIDA, CDC, and SAMHSA have recommended making naloxone broadly available, and standard for all first responders. Nearly all states have now expanded access to naloxone, provided training to first responders in its use, taken steps to ensure that it is available to all first responders and at pharmacy counters, and have passed legislation to permit prescriptions for naloxone that are not patient-specific. (See, for example, New York Penal Law §220.78; New York Practice Criminal Law §26:27.50). This set of initiatives, which equips

police and other first responders to address the health aspects of a drug crisis as a priority over its criminal dimensions marks a new, interesting departure from prior practices.

Specialty or Diversionary Courts

Starting in 2014, the Department of Justice lent its support to more than 2,600 specialty courts, most notably "drug courts" that attempt to provide structured recovery for addicted individuals as an alternative to incarceration. As of 2014, over 120,000 individuals who committed drug-related or drug-involved offenses had participated in court-directed services intended to reduce the rate of offenders' future drug use and criminal recidivism (Department of Justice, 2014). Specialty courts are an important innovation in criminal law responses to non-violent drug-involved offenders, yet their utility and return on investment depends heavily on their structure and implementation. The most successful diversionary courts improve individual and family outcomes, while reducing the social and material costs of incarceration. Diversion can occur at numerous phases, from pre-charging through post-conviction, offering a menu of options tailored to offender characteristics.

Yet, the efficacy of diversionary court programs varies widely. Indeed, if structured and implemented poorly, they can be more coercive and generate higher recidivism than standard criminal sanctions. Factors strongly associated with courts' success include: Appropriate participant selection; provision and encouragement of medication-assisted treatment; and linking the offender with wrap-around services to address social and economic distress contributing to drug abuse behavior (Center for Health & Justice at TASC, 2013). Additionally, diversionary courts have higher rates of success, and exert less coercion, when built on a model of addiction recovery that includes the expectation of intermittent relapse (Center for Health & Justice at TASC, 2013).

Eliminate Abuse by Eliminating Opioids?

One commonly-voiced prescription for ending opioid abuse, however, is misguided: To take the opioid class of prescription drugs off the market. People in pain will just have to live in pain, they say; pain is part of life and the costs of opioids abuse are too great (Ballantyne & Sullivan, 2015; Kaafarani et al., 2017). This recommendation is a lose-lose: First, pain patients generally are not addicted, and addicts generally are not pain patients. Second, while causing needless suffering to pain patients, it foreseeably would increase street drug activity and associated crime, morbidity, and mortality (Warner et al., 2014). In some com-

munities, heroin is "cheaper and … easier to obtain than prescription opioids" (Mars et al., 2014). Heroin is several times more lethal than prescription opioids, because it is more potent and may be cut (unknown to the purchaser) with underground fentanyl. Fentanyl, in turn, is more lethal than heroin. As to prescription drug abusers, eliminating opioids would further push them to street drugs. Street opioids are much more lethal, and their sale supports drug cartels. Restricting or eliminating prescription opioids is counterproductive if doing so leads to whack-a-mole drug abuse escalation and higher rates of death.

Moreover, untreated or under-treated pain is not "just pain." Uncontrolled pain can cause progressive neurological damage, impairing cognitive function, affecting regulation, and critical physiological processes, including circadian rhythms and metabolism (Davis et al., 2017).

Removing Legal Barriers to Integrating Health-Based and Criminal-Law Based Constructive Interventions

One surprising challenge in addressing the opioid epidemic is the law itself: Several federal laws contravene aspects of new initiatives, like those above, aimed at reducing opioid abuse, morbidity, and mortality. Linked to notions that taxpayers should not subsidize drug users, and discredited beliefs in the power of sanctions to change addiction behavior (in the absence of treatment), a significant body of state and federal laws preclude individuals with substance abuse disorders from receiving government-provided benefits and services.

Status as an opioid abuser can preclude individuals from eligibility for essential social services. As of March 2017, 15 states had legislation in place to drug test recipients of state-administered federal benefits programs (National Conference of State Legislatures, 2017). These laws require drug-negative tests for programs including Temporary Assistance for Needy Families (TANF), child care assistance, job retraining, low-income housing, and similar programs (National Conference of State Legislatures, 2017). Wisconsin, for example, is working to condition benefits under the Supplemental Nutritional Assistance Program (SNAP), or "food stamps," on negative drug tests (National Conference of State Legislatures, 2017). Three states condition Medicaid eligibility on negative drug tests [3] (National Conference of State Legislatures, 2017). This creates a Catch-22: Medicaid is the most significant provider of medical addiction treatment, yet a positive drug test precludes individuals in these states from Medicaid eligibility.

[3] These states are Georgia, Kentucky, and South Carolina.

Treatment Over Arrest: Avoiding Opioid Favoritism

Long-term trends toward medication-assisted treatment, supported by developments in addiction neuroscience and growing bipartisan opposition to mass incarceration, are pushing against longstanding mass incarceration policies. As lawmakers expand access to treatment, services, and diversionary programs, they should consider whether new initiatives apply to all drug offenders or, instead, whether they are engaging in opioid-user favoritism.

The opioid epidemic is "the rare social catastrophe that has hit whites far harder than blacks" (Lane, 2016). Ten times as many white Americans die annually from opioids than African Americans (Henry J. Kaiser Family Foundation, 2015); heroin and fentanyl abuse by white Americans has increased by several hundred percent over the last four years. Almost 90% of people who became new users of heroin from the early 2000s onward are white, and nearly 90% of opioid-related deaths are among whites (Cicero et al., 2014). It has become conventional wisdom that opioid abuse is a white, largely suburban and rural scourge.

Whiteness is not incidental to the development of the epidemic nor to the cultural and legal responses to it. White Americans' comparatively privileged access to health care influenced opioid manufacturers to prioritize marketing and distribution in majority white communities. Prescribers, in these targeted communities and elsewhere, on average, provide more analgesia to white patients and are less likely to suspect them of drug-seeking behavior (Pletcher, 2008; Hausmann et al., 2013). Once a high rate of opioid abuse had been established in these communities, addicted individuals increasingly turned to heroin, a new demographic use pattern for this drug.

Yet, opioid abuse is a mosaic; wide-spread drug abuse of any kind, opioid or otherwise, harms all communities. Opioid abuse also is growing, common, and deadly among African Americans. The population-adjusted African American death rate from opioids in 2015 equaled the death rate of whites in 2005 (U.S. Census Bureau, 2015) – and in 2005, white opioid abuse was already a crisis

(Hedegaard et al., 2017). Hispanics have the lowest growth in opioid abuse, and still the Hispanic opioid-related death rate has doubled in the last 15 years (Hedegaard et al., 2017).

Federal and state enforcement priorities going back at least to the 1970s have embedded racialized distinctions into drug laws, most (in)famously in sentencing disparities for offenses involving crack versus powder cocaine. Disproportionate policing and arrest of African Americans, largely for marijuana possession (although rates of marijuana use are similar in majority white populations), has added to the burden that African Americans bear in relation to U.S. drug policy. Arrest and incarceration produce pervasive, harmful second- and third-order consequences: Incarceration damages intergenerational social mobility, and the children of incarcerated parents fare worse on nearly every relevant measure (Knudsen et al., 2006; Turney, 2017; Wildeman, 2009). As the U.S. economy continues its long-term shift toward higher-skilled knowledge work, the disadvantage of school non-completion intensifies (Brynjolfsson & McAfee, 2014). These trends act in a pincer fashion to entrench inequality, particularly among African Americans and among the lowest-income white Americans (Knudsen et al., 2006).

If arrest reduction, diversion, and treatment are applied evenly across categories of drug offenses and populations of drug users, African Americans will experience more relative benefit than their white counterparts because of their current relative disadvantages.

Matching Remedies to Harms: Making Opioid Manufacturers Internalize Costs of Abuse

"We were screaming at the wall. We saw it coming."

- Tom Susman, former head of West Virginia's employee insurance agency (Armstrong 2016)

In simplest terms, the opioid epidemic is a case of privatized profits and socialized losses. Manufacturers' incentives -- indeed, their obligations to their shareholders -- is to promote and sell their product to the fullest extent allowed by law, if not further. The resulting, foreseeable rates of misuse and abuse, and associated economic costs and social disabilities, however, are not re-internalized to manufacturers through any mechanism. Although the profits go to manufac-

turers, the costs largely are borne by taxpayers: Prescription opioids are heavily prescribed through, and subsidized by, Medicaid, Medicare, the Veterans' Administration, and other taxpayer-funded programs. The costs of opioid-related morbidity, mortality, criminality, and incarceration also are borne in large part by state and federal government, and, in turn, by taxpayers.

Although the opioid epidemic is novel in many ways, the U.S. has addressed numerous public health and regulatory problems with similar features. Indeed, aligning commercial incentives and the public good is a core function of law, particularly regulatory law. Three legal models that may be useful to lawmakers in their responses to the opioid epidemic, and future public health problems with similar features, include: (1) initiatives against drunk driving; (2) tobacco litigation and regulation; and (3) regulation of environmental pollution. In each case, after widespread public harm had occurred, new legal regimes required market actors to internalize certain costs of their activities.

Anti-drunk-driving initiatives demonstrate that extending liability back from the individual substance abuser to suppliers can change supplier behavior to reduce overall cost and harm. Although so-called "dram shop" laws, which impose civil liability on bar operators for harms caused by patrons they over served date to the 1800s, only in the 1980s did groups like Mothers Against Drunk Driving push states to enforce these statutes. Some states enacted companion criminal statutes, as well. Previously, a bar operator's incentive was to serve all comers, as much as they would buy. The unit of alcohol that put the driver over the limit could impose substantial costs on the public, but brought the same profit. A bar operator might have refrained in any event from over-serving patrons; but if so, it was against his self-interest. With penalties and possible criminal exposure, the operator's incentives and behavior change as he weighs the potential profit and risk of each additional unit he sells to a customer; now rational self-interest works in the public's favor.

A pharmaceutical company is (somewhat) similarly situated to the bar operator: As long as it can externalize the costs and risks, its incentive is to maximize sales. Opioid marketing fits this model of achieving maximal sales. Manufacturers, most notably Perdue Pharma, have distributed vast quantities of opioids, independent of medically-justifiable market need. And, they have done so through promotional tactics that have ranged from lawful, to questionable, to criminal (Armstrong, 2016).

VIGNETTES:
Rationally Maximizing Opioid Sales

"I'm very certain this is an organized drug ring," a Purdue sales manager wrote to management in 2008, about an LA clinic run out of a "dilapidated" storefront. In the 18 months it was active, it dispensed prescriptions for 1.1 million doses of OxyContin. The manager repeatedly urged reporting the operation to DEA. Purdue reported the operation almost ten years later, many years after it closed (Ryan 2017).

When Purdue sales reps suspected a prescriber was engaged in "pill mill" activity, the prescriber would be included in a particular database ("region zero"). By 2011, the database included over 1,800 prescribers. Despite years of law enforcement inquiries, Purdue consistently declined to disclose prescriber identities on the ground that it could expose innocent physicians to investigation. After Purdue introduced a more tamper-resistant OxyContin tablet, many of these prescribers switched to competitors' opioids. When these prescribers stopped buying Perdue products, Purdue gave the prescriber database to law enforcement (Glover & Girion, 2013).

Through civil and criminal litigation, states have tried -- and continue to try -- to force manufacturers to internalize some of the costs of their over-promotion and over-distribution of opioids. In 2007, 27 state attorneys general sued Purdue for its marketing and promotion practices, settling for $19.5 million. In a related federal criminal case, the company's senior executives paid fines of $634.5 million. In 2016, drug-ravaged West Virginia settled with Cardinal Health, AmeriSourceBergen, and smaller wholesalers for a combined $37 million (Eyre 2016). New suits by states have been filed throughout 2017, including an action by the state of Ohio alleging that, between 2011 and 2015, defendant opioid manufacturers (principally Purdue, Teva, Cephalon, and J&J) flooded the state with 3.8 billion doses of opioids (*Ohio v. Purdue Pharma*).

These cases, though important, constitute a small tax on opioid manufacturers and distributors. The ongoing need for these lawsuits should signal to lawmakers that the litigation approach as currently practiced has limited deterrent value. Moreover, such settlements can create the problem of the dragon eating its own tail: A manufacturer that pays a monetary settlement to a state can pass on those costs through higher drug prices – drug prices then largely paid by the state.

Federal agencies are aware of this challenge and have made some efforts to reduce distorting effects of pharmaceutical marketing on drug demand. Yet, FDA and other agencies have limited power to monitor drug marketing and promotion. In real dollars, in 2016, J&J, Pfizer, Novartis, and Merck, each spent more on marketing than FDA received from Congress as its entire budget for all purposes ($4.9 billion) (FDA, 2015). If FDA did nothing but monitor drug marketing and promotion, it could dollar-for-dollar match one large pharmaceutical company.

The type of marketing activity that played the greatest role in the opioid epidemic would have been hard to detect even if FDA's Office of Prescription Drug Promotion (OPDP), which reviews drug promotion materials for FDA compliance, were resourced at ten times its current level. Face-to-face marketing is particularly effective and particularly difficult to monitor. In the early 2000s, Purdue used a data-intensive approach to maximizing per-provider prescriptions, particularly among primary care physicians. It built a sales army of nearly 100,000 representatives, who converted prescribers to OxyContin one office visit at a time (GAO, 2003). Targeting these doctors was so effective that, by 2003, half of all OxyContin prescriptions originated in a primary care office (GAO, 2003).

A better model than state-by-state litigation, and post-market monitoring of promotional practices, might come from the Tobacco Master Settlement Agreement (MSA, 1998), entered into between the largest tobacco products producers and the attorneys general of 46 states. Tobacco industry actions parallel those of the opioid industry in important ways: Manufacturers misrepresented the risks of illness and death from the product; aggressively marketed products to vulnerable populations; misled lawmakers and regulators; and engaged in lawmaker "capture" where possible. Although government entities did not pay for tobacco prescriptions, tobacco also was a double-subsidy business: Tobacco farmers received farm subsidies, while the costs of smoking-related illnesses were borne by federal and state governments, and individuals.

The MSA, which turns 20 this year, contains numerous provisions to re-internalize the costs of smoking-related illnesses and death to tobacco products manufacturers. Chiefly, the participating manufacturers agreed to pay states $206 billion over 25 years to compensate them for the future costs of smoking-related illnesses; imposed significant restrictions on tobacco marketing and promotion; and created a fund to promote awareness of smoking-related dangers (MSA, 1998; Tobacco Control Legal Consortium, 2015). The MSA laid the foundation for federal legislation (*Family Smoking Prevention and Control Act*), passed in 2009, that brought tobacco under the purview of FDA, further restricted marketing, and strengthened warnings on packaging.

The tobacco model is not perfect. As demand for addictive products is relatively inelastic, the cost of any settlement or fund can be passed on to consumers through higher prices, a concern that would apply at least equally to opioids. Moreover, cash-strapped states have diverted MSA funds to non-tobacco-related public projects. Yet, the settlement's emphasis on marketing restrictions and warnings begins to limit producer behavior and inform the public of risk (MSA, 1998). And, it points toward an integrated, national strategy to address the problem at the source, instead of addict by addict.

A final approach is regulatory, similar to environmental regulation. From the removal of lead in gasoline to national clean air and water standards, federal law comprehensively regulates the extent to which industries can contaminate air, water, and soil in the manufacture of their products. Regulation has a particular role to play in such problems because industry players face a collective action problem: If one adopts stricter, more expensive standards, it disadvantages itself relative to its competitors. But the competitors are unlikely to cooperate in adhering to voluntary standards; even if achieved, actual or feared cheating is likely to lead to widespread defection. Conversely, while each individual has an interest in clean air, soil, and water, the diffuse nature of the harms means that no one individual may be able to establish standing to sue, and case-by-case, post hoc litigation is relatively ineffectual.

While states pursue litigation, FDA has a potentially powerful regulatory tool: FDA already requires manufacturers to submit risk evaluations and mitigation plans for opioid drugs (REMs). FDA and lawmakers might build on this to require manufacturers to calculate the maximum doses of their product per market, per year, based on reasonable medical assumptions subject to independent review, with a process to apply for upward modifications based on demonstrated medical need. Opioid prescribing patterns show why this could be powerful: In 2016, according to the Centers for Disease Control and Prevention, in eight states, prescribers wrote over 100 opioid prescriptions per 100 people – *more opioid prescriptions than people* (CDC, 2017). If manufacturers were required to abide by targets keyed to medical need, no company could distribute such grossly excessive quantities.

Instead of one-time monetary penalties, effective sanctions could include temporary, mandatory delisting of any non-unique drug from a state's Medicaid preferred drug list, with escalating suspensions for repeated violations. Additionally, keyed to predicted risk of misuse and abuse in the REM, manufacturers could set aside a fund to cover states' expenditures for addiction-related morbidity and mortality. No-fault vaccine courts might also provide a precedent, for individual actions against manufacturers.

Conclusion

The range of legal and market actors involved in the opioid epidemic, and the vast number of people harmed directly or indirectly by opioid abuse, defy simple, unitary solutions. Productive interventions can, and must, occur at the local, state, and federal levels, with cooperation across lawmakers, law enforcement, the judiciary, public health agencies, industry, the medical profession, and advocacy groups. Criminal law enforcement has an essential role in aggressively intercepting street drugs like heroin and fentanyl, which have become the most deadly opioids. But criminal law should play a much-reduced role relative to prosecuting individuals for drug possession, a driver of mass incarceration, intergenerational instability, class stagnation, and racial injustice. Instead, legal responses more productively can focus, at the individual level, on drug-user treatment and diversion out of the criminal system, making the drug-user's public health or law enforcement encounter an entry point for matching individuals with services. And the law should get out of its own way, with lawmakers repealing punitive, symbolic statutes that preclude addicted people from receiving the very services they need to escape drug addiction.

Of greatest importance, though, is the law's role relative to the origin and perpetuation of this epidemic, and of the next one: Market incentives created by the legal and regulatory framework. We federally subsidize manufacturers to sell as much of an addictive product as possible, without requiring manufacturers to project and provide for the foreseeable rates and costs of resulting addictions. Until the law reallocates cost and risk from the public back to manufacturers as an offset against their profits, manufacturer behavior will not change – nor should it. No entity is required to act better than required by law. So the law must change, carrying out in this new context its traditional function of allocating the risk of an endeavor toward those that profit from it and away from those who could neither foresee nor avoid its harms.

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Appendix: Major Federal Drug Control Program Agencies

White House

- Bureau of Alcohol, Tobacco, and Firearms (BATF) https://www.atf.gov/
- Department of Justice (DOJ) https://www.justice.gov/
- Drug Enforcement Administration (DEA) https://www.dea.gov/index.shtml
- Federal Bureau of Investigation (FBI) https://www.fbi.gov/
- Office of National Drug Control Policy (ONDCP) https://www.whitehouse.gov/ondcp
- U.S. Marshals Service (USMS) https://www.usmarshals.gov/

Department of Health & Human Services (HHS)

- Center for Substance Abuse Treatment (CSAT) https://www.samhsa.gov/about-us/who-we-are/offices-centers/csat
- Food and Drug Administration (FDA) https://www.fda.gov/
- National Institute on Drug Abuse (NIDA) https://www.drugabuse.gov/
- Substance Abuse and Mental Health Service Administration (SAMHSA) https://www.samhsa.gov/

Department of Homeland Security (DHS)

- U.S. Customs and Border Protection (CBP) https://www.state.gov/j/inl/rls/nrcrpt/2016/vol1/253222.htm
- U.S. Immigration and Customs Enforcement (ICE) https://www.ice.gov/narcotics

References

Anti-Drug Abuse Act of 1988 (1988). P. L. 100-690, 102 Stat. 4181 (1988).

Armstrong, D. (2016, September 22). Exclusive secret trove reveals bold 'crusade' to make OxyContin a blockbuster. *STAT News*. Retrieved from https://www.statnews.com/2016/09/22/abbott-oxycontin-crusade/

Ballantyne, J.C. & Sullivan, M.D. (2015). Intensity of pain – the wrong metric? *New England Journal of Medicine*. 373:2098–2099.

Becker, D. (2016, August 30). Opioid epidemic moves police to help rather than arrest drug users. *NPR: Morning Edition*. Retrieved from https://www.npr.org/2016/08/30/491906530/opioid-epidemic-moves-police-to-help-rather-than-arrest-drug-users

Becker, M. (2017, May 4). A call for a safe place for addicts to inject themselves. *Buffalo News*. Retrieved from http://buffalonews.com/2017/05/04/call-safe-place-addicts-inject/

Bernstein, L. & Higham, S. (2016, December 22). Investigation: The DEA slowed enforcement while the opioid epidemic grew out of control. *The Washington Post*. Retrieved from https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html?utm_term=.89b3718fdc75

Bharel, M. (2017, April 3). Remarks of Commissioner of the Massachusetts Department of Public Health. Opiate Regulation Policies: Balancing Pain and Addiction.

Biotechnology Innovation Organization & Pharmaceutical Research and Manufacturers of America (BIO & PhRMA) (2016). Principles on Responsible Sharing of Truthful and Non-Misleading Information About Medicines with Health Care Professionals and Payers. Retrieved from https://www.bio.org/sites/default/files/PrinciplesReport_FINAL.pdf

Brynjolfsson, E. & McAfee, A. (2014). The Second Machine Age: Work, Progress, and Prosperity in a Time of Brilliant Technologies. New York, NY: W.W. Norton.

Bureau of Justice Assistance (2015). U.S. Department of Justice Controlled Substances Agency Resources Directory.

Burgess, D.J., Nelson, D.B., Gravely, A.A., Bair, M.J., Kerns, R.D., Higgins, D.M., van Ryn, M., Farmer, M., & Partin, M.R. (2014). Racial differences in prescription of opioid analgesics for chronic noncancer pain in a national sample of veterans. *The Journal of Pain*, 15(4), 447–455.

Burns, T., Catty, J., Dash, M., Roberts, C., Lockwood, A., Marshall, M. (2007). Use of intensive case management to reduce time in hospital in people with severe mental illness: Systematic review and meta-regression. BMJ, 335, 336–340.

Butler, M. (2017, May 2). Ithaca gets first look at supervised injection site model. *Ithaca.com*. Retrieved from http://www.ithaca.com/news/ithaca/ithaca-gets-first-look-at-supervised-injection-site-model/article_211dd07a-2f68-11e7-a11e-9f09d4c093c3.html

Center for Health & Justice at TASC (2013). No Entry: A National Survey of Criminal Justice Diversion Programs and Initiatives. Retrieved from http://www2.centerforhealthandjustice.org/sites/www2.centerforhealthandjustice.org/files/publications/CHJ%20Diversion%20Report_web.pdf

Centers for Disease Control and Prevention (CDC) (2017). Annual Surveillance Report of Drug-Related Risks and Outcomes. Table 1C. Retrieved from https://www.cdc.gov/drugoverdose/pdf/pubs/2017-cdc-drug-surveillance-report.pdf

Centers for Medicare and Medicaid Services (CMS) (2016). Opioid Misuse Strategy. Retrieved from https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/Downloads/CMS-Opioid-Misuse-Strategy-2016.pdf

Childress, S. (2016, Feb. 23). How the heroin epidemic differs in communities of color. *Frontline*. Retrieved from http://www.pbs.org/wgbh/frontline/article/how-the-heroin-epidemic-differs-in-communities-of-color/

Cicero, T.J. Ellis, M.S., Surratt, H.L., & Kurtz, S.P. (2014). The changing face of heroin use in the United States: A retrospective analysis of the past 50 years. *JAMA Psychiatry*, 71(7),821-826. Retrieved from http://jamanetwork.com/journals/jamapsychiatry/fullarticle/1874575?;resultClick=3

Congressional Budget Office (CBO) (2009). Economic and Budget Issue Brief: Promotional Spending for Prescription Drugs. Retrieved from https://www.cbo.gov/sites/default/files/111th-congress-2009-2010/reports/12-02-drugpromo_brief.pdf

Controlled Substances Act (1970). P.L. 91-513, 84 Stat. 1236.

Cuomo, A. (2017, January 10). Governor's 2017 State of the State Address: Sweeping, Comprehensive Actions to Combat the Heroin and Opioid Epidemic in New York State. Retrieved from https://www.governor.ny.gov/news/governor-cuomo-presents-26th-proposal-2017-state-state-sweeping-comprehensive-actions-combat

Davis, K.D., et al. (2017). Brain imaging tests for chronic pain: Medical, legal and ethical issues and recommendations. *Nature Reviews Neurology*, 13:624–638.

Dean, R. (2015). Letter of Division Director, OPDP, to Eric Gervais, EVP, Duschenay, Inc., Warning Letter re NDA: 021876 DICLEGIS, MA # 350. Retrieved from https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCcompanies/UCM457961.pdf

Department of Justice (2014, March 10). Attorney General Holder, calling rise in heroin overdoses 'urgent public health crisis,' vows mix of enforcement, treatment. *Justice News*. Retrieved from https://www.justice.gov/opa/pr/attorney-general-holder-calling-rise-heroin-overdoses-urgent-public-health-crisis-vows-mix

Drug Enforcement Administration (DEA) (n.d.). Diversion Control/Prescription Drug Abuse. Retrieved from https://www.dea.gov/ops/diversion.shtml

Drug Enforcement Administration (DEA) (n.d.). Drug Fact Sheet: Marijuana. Retrieved from https://www.dea.gov/druginfo/drug_data_sheets/Marijuana.pdf

Drug Enforcement Administration (DEA), Office of Diversion Control (2006). Practitioners' Manual: An Informational Outline of the Controlled Substances Act. Washington, DC: Department of Justice. Retrieved from https://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual012508.pdf

Drug Enforcement Administration (DEA) (2014). DEA Fact Sheet. Retrieved from http://www.justice.gov/dea/docs/factsheet.pdf

Drug Policy Alliance (2017). Legislation Authorizing Safer Consumption Spaces for Supervised Injection Introduced in New York State. Retrieved from https://www.drugpolicy.org/news/2017/06/legislation-authorizing-safer-consumption-spaces-supervised-injection-introduced-new-yo

Eyre, E. (2016, December 17). Drug firms poured 780M painkillers into WV amid rise of overdoses. *Charleston Gazette-Mail*. Retrieved from: https://www.wvgazettemail.com/news/health/drug-firms-poured-m-painkillers-into-wv-amid-rise-of/article_78963590-b050-11e7-8186-f7e8c8a1b804.html

False Claims Act, 31 U.S.C. §§3729-3733.

Family Smoking Prevention and Tobacco Control Act (2009). P.L. 111-131, 123 Stat. 1776.

Federal Bureau of Investigation (FBI) (2015). Uniform Crime Reporting, Arrest Table; Arrests for Drug Abuse Violations Table 29. Retrieved from https://ucr.fbi.gov/crime-in-the-u.s/2015/crime-in-the-u.s.-2015/tables/arrest_table_arrests_for_drug_abuse_violations_percent_distribution_by_regions_2015.xls

Food and Drug Administration (FDA) (2015). FY 2016 President's Budget. Retrieved from https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM432650.pdf

Gagnon, M.A. & Lexchin, J. (2008). The cost of pushing pills: A new estimate of pharmaceutical promotion expenditures in the United States. *PLoS Med*, 5(1), e1. Retrieved from https://doi.org/10.1371/journal.pmed.0050001

Ghate, S.R. Haroutiunian, S., Winslow, R., McAdam, M.C. (2010). Cost and comorbidities associated with opioid abuse in managed care and Medicaid patients in the United States. *Journal of Pain & Palliative Care Pharmacotherapy*, 24(3), 251.

Glover, S. & Girion, L. (2013, August 11). OxyContin maker closely guards its list of suspect doctors. *Los Angeles Times*.

Government Accountability Office (GAO) (2003). Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem. Pub. No. GAO-04-110. Washington, DC: Government Accountability Office.

Goyal, M.K., Kuppermann, N., Cleary, S.D., Teach, S.J., & Chamberlain, J.M. (2015). Racial disparities in pain management of children with appendicitis in emergency departments. *JAMA Pediatrics*, 169(11), 996–1002.

Harvey, K.B. (2016). Integrating public safety and public health to reduce overdose deaths. *United States Attorneys' Bulletin*, 64(5):37–44. Retrieved from https://www.justice.gov/usao/file/895091/download

Hausmann, L.R., Gao, S., Lee, E.S., & Kwoh, C.K. (2013). Racial disparities in the monitoring of patients on chronic opioid therapy. *Pain*, 154(1), 46–52. doi: 10.1016/j.pain.2012.07.034.

Hedegaard, H., Warner, M., & Miniño A. (2017). NCHS Data Brief: Drug Overdose Deaths in the United States, 1999–2015. Data brief No. 273. Retrieved from https://www.cdc.gov/nchs/data/databriefs/db273.pdf

Henry J. Kaiser Family Foundation (2015). State Health Facts: Opioid Overdose Deaths by Race/Ethnicity. Retrieved from http://kff.org/other/state-indicator/opioid-overdose-deaths-by-raceethnicity/?dataView=0&currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D

Hickton, D.J. & Song, S.C. (2016). Integrating public safety and public health to reduce overdose deaths. *United States Attorneys' Bulletin*. Columbia, SC: Executive Office for United States Attorneys, Office of Legal Education.

Johnson, S.R. (2016, Feb. 24). The racial divide in the opioid crisis. *Modern Healthcare*. Retrieved from http://www.modernhealthcare.com/article/20160224/NEWS/160229947

Kaafarani, H.M., Weil, E., Wakeman, S. & Ring, D. (2017). The opioid epidemic and new legislation in Massachusetts: Time for a culture change in surgery? *Annals of Surgery,* 265(4):731–733.

Kasper, J.D. (2016). The opioid crisis: Northampton police aim to help addicts before it's too late. *Northampton Police Department Gazette*. Retrieved from https://www.northamptonpd.com/about/meet-the-chief/articles-by-chief-kasper/227-the-opioid-crisis-northampton-police-aim-to-help-addicts-before-it-s-too-late.html

Knudsen, E.I., Heckman, J.J., Cameron, J.L., & Shonkoff, J.P. (2006). Economic, neurobiological, and behavioral perspectives on building America's future workforce. *Proceedings of the National Academy of Sciences*, 103(27), 10155–10162.

Lane, C. (2016, August 18). The opioid epidemic: For whites only? *The Washington Post*. Retrieved from https://www.washingtonpost.com/blogs/post-partisan/wp/2016/08/18/the-opioid-epidemic-for-whites-only/?utm_term=.9e9df31357d5

Lynch, L. (2016). Memorandum for Heads of Department Components, Re: DOJ Strategy to Combat Opioid Epidemic. Washington, DC: Office of the Attorney General.

Mars, S.G., Bourgois, P., Karandinos, G., Montero, F., & Ciccarone, D. (2014). "Every 'never' I ever said came true": Transitions from opioid pills to heroin injecting. *International Journal of Drug Policy*, 25(2):257–266.

Master Settlement Agreement (MSA) (1998). Retrieved from http://www.naag.org/assets/redesign/files/msa-tobacco/MSA.pdf

National Alliance for Model State Drug Laws (NAMSDL) (2016). Compilation of Prescription Monitoring Program Maps.

National Conference of State Legislatures (2017). Report: Drug Overdose Immunity and Good Samaritan Laws. Retrieved from http://www.ncsl.org/research/civil-and-criminal-justice/drug-overdose-immunity-good-samaritan-laws.aspx

National Conference of State Legislatures (2017). Report: Drug Testing for Welfare Recipients and Public Assistance. Retrieved from http://www.ncsl.org/research/human-services/drug-testing-and-public-assistance.aspx

Newberry, L. (2016). Heroin crisis: Northampton police take emphasis off drugs possession arrests, instead work to connect addicts to help. *MassLive.com*. Retrieved from http://www.masslive.com/news/index.ssf/2016/03/northampton_police_takes_empha.html

Office of National Drug Control Policy (2016). National Drug Control Strategy. Retrieved from https://obamawhitehouse.archives.gov/sites/default/files/ondcp/policy-and-research/2016_ndcs_final_report.pdf

Ohio v. Purdue Pharma LP (2017). No. CV 17 CI 000261, Ohio Court of Common Pleas (Ross County).

Pletcher, M.J. (2008). Trends in opioid prescribing by race/ethnicity for patients seeking care in U.S. emergency departments. *Journal of the American Medical Association.* 299(1):70-78. Retrieved from http://jamanetwork.com/journals/jama/fullarticle/1149438

Police Executive Research Forum (2016). The Unprecedented Opioid Epidemic: As Overdoses Become a Leading Cause of Death, Police, Sheriffs, and Health Agencies Must Step Up Their Responses. Retrieved from http://www.policeforum.org/assets/opioids2017.pdf

President's Commission on Combatting Drug Addiction and the Opioid Crisis: Final Report (2017). Retrieved from https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-15-2017.pdf

Purdue Pharmaceuticals (1995). Abuse liability of oxycodone. New drug application to FDA for OxyContin, *Pharmacology Review*. Stamford, CT: Purdue Pharma.

Robertson, C. & Kesselheim, A.S. (2016). Regulating off-label promotion—a critical test. *New England Journal of Medicine*, 375, 2313–2315.

Rocky Mountain High Intensity Drug Trafficking Area (2016). Legalization of Marijuana in Colorado: The Impact. Vol 4. Retrieved from http://www.rmhidta.org/html/2016%20FINAL%20Legalization%20of%20Marijuana%20in%20Colorado%20The%20Impact.pdf

Rosen, L. (2015). International Drug Control Policy: Background and U.S. Responses. Congressional Research Service, Report. No. RL 34543.

Ryan, H. (2017, January 19). City devastated by OxyContin use sues Purdue Pharma, claims drugmaker put profits over citizens' welfare. *Los Angeles Times*. Retrieved from http://www.latimes.com/local/lanow/la-me-oxycontin-lawsuit-20170118-story.html

Silverman, E. (2016, February 3). Federal panel supports CDC guidelines for opioid prescribing. *STAT News*. Retrieved from https://www.statnews.com/pharmalot/2016/02/03/cdc-opioid-guidelines/

Sorrell v. IMS Health Inc. (2011). 564 U.S. 552.

Substance Abuse and Mental Health Services Administration (SAMHSA) (2016). Opioid Overdose Prevention Toolkit. Retrieved from https://store.samhsa.gov/shin/content//SMA16-4742/SMA16-4742.pdf

Substance Abuse and Mental Health Services Administration (SAMHSA) (2017). Who We Are. Retrieved from https://www.samhsa.gov/about-us/who-we-are

Swanson, A. (2015, February 11). Big pharmaceutical companies are spending far more on marketing than research. *The Washington Post: WonkBlog*. Retrieved from https://www.washingtonpost.com/news/wonk/wp/2015/02/11/big-pharmaceutical-companies-are-spending-far-more-on-marketing-than-research/?utm_term=.7af07392e017

Tobacco Control Legal Consortium (2015). The Master Settlement Agreement: An Overview. Retrieved from http://www.publichealthlawcenter.org/sites/default/files/resources/tclc-fs-msa-overview-2015.pdf

Turney, K. (2017). The unequal consequences of mass incarceration for children. *Demography*, 54(1), 361–389.

United States v. Caronia (2012). 703 F.3d 149 (2d Cir.).

U.S. Census Bureau (2015). QuickFacts: United States. Retrieved from https://www.census.gov/quickfacts/table/PST045216/00.

Van Zee, A. (2009). The promotion and marketing of OxyContin: Commercial triumph, public health tragedy. *American Journal of Public Health*, 99(2), 221–227.

Warner, M., Hedegaard, H., Chen, L.H. (2014). NCHS Health E-Stat: Trends in Drug-Poisoning Deaths Involving Opioid Analgesics and Heroin: United States, 1999–2012. Atlanta, GA: Centers for Disease Control and Prevention.

White House, Office of the Press Secretary (2015). Continued Rise in Opioid Overdose Deaths in 2015 Shows Urgent Need for Treatment 2016 [Press release]. Retrieved from https://obamawhitehouse.archives.gov/the-press-office/2016/12/08/continued-rise-opioid-overdose-deaths-2015-shows-urgent-need-treatment

White House, Office of the Press Secretary (2016). Fact sheet: Obama Administration Announces Additional Actions to Address the Prescription Opioid Abuse and Heroin Epidemic [Press release]. Retrieved from https://obamawhitehouse.archives.gov/the-press-office/2016/03/29/fact-sheet-obama-administration-announces-additional-actions-address

White House, Office of the Press Secretary (2017). Presidential Executive Order Establishing the President's Commission on Combating Drug Addiction and the Opioid Crisis [Press release]. Retrieved from https://www.whitehouse.gov/the-press-office/2017/03/30/presidential-executive-order-establishing-presidents-commission

Title VII Office of National Drug Control Policy Reauthorization Act of 1998 (1998). P.L. 105-277, Title VII.

Wildeman, C. (2009). Parental imprisonment, the prison boom, and the concentration of childhood disadvantage. *Demography*, 46(2), 265–280.

Zezima, K. (2017, January 27). Awash in overdoses, Seattle creates safe sites for addicts to inject illegal drugs. *The Washington Post*. Retrieved from https://www.washingtonpost.com/politics/awash-in-overdoses-seattle-creates-safe-sites-for-addicts-to-inject-illegal-drugs/2017/01/27/ddc58842-e415-11e6-ba11-63c4b4fb5a63_story.html?utm_term=.043062db95fa


Public health
emergency

CONFRONTING OUR NATION'S OPIOID CRISIS

A Report of the Aspen Health Strategy Group

The mission of the Aspen Health Strategy Group is to promote improvements in policy and practice by providing leadership on important and complex health issues. The group is comprised of 24 senior leaders across influential sectors such as health, business, media, and technology and is part of the Health, Medicine and Society Program at the Aspen Institute. Co-chaired by Kathleen Sebelius and Tommy G. Thompson, both former governors and former U.S. Secretaries of Health and Human Services, the Aspen Health Strategy Group tackles one health issue annually through a year-long, in-depth study. This book is a collection of papers on the group's second subject: Confronting the nation's opioid crisis. The papers address topics related to the health care system, financing, and the law's response to the opioid epidemic and include a final consensus report based on the group's work.

THE ASPEN INSTITUTE HEALTH STRATEGY GROUP

THE ASPEN INSTITUTE Health, Medicine and Society Program

funding for this report provided by:

Robert Wood Johnson Foundation

ljaf laura and john arnold foundation

Laurie M Tisch ILLUMINATION FUND

17/019