Addressing Prescription Opioid Abuse Concerns in Context: Synchronizing Policy Solutions to Multiple Public Health Problems

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ADDRESSING PRESCRIPTION OPIOID ABUSE CONCERNS IN CONTEXT: SYNCHRONIZING POLICY SOLUTIONS TO MULTIPLE COMPLEX PUBLIC HEALTH PROBLEMS

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I. Introduction

An ethically and clinically sound public policy response will neither discount nor disfavor one crisis to obsessively focus upon the other.-Ben Rich

Hyrum Neizer would be dead today if his wife hadn’t walked in on him with the gun in his mouth. He was in unremitting pain....his life was ruined not just by his chronic physical pain but by the very people who were supposed to be helping him...they eventually made him believe that, because he relied on pain relievers, he was a drug abuser. He was not. He was simply, like 100 million other Americans, a person in chronic pain.

Primary pain conditions are among the most medically complex problems that providers face. Compounding this complexity are misguided policy solutions as well as the historical, social, political, psychological, and legal realities particular to pain that leave a significant group of patients mistreated, undertreated, and untreated. Decades of thoughtful, interdisciplinary policy work in the 1990s and early 2000s improved the environment for both patients in pain and their providers. Some of that progress, however, is compromised by the understandable

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4 See generally, KEITH WAILOO, PAIN: A POLITICAL HISTORY (2014).
5 Years of widespread efforts by health care advocacy and regulatory groups to improve the treatment of patients in pain resulted in modest but palpable progress in the early 21st century. See, e.g., Sandra H. Johnson, Relieving Unnecessary, Treatable Pain for the Sake of Human Dignity, 29 J.L. MED. & ETHICS 11 (2001) (introducing the interdisciplinary Mayday Project on unrelieved pain). See also, Diane E. Hoffmann & Anita J. Tarzian, Achieving the Right Balance in Oversight of Physician Opioid Prescribing for Pain: The Role of State Medical Boards, 31 J.L. MED & ETHICS 21 (2003); Ben Rich, An Ethical Analysis of Barriers to Effective Pain Management, 9 CAMBRIDGE QUARTERLY OF HEALTHCARE ETHICS 54-70 (2000). Providers encouraged measured treatments, including opioid therapy, and regulatory gains included more deferential state medical board policies and intractable pain treatment acts. The Affordable Care Act directed Health and Human Services to work with the Institute of Medicine to
but ultimately incoherent responses to the reported rise in prescription drug
overdose deaths in the United States (U.S.).

Several years ago, the Centers for Disease Control and Prevention (CDC)
described increased rates of opioid related overdoses (OROs), eventually declaring
an epidemic of ORO deaths. This, in turn, triggered an unbalanced and
disproportionate response by policymakers, practitioners, and the media that
focused on opioids and their use in treating pain without a careful examination of
the root causes. Although the problems surrounding opioids and those surrounding
the undertreatment of pain are empirically distinct, they are now conflated in ways
that unnecessarily harm patients.

The epidemic of deaths associated with opioid use transitioned without
notice into an “epidemic of opioids;” by 2012, Manchikanti and colleagues omitted

“increase the recognition of pain as a significant public health problem for the United States” and the
National Institutes of Health to fund further research and curricula development on pain treatment.

OFFICE OF THE LEGIS. COUNSEL, 111–1 PATIENT PROTECTION AND AFFORDABLE CARE ACT HEALTH-RELATED
PORTIONS OF THE HEALTH CARE AND EDUCATION RECONCILIATION ACT OF 2010 (2010) available at,

6 This is the formal name for narcotic pain relievers or “pain medicine.” Opioids are “any compound
that binds to an opioid receptor.” RELIEVING PAIN IN AMERICA: A BLUEPRINT FOR TRANSFORMING
PREVENTION, CARE, EDUCATION AND RESEARCH, INST. OF MED. at 278 (2011), available at
www.iom.edu/Reports/2011/Relieving-Pain-in-America-a-Blueprint-for-Transforming-Prevention-Care-Education-Research.aspx (hereinafter IOM, Relieving Pain in America). They include drugs like
oxycodone, hydrocodone, morphine, codeine, meperidine, methadone, and hydromorphone.

7 They did, however, carefully list the limitations of their findings, a fact that garnered little attention.

CENTERS FOR DISEASE CONTROL AND PREVENTION, Unintentional Poisoning Deaths,
MORBIDITY & MORTALITY WEEKLY REPORT 5, 93-96 (Feb 2007). available at
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5605a1.htm (listing the following limitations
with the study, “[f]irst, mortality coding assigns the underlying cause of death to broad drug categories
rather than to specific drugs. Second, death certificates do not reveal the circumstances of drug use.
Third, determining the intent of a person who took a drug is often difficult for a coroner or medical
examiner and might result in misclassification; some of these deaths might have been suicides,
although not classified as such, and some deaths categorized as suicides or of undetermined intent
might have been unintentional and therefore not analyzed in this study. The extent of this error is not
known” (emphasis added)).

8 The issue of prescription drug deaths is of great concern and should not be minimized. However,
solutions to that problem should be tailored to the causes of the problem and not at the expense of
patients in pain.

9 Laxmaiah Manchikanti et al., Opioid Epidemic in the United States, 15 PAIN PHYSICIAN ES9-ES38
the words “overdoses” or “poisonings” altogether in publications and instead declared an “opioid epidemic with adverse consequences” that placed blame on everything from liberalized laws, to the Joint Commission on Accreditation of Healthcare Organizations, pharmaceutical companies,\(^\text{10}\) and even campaigns “touting the \textit{alleged} undertreatment of pain.”\(^\text{11}\) The “opioid epidemic” language is now in mainstream use without qualification.\(^\text{12}\) This is one of several common uses of infectious diseases vocabulary to attribute pathogen status to prescription opioids and patients in pain.\(^\text{13}\) Theses responses come at the expense of patients already vulnerable to stigmatization and inappropriate treatment, threatening to unravel decades of work to improve the regulatory and care environment.\(^\text{14}\) Some providers and policymakers seem invested in the wholesale rejection of not only opioids, but of patients themselves.\(^\text{15}\)

\(^{10}\) The aggressive and illegal marketing by some pharmaceutical companies undoubtedly influenced prescribing of opioids and may have led some physicians to believe, albeit unreasonably, that some of the newer drugs, such as Oxycontin, were safer than in reality. In turn, some doctors may have been less careful than warranted in instructing patients. United States v. Purdue Frederick, 495 F.Supp2d 569 (W.D. Va. 2007). \textit{See also} Kathleen M. Boozang, \textit{Responsible Corporate Officer Doctrine: When is Falling Down on the Job a Crime?} 6 \textit{St. Louis U. J. Health L. Policy} 1, 77-112 (2012).

\(^{11}\) \textit{Id}.. There is a significant difference between an epidemic in opioid related drug overdoses and an epidemic of opioids as prescribed but this distinction went almost unchallenged.


\(^{13}\) For example, the term “universal precautions,” meaning the practice of wearing protective gear to prevent infection transmission, is now short hand for a number of practices recommended for treating patients with opioids. \textit{See infra} Section V.

\(^{14}\) The work of interdisciplinary scholars including David Brushwood, Sandra H. Johnson, Diane E. Hoffmann, and Ben Rich were instrumental in changing the regulatory environment. Work of institutes such as the Wisconsin Pain and Policy Studies Group and the Mayday Fund advanced research in the treatment and regulations surrounding pain for decades. \textit{See Mayday Fund, History of Grant Making}, available at \url{http://www.maydayfund.org/sft211/grantshistory93to13.pdf}.

Policy efforts focused almost exclusively on reducing the availability of prescription opioids, a strategy without consideration of the consequences. First, these strategies failed to acknowledge or address the specific nature of the OROs, most of which involved combined substances and some of which were suicides. Second, they failed to account for the serious underlying chronic and complex nature of substance use disorders, pain, and multiple comorbid conditions, such as suicidality. Third, they proposed changes only to opioid use, not to the care of the patients involved. Without considering the need for new approaches to treatment of patients with pain, substance use disorders, and the significant comorbidities, policy “solutions” left those suffering without assistance and in some cases, increased the barriers to treatment.

Too many stories like that of Hyrum Neizer, a man with chronic, intense pain from debilitating headaches and suicidality, are symptomatic of the fragmented and distorted care many patients in pain receive.\(^\text{16}\) Neizer’s search for relief was characterized by unfruitful and humiliating trips to emergency departments (EDs) and doctors’ offices.\(^\text{17}\) He attempted suicide multiple times.\(^\text{18}\) Although opioids relieved his pain, doctors stopped prescribing opioids altogether and convinced Neizer he was addicted to opioids. He even admitted himself into group treatment for addiction, an experience he later described this way: “my heart felt for them but their stories weren’t my story. I didn’t have the desire to sell a kidney for drugs. I didn’t want to rob pharmacies for OxyContin.”\(^\text{19}\) He only wanted his pain to stop.\(^\text{20}\)

\(^{16}\) See Judy Foreman, A NATION IN PAIN, supra note 2.  
\(^{17}\) Id.  
\(^{18}\) Id. at 126-127.  
\(^{19}\) Id.
In 2015, Mr. Neizer may well have faced criminal prosecution under a doctor shopping statute, limited or no access to pain management physicians and providers even more reluctant or unable to prescribe opioids to treat his pain. Myriad policy and practice level responses have emerged in the wake of a very serious public health problem of increased opioid abuse morbidity and mortality. Many of these responses do not address the actual harms—substance use related health and functional declines and premature death—and instead reflect a moral panic fueled by longstanding biases and stigmatization of individuals who have chronic or persistent pain (CP), substance use disorders (SUD), any mental illness (MI) or serious mental illness (SMI), suicidality, or a combination thereof.

20 In reality, Mr. Neizer had two brain aneurysms that were discovered when a physician comprehensively evaluated him. Id. 21 See, e.g., TENN. CODE ANN. § 71-5-2601(a)(1)(A)(iii) (2015) (hereafter Tenn. Doctor Shopping Statute). This statute makes it a criminal offense for Tennessee Medicaid patients to obtain a prescription for controlled substances from more than one doctor in any 30 day period. 22 See, e.g., Florida’s restrictions and oppressive regulatory requirements for pain management physicians. FLA. STAT.§ 456.44 (2012) (mandating a detailed list of specific practice and prescription requirements). 23 See, e.g., Hilary Wilson et al., Clinicians Attitudes and Beliefs About Opioid Survey (CAOS): Instrument Development and Results in a National Physician Survey, 14 J. PAIN 6, 613-617 (June 2013) (examining differences in physician attitudes about opioid prescribing and revealing that younger physicians as well as those who did not have a large number of patient in chronic pain were more reluctant to prescribe opioids). See also Ken Solis, Ethical, Legal, and Professional Challenges Posed by “Controlled Medication Seekers” to Healthcare Providers, 7 AMERICAN J. CLINICAL MED. 2, 86-97 (2010) at 91 (describing letters from Wisconsin ED to “frequent flyers” that they would no longer receive pain medication for their pain). 24 Margaret Warner et al., Increase in fatal poisonings involving opioid analgesics in the United States, 1999-2006, NCHS DATA BRIEF, No.22. HYATTSVILLE, MD: NATIONAL CENTER FOR HEALTH STATISTICS; 2009, available at http://www.cdc.gov/nchs/data/databriefs/db22.htm. See also, CENTERS FOR DISEASE CONTROL AND PREVENTION, Vital Signs: Overdoses of Prescription Opioid Pain Relievers — United States, 1999-2008, 60 MMWR 43, 1487-1492 (2011). 25 Chronic pain is traditionally defined as pain that lasts at least three month but chronic pain can be intermittent and thus, would not always meet the definition of persistent pain, which usually requires constant or frequent pain. When persistent pain lasts 90 days, it generally meets the definition of chronic pain. See, e.g., Jane C. Ballantyne, Opioid Therapy in Chronic Pain, 26 PHYS MED REHABIL CLIN N AM 2 (2015) (“Ninety days is also the point at which persistent pain is termed chronic.”). For a discussion of persistent pain, see Jae Kennedy et al., Prevalence of Persistent Pain in the U.S. Adult Population: New Data From the 2010 National Health Interview Survey, 15 J. PAIN 10 (2014) (defining persistent pain as pain that that is constant or frequent lasting at least 3 months and analyzing recent data to conclude that persistent pain effects at least 19 million Americans in contrast to the 100 million who have chronic pain as described by the Institute of Medicine Report from 2010).
This issue deserves attention and responses designed to address the complexity of issues surrounding pain treatment and SUDs. Solutions must reduce overall harms without diminishing access and care to patients, including those in pain who benefit from opioid therapy. Many of the responses to date lack the

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26 The American Psychiatric Association’s Diagnostic and Statistical Manual, Fifth Edition (DSM V), combines previous definitions of substance abuse and substance dependence into a spectrum called Substance Use Disorder that ranges from mild to severe. I generally use this term throughout the paper in the context of individuals who are addicted to substances such as those who misuse or abuse prescription medications in ways that are not to treat underlying pain. I do not use the term when describing patients in chronic pain who may appear to be drug seeking but are doing so because of under treated pain (often called pseudoaddiction). For more information on SUD, see American Psychiatric Association, Substance Related and Addictive Disorders, available at http://www.dsm5.org/Documents/Substance%20Use%20Disorder%20Fact%20Sheet.pdf. See also, Deborah S. Hasin et al., DSM-5 Criteria for Substance Use Disorders: Recommendations and Rationale, 170 Am. J. Psychiatry 8 (August 2013).


28 By suicidality I include everything from ideation to a completed suicide. The CDC separately defines suicide (death caused by self directed violence), suicide attempt (non-fatal self directed injury with any intent to die), and suicidal ideation (thinking about, planning, or considering suicide). See Centers for Disease Control and Prevention, Injury Prevention & Control: Division of Violence Prevention, Definitions, available at http://www.cdc.gov/violenceprevention/suicide/definitions.html. The American Psychiatric Association listed Suicidal Behavior Disorder as a condition for further study in the DSM V, adopting to continue treating it as a subcomponent of serious mental illness rather than a separate entity despite the fact that 10% of people who attempt or complete suicide have no discernable psychiatric diagnosis. See, e.g., Maria A. OQuendo et al., Issues for DSM-V: Suicidal Behavior as a Separate Diagnosis on a Separate Axis, 165 Am J Psychiatry 11, 1383-1384 (2008).

29 This will require a shift in drug policy that favors treatment and rehabilitation. The authoritarian policies of the war on drugs have not succeeded—an embarrassment that Mark Kleiman describes saying, “It turns out to be substantially easier to announce that one is opposed to drug taking than to craft public policies to reduce the damage it does…a policy of announced hostility toward drug taking and drug takers will tend to make the remaining drug takers worse off, and more dangerous to others, than they would have been otherwise.” Mark Kleiman, Drug Abuse Control Policy: Libertarian, Authoritarian, Liberal, and Communitarian Perspectives, The Essential Communitarian Reader, ed. Amitai Etzioni, (BOWMAN & LITTLEFIELD, 1998).

30 I do not advance that opioids are appropriate or even indicated in all circumstances. However, the careful use of opioids can make a significant difference in functional ability of certain patients in chronic pain and are almost always appropriate for moderate to severe acute pain such as post-surgery or in temporary but pain conditions such as kidney stones. For a review of the benefits and
nuance required. Regulatory overreach, regression to old notions of patient legitimacy, and puritanical approaches to complex chronic conditions will ultimately do more harm than good. Instead, patient-centered laws and policies are needed, what Sandra H. Johnson has defined as those that serve the core values in medicine of relieving suffering, enhancing well-being, and increasing availability of effective treatments.\(^{31}\)

This article will call for a careful examination of the facts, circumstances, and decision-making surrounding the recent round of restrictive policies regarding prescription opioids and the trickle down impact on the patients in pain and their providers.\(^ {32}\) Part II will provide an overview of the data and facts surrounding opioid related injuries and deaths in context and what they mean for patients with pain and related conditions. Part III will explore the complexity of the problems of pain, and examine the related and co-morbid disorders that are often erroneously compartmentalized or ignored in practice and policy. Part IV will provide an overview of some common decision-making biases and errors and how these may be reflected in the responses of providers and policymakers to the opioid overdose epidemic. Part V will examine current reactions of law enforcement, legislatures, and policymakers, including legal frameworks surrounding the use of opioids in health care and their relationship to provider behavior. Part VI will endorse policy

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options synchronized to available data that do not devalue patients, or damage provider-patient relationships.

II. The Misuse of Opioids: Realities and Minimized Concerns

If the competent and compassionate medical management of... chronic pain... were not already challenging, these have recently become more arduous because of the near hysteria that has attended the significant spike in prescription drug overdoses.33

There are harms associated with drug abuse or misuse of any kind.34 Premature death from drug poisoning (overdose) is the most serious of those harms, regardless of the drug involved. However, the responses to the problem of opioid related overdoses (OROs) are causing harm in their own right by (1) conflating the appropriate use of prescription opioids with a root cause of misuse and overdose, (2) labeling all overdoses as “opioid related” no matter what role opioids play in the injury, (3) deflecting attention from other very serious trends reflected in these statistics, and (4) contributing to serious decision-making errors by policymakers and providers. These collectively indicate that moralistic attitudes and ingrained socio-cultural biases against people in pain and the use of opioids were only thinly cloaked by the serious advocacy efforts in the last twenty years.35

Steven Passik described it this way, “[p]eople have returned to talking about opioids

34 There are various, conflicting uses of abuse and misuse in this context. I will use the terms in this paper to mean for non-medical use, such as euphoria, involving illicit drugs or use of prescription drugs that are not prescribed to the user or by those to whom they are prescribed in ways that substantially deviate from the directed uses.
35 See generally, Carl May et al., Framing the Doctor-patient Relationship in Chronic Illness: a Comparative Study of General Practitioners’ Accounts, 26 SOCIOLOGY HEALTH & ILLNESS 2 (2004) (describing chronic pain patients as the most frustrating for providers, even as compared to patients with depression and menorrhagia).
in religious terms, as if the drugs themselves are good or evil, and those emotions lead them to say, and even believe, things that are demonstrably false.”

Despite zealous policy reactions, very little progress to reduce the harms associated with misuse and overdose is evident, while the increases in harm to patients living in pain are palpable. In part, this is likely because the actual harms have not been carefully articulated; instead, prescription opioids and the patients in pain who benefit from them may be a stand-in for what are actually a network of public health problems with various degrees of overlap and intersection. Slanted presentation of data has been described as an ethical problem in its own right; this is because of the likelihood of harm to patients when policy and practice is based upon the “faulty mechanisms and procedures by which scientific data are interpreted for professionals, administrators, policymakers, news media, and the general public.” Synchronizing future solutions to actual harms requires a careful examination of existing facts.

A. Rises in Prescriptions and Opioid Related Injuries: An Illusory Correlation?

36 PAINWEEK NEWS, False Arguments and False Hope: An Oconoclastic Take on the Battle Over Prescription Opioids (September 2012) (reporting on lecture by Steven D. Passik entitled “Jesus, Bacon, and Hyperalgesia: Intellectual Honesty and Dishonesty in Opioids for Chronic Pain Management”).

37 While a decrease in prescription opioid overdoses have occurred in states with restrictive policies, a corresponding rise in heroin use and overdose has accompanied those decreases. See infra Section V.

38 See, e.g., Ken Armstrong and Michael J. Berens, New State Law Leaves Patients in Pain, SEATTLE TIMES (December 11, 2011).

39 I explore this as a kind of opioid heuristic later in Section IV.

40 GRIFFIN TROTTER, INTERPRETING SCIENTIFIC DATA ETHICALLY: A FRONTIER FOR RESEARCH ETHICS, IN RESEARCH ETHICS, ED. ANA ILTIS, 165-177 (ROUTLEDGE, 2006) at 166.

41 Id.
Opioid prescriptions have increased over the last three decades in the U.S., as have the number of all prescriptions. The numbers are absent any context; the increase may be, in part, a positive outcome of the efforts in the late 1990s to decrease physician fears of prescribing and improving the treatment of pain. The rates of opioid diversion and illicit use have also increased. Most assume the rise in prescribing caused the increase in illicit use. While there is a relationship, the available data does not support a direct doctor to “patient” to “addict” relationship; instead the correlation might be described as illusory, or “the tendency to perceive two events as causally related, when in fact the connection between them is coincidental.”

The vast majority of people who abuse, misuse, or overdose on prescription opioids are not the patients for whom they are prescribed. The lack of relationship

42 See, e.g., Margaret A. Caudill-Slosberg et al., Office visits and analgesic prescriptions for musculoskeletal pain in US: 1980 vs. 2000, 109 PAIN 514-519 (2004); Hilary Wilson et al., supra note 23 at 613-617 (citing to other sources).
44 See Margaret A. Caudill-Slosberg et al., supra note 42. See generally, Ben Rich, Distinguishing Difficult Patients from Difficult Maladies, supra note 33.
45 Andrew Golub et al., The Opiate Pain Reliever Epidemic Among U.S. Arrestees 2000-2010: Regional and Demographic Variations, 12 J. ETHNICITY SUBSTANCE ABUSE 1, 1-29 (2013); See also Richard Spoth et al., Longitudinal Effects of Universal Preventive Intervention on Prescription Drug Misuse: Three Randomized Controlled Trials with Late Adolescents and Young Adults, 103 AMER. J. PUBLIC HEALTH 4, 665-673 (2013)(describing some promising work to reduce drug misuse through middle school interventions).
46 See, e.g., Nicholas B. King et al., Determinants of Increased Opioid-Related Mortality in the United States and Canada, 1990–2013: A Systematic Review, 104 AMER. J. PUBLIC HEALTH 8, e32-e42 (2014) (“it is still unclear whether high-volume prescribing is a direct driver of increased mortality”).
47 Ben A. Rich, Distinguish Difficult Patients from Difficult Maladies, supra at note 33. (“Often glossed over in such analyses is the fact that the victims of such drug overdoses were not the patients for whom the medications were prescribed, and in most instances the opioid was but one of a number of other drugs, as well as alcohol, which together resulted in the victim’s hospitalization or death”). See also, David E. Joranson & Aaron M. Gilson, A Much Needed Window on Opioid Diversion, (Editorial) 8 PAIN MED. 2 (2007) (“we question the validity of asserting, absent direct evidence, that it [opioid overdoses] resulted from treating pain patients”).
49 SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION, RESULTS FROM THE 2013 NATIONAL SURVEY ON DRUG USE AND HEALTH: SUMMARY OF NATIONAL FINDINGS, NSDUH SERIES H-48, HHS PUBLICATION
between receiving a prescription and misuse of the drug has been demonstrated by a variety of studies, including first person accounts, as well as analyses of pharmacy and health care data. For example, a 2011 study by Cicero and colleagues showed the vast majority of drug abusers obtained their prescription medication from dealers and from sharing with friends and family. Only 13.8% obtained their prescription through their regular doctor or through doctor-shopping (filling multiple prescriptions for opioids from multiple prescribers). Of those that originated with a legitimate prescription, the source was typically primary care providers, not pain treatment clinics. The National Survey of Drug Use and Health (NSDUH) indicate that the vast majority of those who misuse or abuse prescription drugs use pills that were never prescribed for them. McDonald and Carlson examined analyzing opioid prescription pharmacy data from 76% of retail pharmacies in the U.S. Of the 146.1 million opioid prescriptions dispensed in 2008, only about 4% of medication dispensed was to doctor-shopping individuals, who constituted just 0.7% of purchasers, and purchased 1.9% of all opioid

No. (SMA) 14-4863 (2014) ("more than half of the nonmedical users of pain relievers, tranquilizers, stimulants, and sedative... got the prescription drugs they most recently used "from a friend or relative for free"). In addition, drugs can be diverted before they become the object of prescription, such as manufacturing and distribution thefts. See Nat’l Center on Addiction and Substance Abuse, Under the Counter: The Diversion and Abuse of Controlled Prescription Drugs in the U.S., The CASA NAT’L ADVISORY COMMISSION ON THE DIVERSION AND ABUSE OF CONTROLLED PRESCRIPTION DRUGS (July 2005). Theodore J. Cicero et al., Multiple determinants of specific modes of prescription opioid diversion, 41 J. DRUG ISSUES 2, 283-304 (2011).

Id. 287. See also Khary K. Rigg et al., Prescription Drug Abuse and Diversion: Role of the Pain Clinic, 40 J DRUG ISSUES 3 (2010). (providing a qualitative analysis of methods used by those involved in the prescription drug trade).

Khary K. Rigg et al., supra note 51.

SAMHSA, RESULTS FROM THE 2013 NSDUH, SUMMARY FINDINGS, 14-4863 (2014) supra at note 49 (Reporting that among persons aged 12 or older in 2012-2013 who used pain relievers non-medically in the last year, 53.0 percent got the pain relievers they most recently used from a friend or relative for free. Another 10.6 percent of these nonmedical users in 2012-2013 bought pain relievers from a friend or relative, and 4.0 percent took pain relievers from a friend or relative without asking. An annual average of 4.3 percent got the pain relievers from a drug dealer or other stranger; 2.6 percent got pain relievers from more than one doctor; 0.1 percent bought pain relievers on the Internet; and 4.3 percent got pain relievers in other ways, including 0.7 percent who stole pain relievers from a doctor’s office, clinic, hospital, or pharmacy).
prescriptions. The vast majority of opioid prescriptions involved a single prescription from one healthcare provider and most patients seemingly...used them sparingly."

Exposure to opioids alone does not create SUD. Of course, some patients are more susceptible than others; factors such as a history of alcoholism or other substance abuse are more predictive of misuse of prescription opioids, but the overall rates of developing SUD after treatment for pain remain low. A study by Cepeda and colleagues found that only three out of one-thousand people exposed to opioids goes on to exhibit any doctor shopping behavior (whether because of addiction or pseudo-addiction). Those who receive an opioid prescription for an acute or temporary pain episode tend to take them as prescribed for pain and end up with leftover pills; literally thousands of tons of opioid prescription pills were collected in just a few years through drug take back programs. Thus, there is scant evidence that use of opioids as prescribed for pain predisposes patients to future

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55 S.B. Leavitt, How common is doctor shopping for opioids? PAIN-TOPICS.ORG NEWS (Sept 13, 2013) (commenting on the study by McDonald and Carlson, supra at note 54).
56 Addiction is a complex mechanism that involves particular vulnerabilities such as genetic predispositions, exposure to particular stressors, and neurobiological mechanisms. See, e.g., Rajita Sinha, Chronic Stress, Drug Use, and Addiction, ANN NY ACADEMY SCI. 1141 (October 2008); The Nat’l Center of Addiction and Substance Abuse, Addiction Medicine: Closing the Gap between Science and Practice, THE CASA COLUMBIA NATIONAL ADVISORY COMMISSION ON ADDICTION TREATMENT (June 2012).
57 See David A. Fishbain et al., What Percentage of Chronic Nonmalignant Pain Patients Exposed to Chronic Opioid Analgesic Therapy Develop Abuse/Addiction and or Aberrant Drug-related Behaviors? A Structured, Evidence-Based Review, 9 PAIN MED 4, 444-459 (2008). (Rates of abuse/addiction ranged between 0.19% (those with no history of substance abuse) to 3.27% (those with history of substance abuse)).
SUD or overdose. Absent the predisposing genetic and environmental factors, "the
drug does not have the power to change people in that way."  

Nonetheless, some groups and providers continue to respond as though
prescription opioids are harmful in all circumstances. For example, Herzig and
colleagues recently published an article in which they looked at the raw numbers of
in-hospital opioids prescriptions. They eliminated all patients with any type of
surgical code, presuming they all had "legitimate" reasons for opioids. They then
analyzed the prescription rates for all non-surgical hospital patients with no
additional context. Considering no information such as diagnoses, histories, acuity of
illness, or the like, the authors declare the prescribing practices inappropriate,
strongly implying doctors are placing their patients in jeopardy through improper
medical practice. A recent article by Kolodny and colleagues explicitly states
without citation, "the disease of opioid addiction arises from repeated exposure to
opioids." The authors also strongly recommend decreased prescribing of opioids
across the board, even suggesting that patients in pain should be deprived pain-
relieving drugs to minimize the risk of diversion by family members or friends.

60 Charles von Guten, appearing in Short Film 4: Opiophobia, Life Before Death, lifebeforedeath.com, available at http://www.lifebeforedeath.com/movie/short-films.shtml (explaining that opioids for pain relief do not fundamentally change the person to whom they are prescribed; if a person has lived their entire life without problems with addiction, they are not going to go out and become an addict in response to pain medication).
62 Id. This is an example of another disturbing trend in wholesale legitimization of some classes of patients such as those who had surgery (regardless of type) and those with cancer (regardless of type, duration, prognosis, etc.). Those remaining are presumed not legitimate until proven otherwise.
63 Id.
64 Id.
65 Andrew Kolodny et al., The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction, 36 ANNUAL REVIEW OF PUBLIC HEALTH 559-574 (2015).
66 Id. at 567 (using the fact that most nonmedical users obtain drugs from friends or family to justify a reduction in prescribing, or what they call "cautious prescribing").
B. Broad Definitions and Tunnel Vision in Nonmedical Use

The most cited statistics for the alleged epidemic of opioids are those that appear in survey reports from the Substance Abuse and Mental Health Services Administration (SAMHSA) that track rates self-reported non-medical use, ED visits, and deaths related to opioids. The primary source for non-medical use information is the annual National Survey on Drug Use and Health (NSDUH); however, information in the NSDUH on opioid use only dates back to 2002, the year they started tracking it. In addition, while the NSDUH survey asks about nonmedical use, except for inhalants, the survey does not separate out whether a respondent took the medicine to treat underlying pain or to “get high.” The NSDUH does not indicate any substantial changes in non-medical use of prescription opioids since 2002; moreover, the 2013 rates are lower than several of the previous years. Independent of substance abused, the overall rates of SUDs have also been stable over the last decade, although it endures as a serious public health problem in the U.S. With a stable rate of both SUD and non-medical use of opioids, the increased rate of ORO ED visits are likely attributable to a complex web of factors, rather than to opioids alone.

68 Id. at 2. In the NSDUH, nonmedical use is defined as 1) use without a prescription of the individual’s own or 2) simply for the experience or feeling the drugs caused. SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION, RESULTS FROM THE 2012 NATIONAL SURVEY ON DRUG USE AND HEALTH: SUMMARY OF NATIONAL FINDINGS, NSDUH SERIES H-46, HHS PUBLICATION NO. (SMA) 13-4795 (2013).
69 SAMHSA, RESULTS FROM THE 2013 NSDUH, SUMMARY FINDINGS, 14-4863 (2014), supra at note 49.
70 Id. at Figure 2.2 (“The percentage of persons aged 12 or older who were current nonmedical users of psychotherapeutic drugs in 2013 (2.5 percent) was lower than the percentages in 2006, 2007, and 2009 (ranging from 2.8 to 2.9 percent), but it was similar to the percentages in all of the other years from 2002 to 2012 (ranging from 2.4 to 2.7 percent).”)
71 See, e.g., Id. at Table 8.4.
1. Emergency Department Visits

The Drug Abuse Warning Network Survey (DAWN Survey) is the most common source of information about ED visits related to drug use and poisonings. The DAWN Survey estimates alcohol, pharmaceutical, and illicit drug use-related visits to EDs based on surveys of selected metropolitan areas from 2004 through 2011.\(^{72}\) The definitions used in the DAWN survey mean that many types and degrees of medication are counted. For example, any one of the following conditions may qualify a visit as drug related: (1) the drug is part of the visit, whether or not it is the reason for the visit\(^{73}\) and (2) any of the following criteria are met:

[a] taking more than the prescribed dose of a prescription drug; [b] taking more than the recommended dose of an over the counter pharmaceutical or supplement; [c] taking a drug prescribed for another individual; [d] taking a drug obtained illegally or without a legitimate prescription; [e] deliberate poisoning with a pharmaceutical by another person; [or] [f] any use that the ED staff document as misuse or abuse.\(^{74}\)

Under this standard, a person who took four ibuprofen tablets over the counter (an acceptable prescription dose), or took their prescribed pain medication early because they were in pain (e.g. at three hours and fifty minutes instead of waiting the full four hours), or even people on a prescribed regime of Methadone, may be counted in these statistics.\(^{75}\)

While the survey authors explicitly


\(^{73}\) "DAWN does not assess the medical reason for the visit and it cannot be assumed that the drug was the direct cause of the medical emergency," and "while DAWN seeks to include drugs related to the visit, some unrelated drugs may be included." \(\textit{Id.}\) at 8, 20.

\(^{74}\) \textit{Id.} at 20.

\(^{75}\) \textit{Id.} at 8 (explaining that they count visits such as when "ED records may mention Methadone but fail to mention that the patient was enrolled in a Methadone program").
acknowledge these limitations, many interpreters of the study have overlooked them.

The rate of visits to EDs for non-medical use of any pharmaceutical (any prescription, over the counter drugs, and supplements) increased by 132% between 2004 and 2011.\textsuperscript{76} Visits for opioids increased by 183% over that same time period.\textsuperscript{77} The increase is not just limited to opioids. For example, stimulants increased 307% (drugs used to treat attention deficit disorders),\textsuperscript{78} benzodiazepines increased 149% (anti-anxiety agents such as Xanax or Valium),\textsuperscript{79} and anxiolytics, sedatives, and hypnotics increased 138%.\textsuperscript{80} Between 2009 and 2011, opioid related visits were stable, with no significant increases while other drug related visits rose.\textsuperscript{81}

The DAWN Survey report included important information about trends in shifts away from misuse of prescription opioids; however, it appears the misuse of other classes of drugs may be filling the void.\textsuperscript{82} Specifically, between 2009 and 2011, between 2009 and 2011, opioid related visits were stable, with no significant increases while other drug related visits rose.\textsuperscript{81}

The DAWN Survey report included important information about trends in shifts away from misuse of prescription opioids; however, it appears the misuse of other classes of drugs may be filling the void.\textsuperscript{82} Specifically, between 2009 and 2011,

\textsuperscript{76} \textsc{Substance Abuse and Mental Health Services Administration, Drug Abuse Warning Network, 2011: Selected Tables of National Estimates of Drug-Related Emergency Department Visits, Center for Behavioral Health Statistics and Quality (2013) (hereafter SAMSHA, DAWN Selected Tables Spreadsheet (2013)) (sheet labeled ED Visits by Drug, Column Z, Row 8).

\textsuperscript{77} Id. at Column Z, Row 92.

\textsuperscript{78} Id. at Column Z, Row 195.

\textsuperscript{79} Id. at Column Z, Row 173.

\textsuperscript{80} Id. at Row 168. Rates of other drugs also increased; alternative medicine substances increased 269%, MDMA (ecstasy) increased 247%, and heroin increased 169%. Id. at Rows 287, 24, and 16 respectively.

\textsuperscript{81} Stimulants rose by 85% during that two-year time frame. Id. at Column AA, Row 198. Other reports confirm similar trends. See, e.g., \textsc{Substance Abuse and Mental Health Services Administration, DAWN Report: Emergency Department Visits Involving Attention Deficit/Hyperactivity Disorder Stimulant Medications (January 24, 2013), available at http://archive.samhsa.gov/data/2k13/DAWN073/sr073-ADD-ADHD-medications.htm} (Stimulant medications increased between 2005 and 2010 from 13,379 to 31,244 visits. The number of ED visits involving ADHD stimulant medications increased among both males and females: visits among females increased between 2005 and 2010 from 4,315 to 14,068 visits, and visits among males nearly doubled from 9,059 to 17,174).

\textsuperscript{82} \textsc{Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. The DAWN Report: Highlights of the 2011 DAWN Findings on Drug Related Emergency Department Visits (2013).}
the rates of misuse of anti-anxiety and insomnia medications, stimulants, marijuana, and other illicit drugs increased while the overall rate of visits involving prescriptions remained stable. Individuals may be abusing drugs at the same rate but shifting the drugs of abuse over time. As such, focusing on opioids alone rather than SUDs overall is a red herring. There are pressing needs for improved treatment efforts for individuals with SUD, education of patients about the proper use of and secure storage and disposal of medication, and the dangers of polysubstance use (mixing drugs and alcohol or mixing opioids and benzodiazepines).

2. Opioid Related Overdose Deaths

“The reasons for the deaths are multifactorial, encompassing provider behaviors, patient contributory factors, non-medical use patterns, and systemic failures.” There particular difficulties with the statistics on ORO deaths; for example, there are (1) no standardized definitions for post mortem toxicology, (2) no standard qualifications or training for individuals who complete death certificates, (3) overlapping and confusing ICD-10 categories for death, and (4) no standard definition for “opioid related death.” In addition, the spotlight on ORO deaths is somewhat disproportionate to other also very serious causes of death related to ingested substances. For example, in 2010, all opioid-related deaths numbered 16,651 (only about 5,000 are attributable to opioids alone), while suicide killed 38,364 people. Non-steroidal anti-inflammatory drugs (such as Motrin or

83 Id.
85 Id. See also, Robert K. Twillman, What’s Really Driving Opioid Related Death Rates? Supra at note 67.
86 See Foreman, supra note 2 at 128-131; CDC, FATAL INJURIES REPORTS, 1999-2011, available at
Naproxen) are estimated to kill up to 10,000 people a year (double the number that opioids alone kill), and approximately 88,000 deaths each year are attributable to excessive alcohol intake. Why is the focus on the harms of opioids alone? Judy Foreman sums it up by saying “our collective thinking is out of whack.”

a. \textit{High Risk Polysubstance Use and Relative Opioid Risk}

Oversimplification and broad-brush treatment has infected discourse in this area. The labeling of overdoses as “opioid overdoses” is one example. Opioids are rarely the only drug in system of individuals with OROs; in at least two-thirds of the cases, alcohol, benzodiazepines, or illicit drugs are also present. This makes cause attribution difficult to impossible. Nonetheless, the default label is ORO; labeling them “polysubstance related overdoses” seems more accurate and “benzodiazepine-related overdoses” is just as appropriate. The opioid-related label stuck and

\begin{itemize}
  \item \textit{http://www.cdc.gov/injury/wisqars/fatal_injury_reports.html} (screenshot of inquiry on file with author).
  \item See Foreman, \textit{supra} note 2 at 128-131.
  \item \textit{Id. See also CDC, ALCOHOL DEATHS, available at http://www.cdc.gov/features/alcohol-deaths/index.html.}
  \item See Foreman, \textit{supra} note 2 at 130.
  \item \textit{Id. at 129} (Of the 16,651 opioid-related deaths in 2010, nearly 12,000 included multiple mixed substances such as alcohol and benzodiazepines). \textit{See also SAMSHA, DAWN 2011: NATIONAL ESTIMATED OF ED VISITS, 13-4760} (2013), \textit{supra} at note 72.
  \item Olaf H. Drummer, \textit{Recent Trends in Narcotic Deaths}, \textit{27 THER DRUG MONITOR 6} (December 2005) (“The most difficult aspect of dealing with opioids is that without exception there is no relationship between blood and tissue concentration of drug and outcome. This means that before any interpretation can be made of the possible significance of any result, due regard is needed on the circumstances of the case. This includes ...the involvement of CNS depressants capable of exacerbating any opioid effects. Moreover, most cases of death from opioid use involve other drugs. Indeed, in many of these cases amphetamines or cocaine may be present, alcohol in high concentrations (0.15 g/100 mL), and other CNS depressants. Consequently, determining whether a death was caused by an opioid can be quite difficult because other possible causes must be excluded. This applies particularly to other drugs detected in the case. Statistics associated with opioid deaths should therefore be viewed with this in mind: some deaths may be misclassified because of an inaccurate assessment of the role of opioids, assuming of course that toxicology testing was conducted in the first place in all relevant cases”).
\end{itemize}
probably contributes to lingering one-dimensional concerns—as well as harms from
ignoring the specific dangers of mixing prescription drugs and alcohol—through
availability cascades.\textsuperscript{92} Even though the dangers of polysubstance use were clear for
over a decade, policymakers did not address the specific risks that mixing
benzodiazepines with opioids or alcohol presents until 2014.\textsuperscript{93}

Some opioids are disproportionately risky, such as Methadone.\textsuperscript{94} Methadone
accounts for less than five percent of all opioid prescriptions, but is involved in one
third of opioid related accidental deaths,\textsuperscript{95} as well as thirty percent of non-fatal
overdoses.\textsuperscript{96} The disproportionate danger relates, in part, to specific cardiovascular
risks and physician knowledge deficits.\textsuperscript{97} Worse yet, between 1999 and 2006,
Methadone related ED visits rose sevenfold.\textsuperscript{98} The rise in ED visits may relate to
Methadone’s increased use as a less addictive opioid alternative, or as part of an
opioid dependence plan (or medication assisted treatment or MAT),\textsuperscript{99} or subject to
payer policies that mandate Methadone because of its relative inexpensiveness.\textsuperscript{100}

\textsuperscript{92} See Section IV \textit{infra}.
\textsuperscript{93} Even the recent attention has been exceedingly modest in comparison. \textit{Substance Abuse and Mental Health Services Administration, The DAWN Report, Benzodiazepines in Combination with Opioid Pain Relievers or Alcohol: Greater Risk of More Serious ED Visit Outcomes (December 18, 2014)}; Uzor C. Ogba, \textit{Polysubstance Abuse: Alcohol, Opioids and Benzodiazepines Require Coordinated Engagement by Society, Patients, and Physicians}, 16 \textit{West J Emerg Med.} 1 (Jan 2015).
\textsuperscript{94} The rate of injury and death compared to the rate of prescriptions is disproportionate. \textit{Substance Abuse and Mental Health Services Administration, Data Summary: Methadone Mortality Reassessment (2010),} available at \url{http://www.dpt.samhsa.gov/pdf/Methadone_Mortality_Data_2010.pdf}. See also, Nicholas B. King et al., \textit{supra} at note 46.
\textsuperscript{95} See Lynn R. Webster et al., \textit{supra} at note 84. See also, \textit{U.S. Gov’t Accountability Office, Methadone-Associated Overdose Deaths: Factors Contributing to Increased Deaths and Efforts to Prevent Them}, GAO-09-341(March 2009).
\textsuperscript{96} Id.
\textsuperscript{97} Id.
\textsuperscript{98} Margaret Warner et al., \textit{Increase in Fatal Poisonings Involving Opioid Analgesics in the United States, 1999—2006}, supra note 24.
\textsuperscript{100} Id.
Combined with the danger of benzodiazepines and alcohol, these dangers deserve customized monitoring and interventions aimed at reducing overall harm, rather than painting all opioids with a broad-brush.

b. Suicide

The broad-brush treatment pervades statistics as well. Inexplicably, the CDC groups suicides and homicides together with unintentional opioid overdoses. This underlies the CDC’s claim that opioid related overdoses are the leading cause of injury related death. Unintentional poisonings are actually the third leading cause of injury mortality behind (1) suicide and (2) motor vehicle accidents. Grouping accidental and intentional overdoses obscures the root cause of the harm and obstructs synchronized harm reduction solutions.

Suicide is a growing public health problem in its own right and is now the leading cause of injury death in the U.S. In 2010, one million people attempted suicide. Suicide morbidity and mortality outnumbers opioid related morbidity and mortality each year. The rate of drug-related suicide attempts rose forty-one

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101 See, CDC, Vital Signs, 60 MMWR 43, supra note 24; Margaret Warner et al., supra note 24 at 6. (“poisoning deaths include...unintentional or intentional overdoses of a drug”).
103 Id. (emphasis added). This is true of 2013 as well with suicides (41,149) exceeding motor vehicle accidents (33,612) and unintentional poisonings (35,663) again. See CDC, NATIONAL CENTER FOR HEALTH STATISTICS, 10 LEADING CAUSES OF DEATH 2013 (available through inquiry at http://webappa.cdc.gov/sasweb/ncipc/leadcaus10_us.html (print out on file with author); CDC, NATIONAL CENTER FOR INJURY AND PREVENTION CONTROL, 2013 UNITED STATES UNINTENTIONAL DRUG POISONING DEATHS AND RATES PER 100,000; CDC, NATIONAL CENTER FOR INJURY AND PREVENTION CONTROL, 2013 UNITED STATES OVERALL MOTOR VEHICLE DEATHS AND RATES PER 100,000, (available through inquiries at http://webappa.cdc.gov/sasweb/ncipc/mortrate10_us.html)(print outs on file with author).
104 SAMSHA, Results from 2012 NSDUH, Mental Health Findings (2013) supra note 27.
105 The highest yearly estimates for opioid related visits and death is just under 600,000 for 2011. SAMSHA, DAWN Selected Tables Spreadsheet (2013) Supra note 76. (Highest Cl estimate for 2011 for all opioids was 590,001). In 2012, 483,596 people visited the ED for non-fatal self-harm and when combined with deaths caused by suicide, the annual number is estimated at more than 650,000.
percent between 2004 and 2011,\textsuperscript{106} and fifty-one percent between 2007 and 2011.\textsuperscript{107} In fact, since 2005, the number and population adjusted rates of suicide have steadily increased from 10.9 per 100,000 persons in 2005 to 12.57 in 2013.\textsuperscript{108} These premature intentional deaths need attention; attention is lacking in this and other drivers of morbidity and mortality in the vulnerable populations surrounding opioids, such as patients with CP, MI, or SUD.

Addressing underlying causes of morbidity and mortality in context is critical; instead, the non-discriminant focus is on opioid prescriptions of any type, the prescribers, and the patients to whom they are prescribed. They have become the folk devils in another moral panic in the “war on drugs.”\textsuperscript{109} When devising strategies of care and prevention of harm, decision-makers must understand the problem as complex, dynamic, and deserving of contextual solutions that go far beyond single dimensional efforts to reduce the supply of opioids alone.

\begin{itemize}
\item SAMSMA, DAWN 2011: National Estimated of ED Visits, 13-4760 (2013), supra note 72 at Section 6 and Table 25.
\item Id. at 5. See also Substance Abuse and Mental Health Services Administration, Emergency Department Visits for Drug-Related Suicide Attempts Have Increased (August 7, 2014)(within that group, more than twice as many people used benzodiazepines than opioids when attempting suicide).
\item Centers for Disease Control and Prevention, Fatal Injury Reports, National and Regional, 1999 – 2013 (available through inquiries at http://webapp.cdc.gov/sasweb/ncipc/mortrate10_us.html)(print outs for each year on file with author).
\item Folk devils is the term sociologists use to refer to the person or item that becomes the stand in representation of the cause of the evil or problem in a moral panic. See Erich Goode & Nachman Ben-Yehuda, Moral Panics: The Social Construction of Deviance, (2nd ed., Wiley-Blackwell 2009). For an excellent discussion of moral panics related to particular drug types, see Nicholas Rasmussen, Goofball Panic: Barbiturates, Dangerous and Addictive Drugs, and the Regulation of Medicine in Postwar America, in Prescribed: Writing, Filling, Using, and Abusing the Prescription in Modern America, (Eds. Jeremy A Green & Elizabeth Siegel Watkins, Johns Hopkins U. Press 2012) (describing a moral panic as a disproportionate but "vigorous, morally charged social reaction involving issues, some of them unconscious, that are much broader than any explicit threat.").
\end{itemize}
III. Pain—One of Multiple Interactive, Dynamic, Complex Public Health Problems

Pain and suffering—they go together like love and longing. Not the same thing, and not cause and effect, but so tightly woven that it’s hard to imagine one without the other.¹¹⁰

The inappropriate treatment of pain is “long standing public health problem—some would say a public health crisis.”¹¹¹ A “leading cause of disability and major contributor to health care costs,”¹¹² pain alone affects at least 100 million U.S. adults.¹¹³ “Annual U.S. expenditures are higher than those for cancer, heart disease, and diabetes combined.”¹¹⁴ The total financial cost of pain to society ranges from $560 to $635 billion,¹¹⁵ far more than the $193 billion annual cost of all illicit drugs.¹¹⁶

The inappropriate treatment of pain is rooted in a web of entangled and relational barriers originating from systems, providers, and patients.¹¹⁷ Systems

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¹¹⁰ SCOTT FISHMAN (WITH LISA BERGER), THE WAR ON PAIN, 15 (HARPER COLLINS 2001).
¹¹¹ Arthur G. Lipman, Opioid Overdose Deaths: Reactions and Overreactions, 26 J. PAIN AND PALLIATIVE CARE PHARMACOTHERAPY, 3-4 (2012) (asserting that opioids remain the most broadly effective medication for treatment).
¹¹³ The rates of patients in chronic pain are rising steadily for reasons related to 1) the aging population, 2) increased rates of obesity, 3) progress in treating illness and injuries for patients that would have died from them in the past, 4) the rise in outpatient surgeries with poorly controlled post-operative pain that progresses to chronic pain and 5) increased access to health care for patients in pain. Id. at 62-63. Living in pain significantly reduces quality of life and function, as does living with SUD or SMI. IOM, RELIEVING PAIN IN AMERICA (2011), supra note 6. See also Philip A. Pizzo & Noreen M. Clark, Alleviating Suffering 101-Pain Relief in the United States, 366 NEW ENGLAND J. MED. 3, 197-199, 197 (2012).
¹¹⁴ Pizzo & Clark, supra note 113 at 197 (emphasis added) (including direct medical costs and lost wages).
¹¹⁵ This excludes children, prisoners, individuals in the military, or those in long term care. IOM, RELIEVING PAIN IN AMERICA, supra note 6 at 302-3 (evaluating costs based on two components: “(1) the incremental costs of medical care due to pain, and (2) the indirect costs of pain due to lower economic productivity associated with lost wages, disability days, and fewer hours worked.” Estimates are in 2010 U.S. dollars.). See also, Pizzo & Clark, supra note 113.
¹¹⁷ For an overview of the barriers to effective treatment, See, e.g., Sigrid Frey-Revere & Elizabeth K. Do, A Chronic Problem: Pain Management of Non-Cancer Pain in America, 16 J. HEALTH CARE L. & POL’Y
level barriers include formal legal and regulatory proscription, as well as organizational policies and recommendations; at their core, individuals with varying levels of power, bias, and priorities influence them. Disparities in pain treatment also reflect ingrained biases based on gender, race, socioeconomic status, and other perceived differences.

Recent public health concerns surrounding opioid related overdoses only magnify the complexity. Makota and colleagues found that provider “fears surrounding opioids intersect powerfully with existing biases,” and resulted in disparate prescribing practices. They also illuminate the inadequacy of a binary public health model of balance in which adequate treatment of pain is on one side and prevention of opioid misuse is on the other. The Pain & Policy Studies Group at 193 (2013). Patient level barriers may include fear of taking medication, difficulties in accessing health care, and other barriers. A discussion of these issues is outside the scope of this paper. For basic information on those issues, see IOM, RELIEVING PAIN IN AMERICA, supra note 6 at 44-49 and 156-157.

118 One common barrier is provider fear of regulatory scrutiny for prescribing, often called the chilling effect. See, e.g., David B. Brushwood, Drug Enforcement Administration Liability for False Arrest of Physicians, 23 J. PAIN & PALLIATIVE CARE PHARMACOTHERAPY 2 (2009).

119 See, e.g., Anne Werner & Kirsti Malterud, It is hard work behaving as a credible patient: encounters between women with chronic pain and their doctors, 57 SOCIAL SCIENCE & MED. 1409-1419 (2003).


123 Megan Crowley-Matoka & Gala True, No One Wants to Be the Candy Man, 27 CULTURAL ANTHROPOLOGY 4 689-712 (2012).

124 Id. (reporting reasons ranged from “the blatant (as more likely to be drug addicted . . .) to more subtle (as simply less easily understood, and thus less easily trusted”).
the University of Wisconsin frames the issue this way: “There are important ongoing efforts in the U.S. to address simultaneously two major public health crises—(1) the medical undertreatment of pain and (2) the non-medical use of controlled substances—both of which involve the opioid analgesic class of medications.”

This is true but incomplete. Putting patients in pain in one box and those who might misuse opioids in another neither reflects reality nor provides the nuanced approach this complex problem requires.

Patients who request or take opioids are not either “legitimately in pain” or “drug addicts.” The picture is far more complicated. Those who misuse opioids are just as deserving of care and treatment as those who are on prescribed opioids that are functionally helpful. Patients who request opioids may do so for a variety of reasons, none of which are mutually exclusive; most do so because they are in pain. Others may request opioids to feed an underlying SUD; those in CP may fear being without pain medication for future exacerbations and therefore hoard medication while those with MI may use opioids to self-medicate. Any patient may hoard medication as part of a suicide plan. A small percentage of criminals may deceive physicians into prescribing opioids for the purposes of diversion (as opposed to

126 See Sandra H. Johnson, Test-Driving “Patient-Centered Health Law,” supra note 31 at 1480 (“One should certainly include addicted individuals, whether currently receiving medical care or not, as part of our population of patients about whom patient centered health law must be concerned....[it] would seem to demand that attention be paid to all patients and all suffering, not just select categories.”)
127 Here, I use the term criminal only to mean those who are knowingly and intentionally involved in drug diversion for profit.
reasons related underlying disorders). Sometimes opioids are appropriate and other times they are not, for a multitude of reasons; context is fundamental to this assessment. Providers are obligated to carefully evaluate and treat each patient. Any of those patients may have one or more conditions that require additional attention and care, such as CP, MI, suicidality, or SUD.

Often ignored in scholarship and policy is that patients with CP, SUD, or MI are all equally deserving of respect and treatment; they are also not diagnoses of mutual exclusion. They have much more in common than current policy recommendations reveal; they are all highly stigmatized, seriously undertreated, and underfunded. Providers regard individuals with these conditions challenging and those individuals express difficulty with access, discounting, and disbelief by providers. Each diagnosis has high rates of comorbidities, such as suicidality, that garner little attention in the literature. Thousands of pages are devoted to the harms associated with opioids and the screening patients for illicit drug use or not using the prescribed opioids. Almost no literatures draw attention to the very real and more widespread concerns about screening and treatment for SUD (as opposed to diversion), MI, and suicidality to prevent the serious associated harms, including premature deaths.

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129 Id. See also infra Sections III.A.-C.
130 SAMHSA carefully tracks the incidence, treatment rates, and comorbidities of SUD, AMI, SMI, and suicidality; however, they do not track CP. Although there are existing data on comorbidity, the full extent of the overlap between CP and the other conditions is still ripe for study.
131 See SAMHSA, Results from 2012 NSDUH, Mental Health Findings (2013), supra note 27. See generally, Sigrid Frey-Revere & Elizabeth K. Do, supra note 117.
133 See SAMHSA, Results from 2012 NSDUH, Mental Health Findings (2013), supra note 27; SAMHSA, Results from 2012 NSDUH, Summary Findings, 13-4795 (2013), supra note 68.
A. Suicidality

A mostly overlooked consequence of undertreated pain is the very real risk of suicide. The rate of comorbid suicidality in patients with CP ranges from 17% to 66% of the population; even at the lowest estimates of 17%, it far exceeds the approximate 4% rate in the general population. In fact, pain and disability perception (belief that one is disabled) are two important risk factors for suicide; in patients with CP, disability perception coupled with a preference for death over disability is a significant predictor of suicidality. Kanzler and colleagues found perceived burdensomeness was a strong predictor of suicidality in patients with CP, even suggesting the possible usefulness of a single-question screening tool for suicidal ideation.

Individuals with certain types of CP syndromes may be at higher risk. After controlling for comorbid psychiatric disorders, Ilgen and colleagues found a significant association between suicide death and three particular kinds of pain: (1) back pain; (2) migraine; and (3) psychogenic pain. Many other studies have

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134 See Kathryn E. Kanzler et al., Suicidal Ideation and Perceived Burdensomeness in Patients with Chronic Pain, 12 PAIN PRACTICE 8, 602-609 (2012); Mark A. Ilgen et al., Noncancer Pain Conditions and Risk of Suicide, 70 JAMA PSYCHIATRY 7, 692-697 (2013).
135 Kanzler et al., supra note 134 at 603 (citing to previous work by Fishbain and colleagues).
137 See David A. Fishbain et al., Exploration of the Relationship Between Disability Perception, Preference for Death over Disability, and Suicidality in Patients with Acute and Chronic Pain, 13 PAIN MED. 552-561 (2012).
138 Id. at 559.
139 Kanzler et al. supra note 134.
140 For example, persons with chronic severe headaches or painful gastrointestinal conditions have higher rates of suicidality. See Elizabeth D. Ballard et al., Recent Medical Service Utilization and Health Conditions Associated with a History of Suicide Attempts, 36 GENERAL HOSPITAL PSYCHIATRY 437-441 (2014).
141 Ilgen et al. supra note 134. See also IOM, RELIEVING PAIN IN AMERICA, supra note 6 at 88. (citing to research finding patients with chronic headache pain are 6.5 times more likely than those without
“demonstrated a link between CP and suicidal ideation, planning and attempts.”\textsuperscript{142}

Patients who have two or more painful conditions are also much more likely to attempt suicide.\textsuperscript{143} First person accounts by patients with CP are infused with references to suicidality and the fact that for some patients, opioids are the only treatment that has prevented their suicide.\textsuperscript{144} Yet, there are currently no suicide prevention efforts that focus on pain as an independent risk factor.\textsuperscript{145}

Approximately 90\% of individuals who attempt or die by suicide have one or more MIs, although only about half of them were formally diagnosed before the attempt or death.\textsuperscript{146} Although many suicidal individuals did not receive mental health care in the year before death, a vast majority of them saw primary care and non-psychiatric specialty providers;\textsuperscript{147} the same specialties likely to see patients with CP. MI is prevalent in patients with CP as well, with rates ranging from 30-60\%.\textsuperscript{148} Therefore, primary care and specialty providers are well suited, and

\textsuperscript{142} IOM, RELIEVING PAIN IN AMERICA, supra note 6 at 692 (citing to eight previous studies).
\textsuperscript{143} Id. at 89 ("people having two or more types of chronic pain were almost three times more likely to report a suicide attempt than those without pain").
\textsuperscript{144} See, e.g., Craig L. Winberg, Comment on Food & Drug Administration, Physicians for Responsible Opioid Prescribing—Citizen’s Petition (August 30, 2012), available at http://www.regulations.gov/#/documentDetail;D=FDA-2012-P-0818-0258 (“Had it not been for morphine products I would have put a shotgun in my mouth years ago”); Maria Rago, Comment on Food & Drug Administration, Physicians for Responsible Opioid Prescribing—Citizen’s Petition (Oct. 18, 2012), available at http://www.regulations.gov/#/documentDetail;D=FDA-2012-P-0818-0522 (“If the pain had continued the way it was, I did not plan to continue to live").
\textsuperscript{145} IOM, RELIEVING PAIN IN AMERICA, supra note 6 at 89.
\textsuperscript{146} The 90\% has been determined by psychological autopsy studies in which researchers interview surviving family members and suicide survivors to determine the rate of mental illness. See Brian K. Ahmedani et al., Health Care Contacts in the Year Before Suicide Death, 29 J. GEN. INTERNAL MED. 6, 870-877 (Feb 2014).
\textsuperscript{147} Id. (83\% of people who died by suicide had health care provider interaction in the previous year). See also, AMERICAN FOUNDATION FOR SUICIDE PREVENTION, KEY RESEARCH FINDINGS, available at https://www.afsp.org/understanding-suicide/key-research-findings.
\textsuperscript{148} See, e.g., FOREMAN, supra note 2 at 101.
arguably obligated, to assess patients for mental illness and suicidality and attempt to reduce the associated harms.

Patients with chronic pain are more likely to be suicidal than addicted and yet screening recommendations focus exclusively on detecting SUDs through complex risk stratifications and urine drug screenings.\(^\text{149}\) The harms associated with suicidality are more serious than those associated with SUD; nonetheless, beyond a handful of articles, there are no practice recommendations or calls for universal suicide screenings of patients in pain.\(^\text{150}\) Further study of the relationship between pain and suicidality as well as effective screening tools should be part of coherent practice and policy recommendations.

**B. Mental Illness**

Another area of concern in practice and policy is the failure to prioritize and address comorbid MI. Estimates of the extent of comorbid MI vary widely by population and treatment setting surveyed, although they exceed the rate of MI in the general population across the board.\(^\text{151}\) For example, the mean prevalence of comorbid depression is estimated between 50 and 60% among patients treated in pain clinics and orthopedic and rheumatology clinics but only around 30% of patients in primary care clinics.\(^\text{152}\) The rates of anxiety disorders are also

\(^{149}\) See infra Section V.

\(^{150}\) See generally, IOM, RELIEVING PAIN IN AMERICA, supra note 6 at 89.

\(^{151}\) See, e.g., Martin D. Cheatle, Depression, Chronic Pain, and Suicide by Overdose: On the Edge, 12 PAIN MED. S43-48 (2011).

\(^{152}\) Id. at S44 (summarizing a variety of studies). See also Catherine Q. Howe & Mark D. Sullivan, The Missing “P” in Pain Management: How Current Opioid Epidemic Highlights the Need for Psychiatric Services in Chronic Pain, 36 GEN. HOSPITAL PSYCHIATRY 99-104 (2014).
substantially higher in patients with CP than in the general population.\textsuperscript{153} Addressing comorbid MI is delicate for providers, in part because patients often equate these concerns with being told their pain is imaginary.\textsuperscript{154} Years of theory, linking medically unexplained symptoms to somatization (emotional problems expressed through bodily ailments), worsen these concerns.\textsuperscript{155} Cross training that prepares providers to care for patients with multiple complex problems is rare.\textsuperscript{156} These comorbidities are often difficult to assess and diagnose both because of provider lack of training and the overlapping of symptoms of pain and depression.\textsuperscript{157} It takes a skillful clinician and a thoughtful patient to sort out the problems,\textsuperscript{158} all the while operating in an environment that rewards procedures over process and therapy. Howe & Sullivan have advocated that every patient presenting in CP should receive a comprehensive assessment of psychological health and appropriate referrals when needed.\textsuperscript{159}

\textsuperscript{153} Howe & Sullivan, \textit{supra} note 152.
\textsuperscript{154} This was consistent with my personal experience working as a nurse in a chronic pain practice. \textit{See also}, Scott Fishman, \textbf{The War on Pain}, \textit{supra} note 110 at 160-167; Martin D. Cheatle, \textit{supra} note 151 at S44 (“Patients tend to resist seeking psychiatric or psychological care for fear that their pain symptoms will be minimized or considered reflective of an underlying mental disorder”).
\textsuperscript{156} \textit{See, e.g.}, Igor Elman et al., \textbf{The Missing “P” in Psychiatric Training: Why is it Important to Teach Pain to Psychiatrists?}, \textit{68 ARCHIVES GEN. PSYCHIATRY} 1, 12-20 (2011).
\textsuperscript{157} \textit{See, e.g.}, Scott Fishman, \textbf{The War on Pain}, \textit{supra} note 110 at 66-67 (explaining that someone in terrible pain all the time may find it hard to separate that from the symptoms of depression). \textit{See also} Ajay D. Wasan et al., \textbf{Psychiatric Illness, Depression, Anxiety, and Somatoform Pain Disorders}, in Scott M. Fishman, Jane C. Ballantyne, & James Rathamell, \textbf{Bioca’s Management of Pain} (Lippicott, Williams, and Winkins 2006).
\textsuperscript{158} Scott Fishman, \textbf{The War on Pain}, \textit{supra} note 110 at 257-258 (“describing how he requires a full psychological evaluation for every patient because living in chronic pain “must be having negative effects on the patient’s life” and advocating for comprehensive care of patients in pain”).
\textsuperscript{159} Howe & Sullivan, \textit{supra} note 152 (including screenings for anxiety, depression, and SUD with appropriate referrals to improve care).
Lack of access to or payment for mental health care and integrated multidisciplinary care is a significant obstacle to care. The communication and knowledge barriers to comprehensive assessment compound the problems, leaving many patients with undiagnosed or untreated comorbid MI and possibly suicidality; this only worsens morbidity and mortality. Harm reduction strategies in the future should include screening patients for depression and other conditions and appropriate referrals if needed.160

C. Substance Use Disorders

Patients with substance use disorders can and should be treated with dignity, respect, and the same quality of pain assessment and management as all other patients.161

Acknowledging that patients with CP may also have SUD, or even engaging in a dialogue about potential for abuse, is even more delicate than addressing mental illness. In addition to stigmatization, the behavior associated with the disease is more likely to lead to criminalization than treatment.162 Moreover, patients in pain tell a near universal story of at some point of having their reported level of pain or motivations questioned by providers, with providers suspecting them of “drug seeking,” or criminal activity associated with drug diversion.163

160 One of the few researchers to call attention to the very real risks of depression, suicidality and death is Martin Cheatle. His article in PAIN MEDICINE in 2011 provides a thoughtful overview of possible screening instruments and referral strategies. Martin D. Cheatle, supra note 151.


162 The vast problems and failures of US drug policy are far outside the scope of this article. Instead I confine my comments to the ways in which it adversely impacts patients in pain. For an excellent discussion of the recent history of drug policy, see Peter Reuter, Why Has US Drug Policy Changed So Little over 30 Years? 42 CRIME & JUSTICE 1, 75-140 (2013).

163 See, e.g., Joseph O. Merrill et al., Mutual Mistrust in the Medical Care of Drug Users, 17 J GEN. INTERNAL MED. 327-333 (2002) (“Maybe they thought I was coming in to get high. I didn’t care what they gave. Just a local would have been fine. It’s painful to cut into someone’s arm. I thought they
opioids as one tool in the toolbox of pain treatment occupies a unique position in medicine. Physicians often prescribe other drugs with the potential for abuse and often care for patients engaged in illegal activity; however, no other area has succeeded in impinging on the providers' obligation to the patient before them with an obligation to investigate crime. Until law and policy allows providers to embrace the complexity of pain coupled with an obligation to provide care and treatment or referral to patients with SUD, these interactions won’t improve. This will require a reexamination of the kinds of prescribing that warrants scrutiny and the expectations of providers and policy makers.

Drug policy in the U.S. has been predominately one of shock and awe, focused nearly exclusively on what Reuter and McCoun call “use reduction.” Drug use is easier to measure, and measuring the use of one kind of drug is even easier (such as opioids alone), but it doesn’t get to the substance of the problems. It is also grounded in moralistic, criminal justice approaches rather than a public health approach of harm reduction. According to Mark Kleiman,
It turns out to be substantially easier to announce that one is opposed to drug taking than to craft public policies to reduce the damage it does...a policy of announced hostility toward drug taking and drug takers will tend to make the remaining drug takers worse off, and more dangerous to others, than they would have been otherwise. Moreover, it leads citizens and their representatives to shy away from the part of drug control policy that involves providing services to drug takers to help them quit, moderate their behavior, or better integrate themselves into the broader society.168

The rejection of a harm reduction model has trickled down into poor access to care and a lack of providers for SUD.169 Indeed the common construction of patients with “real” pain as legitimate expressly excludes the possibility of comorbid SUD, leaving individuals with addiction portrayed as out-group members, illegitimate, and undeserving.170 Changing the approach to addressing SUD, especially discussing it with patients in pain, will require policy makers and providers to address their own underlying biases and to embrace the goal of harm reduction for their patients.171

Current research suggests the rates of comorbid CP and SUD are variable.

Within this discussion, there are two distinct ways of viewing the degree of

http://www.fda.gov/downloads/Drugs/NewsEvents/UCM304621.pdf. (“Another thing that we can actually all agree on now is how well proven, from a public health and scientific point of view, and from an epidemiological point of view, harm reduction has been. We don’t really have to talk about harm reduction or treatment. Harm reduction has always incorporated a real desire to get people into treatment, helped to get people treatment when they’re ready for it, when they want it, when it’s the right thing for them. There’s no conflict here. And harm reduction has worked”).

168 MARK KLEIMAN, supra note 29.

169 For an excellent overview of some of the barriers to treatment, see Ellen M. Weber, Failure of Physicians to Prescribe Pharmacotherapies for Addiction: Regulatory Restrictions and Physician Resistance, 13 J. HEALTH CARE L. & POLICY 49 (2010); see also Roger A. Rosenblatt et al., Geographic and Specialty Distribution of US Physicians Trained to Treat Opioid Use Disorder, 13 ANNALS OF FAM. MED. 1, 23-26 (2015) (noting a drastic lack of physicians trained to treat SUD related to opioid abuse).


171 Harm reduction is the theoretical framework for drug policy in much of the industrialized world, excluding the U.S. and advances that policy strategies should be tailored to address the greatest harms, rather than aimed at overall use reduction. See Peter Reuter & Robert J MacCoun, supra note 166; Peter Reuter, Why Has US Drug Policy Changed so Little over 30 Years? 42 CRIME & JUSTICE 1 (2013).
crossover: (1) those with a primary diagnosis of SUD who also report significant pain, and (2) those with a primary diagnosis of pain who develop an opioid use disorder during treatment. The numbers for the first are well above the general population. The number of people with CP who develop a SUD without a history are at or below the level of the general population. Providers tend to overestimate the rate of the second group, leading to avoidance of opioids in otherwise appropriate cases and undertreated pain in many patients (with or without SUD). Even among patient with a history of substance abuse, physicians are reluctant to address the risks in the context of pain treatment, also leading to undertreatment. Work by Merrill and colleagues indicate providers have great difficulty navigating the comorbid treatment of pain and SUD and that patients may suffer as a result. They found several common themes including providers' fears of being deceived, non-standardized approaches to pain assessment in patients with SUD, and avoidance of patients; patients expressed fears of mistreatment or

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172 See, e.g., Kelly E. Dunn et al., Severity and Interference of Chronic Pain in Methadone-Maintained Outpatients, 15 PAIN MED. 9, 1540-1548 (2014) (reporting 60% of patients in a methadone maintenance program reported untreated or undertreated chronic pain); Substance Abuse and Mental Health Service Administration, Managing Chronic Pain in People with or in Recovery from Substance Use Disorders: Updated Findings from the Literature, TREATMENT IMPROVEMENT PROTOCOL 54 (2014)(citing work by Barry et al. finding that 36% of patients entering SUD treatment reported also having CP).

173 See, e.g., Silvia Minozzi et al., Development of dependence following treatment with opioid analgesics for pain relief: a systematic review, 108 ADDICTION (2012) (reporting no significant risk of developing SUD from treatment with opioids for chronic pain).


175 Robert N. Jamison et al., Substance Misuse Treatment for high risk Chronic Pain Patients on Opioid Therapy: A Randomized Trial, 150 PAIN 390-400 (2010) (testing a counseling intervention added to opioid therapy for patients with a history of SUD and explaining “There is a greater potential for inadequate treatment of pain for patients with a history of substance misuse due, in part, to a reluctance of some physicians to address the risks of substance misuse in the context of prescribing opioids.”).
punishment by providers for their SUD.\textsuperscript{176} An integrated care approach for patients with pain and co-morbid conditions, such as the one explained by Jacobson and Hatchett, is needed to emphasize holistic, contextual assessment and ongoing care.\textsuperscript{177} An integrated approach would do far more to reduce morbidity and mortality of these complex chronic conditions than narrow, opioid focused supply side efforts.

D. Providers’ Obligations to the Patient & Self-regulation through Virtue

Physicians require the virtue of humility (understood as self-knowledge and an openness to the perspective of others rather than as meekness) to support use of the habits, or “compensatory strategies,” that will enable physicians to prioritize the goals of medicine over their own self-interest.\textsuperscript{178}

There is certainly evidence that many providers are able to work through the complexities and competing concerns involved in treating pain, including prescribing opioids.\textsuperscript{179} Patients want to be heard and judged trustworthy more than any particular therapy or treatment. They repeatedly express their desire to be listened to and legitimized.\textsuperscript{180} Bergman and colleagues recently identified frustration among CP patients who felt providers were disengaged, finding many

\textsuperscript{176} Merrill et al., supra note 174.
\textsuperscript{177} Teresa Jacobson & Gregory Hatchett, Counseling Chemically Dependent Chronic Pain Patients in an Integrated Care Setting, 35 J. ADDICTIONS & OFFENDER COUNSELING 57-61 (2014).
\textsuperscript{180} See, e.g., LOUS HESUSUS, INSIDE CHRONIC PAIN: AN INTIMATE AND CRITICAL ACCOUNT, 61 (2009) (describing a certain patient’s perspective of an interaction with his doctor: “He had nothing to offer, and I felt badly for him...I know you don’t have the answers either,’ I said. He quietly responded, ‘But I can listen.’ Immediately, I experienced a certain calmness. I felt relieved. Here was a doctor acknowledging that, indeed, he did not have the answer either. But he spoke the truth. He would listen. And he did.”). See also, Susan C. Slade et al., Listen to me, tell me: A Qualitative Study of Partnerships in Care for People with Non-Specific Chronic Low Back Pain, 23 CLINICAL REHABILITATION 270-280, 275 (2009).
patients “wanted more priority placed on discussing pain...expressed desire for their pain to be recognized as real, [and] were not seeking to discuss opioids; many were, in fact, avoiding opioids and looking for a sympathetic ear.”

Epstein and Gramling describe the process of “collaborative cognition" this way,

Engaging patients in constructing preferences in the face of complexity, inadequate evidence, and irreducible uncertainty involves more than the provision of information and an invitation to choice...[it] is relational, dynamic, iterative, provisional, and conditional—it involves building relationships, providing information, and exploring preferences, which then strengthen relationships, understanding, and involvement in decisions.

The importance of humility and doing the work of attending to the patient in context and considering possible factors that may unduly influence decisions is advanced by many experts under many names, ranging from mindfulness to self-monitoring to empathy to cognitive debiasing. These strategies are effective for appropriate care. The IOM also called upon providers to develop care that is patient-centered, comprehensive, and interdisciplinary.

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181 Alicia A. Bergman, Marianne S. Matthias et al., Contrast Tensions Between Participants and PCPs in Chronic Pain Management: A Qualitative Study, 14 PAIN MED. 1689-1697, 1694 (2013).
184 Halpern, From Detached Concern to Empathy, supra note 183 at xiv (“missing important emotional cues from patients wastes time, leading to missed diagnoses, inadequate treatment adherence, and inadequate understanding of patients' values in the face of tough medical decisions”). See also Hannah Bayne et al., A Comprehensive Model for Optimizing Empathy in Person Centered Care, 93 PATIENT EDUC. & COUNSELING, 209-215, 213 (2013). (physicians who worked to understand the patient's perspective in encounters are “more concerned with cognitive processes and accurate reflections . . . value flexibility in assessment and treatment . . . based on individual and situational factors . . . pay attention to subtle cues from patients, [and] recognize biopsychosocial factors that enable unique treatment plans for each patient.”)
185 IOM, RELIVING PAIN IN AMERICA, supra note 6 at 164 (“Pain assessment should focus on soliciting a careful history of the pain experience, the impact of pain on functioning and quality of life and emotional suffering, and the patient’s goals and values.”).
Individualized, contextual practices reflect providers’ adherence to certain dispositions that advance the ends of medicine, and enable providers to prioritize the wellbeing of the patient before them in the context of the patient’s particular vulnerabilities and needs.\textsuperscript{186} In order to achieve those ends, especially in this context, virtue is paramount. DuBois and colleagues explained virtue this way: “dispositions (or traits, in the language of psychology) define how we behave when no one else is watching; accordingly, they serve as a bedrock for professional self-regulation, particularly at the level of the individual physician.”\textsuperscript{187} In the specific context of pain medicine, James Giordano has argued for what he calls “an agent-based virtue ethics of pain medicine;”\textsuperscript{188} a necessity because of the unique and profound character of pain and the need for both equanimity and empathy in caring for the patient.\textsuperscript{189} Combining the work of Dubois and colleagues with Giordano’s creates a virtue-based ethic in the care of patients in pain that emphasizes humility (including self-knowledge, reflection, and intellectual honesty), compassion, empathy, and practical wisdom. Embracing a virtue-based ethic also allows providers and policy makers to more readily avoid common decision-making errors that adversely impact patients.

IV. Decision-making Errors by Providers & Policymakers

It is hard to understand why decision makers ranging from individual providers to policymaking bodies craft solutions that are inconsistent with the

\textsuperscript{186} For an elegant description of the need to focus on the patient before the disease, see Eric J. Cassell, The Nature of Clinical Medicine (2014).
\textsuperscript{187} James M. Dubois et al., supra note 178.
\textsuperscript{189} Id.
problems they are meant to address. In terms of policymaking, researchers have discovered that factors such as public opinion and salience (the degree to which the issue stands out against others) are significant influences. Other research indicates that policy makers, at best, only indirectly use public health research and evidence to inform policy recommendations; therefore, it is not surprising that policy solutions are not synchronized to problems. There is some evidence that a better understanding about how and why providers make decisions can improve their decisions in the future.

A. Social Cognitive & Moral Decision Making

A more refined appreciation of human tendencies—both their operation and their possible origin—may help us to better understand what educational and policy interventions may facilitate good conduct and ameliorate bad conduct.

Ultimately, both policy and provider level decisions surrounding opioids are in the realm of ethics and moral decision-making and strongly impact patients with pain or SUD. James Rest’s interdisciplinary model of moral decision making

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192 See, e.g., Pat Croskerry et al., supra note 183.
194 The decisions are within the control of the decision-maker and those decision will either show respect or fail to show respect for individuals, such as patients in pain or those with SUD. See James DuBois, A Framework for Analyzing Ethics Cases in Ethics in Mental Health Research (Oxford Univ. Press 2008).
195 Even those drug "use reduction" policies are ultimately unethical when then do not actually reduce the harm to individuals who have SUD by reducing supply to just one kind of drug of abuse and failing to increase treatment options. Criminalization of the disease of SUD fails to respect those with the condition.
includes four distinct but dynamic, non-linear components: (1) awareness or sensitivity (capacity to recognize that a situation has moral content); (2) judgment (evaluation and reasoning between options and attendant consequences); (3) intention or motivation (commitment to choose one of the options that is the most morally right, even in the presence of choices that offer more personal gain); and (4) action (enacting the choice). Failure in one will weaken or may prevent a person from making the ethically appropriate choice.

Moral decision-making is also influenced by the degree of proximity, social consensus, and the magnitude and extent of the consequences. Proximity influences moral awareness. Low levels of empathy for patients in pain may obscure moral awareness. This concept complements other research describing the persistent stigmatization, and discounting of patients in pain (as well as those with MI and SUD); as well as my previous work on providers’ moral

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197 Id. at 57.
198 Id.
199 Id.
200 These are collectively understood as components of moral intensity. Id. at 57-60 (citing to the work of Thomas Jones in Ethical decision making by individuals in organizations: An Issue-Contingent Model, ACADEMY OF MANAGEMENT REVIEW (1991)).
201 Id. at 66. (the “closer an individual feels to the individual(s) affected by his/her actions, the greater the likelihood that s/he will be aware of the moral issue.”)
202 The lack of empathy (or at least decreased empathy) of providers toward some patients in pain is fairly well established and combined with possible research on moral awareness, has implications for the treatment of pain. See, e.g., Luis Sebastian Conteras-Huerta et al., Racial Bias in Neural Empathic Response to Pain, 8 PLOS ONE 12 (December 2013) (reviewing previous research on empathic responses to pain and using fMRI research to demonstrate decreased empathic response to pain based on race, and to a lesser extent, social “out-group” members); See also Sophie Trawalter et al., Racial Bias in Perceptions of Others’ Pain, 7 PLOS ONE 11 (2012) (finding perceptions that people of lower status felt less pain).
203 See Section III supra.
disengagement of patients in pain, particularly when providers do so by sulllying the victim (or patient). 204

The strongest contributors to moral decision-making overall are social consensus, the magnitude of the consequences, and the probability of effect. 205 In particular, social consensus—expressed informally through group interactions and practices or formally through rules or laws—is a powerful mediator of moral awareness, judgment, and intention. Thus, in the context of decisions about patients in pain, the attitudes of other providers as well as organizational policies and regulation may heavily influence decisions. 206 In addition, the extent of and likelihood of the perceived consequences of a decision-maker’s actions may influence their willingness to act. 207 For example, if a provider fears regulatory scrutiny or even prosecution for prescribing opioids in an uncertain clinical encounter, the less likely she is to weigh a prescription as a viable option. Likewise, if she is (reasonably or unreasonably) concerned about addiction, the less likely it is that she will consider an opioid prescription. The degree of these beliefs, with or without supporting evidence, may contribute to incoherent decision-making.

Decision-making is part of social cognition; 208 a wealth of literature exists on theories of decision-making in general, 209 in health law & policy, 210 and in the

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205 Id.
206 See generally, Sandra H. Johnson, supra note 32.
207 See Lincoln & Holmes, supra note 196 at 58-67.
208 See Raymond C. Tait et al., Provider Judgments of Patients in Pain: Seeking Symptom Certainty, 10 PAIN MED. 11, 13 (2009).
209 A discussion of the various decision-making theories is outside the scope of this article. These theories are variously referred to as residing in the disciplines of behavioral economics, social psychology, and behavioral psychology, among others. For a discussion of the evolution from rational choice theory to bounded rationality to prospect theory, see e.g., Joshua D. Wright & Douglas H.
context of medical diagnosis. Unfortunately, very little research exists on decision-making errors in ongoing treatment decisions (as opposed to diagnosis), in the context of pain, or on the policy decisions surrounding controlled substances, including opioids, and patient care. This is critical because clinical encounters with patient in CP are highly complex, objective findings are often inconclusive, and options are ambiguous. Acknowledging the moral and clinical complexity of caring for patients in pain may allow providers to adjust their approach to decision-making and patient engagement.

B. Dual Process Models of Decision Making

Decision-making involves complex coordinated neurological computations and processes; we often change our decision-making strategies through experience. Dual process theories dominate discussions of decision-making as

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See Newman-Toker, *supra* note 211 (discussing the overlap between diagnostic and therapeutic decisions and advancing that although we think of the complex relationship as separate, “these two processes are usually intertwined”).

See, e.g., Croskerry et al. *supra* note 183 at ii58. No research directly on these errors and the undertreatment of pain exists although some examples used in existing research are related.

Epstein & Gramling, *supra* note 182 (using treating chronic pain as an example of a complex problem, as opposed to a simple or even complicated problem).

Id. at 97S.

well as theories surrounding the existence of moral intuitions and their relative value. In the context of medical decision-making, Croskerry and colleagues offer a thoughtful overview of psychological factors that influence cognitive performance in provider decision-making through a discussion of the Dual Process Theory (DPT) and the influence of cognitive biases and distortions on decisions.

Under DPT, decisions are made in either an intuitive (Type 1) or an analytical (Type 2) mode; “clinical expertise depends upon the ability to move back and forth between the two modes.” The default mode Type 1 and is unconscious, fast, and efficient; it is also “characterized by heuristics-short cuts, abbreviated ways of thinking, maxims, seen this many times before, ways of thinking.” The use of heuristics (rules of thumb) are strategies in Type 1 processing of attribute substitution, ignoring “part of the information, with the goal of making decisions more quickly, frugally, and/or accurately than more complex methods.”

Heuristics function efficiently by attribute substitution to fill in missing information

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217 The iconic work of Tversky & Kahneman was foundational in this area. See Amos Tversky & Daniel Kahneman, Judgment under Uncertainty: Heuristics and Biases 3 (Cambridge Univ. Press 1982). For an excellent discussion of two competing camps in the area of intuitive reasoning, the Heuristics and Biases theory and the Fast and Frugal theory, see Mark Kelman, Moral Realism and the Heuristics Debate, 5 J. Legal Analysis 2, 339-397 (Winter 2013).


219 See, e.g., Pat Croskerry et al., supra note 183 (describing biases as “predictable deviations from rationality”).

220 These are referred to as Types 1 and 2 or Systems 1 and 2. In either case, the first refers to intuitive, autonomic processing and the second to analytical, reflective processing.

221 Epstein & Gramling, supra note 182 at 99S.

222 Id. See also Valerie Thompson, Why it Matters: The Implications of Autonomous Processes for Dual Process Theories—Commentary on Evans & Stanovich, 8 Perspectives on Psychological Science 253-256 (2013) (describing the work of Evans and Stanovich’s, including framing intuitive or type I processing as autonomous but advancing that Type II processing should be framed as voluntary processing as a complement to autonomous processing).

223 Croskerry et al., supra note 183 at ii58. The “automatic pilot” experience is part of these intuitive processing mechanisms.

or to save the mental work of analyzing a large amount of information.\textsuperscript{225} Always efficient, they are not always effective; an understanding of the difference is crucial to appropriate decision-making.

The fuzzy-trace model expands upon the DPT by describing two distinct forms of Type I decision-making: “impressionistic thinking using vague gist representations” (impressionistic thinking) and “insightful intuition.”\textsuperscript{226} Insightful intuition would include knowledge assimilation, such as emergency treatment protocols that through learning and practice transition from Type 2 into Type 1. Type 1 may also be responsible for the “gut feeling” or sense that many clinicians describe that can contribute to good care.\textsuperscript{227} On the other hand, impressionistic thinking may include the culturally assimilated bias against patients who have a SUD. Thus, the use of Type 1 processing is neither inherently good nor bad. While Type 1 processing is indispensable in certain situations, such as lifesaving procedures, other situations call for more reflective reasoning.\textsuperscript{228}

Type 2 processing is the reflective, analytical mode involving metacognition (thinking about thinking); it is “fairly reliable, safe and effective, but slow and resource intensive.”\textsuperscript{229} Type 2 processing occurs whenever the actor is consciously thinking about what she is doing, such as following a checklist, weighing options, or questioning her own assumptions. Using the wrong rules of analysis contribute to

\textsuperscript{225} See Cass Sunstein, \textit{supra} note 218 at 1566.
\textsuperscript{227} See, e.g., Erik Stapler et al., \textit{Gut Feelings as a Third Track in the General Practitioners Diagnostic Reasoning}, 26 J. GEN. INTERN MED. 2, 197-203 (2010) (describing the role of affect as a heuristic and the value of the alert function).
\textsuperscript{228} Pat Croskerry et al., \textit{supra} note 183 at ii61.
\textsuperscript{229} \textit{Id.} at ii58.
decision making errors in Type 2 processing as do factors that contribute to
cognitive overload. 230 Errors related to bias are more common in Type 1 mode;
Type 2 processing is required for correction. 231

C. Biases & Heuristic Failure in Decision-Making Errors

There are clinical situations that compound the risk for biased reasoning or
failed heuristics, what Wilson and Brekke call "mental contamination." 232 Some of
these situations are characteristic of providers’ encounters with patients with CP, as
well as those with comorbid MI or SUD. According to Graber and colleagues, "errors
are more likely when the level of uncertainty is high, if clinicians are unfamiliar with
the patient, and when there are atypical or non-specific presentations...or
distracting co-morbid conditions." 233 Decisional errors are common when they
involve individuals in groups prone to stereotyping, such patients with CP, SUD, or
MI. 234 According to Klein, “the greatest obstacle to making correct decisions is
seldom insufficient time but distortions and biases in the way information is
gathered and assimilated." 235 While no researcher has specifically examined
providers’ and policy makers’ cognitive biases and failed heuristic in the context of

230 Pat Croskerry, From Mindless to Mindful Practice—Cognitive Bias and Clinical Decision Making, 368
NEW ENGLAND J. MED. 2445-2448 (2013) ("other factors come into play, such as cognitive overload,
fatigue, sleep deprivation, or emotional perturbations."). See also, Valerie Thompson, supra note 222
(any strain on working memory compromises Type 2 processing).
231 Pat Croskerry et al., supra note 183 at ii61.
232 Id. (citing to TD Wilson & N Brekke, Mental contamination and mental correction: unwanted
influences on judgments and evaluations, PSYCH. BULLETIN (1994)).
233 Mark L. Graber et al., Cognitive Interventions to Reduce Diagnostic Errors: a Narrative Review, 21
234 See Croskerry, et al., supra note 183 at Table 1. See also Cayla R. Teal et al., Helping Medical
Learners Recognise and Manage Unconscious Bias Toward Certain Patient Groups, 46 MEDICAL
EDUCATION 80-88, 81 (2012) (explaining that unconscious bias "interacts with the patient’s
characteristics to produce a treatment outcome in which the influence of unconscious bias can be
magnified when data are ambiguous...unrecognized and unmanaged, unconscious bias can lead to
health care disparities.").
235 Klein, supra note 48 at 783.
patients with CP, an examination of some of the potential heuristic errors and biases is warranted.

1. Confirmation and Anchoring Biases, Representative Heuristic

One of the most well described biases is confirmation bias, a “tendency to look for, notice, and remember information that fits with our preexisting expectations...information that contradicts those expectations may be dismissed as unimportant.” It is a way to resolve cognitive dissonance (the discomfort of holding two contradictory ideas simultaneously) by interpreting subsequent information to fit the initial idea. Epstein and colleagues describe the interaction between Type 1 processes and confirmation bias as a consequence of biology: “our brains—evolved to guess the most plausible interpretation of the limited evidence available, in which the mind ‘imposes a definition on things and then mistakes the definition as actual experience’—and also ignores disconfirming data.” The operation of confirmation bias can jeopardize accurate and appropriate treatment.

Anchoring bias is related and occurs when an incorrect initial impression is made and then all subsequent work focuses on that incorrect impression. Ely and colleagues describe it as “the tendency to perceptually lock onto the salient features of the patient’s presentation too early...and failing to adjust this impression in light

\[237\] Id. at 91; Jill G. Klein, supra note 48 at 781-783.
\[238\] James M. Pines, supra note 236.
\[239\] Epstein et al., supra note 183 at 7 (internal quotations omitted).
\[240\] R. Mendel, Confirmation Bias: Why psychiatrists stick to the wrong preliminary diagnosis, 41 PSYCHOLOGICAL MED. 12, 2651-2659 (2011) (only 30% of patients who picked the wrong diagnosis corrected for it later).
\[241\] Pines at 91.
Rather than just selectively interpreting subsequent evidence to fit the initial impression, as is the case with confirmation bias, providers would focus all efforts on the initial idea. This, of course, can work in concert with confirmation bias to lead providers to both attend more heavily to information that confirms their assumptions and proceed to make subsequent decisions based on the initial anchor.

An overlapping problem is reliance on the representative heuristic; this is the tendency to look for prototypical manifestations while failing to consider atypical presentations. Decision makers may misjudge the actual situation and ascribe more value to one piece of information. This is particularly concerning when a large variety of patients are grouped together, as is the case with “chronic pain patients” or patients with malignant (cancer) pain verses “non-cancer pain,” a dubious distinction at best with no “physiological, pharmacological or even philosophical basis.”

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243 This is also known as representative restraint. Pat Croskerry, *The Importance of Cognitive Errors in Diagnosis and Strategies to Minimize Them*, 78 *Acad. Med.* 8, 775-780, 778 (2003).
244 *Id.* See also John W. Ely et al., *supra* note 242; Jill G. Klein, *supra* note 48.
245 Jill G. Klein, *supra* note 48 at 782; See also Cass Sunstein, *supra* note 218 (explaining the representative heuristic and providing examples such as people’s judgments that organic food is better regardless of further details and the role of the representative heuristic in the internment of Japanese Americans during WWII).
246 Robert K. Twillman, *Rescheduling Hydrocodone*, Livestrong Foundation Blog (Feb 5 2013), http://blog.livestrong.org/2013/02/05/rescheduling-hydrocodone/. He is not alone in this assertion. Many official statements and comments include this concern. Cancer pain is essentially a short hand for painful terminal illnesses but it is now completely inaccurate as cancer is often chronic and not painful. Chronic non-cancer conditions are arguably more painful. Conversely, patients with terminal non-cancer illnesses may be in severe pain and limited by this distinction. See, e.g., Nat’l Hospice and Palliative Care Organization, comment letter on the FDA-2012-P-0818 Citizen’s Petition, November 27, 2012, available at http://www.regulations.gov/#/documentDetail;D=FDA-2012-P-0818-0678 (“Pain is a highly prevalent symptom in many life-limiting illnesses other than cancer, and pain treatment for patients with these non-cancer illnesses is as essential for health and quality of life as it is for those with cancer”).
meant pain at the end of life.\textsuperscript{247} The distinction is now without meaning. For example, does the appropriate treatment of post amputation pain change whether the amputation was caused by a tumor or a traumatic injury?\textsuperscript{248} Others have advanced compelling examples to illustrate the absurdity of the distinction, such the exclusion of patients with sickle cell crisis (a painful non-cancer chronic condition),\textsuperscript{249} or patients with painful, terminal non-cancer conditions.\textsuperscript{250} These kinds of distinctions also illustrate the representative heuristic that may operate in providers’ reliance on disease as a entity independent from the patient.\textsuperscript{251}

The negative impact of the operation of these biases may account for the predominant notion that providers can tell upon first impression whether a patient is actually in pain or “on the level.”\textsuperscript{252} Perhaps a patient appears comfortable and happy when the provider sees her sitting in the exam room; when she reports severe, even crippling pain after walking to the exam room, they provider may

\textsuperscript{248} This example appeared in multiple examples in comments to the FDA on the Citizen’s Petition from Physicians from Responsible Opioid Prescribing in 2012. See, e.g., The Florida Academy of Pain Medicine, comment on the FDA-2012-P-0818 Citizen’s Petition, FDA-2012-P-0818-0333, August 25, 2012, available at http://www.regulations.gov/#!documentDetail;D=FDA-2012-P-0818-0333 (“The most disturbing flaw in the petitioner’s proposal revolves around a false distinction between two categories of chronic pain, “cancer related pain” and -non-cancer related pain.” While both categories of patients may be suffering with moderate to severe pain, only those with cancer will be entitled to adequate pain relief with long term use of opioid analgesics even though both groups of patients may share the same underlying pathophysiology ...this seems illogical and inhumane!”).
\textsuperscript{249} See, e.g., Sophie Lanzkron, a physician who specializes in treating Sickle Cell Disease, comment on the FDA-2012-P-0818 Citizen’s Petition, ID FDA-2012-P-0818-0301, posted September 4, 2012, available at http://www.regulations.gov/#!documentDetail;D=FDA-2012-P-0818-0301 (“I see that individuals with cancer pain are excluded from the changes suggested by PROP and it is unclear to me why individuals with sickle cell disease are not excluded as well...this unique disease is characterized by episodes of excruciating pain and for many of my patients, chronic debilitating pain”).
\textsuperscript{250} See, e.g., The Florida Academy of Pain Management, \textit{supra} note 248.
\textsuperscript{251} See Eric J. Cassell, \textit{supra} note 186.
\textsuperscript{252} See, e.g., Hinze et al., \textit{supra} note 121 at 249 (a physician interviewed in this study offered he uses “intuition” to decide whether a patient in pain is “on the level”).
decide she is not “on the level” and ignore other information. In reality, this is a
typical presentation with lumbar stenosis.253

Confirmation and anchoring bias may combine to explain the unfortunate
effects of provider and institutional reliance on “red flags” for diversion.254 One such
red flag is when a patient asks for a particular opioid drug by name. Suppose a
patient said, “Vicodin makes me itch but Percocet worked well for me when I hurt
my back a few years ago.”255 If the provider has decided the patient is not diverting
based on an initial impression, they may interpret the patient’s statement as an
indicator she is a good historian. Otherwise, she would quickly be suspected of
diverting and denied a prescription that would otherwise relieve the acute pain.

Confirmation and anchoring biases in this arena is not limited to providers.
For example, the Inspector General of Tennessee believes that providers can
intuitively know the difference between a patient in pain and someone wishing to
divert, saying “It’s not easy for a physician or pharmacist to be able to tell the
difference between a legitimate patient and a drug abuser, but providers in
Tennessee have developed a good sense of distinguishing the abusers.”256 Dr. Gary
Jay expressed dismay at the negative experiences of some of his long-time patients
after Walgreens, a national drug chain, adopted the use of “red flags” to deny filling

253 See, e.g., Cleveland Clinic, Lumbar Canal Stenosis, available at
http://my.clevelandclinic.org/health/diseases_conditions/hic_Lumbar_Canal_Stenosis.
254 See generally, Gary W. Jay, So Patients Suffer-It’s for Their Own Good, 22 AMERICAN J. THERAPEUTICS
80-84 (2015).
255 This is actually something I said when I had surgery, preceded several years before that by a
herniated disc. Luckily, my doctor treated me like a good historian.
256 Deborah Faulkner, Inspector General of Tennessee, Davidson County Woman Charged with
TennCare Doctor Shopping, State of Tennessee, Newsroom & Media Center, January 2, 2013, available
at https://news.tn.gov/node/10107 (accessed June 3, 2015). This statement also reflects the
unfortunate idea that people with SUD are not “legitimate” patients.
prescriptions for opioids. One red flag (or anchor) is enough, without other contextual information, to justify denying the patient a prescription. Payment in cash, one red flag, is grounds for denying patients their prescription, regardless of the reasons. Another red flag is multiple pharmacy customers with the same diagnoses and prescriptions from one provider. Other specialty physicians, such as pulmonologists who have multiple patients with asthma all prescribed bronchodilators, aren’t subject to the same suspicion as similarly situations pain physicians.

2. Availability Bias and Availability Cascades

Availability bias (or availability heuristic) occurs when the likelihood of an issue is “tied to the ease with which its occurrence can be brought to mind.” Inordinate weight is placed on examples or categories of previous situations, with stronger memories often afforded more credence. The corollary to availability bias is base-rate neglect, which is the tendency to ignore the true prevalence of disease. Combined they “can lead to serious errors of fact, in the form of excessive fear of small risks and neglect of large ones.” The media, public health, and scholarly attention to OROs make the risks of opioid misuse more available than

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258 *Id.* at 82 (this is a DEA created red flag).
259 Timur Kuran & Cass Sunstein, *Availability Cascades and Risk Regulation*, 51 STAN. L. REV. 683, 685 (1999); Pat Croskerry, *supra* note 243 at 777 (the “disposition to judge things as being more likely, or frequently occurring, if they readily come to mind. Thus, recent experience with a disease may inflate the likelihood of its being diagnosed.”).
260 Jill G. Klein, *supra* note 48 at 782; *See also*, John W. Ely et al., *supra* note 242.
261 John W. Ely et al., *supra* note 242 at 309.
concerns with objectively greater morbidity and mortality. This may explain why providers and policy makers overestimate risks of addiction, discount the extent and consequences of persistent pain, and neglect assessments for MI and suicidality. Availability bias may also extend to the decisions made by coroners and physicians in selecting a cause of death on death certificates. The significant publicity around opioid related deaths may increase the attribution of death to “opioid poisoning” over the multiple other drugs or alcohol present in their systems of most victims.

Availability bias may explain some policy decisions; for example, the disproportionate focus on opioids over polysubstance abuse concerns may be a product of availability bias. Likewise, the significant attention to diversion detection in CP treatment guidelines with little to no attention of greater causes of morbidity and mortality may arise, in part, from availability bias.

This may be a product of availability cascades, a phenomenon that Kuran and Sunstein explain as an interaction between initial availability heuristic and social mechanisms resulting in snowballing or bandwagon effects of “persistent social availability errors.” The social mechanisms of informational and reputational cascades are part of availability cascades. Information cascades occur when individuals with incomplete information rely on others (often too with incomplete

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263 Alicia A. Bergman et al., supra note 181 (Reporting attitudes by physicians that chronic pain patients had a high rate of diversion, one stated “the problem always comes when I don’t know the person. Then you don’t know what they were before and you know diversion is pretty common”).

264 Jill G. Klein, supra note 48 at 782 (emphasis added) (doctors tend to “overestimate the risk of addiction when prescribing opioid[s] . . . and to undertreat severe pain as a result. Risk of addiction is actually low when patients receive opioids...for pain but opiate addiction tends to receive high publicity and so—through the availability heuristic—its likelihood may be overestimated.”).

265 See Section II.A.2.b. supra.

266 Timur Kuran & Cass Sunstein, supra note 259.
information) in formulating beliefs. Reputational cascades are motivated by social approval needs and occur when individuals choose to indicate, or refrain from rejecting, the beliefs of others. These interdependent cascades can snowball and become self-reinforcing for the groups that espouse particular views and “public discourse will rest of flawed judgments,” leading to serious social harm through narrow and ill-informed policy making, media attention, and a focus on slight risks at the expense of important risks. Availability cascades “constitute a major...source of risk-related scares that have cramped federal regulatory policy at both the legislative and executive levels, with high costs in terms of lives lost, lowered quality of life, and dollars wasted...cascades force governments to adopt expensive measures without careful consideration of the facts.”

Some of the recent regulatory efforts aimed at reducing opioid use may be incoherent because of availability cascades. For example, state guidelines that ultimately decrease access to opioids for all patients come with significant administrative and enforcement costs, as well as social costs in the form of patient suffering and even increased use of more dangerous illicit drugs such as heroin. States laws that mandate urine testing for all patients taking opioids create significant financial costs to individual patients and third party payers. Prescription Drug Monitoring Programs that are costly but do not report in real time are almost useless in detecting diversion. These policies that are not synchronized to the

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267 Id. at 685-87.
268 Id.
269 Id. at 742.
270 Id. at 742-763.
271 Id. at 746.
problems they aim to address, discussed in Section V below, may be a product of availability cascades.

3. Framing Errors and Illusory Correlations

Framing of antecedent conditions to decisions strongly influence subsequent decision-making. For example, the same surgery described two different ways elicits different preferences; more people agree to the surgery when told ninety percent of people are alive after five years than when they are told ten percent are dead after five years. It is not surprising that when reports frame the problems with opioids as primarily that of diversion leading to death—with little or no mention of the utility of the medication for some patients in pain—that people are willing to sacrifice pain control for a perceived greater good. Framing polysubstance deaths as OROs, with little to no mention of the predominant role of co-mixed alcohol and benzodiazepines, only furthers the scapegoating of one particular class of drugs and may decrease critical warnings about the risks of polysubstance use. It may also cause wholesale avoidance of the entire class of drugs by providers and patients, even when they may be appropriate and helpful in some circumstances.

Another impairment to decision-making is narrow framing, or the “tendency to define our choices too narrowly, to see them in binary terms.” The false binary pervades this area. Treatments are seen as bad (dangerous, addictive, and deadly) or good, with opioids falling in the “all bad” category. Patients are seen as legitimate or illegitimate, a pain patient or a drug-addict, a complete manipulator or a ‘straight

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272 Pat Croskerry, supra note 243 at 778.
273 Cass Sunstein, supra note 218 at 1590.
274 CHIP HEATH AND DAN HEATH, DECISIVE: HOW TO MAKE BETTER CHOICES IN LIFE AND WORK (2013) (describing narrow framing/false dichotomies as one of the villains of decision making).
shooter,” deserving or undeserving. Why a patient with SUD or other related
conditions is seen as illegitimate or undeserving is hard to understand.\textsuperscript{275} Pain is
also grouped into nonsensical categories, such as cancer and non-cancer pain or
surgical and non-surgical pain. Finally, the narrow framing and interpretation of the
principle of balance in prescribing is illustrative.\textsuperscript{276}

4. Visceral Biases: Indignation, Outrage, and Betrayal

Personal feelings and emotions are powerful drivers of poor decision-
making.\textsuperscript{277} Sunstein describes particularly strong feelings as heuristics in their own
right;\textsuperscript{278} the betrayal of trust heuristic is so strong, according to Sunstein, that
people will actually substantially increase risks to themselves simply to avoid
betrayals of trust.\textsuperscript{279} Closely related are the feelings of outrage and indignation, both
of which combine with betrayal to create disproportionate perceptions of threat and
desire to act to reduce the threat.\textsuperscript{280} Worse yet, when groups of people prone to
share indignation and betrayal deliberate together, the groups “end up more
indignant than their median member.”\textsuperscript{281} Although not studied in the context of
health care generally or pain specifically, this has serious implications for providers
caring for patients who present in pain. Nowhere in the practice of medicine are the
feelings of betrayal and indignation stronger than around the idea of a patient

\textsuperscript{275} See generally, Sandra H. Johnson, supra note 31.
\textsuperscript{276} See infra Section V.
\textsuperscript{277} Ogdie et al. supra note 211 at Table 1.
\textsuperscript{278} See Sunstein, supra note 218 at 1573-74 (describing the betrayal heuristic); Cass R. Sunstein, Some
drivers of incoherence in law).
\textsuperscript{279} Sunstein, supra note 218 at 1573-74 (explain that people prefer a chance of dying in a car crash in
a car without airbags at all than dying in a crash as a result of a faulty airbag).
\textsuperscript{280} Sunstein, supra note 278 at 420 (2009).
\textsuperscript{281} Id. (describing this phenomenon in terms of criminal law).
deceiving a prescriber to obtain opioid for diversion purposes. Matoka and True described providers’ reactions this way,

> We were struck by how merely noting a research interest in pain (in the most general of terms) often elicited powerfully charged emotion, **prompting clinicians to offer up expressions of frustration, anger, and even disgust in vivid terms**: “Ugh, pain patients—I hate those back pain guys. I just want to turn and run when I see one coming.” And “Pain patients, well, you’ve picked a doozy there. What a waste, the kind of energy they spend trying to get their meds—makes me sick!” Notably, these sorts of virulent—even visceral—reactions often existed right at the surface...clinicians frequently seemed so willing to talk about their patients with pain precisely because it is an area of their daily practice about which they often feel a deep sense of vulnerability, unease, and even failure.282

If the betrayal and indignation heuristics operate the same way in this context, it could explain why providers believe far more patients are addicted or attempting to divert than evidence reveals. It could also explain their willingness to risk treating a patient in pain poorly and allow unnecessary suffering if it allows them to avoid any risk of betrayal. According to Sandra H. Johnson,

> What the debate between deceived doctors and earnest pain management advocates also often misses is the emotional burden that deception exerts on physicians and the behaviors that those emotion-laden circumstances produce. Absent recognition of the emotional state of mind of physicians in practice, however, it is unlikely that persistent calls for more trust between patient and physician will achieve the desired outcome.283

5. The Opioid Heuristic and Provider and Institutional Practices

If treating certain conditions increases the risk of being called a bad doctor, many doctors will focus their efforts elsewhere. Doctors are, after all, only human.284

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282 Megan Crowley-Matoka & Gala True, supra note 123 (emphasis added).
283 Sandra H. Johnson, supra note 31 at 1480.
It is no surprise doctors are avoiding patients in pain. Now that the phrase “opioid epidemic” has pervaded the professional literature and public discourse, the landscape for the patients in pain for whom opioids provide a benefit is bleak. The epidemic metaphor has succeeded in exacerbating the availability cascade regarding prescription opioids. Positive or value neutral things are not equated with contagion and plagues: these are things to be avoided at all costs. There is now what I will call an opioid heuristic; opioids are standing in for a host of negative sequelae and triggering avoidance by providers. Quite literally, the word opioid has replaced “opioid related overdoses,” ascribing the power of danger on contact for any reason. This is not completely new, described in the past as opiophobia, but is aggravated by the epidemic metaphor and availability cascades surrounding the rise in overdoses.

For decades providers have contended that they fear the use of opioids because of potential investigations by the DEA or state board for prescribing violations. This fear is understandable given that this is one of the few areas in which a prescriber could find themselves embroiled in federal and state criminal, administrative, and even civil proceedings. Others fear “causing” addiction in their patients, a fear likely fueled by resurgence of the word addiction related to

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286 See, e.g., Donald M. Goldenbaum et al., Physicians Charged with Opioid Analgesic-Prescribing Offenses, 9 PAIN MED. 737, 745 (2008). But see, Sandra H. Johnson, Assessing Legal Risk, 9 PAIN MED. 748 (2008) (“This consistent evidence-based message cannot compete with the grapevine and news headlines of the rare horror story”).
287 Physicians can be prosecuted criminally under drug laws, face administrative proceedings regarding their license to practice as well as their authorization to prescribe controlled substances under state and federal law, and they may find themselves facing negligence actions by patients or patients’ family members.
288 This fear is not based on evidence. The rate of addiction is very similar to or less than that of the general population. See, e.g., Silvia Minozzi, supra note 173.
use of opioids in the last five years, in everything from media sources to statements of some provider groups. While concerns about diversion and addiction are not completely unreasonable, these concerns are relatively modest in comparison to other risks and must not supersede comprehensive evaluation and treatment of patients. Most importantly, these concerns must not eclipse the overall treatment of a person in pain, with or without the use of opioids; opioids are just one tool in the diverse and context dependent treatment of patients.

V. Regulation, Policy, & Practice: Responses from Incoherent to Rational

Experts have long strived for a regulatory stage that allowed for an evidence-based treatment of pain. Future policy should aspire to reduce overall harms, including morbidity and mortality related to pain, SUD, MI and suicidality. This includes caring for patients who are candidates for opioids, offering treatment, rather than criminal justice options for those with SUD, and providing resources for those who have MI or are suicidal. Providers, of course, must do this without compromising appropriate medical practice or adherence to reasonable documentation and evaluation practices.

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289 See, e.g., Physicians for the Responsible Opioid Prescribing, FDA cracks down, Finally, on Painkillers, MANSFIELD NEWS J., November 14, 2013 (describing Vicodin as “the deadliness drug in America).


291 See, e.g., Daniel S. Goldberg, On the Erroneous Conflation of Opiophobia and the Undertreatment of Pain, 10 AMER. J. BIOETHICS 11, 20-22 (2010) (“Despite the undeniable fact that opioid analgesics are an important and even front-line therapy for many kinds of pain, they are simply one tool in the toolbox”).

292 See, e.g., Ben Rich, supra note 1.
Incoherent policies risk undoing the considerable advancements made over time that validated opioids in certain contexts, among other treatments, and did not unduly burden patients in pain or their providers.\textsuperscript{293} Among the policy successes was the use of the metaphor of balance for regulatory obligations.\textsuperscript{294} In that context, balance is an obligation on governments to ensure availability of opioids for appropriate medical use while addressing the diversion of opioids for non-medical use.\textsuperscript{295} Unfortunately, the obligation of balance adopted in an unintended way: individual providers began using the metaphor to convey an obligation to balance the wellbeing of their own patients against social concerns surrounding diversion in the community.\textsuperscript{296} This is a perversion of a provider’s primary obligation. David Brushwood and colleagues quoted Hans Jonas to convey the provider’s obligation in this regard.


\textsuperscript{294} See Pain & Policies Studies Group, supra note 125 (“Policy efforts to address pain relief and non-medical use share the common aim of protecting public health and improving quality of life, either by alleviating pain and its debilitating effects or by addressing substance use disorders and their tragic consequences. If done in a balanced manner, both efforts should have measurably effective outcomes and neither should interfere with the other.”). For a concise history of the use of balance as a metaphor in this area, see Federation of State Medical Boards, Policy Brief: Balance, Uniformity, and Fairness: Effective Strategies for Law Enforcement for Investigating and Prosecuting the Diversion of Prescription Pain Medications While Protecting Appropriate Medical Practice (February 2009) at 5.

\textsuperscript{295} This was initiated by the Pain & Policies Study Group decades ago. See, e.g., Scott M. Fishman et al, Regulating Opioid Prescribing Through Prescription Monitoring Programs: Balancing Drug Diversion and Treatment of Pain, 5 PAIN MED. 3, 309-324 (Sept 2004). See also, Pain & Policies Study Group, supra note 125 at 27.

\textsuperscript{296} See e.g., Rollin M. Gallagher & Lisa J. Rosenthal, Chronic Pain and Opiates: Balancing Pain Control and Risks in Long-Term Opioid Treatment, 89 ARCHIVES PHYSICAL MED. & REHABILITATION 3, S77-S82 (March 2008) (“The risks and benefits of opioid analgesics for chronic pain conditions and diseases are discussed in the context of the concern about the public health problems of poorly managed pain and prescription drug abuse and addiction.”)(emphasis added).
In the course of treatment, the physician is obligated to the patient and to no one else. He is not the agent of society, nor of the interests of medical science, the patient’s family, the patient’s co-sufferers, or future sufferers of the same disease. The patient alone counts when is under the physician’s care.297

The balance metaphor is no longer sufficient for reasons beyond its distortion. The binary, adversarial structure it evokes—pain relief verses diversion prevention—does not adequately reflect or illustrate the complexity of the problems now faced.298 The narrow frame may contribute to the use of opioid heuristic as a stand in for the harms of diversion and misuse. There is an urgent need for models that instead communicate the integrated, overlapping, complex approach required to prevent and reduce the harms of morbidity and premature deaths of all kinds (accidental, intentional, and as a result of sequelae of untreated conditions). Providers and policymakers should strive to improve the quality of life for people who are suffering: those with pain, SUDs, MI, suicidality and any combination thereof. This requires a holistic, integrated, relational approach—an approach of what I will call central coherence—a term I borrow from psychology literature.299 Many current approaches lack central coherence, meaning they attempt to address a fragmented part of the problem while ignoring or even further

297 Brushwood et al., supra note 165 (quoting Jonas, Philosophical Reflections on Experimenting with Human Subjects (1969)).
298 It also oversimplifies the considerations involved, excluding innumerable other integral forces. In theory, the balance metaphor could work if one envisions balancing spinning plates rather than the see-saw or scales of justice, but the bifurcated approach dominates. For an example of the power of metaphor on decision-making, see Paul H. Thibodeau & Lera Boroditsky, Metaphors We Think With: The Role of Metaphor in Reasoning, 6 PLOS ONE 2, e16782 (2011).
299 “Central coherence” is from the psychological literature and describes a cognitive process or ability to put together the fragments or parts of what is actually a collective whole and see the relatedness of those parts. It is often used to contrast the processing of some individuals with autism spectrum disorder or certain eating disorders who may display weak central coherence (focus on the fragments without seeing the whole). See, e.g., David Williams & Dermot Bowler, Autism Spectrum Disorders: Fractionable or Coherent, 18 AUTISM 1, 2-5 (2014); Katie Lang et al., Central coherence in eating disorders: An updated systematic review and meta-analysis, 15 WORLD J. BIOLOGICAL PSYCHIATRY 8, 586-598 (2014).
harming other fragments and, consequently, the related, integrated whole. Often the harms are simply shifted rather than addressed because results are measured within the fragment only. It is essential for patients in pain and for their providers that the opioid heuristic doesn’t drive incoherent law and policy.

A. Regulating Prescribing at Federal Level

A number of agencies are involved in opioid prescribing; at the federal level, the primary agencies are the DEA, a law enforcement agency, and the Food and Drug Administration (FDA), a public health agency. The DEA and is responsible for the enforcement of the Controlled Substance Act (CSA), a federal drug trafficking and distribution statute. The DEA categorizes drugs under the CSA into one of five categories based on their potential for medical use, abuse, misuse, physical, and psychological dependence. Schedule I drugs have no acceptable medical or safe use and a high potential for abuse and dependence. Schedules II-V drugs have medically acceptable uses, are available by prescription only, and have potential for abuse and dependence ranging from high (schedule II) to the low (Schedule V).

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300 One example is the focus on reduced OROs without addressing the increase in heroin overdoses.
301 A comprehensive overview is outside the scope of this note but regulation of narcotics and the role of physicians in using them in treatment dates back to the HARRISON NARCOTIC ACT, 38 STAT. AT L. 785 (2014). See, e.g., A. Christopher Bryant, The Third Death of Federalism, 17 CORNELL J.L. & PUB. POL’Y 101 (2007).
302 The DEA is a branch of the Federal Bureau of Investigation with the Department of Justice, all of which are housed under the Attorney General of the United States.
305 Id. See also 21 U.S.C. § 812.
306 Id.
Most opioid prescription drugs used for pain but also implicated in drug related morbidity and mortality are in Schedule II or III. Many of the benzodiazepines implicated in polysubstance abuse, such as Ativan, Valium, and Xanax are Schedule IV drugs. Scheduling is relevant to the requirements for valid prescriptions and impacts patient care, such as the ability to call or fax in orders to the pharmacy or issue refills.

The Attorney General, through the DEA, authorizes providers to prescribe controlled substances through a certificate of registration. That authority is limited to the prescription of controlled substances (1) for a legitimate medical purpose and (2) in the usual course of professional practice. Conduct pursuant to these standards exempts prescribers from prosecution under the CSA; however, what constitutes the limits of legitimate medical purposes and professional practice is amorphous and a range of provider behavior has resulted in liability.

Sometimes that conduct is obviously outside the care relationship, such as exchanging prescriptions for money without conducting a history or examination.

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307 Id. Example of Schedule II drugs include morphine, Demerol, oxycodone, Dilaudid, and Fentanyl.
308 Id. This is the case despite very real concerns surrounding the involvement of benzodiazepines in polydrug overdoses.
309 See 21 C.F.R. §1306. State laws often impose additional requirement, such as triplicate forms. See, e.g., Dep’t of Justice, 79 FEDERAL REGISTER 163, infra note 33 at 49668. (“Neither the CSA nor DEA regulations require prescriptions to be prepared in triplicate. The DEA recognizes that some states, such as Texas and California, require the use of triplicate prescription forms for some or all controlled substances...the DEA supports the efforts of States to take the specific action they deem necessary to prevent diversion.”)(internal quotations omitted).
311 21 C.F.R. §1306.4(a) (“a prescription for controlled substance...must be issued for a legitimate medical purpose by an individual practitioner action in the usual course of his professional practice”); 21 U.S.C. §829. (“No controlled substance in schedule II [or III or IV]...may be dispensed without the written prescription of a practitioner”).
312 See Diane E. Hoffmann, supra note 303.
313 See, e.g., United States v. Kaplan, 895 F.2d 619 (9th Cir. 1990) (issuing numerous prescriptions for controlled substances without a documented physical exam is evidence of conduct outside the bounds of usual professional practice).
but this is not always the case. David Brushwood has argued that the standard should mean “without a medical purpose” to protect physician good faith treatment decisions from criminal scrutiny; courts and agencies have repeatedly declined further clarification.

1. Chilling Effect

Concerns about the unjust investigation and prosecution of physicians prescribing controlled substances in good faith remain, as does the chilling effect that news of such investigations can create in the physicians, perhaps through availability cascades. The DEA can investigate providers for any reason; at the same time, The DEA contends that that the “types of cases in which physicians have been found to have dispensed controlled substances improperly under federal law generally involve facts where the physician’s conduct is not merely of questionable legality, but instead is a glaring example of illegal activity.” Nonetheless, arrest and indictment, whether or not they are convicted, can destroy providers’ career. Dr. Andrew Nguyen’s case is an example; he was taken into custody and indicted.

315 Id.
316 The chilling effect was described as a myth by the DEA and researchers have asserted that the risks of prosecution are very small. Nonetheless, providers continue to report fears of investigation and prosecution. See, e.g., Marcus M. Reidenberg & O. Willis, Prosecution of Physicians for Prescribing Opioids to Patients, 81 CLINICAL PHARMACOLOGY & THERAPEUTICS 6 (June 2007).
317 United States v. Morton Salt Co., 338 U.S. 632, 642-643 (1950)(“it is a longstanding legal principle that the government can investigate merely on suspicion that the law is being violated, or even just because it wants assurance that it is not”).
318 Dep’t of Justice, Drug Enforcement Agency, Dispensing Controlled Substances in the Treatment of Pain, 71 Federal Register 172, 52715-52723 (September 6, 2006). But see, Diane E. Hoffmann, supra note 303 for an analysis of recent cases against physicians that reflect aggressive prosecutions.
319 See Reidenberg & Willis, supra note 316 (finding questionable prosecutions in a large number of physician prosecutions for which the state board never reviewed the prescribing practices before an indictment).
based on a false affidavit.\textsuperscript{320} Without notice, he was escorted out of his office by law enforcement, jailed, lost his DEA certificate of registration, and subsequently his contracts with insurance companies.\textsuperscript{321} He suffered millions of dollars in damages in terms of lost patients and reputational loss. The charges were eventually dismissed but the harm was done.\textsuperscript{322}

The fact that prescribing scrutiny is focused on opioids rather than other drugs that result in harm or death has also been identified as a problem; for example, physicians don't seem to be prosecuted after a patient overdoses on antidepressants while they are sometimes charged with murder for the same outcome involving opioids.\textsuperscript{323} According to Reidenberg and Willis, “when doctors must continually be suspicious of patients claiming to be in pain because being deceived can lead to criminal prosecution, their willingness to treat patients in pain with opioids diminishes.”\textsuperscript{324}

2. Rescheduling Controlled Drugs

In 2009 the DEA asked the FDA for a recommendation for rescheduling hydrocodone, then in Schedule III combination drugs, such as Vicodin.\textsuperscript{325} Unless prohibited by state law, Schedule III drugs can be refilled and in some states, can be called or faxed into the pharmacy.\textsuperscript{326} This allows providers to manage increased

\begin{itemize}
\item \textsuperscript{320} See David Brushwood, \textit{supra} note 118.
\item \textsuperscript{321} \textit{Id}.
\item \textsuperscript{322} \textit{Id. See also}, Diane E. Hoffmann, \textit{supra} note 303.
\item \textsuperscript{323} Reidenberg & Willis \textit{supra} note 316 at 905.
\item \textsuperscript{324} \textit{Id}.
\item \textsuperscript{325} See Janet Woodcock, Statement of Proposed Hydrocodone Reclassification, Food &Drug Administration, Center for Drug Evaluation &Research, October 24, 2013, \textit{available at} http://www.fda.gov/drugs/drugsafety/ucm372089.htm.
\item \textsuperscript{326} 21 U.S.C. § 829.
\end{itemize}
pain or acute pain flexibly and remotely. This may be useful, for example, in postoperative patients sent home on a small supply of Schedule II drugs who continue to experience pain. In October 2013, the FDA announced “due to the unique history of this issue and the tremendous amount of public interest,” that they were recommending a reclassification to Schedule II.327 This was initiated by Physicians for Responsible Opioid Prescribing (PROP), who advance that there is no reason for the “non-cancer patient” to take opioids.328

Concerns about the unintended consequences of the change are numerous,329 such as burdensome administrative requirements, decreased access to appropriate drugs for acute pain, decreased access to providers, increased costs and overutilization of health care services, and even the possibility of higher quantities per prescription.330 Providers in states that require triplicate forms for schedule II drugs are concerned about the administrative burden of state law requirements.331

327 See Janet Woodcock, supra note 325.
329 See, e.g., John Keilman, Doctors Consider Consequences of New Vicodin Rules, CHICAGO TRIBUNE, October 6, 2014 (“the new rules...are meant to cut down on problems by making patients jump through more hoops to get the drugs”).
330 Id., See also, Anonymous nurse practitioner, Comment to Drug Enforcement Agency’s Proposed Rule: Schedules of Controlled Substances: Rescheduling of Hydrocodone Combination Products from Schedule III to Schedule II (February 28, 2014) available at http://www.regulations.gov/#/documentDetail;D=DEA-2014-0005-0018 (“I am a nurse practitioner in a state that does NOT allow us to write class II narcotics. For many patients we are their only healthcare provider. This change will severely affect our patient’s ability to obtain their pain medications”).
331 See, e.g., Christopher Ziebell, Comment to Drug Enforcement Agency’s Proposed Rule: Schedules of Controlled Substances: Rescheduling of Hydrocodone Combination Products from Schedule III to Schedule II (March 18, 2014) available at http://www.regulations.gov/#/documentDetail;D=DEA-2014-0005-0111. (“I run a level 1 trauma center. Rescheduling hydrocodone as schedule 2 is a bad idea from my perspective due to issues of access. In Texas, schedule 2 medications can only be prescribed on special prescription pads...Most Emergency Physicians do not have the special triplicate prescription pads that are required, for a number of valid reasons...changing hydrocodone to schedule 2 will eliminate access to it for the majority of patients for whom it is appropriate...we will be prescribing
Some surgeons have expressed their intention to write larger quantities of hydrocodone for post-operative pain because they can no longer call in a refill for patients who require additional medication. This is especially problematic for patients in rural areas or who travel long distances for specialty surgeries. This could result in more leftover pills, a serious concern since many of those who abuse prescription medications obtain them from relatives or friends with extra medication. Nonetheless, DEA finalized the rescheduling.

3. FDA Actions

The Food and Drug Administration is responsible for the safety and effectiveness of drugs in the United States, approving all labels and labeling changes of drugs, and advice on scheduling of controlled substances. The FDA has taken several actions related to opioids recently, including requesting a labeling change for oxycodone products to remove the indication for moderate pain (leaving the only indication as severe pain, although the drug itself did not change), enacting 334Tylenol #3 or Ibuprofen for things like broken bones and kidney stones. It is clear that prescription drug abuse is a problem in the US, but reducing access to the medication for people who really need it is not the solution”).

332 See, e.g., Andrew Gurman, comment to FR# 2014-0433, ID: DEA-2014-0005-0100 (March 13, 2014) available at http://www.regulations.gov/#/documentDetail;D=DEA-2014-0005-0100 (“it has been usual practice among providers to prescribe 30 tablets for a routine surgical procedure. Recent studies show that 75% of people will take 12-15. So the best way to address this is to write a prescription for 15 tablets with one refill. That will allow the 25% who need more to get it, and will lead to less over prescribing for the other 75%. If the drug is rescheduled, no refills can be written, phone renewals are not possible, so docs will prescribe more than 30, just to make sure that everyone is covered. This is what many physicians have told me they will do. In my own practice, where I am the only hand surgeon for many miles, and my patients sometimes drive 2 hours to see me, it is not possible for them to just swing by the office for another prescription.”).


requirements for Risk Evaluation and Mitigation Strategy (REMS) programs for some drugs,\textsuperscript{335} approving one and incentivizing the formulation of more “abuse deterrent” formulations of opioids,\textsuperscript{336} and multiple other activities aimed at solving the “opioid epidemic,” a term the agency has embraced.\textsuperscript{337} Some of these strategies, such as the REMS program, may have unintended consequences; for example, one study found a significant number of family physicians would consider refusing to prescribe opioids subject to REMS because of the increased safety, education, and training requirements for providers.\textsuperscript{338} Nonetheless, these requirements may be a small price to pay for continued access to opioids for those patients that benefit from their use.

One recent action by the FDA elicited outrage by groups committed to a strategy of eliminating opioid use: the approval of a long acting hydrocodone product, Zohydro ER.\textsuperscript{339} An open letter signed by over a dozen anti-addiction groups called for the resignation of then FDA Commission Margaret Hamburg; in addition, several legislators initiated hearings on the decision.\textsuperscript{340} In response, three FDA

\textsuperscript{335} See Jon Peppin et al., Issues and Critiques of the Forthcoming Risk Evaluation and Mitigation Strategies for Opioids, 27 ISSUES IN LAW &MED. 91 (2011).


\textsuperscript{337} See Food &Drug Administration, supra note 334.

\textsuperscript{338} See Kieran A. Slevin & Michael A. Ashburn, Primary Care Physician Opinion Survey on FDA Opioid Risk Evaluation and Mitigation Strategies, 7 J. OPIOID MANAGEMENT 2, 109-115 (2011).

\textsuperscript{339} Multiple groups, including some New England governors, sent a letter to HHS Secretary Burwell urging her to overturn the FDA’s approval. See, Ed Silverman, Governors to HHS: Rescind FDA Approval of Zohydro Painkiller, WALL STREET J., September 4, 2014.

officials wrote a thoughtful article for the Journal of the American Medical Association, detailing the rationale for the agency’s decision and highlighting the incoherent nature of some of the policy responses, saying “the risk of singling out a single drug...in this complex, multidrug epidemic is that resulting policy is unlikely to have an effect on the underlying causes.”341 This singling out of one drug or one class of drug may reflect the underlying opioid heuristic.

B. Regulating Prescribing and Practice at the State Level

“Psychological, social, economic, political, legal and educational factors—including inconsistencies and restrictions in state pain policies—can either facilitate or impede the ability and willingness of physicians to manage patients with pain.”342 States regulate controlled substances and provider practice through a variety of legal regimes.343 Professional practice is regulated through state medical boards (SMBs).344 SMBs regulate entry to practice as well as investigate and discipline providers who act contrary to professional standards as defined by state practice acts and regulations.345 In the past, SMBs have taken action to improve the care of

341 Christopher M. Jones, Peter Lurie, & Janet Woodcock, Addressing Prescription Opioid Overdose: Data Support a Comprehensive Policy Approach, 312 J. AMER. MED. ASS’N 17, 1733-1734 (2014) (“news reports, actions by states, and congressional legislation that single out...Zohydro ER raise critical questions about the most effective policy needed to reverse the problem”).

342 Federation of State Medical Boards, Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain (July 2013).

343 For example, each state has drug enforcement agencies, such as bureaus of narcotics; those agencies tend to be more restrictive than the DEA. See, e.g., Diane E. Hoffmann and Anita Tarzian, supra note 5.


345 See Sandra H. Johnson, Customary Standard of Care, 43 HASTINGS CENTER REPORT 5, 9-10 (2013).
patients in pain, such as instituting rules and advocating for legislation that enhanced protections for the good faith treatment of pain.346

1. Incoherent and Harmful State Action

Progress in reducing barriers to appropriate treatment is eroding at the state level in response to opioid related morbidity and mortality; some state legislatures are responding in incoherent ways to the perceived threat of abuse of prescription drugs by attacking opioids alone and by incentivizing physicians to avoid or abandon opioid use and patients in chronic pain and related disorders.347

a. Repealing Intractable Pain Treatment Acts

Intractable pain treatment acts were a major policy initiative and achievement in the last two decades aimed at reducing prescribers’ fears of regulatory scrutiny for treating patients in pain appropriately.348 The primary purpose was “to terminate actions against providers engaging in justifiable pain management practices as early as possible in the disciplinary or criminal process.”349 The acts incorporated accepted pain management practices of careful prescribing as a shield from disciplinary action and state statutes were chosen as “an external standard by which [state professional boards] policies and actions can

346 See Pain & Policy Study Group, supra note 125. See also Federation of State Medical Boards, supra note 342.
be reviewed.”350 At the same time, the acts acknowledged the important role of
disciplinary review for providers who demonstrate carelessness.351 During the last
twenty years, states adopted intractable pain treatment acts and state professional
licensure boards enacted regulations to ease prescribers’ fears and facilitate
appropriate treatment of patients in pain.352

In response to OROs, some states are willing to sacrifice those advances for
pain treatment. For example, Tennessee’s Intractable Pain Treatment Act,353 a law
originally passed in 2001, included a patient’s bill of rights, the acknowledgment
that some kinds of chronic pain requires long term opioids, and explicit continued
authority for the state medical board to investigate and discipline careless
prescribers,354 is deleted in its entirety as of July 2015.355 In addition to deleting the
entire act, the new legislation requires the state boards of medicine, osteopathy, and
nursing to repeal any rules promulgated under that act.356 The sponsors of the bill
effectively rewrote history, arguing on the floors of the senate and house that the
Intractable Pain Treatment Act was originally enacted only because of “lies
promulgated by a pharmaceutical company.”357 In addition, they argued the act has
caused undue harm to citizens of Tennessee, that these “types of treatments are not
needed” and described the use of prescription opioids—in contagion terms—as a

350 Id.
351 Id.
352 State by state breakdowns of law and regulations are available from several sources. See Pain &
Policy Study Group, supra note 125; Federation of State Medical Boards, supra note 348.
354 Id.
355 TENN. PUB. CHAP. NO. 26, SENATE BILL NO. 31 (effective July 2015) (signed by the governor on March
27, 2015).
356 Id.
357 Janice Bowling, Statements before the Tennessee Senate, February 26, 2015, video available at
plague. A review and revision (not deletion) was recommended as part of a state plan that included conclusory language of its own that “the perceived under-prescribing of opioids by Tennessee physicians in 2001 has now been replaced by overprescribing.” The repeal was supported by state law enforcement agencies, the Tennessee District Attorneys and the Tennessee Bureau of Investigation, who objected to language in the Intractable Pain Treatment Act that required doctors to refer patients to whom they would not prescribe opioids to other providers. One county attorney general’s use of the opioid heuristic was evident in an interview with a Tennessee newspaper:

One of the next steps that needs to be taken...is to look at laws that will put more regulations and pressure on pain clinics. Some of the regulations would be that pain clinics must accept referrals from other doctors before accepting a patient, psychological testing and better record keeping, among others. He also wants stricter regulations on addiction clinics offering Suboxone and Subutex as alternatives to prescription drugs. He would like the facilities to wean people off of drugs over time.

What is missing in these statements is any consideration of the potential impact on patients or medical standards, including the fact that blanket abstinence-only approaches are outdated in addiction medicine while chronic management models


360 Senator Janice Bowling, supra note 358.

361 TENN. CODE ANN. § 63-6-1103 (11) (2010). See also, Tommy Campbell, Law Enforcement Officials Hopeful that Intractable Pain Act will be Repealed, ROGERVILLE REVIEW, March 6, 2015.

and harm reduction models, such as medication assisted therapy, are endorsed as highly effective for patients with opioid use disorders.\textsuperscript{363}

\begin{itemize}
\item \textit{Redefining and Restricting Pain Management Practices}
\end{itemize}

A number of states have enacted a multitude of legislative and regulatory strategies that 1) severely restrict the ability of physicians to practice independently, treading back into dosing limit regulations, and worse,\textsuperscript{364} 2) actively discourage pain practice,\textsuperscript{365} and 3) curtail primary care providers from treating chronic pain patients.\textsuperscript{366} Some have proposed legislation that further scrutinizes prescribing practices of opioids only.\textsuperscript{367} For example, the Texas Pain Management Act, combined with medical board rules, require 40 plus specific documentation and care requirements for patients treating chronic pain.\textsuperscript{368} Maine’s Medicaid program instituted rules that significantly reduced coverage of opioids, requiring those in

\textsuperscript{363} See, e.g., Nat'l Center on Addiction & Substance Abuse, supra note 56.

\textsuperscript{364} See, e.g., Fla. Stat § 456.44 (2012), supra note 22 (mandating pain contracts, substance abuse screening, referrals under certain circumstances, and many other detailed requirements for each patient encounter);

\textsuperscript{365} Much of this has come through narrow definitions of pain clinics that subsume many prudent primary care practices, restrictive regulations, and even criminal penalties for those who are out of compliance. See e.g., Fla. Stat § 458.3265 Pain Management Clinics (2012); Ohio Admin. Code §§ 4731-29, Pain Management Clinics (2011) (requiring among other things, special daily logs of patients).

\textsuperscript{366} See, e.g., Fla. Stat § 458.3265, supra note 365 (mandating extension additional regulatory requirements for any provider who in any given month, treats 50.1\% or more of their patients for chronic pain and mandating criminal penalties for noncompliance).

\textsuperscript{367} See, e.g., N. MEX. COMP. CODE §§ 170.1-170.3 (2014). See also Louis Leichter, The Texas Intractable Pain Management Act and Chronic Pain, Texas Medical Licensing Law Blog, March 11, 2013, \url{http://www.tmmemlicensinglaw.com/2013/03/articles/texas-medical-board/the-texas-intractable-pain-treatment-act-and-chronic-pain/} (“whereas the Intractable Pain Management Act required heightened monitoring and rigorous documentation merely for known drug abusers, the Board’s most recent rules make that standard applicable to all long-term pain management patients”).
chronic pain to engage in alternate therapies for a year.\textsuperscript{369} Maine touted the success of that program by noting the drop in number of prescriptions for patients covered under Medicaid as well as private insurers, and that the guidelines were necessary to combat the “epidemic of opioid prescriptions.”\textsuperscript{370} On the other hand, the use of heroin has steadily increased over that same time period and there were new discrepancies in treatment based payer source.\textsuperscript{371} There is no concern reflected in these proposals for any of the harms of other classes of drugs, the risks of polydrug interactions, or the administrative costs required to effect the changes. They reflect an unfortunate opioid heuristic on the part of state legislatures.

Washington State is illustrative. In 2010, despite widespread opposition, the state legislature passed a bill for the purpose of reversing the increased trend of overdose deaths that applies only to the treatment of chronic non-cancer pain.\textsuperscript{372} Washington has fully embraced the attitude of Physicians for Responsible Opioid Prescribing who advance different treatment based on whether pain is cancer related or not. Washington State’s Agency State Medical Directors’ Group web site has all of their opioid prescribing “education” in a box entitled “Educational Materials presented by Physicians for Responsible Opioid Prescribing.”\textsuperscript{373}

\textsuperscript{370} See Blake Davis, \textit{supra} note 369 (quoting Roy McKinney, the director of Maine’s DEA).
\textsuperscript{371} Id.
\textsuperscript{373} Agency Medical Directors Group, State of Washington, \textit{available at http://www.agencymeddirectors.wa.gov/default.asp} (ironically, this is listed just to the right of Evidence Based Medicine).
The state law sets limits of dosing and treatment; it requires consultation with a pain management provider for any patient on daily doses of opioids at or over 120mg (in morphine equivalents). Using the Washington state’s opioid dose calculator, 120mg per day is a small to moderate dose: a typical prescription for acute pain in opioid naïve patients is 5mg hydrocodone/325mg acetaminophen combination pills with instruction of 1-2 pills, every 4-6 hours as needed for pain. A patient who follows those directions and takes one pill every 4 hours receives 30mg of hydrocodone in one day (equivalent of 120 morphine equivalents). These are not pain management doses and recall that the biggest risks involve polysubstance abuse, an issue unaddressed by the law. It is no wonder providers fear prescribing opioids at all. This is echoed by a Seattle Times article that quotes Dr. Peter McGough, chief medical officer for UW Medicine’s Neighborhood Clinics, saying “I think there’s been a fair amount of patient abandonment going on...a lot of physicians are saying it’s more trouble than it’s worth, so I’m just going to send my patients away.”

Of course, Washington already had a shortage of pain management providers, and some left the area in the wake of the restrictive regulations. The state health department, realizing that chronic pain patients would not have access, generously suggested they try alternative treatments like “yoga and massage.”

374 Id.
377 Over a third of primary care providers in Washington have trouble finding a pain specialist to consult. Gary Franklin et al., Changes in Opioid Prescribing for Chronic Pain in Washington, 26 J. AMER. BOARD FAM. MED. 4, 394-400 (2013).
378 Marshall P. Heringola, supra note 372.
although state Medicaid plans do not cover any of those costs.\textsuperscript{379} It also includes a host of practice requirements, including mandatory treatment agreements, mandatory pain care plans, and mandates that make providers responsible for monitoring patient “compliance.”\textsuperscript{380} An article in the Seattle Times highlighted the very real harm to patients with CP,\textsuperscript{381} describing the plight of a man with CP from chronic liver disease who had managed his pain for eight years on a small and steady dose of oxycodone (a generic short acting opioid). After the law took effect, every doctor in his clinic stopped prescribing opioids, rendering him and other patients far less functional and with increased suffering for no justifiable medical reason.

c. Medicaid Fraud as Drug Control

Some states, such as Tennessee, have also committed serious time and resources to fraud investigations; for example Tennessee Medicaid (TennCare) recipients are aggressively prosecuted for violation of the doctor-shopping statute,\textsuperscript{382} which makes it a crime for TennCare recipients to receive more than one prescription for any controlled substance from more than one doctor in any thirty-day period.\textsuperscript{383} The reason for the second prescription may not matter: all prescribers are now required to register prescriptions of opioids, benzodiazepines,

\textsuperscript{379} Id. (citing Patricia Murphy, Washington State Pain Management Law Will Take Effect Soon, KUOW News, June 24, 2011).
\textsuperscript{380} Id.
\textsuperscript{381} Ken Armstrong & Michael J. Berens, New State Law Leaves Patients in Pain, supra note 38.
\textsuperscript{382} See e.g, Tennessee News and Media Center, Hamblen Co. Woman Charged with TennCare Drug Fraud (March 3, 2015) available at https://news.tn.gov/node/13590 (“We hope those that are abusing the TennCare program are getting the message that we are aggressively pursuing TennCare fraud and making arrests statewide,” Inspector General Manny Tyndall said. “We made 22 arrests last month and we have many more cases in the pipeline.”)
and select other drugs with Tennessee’s prescription drug monitoring program (PDMP) and may not ever prescribe more than a thirty day supply, regardless of the circumstances. Access to the PDMP by law enforcement, including the office of the inspector general investigating TennCare fraud, does not require probable cause.

**d. Prescription Drug Monitoring Programs**

Along with Tennessee, 48 other states have PDMPs but their efficacy varies widely from helpful to completely ineffective. On the whole, they have not reduced the amount of opioids prescribed, although the value of that fact is questionable, particularly if the goal is to decrease diversion. Most of the time, as currently executed, the information included in the PDMPs is incomplete at best. Most states do not require prescribers to consult the database before prescribing or to report their prescriptions in all circumstances. There is some evidence that prescriber participation is highly variable. Even for those that use PDMPs, the utility can be limited by delays in reporting (many are updated only weekly or monthly).

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384 TENN. CODE ANN. §53-11-308 (2015) (Section (e) states “no prescription for any opioids or benzodiazepines may be dispensed in quantities greater than a thirty-day supply” and section (f) states, in relevant part, “If a prescriber dispenses any opioids, benzodiazepines, barbiturates, or carisoprodol, then the prescriber shall submit the transaction to the controlled substances monitoring database”).

385 See TENN. CODE ANN. §53-10-306 (2015) (requiring a case number before accessing the database, as well as some other procedures but nothing approaching probable cause).


388 See Allison Lange et al., Variability in Opioid Prescription Monitoring and Evidence of Aberrant Medication Taking Behaviors in Urban Safety-Net Clinics, 156 PAIN 2, 335-340 (2015); Robert K. Twillman et al., Efforts to Control Prescription Drug Abuse: Why Clinicians Should be Concerned and Take Action as Essential Advocates for Rational Policy, 64 CANCER J. FOR CLINICIANS 6, 369-376, 373 (2014) (“one of the biggest challenges...is the generally low adoption of PDMP use by providers”).

389 For example, California and Florida only have weekly updates of data. See Nat’l Alliance for Model State Drug Laws, supra note 387.
level of communication between states also varies. PDMPs are most promising when they are constructed as a clinical tool rather than a law enforcement vehicle, where they can allay any concerns a provider might harbor and mitigate the chilling effect. Policies that require use by clinicians, facilitate real time reporting, and interstate communication may best serve both the providers and patients in pain. On the other hand, there are serious concerns about the impact of PDMPs on 1) providers who are seen as "high volume" prescribers, such as those that specialize in pain treatment; 2) privacy of the information, particularly as PDMPs increasingly involve other clinical data, 3) scrutiny of patients on long term opioids, and 4) the time demands of compliance. In short, more evidence is needed to determine the impact of PDMPs on patient care.

2. Failure to Reduce Harm

All of these efforts, at best, reduce the number of prescriptions available for diversion. The reality is that the rate of substance abuse has remained very stable over time, even as the drugs of choice have changed. In fact, Tennessee and Kentucky have experienced very recent increases in heroin use in the wake of

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390 Id. Florida, for example, has no interstate sharing while having stringent pain clinic and practice laws, a combination sure to discourage reasonable providers from prescribing opioids.
391 Robert K. Twillman et al., supra note 388.
393 Some limits have been placed on law enforcement's unfettered access to PDMPs. For example, in 2014, a federal judge held that a warrant was required before the DEA could access Oregon's state PDMP. See Steve Gorman, U.S. Judge Blocks Warrantless Searches of Oregon drug database, REUTERS (February 12, 2014).
394 Id.
395 For an excellent overview of the ways that prescription opioids are used interchangeably—depending upon supply issues—with "legacy drugs" such as heroin, See Ken Lammers Jr., Rise of the Pills, 15 U. D.C. L. Rev. 91 (Fall 2011).
aggressive targeting of prescription opioids.\textsuperscript{396} Recently the CDC reported, “the death rate from heroin overdose doubled in the 28 states from 2010 to 2012...Comparing the same years, the death rate from prescription opioid overdose declined 6.6%.”\textsuperscript{397} In the South, the contrast was most stark, with an increase of 181% of heroin deaths and a 16.3% decrease in prescription opioid death rate.\textsuperscript{398} In Florida, the overdose death rate related to opioids decreased 28.4% but the heroin overdose death rates increased 122.4% in that same time period.\textsuperscript{399} At best, the policy changes in Florida may have shifted some people with SUD away from prescription opioids; harm reduction overall may be negligible. It also calls into question whether resources would be better spent on access to treatment for SUD and other harm reduction strategies. At the same time suffering of many patients likely went undertreated, an unacceptable solution.

For those providers still willing to prescribe opioids, or even to specialize in pain treatment at all, the administrative burdens necessary to guard against legal entanglement now include a complex mix of additional agreements, testing, screenings and reassessments are part of the unfortunately named, “universal precautions” for pain treatment.\textsuperscript{400} Along with the epidemic metaphor, universal


\textsuperscript{398} Id.

\textsuperscript{399} Hal Johnson et al., Decline in Drug Overdose Deaths after State Policy Changes-Florida: 2010-2012, 63 MMWR 26, 569-574 (July 4, 2014).

\textsuperscript{400} The term was borrowed from the infectious disease literature, where it refers to the protective gear and other measures to guard against unknowing transmission of disease that has not yet manifested in symptoms. I feel comparing patients in pain to infectious micro-organisms does little to
precautions is borrowed from infectious disease, but there they are guarding against an actual pathogen. Here, they seem to effectively construct the patient or the patient’s behavior as an infectious organism to be guarded against. Universal precautions include risk screenings, without any agreement on how to do so, that places patients in one of three risk categories: low, medium, and high.\textsuperscript{401} The higher risk patients receive less medication and much more scrutiny.\textsuperscript{402} Along with longer standing traditions of urine screening and pain agreements, these strategies have turned to detailed mandates in some states.\textsuperscript{403} These requirements are not low risk or without costs: they represent an invasion of the practice of medicine, create significant administrative hurdles, and are financially burdensome for patients and payers.

\textit{a. Pain agreements}

When a physician asks a patient to sign an opioid contract, especially one requiring random drug screens, the message is clarion, “I don’t trust you.” Trust moves in both directions, and if the doctor does not trust his patient, then why should the patient trust his physician?\textsuperscript{404}


\textsuperscript{402} Id.

\textsuperscript{403} Kentucky, Indiana, and Washington all mandate these along with a list of required steps, warnings, and procedures for informed consent and ongoing treatment. Tennessee “strongly suggests” them. See KY.REV.STAT. §218A.172 (2013) & 201 KAR 9:260 (2013) (requiring ongoing drug screenings that are random and unannounced); Indiana Medical Licensing Board, Rule 6, Opioid Prescribing Requirements, 844 IAC 5-6 (2014); WASH.ADMIN.CODE §246-919-856 (2012) (Written Agreement for Treatment).

\textsuperscript{404} Mark Collen, \textit{Opioid Drug Contracts and Random Drug Testing for People with Chronic Pain-Think Twice}, 37 J. L.MED. & ETHICS 841 (2009).
Many physicians require treatment agreements for all patients on opioids, especially over the long term. This practice, while recommended by a multitude of professional guidelines and state laws, has proven to be both unreliable and inconsistent, a sentiment echoed by even those in strong support of limiting opioid use.\textsuperscript{405}

Agreements are controversial and questions are raised regarding their intent, elements, language and tone, readability, physician responsibility, and legal risk...\textsuperscript{406} While the evidence that opioid treatment agreements are effective in reducing misuse is relatively weak and they have not been proven to improve adherence, patient care, or protect the rights of patients or physicians.

Treatment agreements hold the potential to show respect for the patient and enhance autonomy by providing an opportunity for discussion and robust informed consent; they also risk the opposite by serving as a precondition for the receipt of pain relieving drugs or even treatment.\textsuperscript{407} Nonetheless, the pain agreement is probably now the standard of care given the high level of pain specialist adoption, provider groups, and endorsement or mandate by state legislatures and regulatory agencies.\textsuperscript{408} Thus, reasonable prescribers will feel obligated to utilize treatment agreements, whether or not the evidence supports them. On the other hand, when used primarily to “1) document understanding between patient and clinician on


\textsuperscript{407} See Richard Payne et al., \textit{A Rose by Any Other Name: Pain Contracts}, 10 \textit{AM. J. BIOETHICS} 11, 5-12 (2010).

\textsuperscript{408} See, e.g., Federation of State Medical Boards, \textit{supra} note 342.
goals and plans of care and 2) provide informed consent to treatment,”
and combined with a holistic approach to treatment, there is hope that agreements
won’t do more harm than good.

b. Urine and Substance Abuse Screenings

I am a 57 year-old, partially disabled man on a limited income.
Though I don’t use any illicit or illegal drugs, I already have to subject
myself to - and pay for - tests to ensure that I’m not using illicit drugs
whenever I have a hydrocodone prescription filled. Over the years, I
have never tested positive for illegal drugs, yet this insulting procedure
continues to be performed ... If it is felt that measures must be taken
to reduce illicit use, concentrate those efforts on illicit users and do
not make pain patients part of the collateral damage.

Regular and random urine drug screenings are usually part of the treatment
agreement; these are usually coupled with other screening for substance abuse or
misuse, especially at the beginning of therapy. Instituted years ago for risk
management purposes, these tools also rest on a weak evidence base but are now
recommended for patients on opioids, at any frequency, for three months or
more. In addition to testing for illicit drugs, testing for the prescribed drug is
recommended. Even after a series of typical or expected findings, providers are told

409 Martin Cheatle & Seddon R. Savage, supra note 405 at 107.
410 Thomas T. Toups, Comment on FR Doc # 2014-04333, ID# DEA-2014-0005-0164, Rescheduling of
Hydrocodone Combination Products from Schedule III to Schedule II, (April 2, 2014), available at
411 These too are weak in terms of effectiveness. See Joanna L. Starrels et al., Systematic Review:
Treatment Agreements and Urine Testing to Reduce Opioid Misuse in Patients with Chronic Pain, 152
ANNALS INTERNAL MED. 11, 712-720 (2010). This does not stop virtually every group from
recommending them. See, e.g., Laxmaiah Manchikanti et al., ASIPP Guidelines for Responsible Opioid
412 See Ted Jones et al., Comparison of Various Risk Screening Methods, 28 CLINICAL J. PAIN 2, 93-100
(2012).
413 See, e.g., John F. Peppin et al., supra note 405 (reporting on the results of a national panel
convened to examine the decade long practice of urine screening and begin to develop consensus
standards for use).
to test patients at least every six months.\textsuperscript{414} Moreover, some states are now requiring urine testing, a mandate now challenged in several jurisdictions as an unconstitutional search and seizure.\textsuperscript{415}

How providers interpret the findings is paramount. For example, if urine screening shows no opioids in the patients’ system, it could indicate diversion, binge use, or simply that their pain is doing better and they are only taking the medication as needed.\textsuperscript{416} Here, as with other tools, providers need to carefully interpret the information with the patient in context.\textsuperscript{417} Unfortunately, there is some evidence that this is not occurring. For example, in a study by Clancy and colleagues, a survey of clinicians revealed that providers might not be prioritizing the well-being of the patient. When asked what action they take if a urine screening reveals an illicit drug, a greater percentage of the clinicians surveyed would discharge the patient from practice than even those who would talk to the patient about the results or refer them for substance abuse treatment.\textsuperscript{418} This is not an ethically acceptable response; according to Reisfeild and Marschke,

\begin{quote}
Discharging a patient from a medical practice is virtually never an acceptable response to an inappropriate drug test. The clinician
\end{quote}

\begin{footnotesize}
\begin{enumerate}
\item \textsuperscript{414} Id. at 890 (recommending unpredictable drug use monitoring such as a flip of a coin at each visit as well as a “minimum of test conducted every 6 months for patients at low risk of misuse”).
\item \textsuperscript{415} The ACLU has taken up the cause with a class action lawsuit against the Indiana medical board in Wierciak v. The Individual Members of the Licensing Board of Indiana, (S.D. Indiana 2012). The Indiana medical board changed their regulations slightly in November 2014 to remove the mandatory requirement for urine screening and instead make it subject to “medical necessity.” See ACLU of Indiana, ACLU Challenges Required Drug Testing for Patients on Pain Medications, \url{http://www.aclu-in.org/issues/justice/drug-testing/88-state-goes-too-far-drug-testing-pain-med-patients}.
\item \textsuperscript{416} See John F. Peppin et al., \textit{supra} note 405 at 891 (Table 1).
\item \textsuperscript{417} \textit{See}, e.g., Paul J. Christo et al., \textit{Urine Drug Testing in Chronic Pain}, 14 \textit{PAIN PHYSICIAN} 123-143 (2011) (“While its role should not be overstated, physicians should avoid making judgments about patients’ compliance based solely on the results of the urine test”).
\item \textsuperscript{418} Zoe Clancy et al., \textit{The Use of Urine Drug Monitoring in Chronic Opioid Therapy: An Analysis of Current Clinician Behavior}, 9 \textit{J. OPIOID MANAGEMENT} 2 (2013).
\end{enumerate}
\end{footnotesize}
should use drug test results as data points, to be integrated with the patient's history and other relevant pieces of clinical information, to determine whether a clinical problem exists, and, if so, the nature of the problem. Reflexively discharging a patient means forfeiting an opportunity to initiate a dialogue about the patient's drug use, including patterns of use and motivations for misuse, and when appropriate, to initiate or refer for evaluation and treatment of a suspected substance use disorder.  

Perhaps the most under-addressed problem with urine screening is the significant associated costs. One of the few professional articles to mention the issue does so as one sentence, warning that “each time a physician orders a drug test from the lab, he or she should realize that the cost of this is going to be higher than the cost of most of the interventional techniques we will be performing on these patients.” This statement proved predictive: according to a recent article in the Wall Street Journal, “some pain doctors are making more from the testing than from treating.” Described as “roundabout result of the war on pain-pill addiction,” Medicare spending on testing for drugs of abuse has increased 1,423% in the last five years. This is a serious societal cost for testing that is often of no benefit to the patient, especially after an established pattern of consistent results. The cost to the patients is also significant, especially if Medicare does not cover them; some private payers limit the conditions and the frequency with which urine testing is covered. Some doctors have taken advantage of the profit potential and set up

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421 Paul Christo et al., *supra* note 417 at 136 (emphasis added).
422 See Christopher Weaver & Anna Wilde Matthews, *supra* note 420.
423 *Id.*
services in their offices;425 the Wall Street Journal article profiled one doctor who made $1.4 million in one year just for testing his own patients and quoting him as saying, “urine testing is how I pay the bills.”426 Like so many other strategies in this area, how urine testing is conducted (frequency, cost, substances screened for, etc.), its effectiveness in helping providers and patients better manage their medical conditions, and how best to assist those with SUD discovered through testing requires further study.

3. Continuing Panic

The urgency with which these suggestions and others are advanced has intensified, possibly as a result of availability cascades, and there is reason for pessimism for the near future for patients in pain. Robert Twillman and colleagues worry that

the quality of care gains made in pain treatment that have helped preserve the function status and quality of life for many individuals with pain, whether or not the pain is related to cancer, may be in jeopardy. That is a steep and unacceptable price to pay in the name of taking a strong national stand against prescription drug abuse.427

There have been new attempts to discredit the use of opioids in CP; however, some of the reasonable reevaluation of their effectiveness confirmed that they are effective in well selected and evaluated patients.428 In addition to the restrictive

non-covered on page 3 "routine qualitative urine drug testing (e.g., testing at every visit, without consideration for specific patient risk factors, current clinical presentation, current medication program or how the test findings will impact treatment options)”).

425 This is presumably accomplished under the in-office ancillary services exception under the Stark Law, See 42 C.F.R. 411.355(b).
426 See Christopher Weaver & Anna Wilde Matthews, supra note 420 (discussing Dr. Hadley’s practice).
427 Robert K. Twillman et al., supra note 388 at 369.
428 See, e.g., Alec B. O’Connor & Robert Dworkin, Treatment of Neuropathic Pain: An Overview of Recent Guidelines, 122 AMER. J. MED. S22-S32 (2009) (Reaffirming opioids are second line treatments
state laws discussed above, federal legislation was proposed to further restrict labeling of oxycodone containing opioids only. The U.S. Senate Finance Committee launched an investigation aimed at connecting payments from pharmaceutical companies to organizations long known for advocating for the reasonable treatment of people in pain. The Federation of State Medical Boards has revised its Model Policy for Opioid Prescribing, adding much more restrictive language and requirements by which boards of medicine will judge physicians’ practices in this area.

A 2013 study by Bergman and colleagues indicates serious reservations by primary care doctors with respect to their patients in pain, lingering disbelief and worries about diversion. Another article indicated almost outright contempt by some providers for patients in CP. The American Academy of Emergency Medicine developed a model policy that reflects common areas of bias more than evidence, discouraging the use of opioids at all for acute back pain, dental pain,

that be used as first line treatments in certain circumstances); Ewan McNicol et al., Opioids for Neuropathic Pain, Cochrane Database of Systemic Reviews Library, Issue 8, 1-99 (2013) (declaring strengthened evidence for intermediate opioid use).

430 See Ben A. Rich, supra note 1 at 524 (the committee sent letters to Joint Commission, the Mayday Fund, the Center for Bioethics, the Wisconsin Pain & Policy Studies Group, among others)
432 Alicia A. Bergman et al., supra note 181.
433 Jeffrey A. Glassberg et al., Emergency Provider Analgesic Practices & Attitudes Toward Patients With Sickle Cell Disease, 63 Annals of Emergency Med. 4, 293-303 (2013) (emergency providers with the highest patient volumes have the most negative attitudes toward patients with sickle cell and are the least likely to follow practice guidelines of redosing patients with opioids).
pelvic pain, or migraines;\textsuperscript{434} these include some of the types of pain for which patients are at the highest risk of suicide. Worse yet, multiple visits to an ED for pain alone triggers the recommendation that the patient’s chart be “flagged” and that she receive a letter informing her that she will not receive opioids for pain again.\textsuperscript{435} The One hospital in Wisconsin’s emergency department sent letters to all of their repeat patients stating that they would not be prescribing pain medications for any reason.\textsuperscript{436} In New York, the city’s “Discharge Opioid Prescribing Guides” urge physicians to only give a maximum of a three-day prescription (describing a day’s supply as one or two doses) to patients in acute pain; patients in chronic pain should be managed \textit{without any} opioids according to the guidelines.\textsuperscript{437} EDs around the country have taken to posting “pain management” signs declaring that even acute exacerbations of painful conditions will never be treated with opioids.\textsuperscript{438}

\textbf{VI. Policies that Reduce Harm while Preserving Goods}


\textsuperscript{435} American Academy of Emergency Medicine, \textit{supra} note 434. This of course will disproportionately impact those who already have access to care issues, such as the socioeconomically disadvantaged populations who use the ED as a safety net.

\textsuperscript{436} Ken Solis, \textit{supra} note 23 at 91. (describing letters from Wisconsin ED to “frequent flyers” that they would no longer receive pain medication for their pain).

\textsuperscript{437} New York City Dep’t of Health & Mental Hygiene, \textit{NYC Emergency Department Discharge Opioid Prescribing Guidelines} (January 2013).

\textsuperscript{438} \textit{See}, e.g., Robert A. Bitterman, \textit{The Federal Government Blocks South Carolina Hospitals from Posting Pain Management Signs in their Emergency Departments}, \textit{ED LEGAL LETTER} (July 1, 2013), available at \url{http://www.ahcmedia.com/articles/63616-the-federal-government-blocks-south-carolina-hospitals-from-posting-8216-pain-management-signs-8217-in-their-emergency-departments} (“As part of their opioid prescription initiatives, states such as Washington, Oregon, Colorado, and Ohio developed and displayed posters in their emergency departments to “educate” patients regarding the ED’s restrictions”).

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Some sanity remains in the midst of the incoherent policies. For example, the Atlanta Regional Office of CMS blocked South Carolina from posting the “pain management” signs as a potential EMTALA violation.\footnote{Id. (severe pain is component of many emergency medical conditions and preemptively discounting patients with such complaints could lead to a failure to provide an appropriate medical screening and evaluation.)} Such signage may also violate EMTALA as coercive and intimidating to patients and discourage help seeking for painful symptoms.\footnote{Id.} A few professional groups, such as the American Society for Pain Management Nursing, have taken the opportunity to issue policy statements that support the treatment of both patients in pain and patients with substance abuse disorders.\footnote{Julie Oliver et al., supra note 161 (“failure to identify and treat the concurrent conditions of pain and substance use will compromise the ability to treat either condition effectively).} The American Academy of Pain Medicine has been vocal in terms of advocacy as well.\footnote{American Academy of Pain Medicine, \textit{Position Statement: Use of Opioids for the Treatment of Chronic Pain} (February 4, 2013).} Even some community leaders understand the need for overall harm reduction; for example, Dr. Wheeler was quoted as saying “Communities must change their perception of drug abuse...these drug-addicted persons are worth something.’ We have to tell them, ‘you aren't trash. You are a human being, and you are deserving of this community’s respect, and we’re going to help you.’”\footnote{Dr. Wayne Wheeler made this statement at community meeting organized by the Ohio Attorney General on curbing drug abuse. Heather Zachariah, \textit{Scioto County Describes how it Cleaned up Drug Abuse}, \textit{The Columbus Dispatch}, October 24, 2013, available at http://www.dispatch.com/content/stories/local/2013/10/24/scioto-county-describes-how-it-got-clean.html.} Several policy and practice solutions have emerged that reflect overall concern for harm reduction.

A. Safe Storage & Disposal
Providing individuals with a safe way to dispose of their unused prescription drugs, including opioids and benzodiazepines, is an important component of synchronized policy solutions. Recall that most people who abuse opioids obtain them from others (via theft, gift, or sale). Policy efforts in this area have taken the form of take back initiatives, from the federal to the local level. In 2010, the Secure and Responsible Drug Disposal Act of 2010 was passed. The Act amended the CSA to allow users, for the first time, to deliver their leftover controlled substances to another person or entity for disposal, and expanded the permissible methods of collection. The DEA has sponsored take back events since 2010, often in conjunction with local law enforcement. Over the last four years, these events have collected 2,411 tons of unused opioids. Patients prescribed opioids for home use should also use a locked container or drawer for storage, reducing the likelihood of diversion by theft. Legal efforts in this area are scant but the opportunity is significant. In light of the available evidence, the “data reinforce the importance of investing in strategies that educate consumers, prescribers, and pharmacists about the importance of safe medication storage.”

B. Naloxone Access, Distribution, and Immunity


Id. See also, DEPT OF JUSTICE, Disposal of Controlled Substances, Final Rule, 79 FEDERAL REGISTER 174, 53520-53570 (September 9, 2014).

See, e.g., Robert K. Twillman et al., supra note 388 at 372-373.

Drug Enforcement Agency, supra note 59. This also speaks to the fact that exposure alone does not “create addiction.”

See, e.g., The Network for Public Health Law, Requirements for Lock Box Use for Methadone (November 21, 2014), available at https://www.networkforphl.org/resources_collection/2014/11/21/522/requirements_for_lock_box_use_for_methadone (explaining that Colorado requires patients on methadone maintenance through a treatment facility only to have a locked container for storage).

Robert K. Twillman, supra note 388 at 372.
Naloxone hydrochloride (naloxone) is an opioid antagonist; it blocks the effects of prescription opioids and heroin and can prevent or reverse potentially lethal respiratory depression, sedation, and hypotension,\textsuperscript{450} symptoms of which begin approximately one to three hours after consumption of the opioids but progress over an hour or more.\textsuperscript{451} These deaths are almost completely preventable.\textsuperscript{452} Timely administration of naloxone can prevent death;\textsuperscript{453} further, the ability of laypeople and bystanders to safely administer the drug is established.\textsuperscript{454} However, multiple barriers prevent access to or timely administration of the drug.\textsuperscript{455} Naloxone is a prescription drug, thus access is limited to authorized prescribers and the existence of a provider patient relationship.\textsuperscript{456} Fear of criminal liability for illicit drug use by bystanders and participants may also delay or prevent help seeking behavior or attempts to rescue someone experiencing symptoms of opioid overdose.\textsuperscript{457} Thus, the “law is a primary driver” of barriers to Naloxone use.\textsuperscript{458}

\textsuperscript{450} See, e.g., Endo Pharmaceuticals, FDA Approved Labeling for Narcan (brand name naloxone hydrochloride), label 5 1-022.523-00 (July, 2003), available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2002/016636s052s054lbl.pdf.


\textsuperscript{452} Corey Davis et al., Changing Law from Barrier to Facilitator of Opioid Overdose Prevention, 41 J. LAW MED. & ETHICS 33 (Spring 2013).

\textsuperscript{453} It must be timely though. A review in North Carolina showed that equipping first responders is not enough because half of overdose victims died between the time 911 was called and responders arrived. \textit{Id}.

\textsuperscript{454} Id. The drug is also now available in nasal spray form for emergency use. See, e.g., Amanda Robinson & Daniel P. Wermeling, Intranasal Naloxone Administration in Treatment of Opioid Overdose, 71 AMERICAN J. HEALTH SYSTEM PHARMACY 24, 2129-2135 (2014) (finding the use of intranasal administration was comparable to IV administration in the pre-hospital setting).

\textsuperscript{455} See, e.g., Hewlett & Wermeling, supra note 451.


\textsuperscript{457} Id.

\textsuperscript{458} See Corey Davis et al., supra note 452.
The law can also be a solution, as initiatives in several states and communities have shown. More than half the states have taken legislative action to address some or all of these barriers. The most successful of these have 1) comprehensive Good Samaritan provisions that extend immunity for drug related criminal offenses discovered secondary to seeking help, 2) expanded access through third party prescriptions, 3) grants of prescriptive authority to non-physician providers (e.g. pharmacists, nurse practitioners, physician assistants, psychologists), 4) distribution and training to all first responders, 5) and funding for community based education and training. The idea of reclassifying Naloxone as an over the counter drug is being explored. To effectively reduce harm, the laws should operate to put Naloxone in as many hands as possible; including anyone who takes opioids in any form, as well as their friends and family members. The laws must also incentivize its good faith use by removing legal disincentives, such as fears of criminal or civil liability and regulatory scrutiny, and informing would be users of those protections.

Community based programs that educate the population and increase access have been successful. A 2014 article in JAMA featured the work of Project Lazarus, a group in North Carolina that works to educate and distribute Naloxone throughout

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461 *Id.* See also, Davis et al., * supra* note 452.

the community, focusing on the loved ones of persons with SUD, law enforcement, patients with CP on opioids, and community groups.\textsuperscript{463} As of December 2014, nearly 200 community-based groups that distribute naloxone are estimated to have prevented 10,000 overdose deaths.\textsuperscript{464}

Despite the incredible potential to significantly reduce harm, these laws have faced criticism by some,\textsuperscript{465} mostly based on theories of risk compensation, essentially that users will consume opioids more recklessly if they feel protected by the availability of naloxone.\textsuperscript{466} Although the objection is not without precedent, previous study has failed to demonstrate empirical support for the idea in other contexts.\textsuperscript{467} Even accepting the idea of risk compensation as a real phenomenon, research has already shown the naloxone availability is saving lives while the overall level of SUD is stable. Naloxone availability reduces harm across the board and can also serve as a compelling catalyst for treatment.\textsuperscript{468} In testimony before a combined meeting of the FDA, CDC, National Institute of Drug Abuse, and others, Scott Burris put it this way,

\begin{quote}
We know we have a drug. We know how it works. We know it's generally effective for the use to which it's being put...we really don't have any stories of disasters. We have some concerns and some anecdotes, and we certainly have reason to continue to do research.
\end{quote}

\begin{itemize}
\item \textsuperscript{463}Bridget M. Kuehn, \textit{Back from the Brink: Groups Urge Wide Use of Opioid Antidote to Avert Overdoses}, 311 J. AMERICAN MED. ASS'N 6, 560-561 (2014).
\item \textsuperscript{464}The Network for Public Health Law, \textit{supra} note 456 at 2.
\item \textsuperscript{465}See generally, Food & Drug Administration et al., \textit{supra} note 462 at 360-370 (comments of Dr. Madras).
\item \textsuperscript{466}For a discussion of the role of risk compensation in public health polices, see, e.g., Kristen Underhill, \textit{Risk-taking and Rulemaking: Addressing Risk Compensation Behavior through FDA Regulation of Prescription Drugs}, 30 YALE J. ON REG. 377 (2013).
\item \textsuperscript{467}Id. at 392-393 (surveying the many areas in which this has been studied).
\item \textsuperscript{468}Food & Drug Administration et al., \textit{supra} note 462 (comments of Scott Burris).
\end{itemize}
But what we don't have now I think is reason to wait... What we can't do is walk away from here and wait a decade for real change.\textsuperscript{469}

\section{Conclusions}

Policies that address this complex problem with a goal of allowing providers to care for patients without undue interference are needed. Table 1 summarizes the policies that can further harm reduction. Mechanisms to facilitate trusting relationships between patients and providers are needed. Patients in pain and patients with SUD or other comorbid conditions are all legitimate patients. Policy solutions should incentivize treatment, referrals, and engagement with patients without fear of scrutiny. A patient in pain should be treated and those seeking help for suicidal intent or substance abuse must trust their provider to get them appropriate referrals. The trust between provider and patients needed for this level of communication is not facilitated by regulatory efforts that intrude on the relationship and incentivize provider suspicion. Practice guidelines should include concerns about screening patients for suicidality at least as often as screening for diversion. Policies that reduce barriers to interdisciplinary practice as well as access to treatment for SUD are necessary to create a centrally coherent harm reduction policy.

Education may be helpful but to the extent state boards mandate training, that training should include not only education about pain and comorbidities, including SUD and SMI, but also training on cognitive error and biases and strategies to avoid those traps. These represent an important barrier that no level of education

\textsuperscript{469} Id. at 333-334.
about pain will solve. Providers are ethically obligated to minimize the effect of these on decision-making, for the benefit of their patients. Patient education efforts must be emphasized in primary care and should involve information about secure storage of extra medication and information about appropriate disposal. All primary care providers need more support to adequately care for these complicated patients.

Public health campaigns that focus on the problems of suicide, pain, and substance abuse in this area should be encouraged. More standardized data is required, as well as standardization of post-mortem toxicology and death certificate consistency. For example, SAMHSA could add questions about pain to the national survey to develop a better of the overlap between pain, substance abuse, and mental health disorders. In addition, the expansion of existing state naloxone access and immunity laws is warranted. The problems are complex; the solutions must be nuanced and proportionate to provide treatment options for patients in pain as well as those suffering co-morbid disorders.
<table>
<thead>
<tr>
<th>Policy</th>
<th>Level of Implementation</th>
<th>Conditions necessary to enhance patient wellbeing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mandatory Provider Education</td>
<td>SBM</td>
<td>Comprehensive coverage needed of pain, SUD, suicidality, and other comorbid conditions; one sided or fragmented mandates are of little use</td>
</tr>
<tr>
<td>PDMPs</td>
<td>State statutes and regulations, communication may be facilitated through federal channels</td>
<td>Real time reporting, communication with neighboring states, mandatory use by providers and pharmacies, protections for patient privacy</td>
</tr>
<tr>
<td>ED initiatives, notice of refusal to treat patients with CP with opioids</td>
<td>Local and practice level</td>
<td>No justification for a blanket refusal to consider one tool in treating pain outside the context of a specific patient encounter</td>
</tr>
<tr>
<td>Naloxone access and immunity provisions</td>
<td>State statutes; FDA could eventually reclassify as over the counter</td>
<td>Access through third party prescribing (standing orders and good faith immunity for prescribers); provide to first responders, patients with SUD, history of overdose, and those on chronic opioid therapy and their loved ones; fund public education campaigns and community distribution; provide immunity from drug related prosecution for help seeking for overdosing patient; provide immunity from unauthorized practice of medicine claims for rescuers.</td>
</tr>
<tr>
<td>Treatment Agreements</td>
<td>Practice Level; SBM, state statutes</td>
<td>No justification for state mandated agreements. Use in practice to improve communication and appropriate treatment and not as a justification for discharging patient.</td>
</tr>
<tr>
<td>Debiasing Training</td>
<td>Practice level; SBM</td>
<td>Mandatory CMEs that incorporates debiasing but is not diagnosis specific may improve care to all patients but more research needed.</td>
</tr>
<tr>
<td>Urine screening</td>
<td>Practice level; SBM</td>
<td>These should not be mandated by state regulatory agencies. In practice, should focus on those with highest risk of misuse as part of a comprehensive treatment and assessment strategy. They should not be used routinely or simply to generate revenue.</td>
</tr>
<tr>
<td>Safe Storage and Disposal</td>
<td>Federal (DEA), state &amp; local community, law, regulation &amp; outreach; practice level</td>
<td>Treatment agreements should include strong recommendations for patients receiving opioids to have locked storage. Community distribution programs should be explored. Mechanisms for providers to distribute lock boxes to patients without violating self-referral or other fraud and abuse laws should also be explored. Federal government should continue to facilitate already successful take back campaigns and increase community disposal locations.</td>
</tr>
<tr>
<td>Opioid dosing and percentage of patients restrictions</td>
<td>State statutes and SBM</td>
<td>Requirement that pain clinics run by board certified physician reasonable. All other requirements lack evidence base sufficient to justify to burdens on access to care for patients in pain.</td>
</tr>
<tr>
<td>Data collection</td>
<td>Federal &amp; state government; private agencies</td>
<td>Data on rates of chronic or persistent pain should be collected from SAMSHA with other survey data in order to provide a complete picture on overlap of conditions. Reporting on poisonings should separate out those that are intentional vs. unintentional as well as those that are opioid only, the proportion of methadone involvement, and those that involve polysubstance ingestion.</td>
</tr>
</tbody>
</table>