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

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INTRODUCTION

"[A]n ethically and clinically sound public policy response will not dis-count or disfavor one crisis in order to obsessively focus upon the other."\(^1\)

Hyrum Neizer would be dead today if his wife hadn’t walked in on him with the gun in his mouth. He was in un-remitting 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.\(^2\)

Primary pain conditions are among the most medically complex problems that providers face.\(^3\) 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.\(^4\) Decades of thoughtful, inter-disciplinary policy work in the 1990s and early 2000s improved the en-vironment for both the patients in pain and their providers.\(^5\) Some of that progress, however, is compromised by the understandable but ultimately incoherent responses to the reported rise in prescription drug overdose deaths in the United States (U.S.).

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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, 11-12 (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, 21-23 (2003); Ben A. Rich, An Ethical Analysis of Barriers to Effective Pain Management, 9 CAMBRIDGE Q. OF HEALTHCARE ETHICS 54, 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 “increase the recognition of pain as a significant public health problem in 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).
Several years ago, the Centers for Disease Control and Prevention (CDC) described increased rates of opioid related overdoses (OROs),\(^6\) eventually declaring an epidemic of ORO deaths.\(^7\) This 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.\(^8\) 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 “opioid epidemic,”\(^9\) by 2012, Laxmaiah Manchikanti and colleagues omitted the words “overdoses” or “poisonings” altogether in publications and instead declared an “opioid epidemic with adverse consequences.”\(^10\) They blamed everything from liberalized laws, to the Joint Commission on Accreditation of Healthcare Organizations, pharmaceutical companies,\(^11\) and even campaigns “touting the alleged undertreatment of pain.”\(^12\) The opioid epidemic language is now in mainstream use without

\(^6\) This is the formal name for narcotic pain relievers or pain medicine. Opioids are “[a]ny compound that binds to an opioid receptor.” INST. OF MED., RELIEVING PAIN IN AMERICA: A BLUEPRINT FOR TRANSFORMING PREVENTION, CARE, EDUCATION AND RESEARCH 279 (2011), http://www.nap.edu/read/13172/chapter/1. [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. Unintentional Poisoning Deaths—United States, 1999-2004, 56 MORBIDITY & MORTALITY WKLY. REP. 93, 93-96 (Feb. 7, 2007), [hereinafter Unintentional Poisoning Deaths] (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.


\(^10\) Id. at ES9.

\(^11\) 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 in instructing patients. See, e.g., United States v. Purdue Frederick, 495 F. Supp. 2d 569 (W.D. Va. 2007); see also Kathleen M. Boozang, Responsible Corporate Officer Doctrine: When is Falling Down on the Job a Crime?, 6 ST. LOUIS U. J. HEALTH L. & POL’Y 77 (2012).

\(^12\) Manchikanti et al., supra note 9, at ES9 (emphasis added). There is a significant difference between an epidemic in opioid related drug overdoses and an epidemic of opioids
qualification. It is one of several common uses of infectious diseases vocabulary that attributes pathogen status to prescription opioids and patients in pain. These responses come at the expense of patients already vulnerable to stigmatization and inappropriate treatment, and threaten to unravel decades of work to improve the regulatory and care environments. Some providers and policymakers seem invested in the wholesale rejection of not only opioids, but also of patients themselves.

Policy efforts focused almost exclusively on reducing the availability and use of prescription opioids without regard to predictable consequences of these use reduction strategies. First, these strategies failed to acknowledge or address the specific nature of the OROs, most of which involved opioids combined with other 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 comor-

as prescribed but this distinction went almost unchallenged.


14 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. See infra note 401 and accompanying text.

15 The work of interdisciplinary scholars including David Brushwood, Sandra H. Johnson, Diane E. Hoffmann, and Ben A. 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. See History of Mayday Grants: 1993 to 2003, http://www.maydayfund.org/sfh211/grantshistory93to13.pdf (last updated May 1, 2015).

16 See, e.g., Anna Lembke, Why Doctors Prescribe Opioids to Known Opioid Abusers, 367 NEW ENG. J. MED. 1580, 1580-82 (2012) (expressing open contempt at the idea of trusting a patient or accepting their reports of pain); see also Janice Lynch Schuster, Down the Rabbit Hole: A Chronic Pain Sufferer Navigates the Maze of Opioid Use, 33 HEALTH AFF. 1294, 1294-97 (2014).

17 See, e.g., FLA. STAT. § 456.44 (2012) (mandating a detailed list of specific practice and prescription requirements) (amended 2016); see also TENN. CODE ANN. § 71-5-2601(a)(1)(A)(iii) (2004) (making it a criminal offense for Tennessee Medicaid patients to obtain a prescription for controlled substances from more than one doctor in any thirty-day period); Hilary Wilson, Clinicians' Attitudes and Beliefs About Opioids Survey (CAOS), 14 J. PAIN 6, 613-627 (2013) (examining differences in physicians' attitudes about opioid prescribing and revealing that younger physicians as well as those who did not have a large number of patients in chronic pain, were more reluctant to prescribe opioids); Ken Solis, Ethical, Legal, and Professional Challenges Posed by "Controlled Medication Seekers" to Healthcare Providers, 7 AM. J. CLINICAL MED. 86, 91 (2010) (describing letters from Wisconsin ED to "frequent flyers" stating that they would no longer receive pain medication for their pain).

18 See Unintentional Poisoning Deaths, supra note 7.
bid 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 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. Neizer’s search for relief was characterized by unfruitful and humiliating trips to emergency departments (EDs) and doctors’ offices. He attempted suicide multiple times. 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: “[M]y 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.” He only wanted his pain to stop.

In 2016, 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 ad-

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19 See id.
20 See id.
21 See, e.g., Lembke, supra note 16.
22 See FOREMAN, supra note 2.
23 Id. at 126.
24 Id. at 126-27.
25 Id. at 126.
26 Id.
27 Id. In reality, Mr. Neizer had two brain aneurysms that were discovered when a physician comprehensively evaluated him. Id. at 127.
30 See, e.g., Wilson, supra note 17; see also Solis, supra note 17, at 91.
dress the actual harms—substance use related health impairment, functional decline, 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.

MORTALITY WKLY. REP. 1487 (Nov. 4, 2001).

32 Chronic pain is traditionally defined as pain that lasts at least three months, 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 ninety days, it generally meets the definition of chronic pain. See, e.g., Jane C. Ballantyne & Jianren Mao, Opioid Therapy for Chronic Pain, 20 NEW ENGL. J. MED. 1943 (2003) ("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 is constant or frequent and lasts at least three months, and analyzing recent data to conclude that persistent pain affects 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).

33 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 (SUD) 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 undertreated pain (often called pseudoaddiction). For more information on SUD, see AM. PSYCHIATRIC ASS'N, Substance Related and Addictive Disorders (2013), 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 834, 834-51 (2013).

34 Serious mental illness means any diagnosed mental disorder under DSM III-R-to-V, excluding SUDs, that substantially interferes with any major life activity under the formula outlined by the Substance Abuse and Mental Health Services Administration. For additional information, see SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., CTR. FOR BEHAVIORAL HEALTH STATISTICS & QUALITY, PUB. NO. (SMA) 13-4805, RESULTS FROM THE 2012 NATIONAL SURVEY ON DRUG USE AND HEALTH: MENTAL HEALTH FINDINGS (2013) [hereinafter, SAMHSA 2012].

35 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 CTRS. FOR DISEASE CONTROL & PREVENTION, Definitions: Self-Directed Violence (Aug. 28, 2015), http://www.cdc.gov/violenceprevention/suicide/definitions.html. The American Psychiatric Association listed Suicidal Behavior Disorder as a condition for further study in DSM-V, choosing to continue treating it as a subcomponent of serious mental illness rather than a separate entity despite the fact that ten percent 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 1383, 1383-84 (2008).
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 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.

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. 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.

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36 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, in THE ESSENTIAL COMMUNITARIAN READER 217 (Amitai Etzioni ed., 1998).

37 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 abilities of certain patients in chronic pain and are almost always appropriate for moderate-to-severe acute pain such as post-surgery or in temporary pain conditions such as kidney stones. For a review of the benefits and risks of use in chronic pain, see Nalini Sehgal et al., Chronic Pain Treatment with Opioid Analgesics: Benefits Versus Harms of Long-Term Therapy, 13 EXPERT REV. NEUROTHERAPEUTICS 1201 (2013).


opioids in health care and their relationship to provider behavior. Part VI will endorse policy options synchronized to available data that do not de-value patients, or damage provider-patient relationships.

I. 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."40

There are harms associated with drug abuse or misuse of any kind.41 Premature death from drug poisoning (overdose) is the most serious of those harms, regardless of the drug(s) involved.42 However, the responses to the problem of 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.43 These collectively indicate that moralistic attitudes and ingrained sociocultural biases against people in pain and the use of opioids were only thinly cloaked by the serious advocacy efforts in the last twenty years.44 Steven Passik described it this way: “People have returned to talking about opioids 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.”45

41 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. See Nalini Sehgal et al., Prescription Opioid Abuse in Chronic Pain: A Review of Opioid Abuse Predictors and Strategies to Curb Opioid Abuse, 15 PAIN PHYSICIAN J. ES67, ES68 (2012).
42 See id. at ES70.
43 See Johnson, Regulating Physician Behavior, supra note 39, at 1006; Andrew Smith, False Arguments and False Hope: An Inconoclastic Take on the Battle Over Prescription Opioids, PAINWEEK NEWS, Sep. 7, 2012, at 1, 10. See generally infra Part IV.
44 See Carl May et al., Framing the Doctor-Patient Relationship in Chronic Illness: A Comparative Study of General Practitioners’ Accounts, 26 SOC. HEALTH & ILLNESS 135, 139-50 (2004) (describing chronic pain patients as the most frustrating for providers, even as compared to patients with depression and menorrhagia).
45 Smith, supra note 43, at 1 (reporting on lecture by Steven D. Passik entitled Jesus, Bacon, and Hyperalgesia: Intellectual Honesty and Dishonesty in Opioids for Chronic Pain Management).
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 is 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, policy makers, 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?

Opioid prescriptions have increased over the last three decades in the U.S., as have the number of all prescriptions. These numbers are absent any context; the increase of opioid prescriptions 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 prescription opioid diversion and illicit use have also increased. Most assume the rise in prescription opioid overdoses has occurred in states with restrictive policies, a corresponding rise in heroin use and overdose has accompanied those decreases. See infra Part V.

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


See infra Part IV (exploring this as a kind of opioid heuristic).


See infra note 59.

See Caudill-Slosberg et al., supra note 51, at 514. See generally, Ben A. Rich, supra note 40. However, there is evidence that many patients have significant numbers of unused opioids and that is attributable to prescribing practices. These left over pills are often diverted. See e.g. infra note 59.

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
in prescribing caused the increase in illicit use. \textsuperscript{55} While there is a relationship between prescription rates and increase in illicit use, the available data does not support a direct doctor-to-patient-to-addict relationship; \textsuperscript{56} 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." \textsuperscript{57}

The majority of people who abuse, misuse, or overdose on prescription opioids are not the patients for whom they are prescribed. \textsuperscript{58} The lack of relationship 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 most prescription opioid abusers (over 86\%) obtained opioids from dealers and from sharing with friends and family. \textsuperscript{59} Only 13.8\% obtained their prescription through their regular doctor or through doctor shopping (filling multiple prescriptions for opioids from multiple prescribers). \textsuperscript{60} When the source of opioids was via a direct prescription, the prescribers were typically primary care providers rather than pain specialists. \textsuperscript{61} The National Survey of Drug Use and Health

\textsuperscript{55} See, e.g., Nicholas B. King et al., \textit{Determinants of Increased Opioid-Related Mortality in the United States and Canada, 1990–2013: A Systematic Review}, 104 AM. J. PUB. HEALTH e32, e36 (2014) ("It is still unclear whether high-volume prescribing is a direct driver of increased mortality.").

\textsuperscript{56} Ben A. Rich, \textit{supra} note 40, at 25 ("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."). \textit{See also} David E. Joranson & Aaron M. Gilson, \textit{A Much-Needed Window on Opioid Diversion}, 8 PAIN MED. 128, 128 (2007) ("We question the validity of asserting, absent direct evidence, that it [opioid overdoses] resulted from treating pain patients.").


\textsuperscript{58} \textit{Substance Abuse \& Mental Health Servs. Admin., CTR. FOR BEHAVIORAL HEALTH STATISTICS \& QUALITY, RESULTS FROM THE 2013 NATIONAL SURVEY ON DRUG USE AND HEALTH: SUMMARY OF NATIONAL FINDINGS}, (2014) [hereinafter SAMHSA 2013]. In addition, drugs can be diverted before they become the object of prescription, such as manufacturing and distribution thefts. \textit{See Nat’l CTR. ON ADDICTION \& SUBSTANCE ABUSE, UNDER THE COUNTER: THE DIVERSION AND ABUSE OF CONTROLLED PRESCRIPTION DRUGS IN THE U.S.} 48 (2005).

\textsuperscript{59} Theodore J. Cicero et al., \textit{Multiple Determinants of Specific Modes of Prescription Opioid Diversion}, 41 J. DRUG ISSUES 283, 289-96 (2011).

\textsuperscript{60} \textit{Id.} at 293; \textit{see also} Khary K. Rigg et al., \textit{Prescription Drug Abuse Diversion: Role of the Pain Clinic}, 40 J. DRUG ISSUES 681 (2010) (providing a qualitative analysis of methods used by those involved in the prescription drug trade).

\textsuperscript{61} Rigg et al., \textit{supra} note 60, at 689-90.
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(NSDUH) also indicates that the majority of those who misuse or abuse prescription opioids do so with pills that were not prescribed for them.\(^{62}\)

Further, McDonald and Carlson examined opioid prescription pharmacy data from 76% of retail pharmacies in the U.S.\(^{63}\) 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; they purchased 1.9% of all opioid prescriptions.\(^{64}\) In conclusion, "[t]he vast majority of opioid prescriptions involved a single prescription from [one] healthcare provider and most patients seemingly ... used them sparingly."\(^{65}\)

Part of the reason there isn't a direct doctor to patient to addict relationship is that exposure to opioids alone does not create SUD.\(^{66}\) 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.\(^{67}\) A study by Cepeda and colleagues found that only three out of 1,000 people exposed to opioids go on to exhibit any doctor-shopping behavior (whether because of addiction or pseudo-addiction).\(^{68}\) Those who receive an opioid prescription for an acute or tem-

\(^{62}\) SAMHSA 2013, supra note 58, at 3, 32 (reporting that among persons aged 12 or older in 2012-2013 who used pain relievers non-medically in the past year, 53.0% got the pain relievers they most recently used from a friend or relative for free. Another 10.6% of these nonmedical users in 2012-2013 bought pain relievers from a friend or relative, and 4.0% took pain relievers from a friend or relative without asking. An annual average of 4.3% got the pain relievers from a drug dealer or other stranger; 2.6% got pain relievers from more than one doctor; 0.1% bought pain relievers on the Internet; and 4.3% got pain relievers in other ways, including 0.7% who stole pain relievers from a doctor's office, clinic, hospital, or pharmacy.).


\(^{64}\) Id.


\(^{66}\) 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 Vulnerability to Addiction, 1141 ADDICTION REV. 105 (2008); THE NAT'L CTR. ON ADDICTION & SUBSTANCE ABUSE, Addiction Medicine: Closing the Gap Between Science and Practice (2012).

\(^{67}\) 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. 444, 444 (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)).

\(^{68}\) Pseudoaddiction is drug-seeking behavior motivated by continued pain rather than
porary 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 insufficient evidence that the careful use of opioids as prescribed for pain predisposes patients to future SUD or overdose. Absent the pre-disposing genetic and environmental factors, "the drug does not have the power to change people in that way." Nonethelss, 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 opioid 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, "[t]he disease of opioid addiction arises from repeated exposure to opioids." The authors also strongly recommend decreased pre-


70 Id.

71 Id. at 74. 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.

72 Id.

73 Id. at 78.

74 Id.

75 Id.

76 Id.

scribing 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.\textsuperscript{78}

B. \textit{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 SAMHSA that track rates of self-reported non-medical use, emergency department (ED) visits, and deaths related to opioids. The primary source for non-medical use information is the annual NSDUH; however, information in the NSDUH on opioid use only dates back to 2002, the first year they started tracking opioids separately.\textsuperscript{79} In addition, while the NSDUH survey asks about nonmedical use, the survey does not separate out whether a respondent took the prescription opioids to treat underlying pain or to “get high.”\textsuperscript{80} The NSDUH does not indicate any substantial changes in non-medical use of prescription opioids since 2002;\textsuperscript{81} moreover, the 2013 and 2014 rates are lower than several of the previous years.\textsuperscript{82} Furthermore, although all SUDs remain a serious public health problem, the overall rates of SUDs have been stable or declining over the last decade or more.\textsuperscript{83} The rates of both SUDs and the non-medical use of opioids are stable over time; therefore, the increase rates of OROs are not attributable to a simple rise in misuse and abuse. In fact, the reasons for the increased rate of OROs are multifactorial.

\textsuperscript{78} 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”).


\textsuperscript{80} 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 that the drugs caused. SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., CTR. FOR BEHAVIORAL HEALTH STATISTICS & QUALITY, PUB. NO. (SMA) 13-4795, RESULTS FROM THE 2012 NATIONAL SURVEY ON DRUG USE AND HEALTH: SUMMARY OF NATIONAL FINDINGS (2013) [hereinafter NATIONAL FINDINGS 2012].

\textsuperscript{81} 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 that the drugs caused. SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., CTR. FOR BEHAVIORAL HEALTH STATISTICS & QUALITY, PUB. NO. (SMA) 13-4795, RESULTS FROM THE 2012 NATIONAL SURVEY ON DRUG USE AND HEALTH: SUMMARY OF NATIONAL FINDINGS (2013) [hereinafter NATIONAL FINDINGS 2012].

\textsuperscript{82} SAMHSA 2013, supra note 58.

\textsuperscript{83} See, e.g., id. at 110 tbl.8.4; SAMHSA 2014, supra note 82, at 23 fig. 32.
1. **Emergency Department (ED) Visits**

The Drug Abuse Warning Network Survey (DAWN Survey) is the most common source of information about ED visits related to drug use and overdoses (poisonings). The DAWN Survey estimates alcohol, pharmaceutical, and illicit drug use-related visits to EDs based on surveys of selected metropolitan areas from 2004-to-2011. The definitions used in the DAWN survey mean that many types prescription and illicit drug uses are counted as a drug related visit. 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 or 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; and [e] deliberate poisoning with a pharmaceutical by another person; [or] [f] any use ... that ED medical staff document ... as misuse or abuse.

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. While the survey authors explicitly 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. Visits for opioids increased by 183% between 2004 and 2011.

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85 "DAWN does not assess the medical reasons for the visit, and it cannot be assumed that a drug was the direct cause of the medical emergency," and, "while DAWN seeks to report only the drugs that are related to the visit, some unrelated drugs may be included." Id. at 18.

86 Id. at 47.

87 See id. at 18-19 (explaining that they count visits such as when "ED records may mention Methadone but fail to indicate that the patient was enrolled in a Methadone treatment program").

88 SAMHSA, Drug Abuse Warning Network, 2011: Selected Tables of National
over that same time period. The increase is not just limited to opioids. For example, stimulants (drugs used to treat attention deficit disorders) increased 307%, benzodiazepines (anti-anxiety agents such as Xanax or Valium) increased 149%, and anxiolytics, sedatives, and hypnotics increased 138%. Moreover, between 2009 and 2011, there were no significant increases in opioid-related visits while other drug-related visits rose.

The DAWN Survey report included important information about downward trends in the misuse of prescription opioids; however, it appears the misuse of other drugs may be filling the void. Specifically, between 2009 and 2011, the rates of misuse of anti-anxiety and insomnia medications, stimulants, marijuana, and other illicit drugs increased while the overall rate of visits involving prescription opioids remained stable. Coupled with the information about the stable rates of SUDs over time, it appears that individuals may be abusing drugs at the same rate while the drugs of choice are changing. 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).

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89 Id. at Column Z, Row 95.
90 Id. at Column Z, Row 195.
91 Id. at Column Z, Row 176.
92 Id. at Column Z, Row 171. Rates of other drugs also increased: alternative medicine substances increased 269%, MDMA (ecstasy) increased 247%, and heroin increased 169%. Id. at Rows 290, 27, and 19 respectively.
93 See, e.g., id. at Column AA, Row 198 (stimulants rose by 85% during that two-year time frame); id. at Column AA, Row 95. Other reports confirm similar trends. See, e.g., SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., DRUG ABUSE WARNING NETWORK (DAWN) REPORT, Emergency Department Visits Involving Attention Deficit/Hyperactivity Disorder Stimulant Medications (2013) (finding that stimulant medication visits increased between 2005 and 2010 from 13,379 to 31,244. 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.).
95 Id.
2. Opioid Related Overdose (ORO) Deaths

"The reasons for the deaths are multifactorial, encompassing prescriber behaviors, patient contributory factors, non-medical use patterns, and systemic failures."\textsuperscript{96} There are 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."\textsuperscript{97} In addition, the spotlight on ORO deaths is somewhat disproportionate given very the numbers of other types of untimely deaths. 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.\textsuperscript{98} Non-steroidal anti-inflammatory drugs, such as Motrin or Naproxen, are estimated to kill up to 10,000 people a year (double the number that opioids alone kill),\textsuperscript{99} and approximately 88,000 deaths each year are attributable to excessive alcohol intake.\textsuperscript{100} Why is the focus on the harms of opioids alone? Judy Foreman sums it up by saying "our collective thinking is out of whack."\textsuperscript{101}

a. High Risk Polysubstance Use and Relative Opioid Risk

Oversimplification and broad-brush treatment has infected discourse around the dangers of opioids. The labeling of overdoses as opioid overdoses is one example. Opioids are rarely the only drug in the systems of individuals who experience OROs; in at least two-thirds of the cases, alcohol, benzodiazepines, or illicit drugs are also present.\textsuperscript{102} This makes cause attribution difficult to impossible. Nonetheless, the default label is ORO,\textsuperscript{103} however, labeling them "polysubstance related overdoses" seems

\textsuperscript{96} Lynn R. Webster et al., An Analysis of Root Causes for Opioid-Related Overdose Deaths in the United States, 12 PAIN MED. S26, S27 (2011).
\textsuperscript{97} Id. See also Twillman, supra note 79.
\textsuperscript{99} See FOREMAN, supra note 2, at 128-31.
\textsuperscript{100} Id.; see also CDC, ALCOHOL DEATHS, available at http://www.cdc.gov/features/alcohol-deaths/index.html (providing statistics from 2006-2010).
\textsuperscript{101} See FOREMAN, supra note 2, at 128.
\textsuperscript{102} Id. at 129 (finding that of the 16,651 opioid-related deaths in 2010, nearly 12,000 included multiple mixed substances such as alcohol and benzodiazepines); see also NATIONAL ESTIMATES OF ED VISITS, supra note 84.
\textsuperscript{103} Olaf H. Drummer, Recent Trends in Narcotic Deaths, 27 THERAPEUTIC DRUG MONITORING 738, 739 (2005) ("The most difficult aspect of dealing with opioids is that
more accurate and "benzodiazepine-related overdoses" is just as appropriate. The opioid-related label stuck and 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. 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. Earlier intervention aimed at these particular dangers most likely would have prevented harm and even some deaths.

Not all opioids are created equally—some opioids, like Methadone, are disproportionately risky. Methadone accounts for less than 5% of all opioid prescriptions, but is involved in one-third of opioid related deaths, as well as 30% of non-fatal overdoses. The disproportionate danger relates, in part, to specific cardiovascular risks and physician knowledge deficits. In fact, methadone use may be increasing. Between 1999 and 2006, Methadone-related ED visits rose sevenfold. Several factors could account for increased use of Methadone: 1) it is often viewed as a less-addictive opioid alternative for pain treatment; 2) Methadone may be used as part of an opioid dependence plan (or medication assisted treatment 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.

See infra Part IV.

Even the recent attention has been exceedingly modest by comparison. See SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., DAWN REPORT, Benzodiazepines in Combination with Opioid Pain Relievers or Alcohol: Greater Risk of More Serious ED Visit Outcomes (2014); Uzor C. Ogbu, Polysubstance Abuse: Alcohol, Opioids and Benzodiazepines Require Coordinated Engagement by Society, Patients, and Physicians, 16 W. J. EMERGENCY MED. 76, 76 (2015).

The rate of injury and death compared to the rate of prescriptions is disproportionate. See King et al., supra note 55.

See Webster et al., supra note 96; see also U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-09-341, METHADONE-ASSOCIATED OVERDOSE DEATHS: FACTORS CONTRIBUTING TO INCREASED DEATHS AND EFFORTS TO PREVENT THEM (2009) [Hereinafter GAO, INCREASED DEATHS].

Webster et al., supra note 96, at S30.

See id at S29-30; see also GAO, INCREASED DEATHS, supra note 107.

Warner et al., supra note 96, at S27.
and 3) because it is less expensive than other opioids, many payer policies mandate its use. Combined with the hazard of benzodiazepines and alcohol, these dangers deserve customized monitoring and interventions aimed at reducing overall harm, rather than the dominant blanket opioid use reduction efforts.

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 deaths. Unintentional poisonings are actually the third leading cause of injury mortality behind 1) suicide and 2) motor vehicle accidents. These are each serious problems that deserve attention; however, grouping together accidental and intentional overdoses obscures the root causes 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 41% between 2004 and 2011, and 51% between 2007 and 2011. 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{120} These premature intentional deaths deserve attention targeted at their underlying cause, especially because the very populations who have access to opioids have high rates of suicidality.

Addressing the underlying causes of morbidity and mortality in context is critical; yet, policy focuses on the existence of an opioid prescription absent context. Prescription opioids and the prescribers have become the “folk devils” in another moral panic in the “war on drugs.”\textsuperscript{121} When devising strategies of care and harm prevention, decision makers must understand the problem as complex, dynamic, and deserving of contextual solutions. Single-dimensional prescription opioid use reduction efforts are insufficient at best; at worst, they may foster the flourishing of continued suffering by ignoring the root causes of morbidity and mortality.

II. 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.”\textsuperscript{122}

The inappropriate treatment of pain is a “longstanding public health problem—some would say a public health crisis.”\textsuperscript{122} Pain alone affects at least 100 million U.S. adults\textsuperscript{124} and is a “leading cause of disability
and [a] major contributor to health care costs.\textsuperscript{125} "The annual U.S. expenditures related to pain ... are higher than those for cancer, heart disease, and diabetes combined."\textsuperscript{126} The total financial cost of pain to society ranges from $560-to-$635 billion,\textsuperscript{127} far more than the $193 billion annual cost of all illicit drugs.\textsuperscript{128}

The inappropriate treatment of pain is rooted in a web of entangled and relational barriers originating from systems, providers, and patients.\textsuperscript{129} Systems-level barriers include formal legal and regulatory proscription,\textsuperscript{130} as well as organizational policies and recommendations; at their core, individuals with varying levels of power, bias, and priorities influence them.\textsuperscript{131} Disparities in pain treatment also reflect ingrained biases based on gender,\textsuperscript{132} race,\textsuperscript{133} socioeconomic status,\textsuperscript{134} and other perceived differences.\textsuperscript{135}

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\textsuperscript{126} Pizzo & Clark, supra note 124, at 197 (emphasis added) ("(including direct medical costs and lost wages)").

\textsuperscript{127} This excludes children, prisoners, individuals in the military, or those in long term care. IOM, RELIEVING PAIN IN AMERICA, supra note 6, at 302-03 (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 123.


\textsuperscript{129} For an overview of the barriers to effective treatment, see Sigrid Frey-Revere & Elizabeth K. Do, A Chronic Problem: Pain Management of Non-Cancer Pain in America, 16 J. HEALTH CARE L. & POL’Y 193 (2013). Patient level barriers may include fear of taking medication, difficulties in accessing health care, and other barriers. Id. at 194. 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 45-49, 156-57.

\textsuperscript{130} 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 156, 156 (2009).

\textsuperscript{131} Id.

\textsuperscript{132} 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 SOC. SCI. & MED. 1409, 1409 (2003).

Recent public health concerns surrounding opioid-related overdoses only magnify the complexity. Makota and colleagues found that providers' "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 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 under-treatment 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 is 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 medica-

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135 See, e.g., Carmen Green et al., Disparities in Pain: Ethical Issues, 7 PAIN MED. 530 (2006); Annemarie Daly Linares, Opioid Pseudoaddiction: A Casualty of the War on Drugs, Racism, Sexism and Opiophobia, 15 QUINNIPIAK HEALTH L.J. 89 (2011); Janet Kaye Heins et al., Disparities in Analgesia and Opioid Prescribing Practices for Patients With Musculoskeletal Pain in the Emergency Department, 32 J. EMERGENCY NURSING 219 (2006); Joshua H. Tamayo-Sarver et al., The Effect of Race/Ethnicity and Desirable Social Characteristics on Physicians’ Decisions to Prescribe Opioid Analgesics, 10 ACAD. EMERGENCY MED. 1239 (2003); Arvind Venkat et al., The Impact of Race on the Acute Management of Chest Pain, 10 ACAD. EMERGENCY MED. 1199 (2003).
136 Megan Crowley-Matoka & Gala True, No One Wants to Be the Candy Man: Ambivalent Medicalization and Clinician Subjectivity in Pain Management, 27 CULTURAL ANTHROPOLOGY 689, 689 (2012).
137 Id. (reporting reasons ranging from "the blatant (as more likely to be drug addicted ...) to more subtle (as simply less easily understood, and thus less easily trusted").
138 CARBONE CANCER CTR., UNIV. OF WIS. SCH. OF MED. & PUB. HEALTH, ACHIEVING BALANCE IN FEDERAL AND STATE PAIN POLICIES: A GUIDE TO EVALUATION 3 (2014). They do acknowledge that their only policy focus is on efforts that improve the treatment of pain.
139 See Johnson, Test-Driving, supra note 38, 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.").
tion 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\textsuperscript{140} may deceive physicians into prescribing opioids for the purposes of diversion (as opposed to reasons related to underlying disorders).\textsuperscript{141} 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; these are also not diagnoses of mutual exclusion.\textsuperscript{142} They have much more in common than current policy recommendations reveal.\textsuperscript{143} all are highly stigmatized, seriously undertreated, and grossly underfunded.\textsuperscript{144} Providers regard individuals with these conditions as challenging, and those individuals express difficulty with access, discounting, and disbelief by providers.\textsuperscript{145} Each diagnosis has high rates of comorbidity, such as suicidality,\textsuperscript{146} that garner little attention in the literature. Thousands of pages are devoted to the harms associated with opioids and the screening of patients for illicit drug use, or for not using their prescribed opioids. Almost no literature draws 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 death.

\textsuperscript{140} Here, I use the term criminal only to mean those who are knowingly and intentionally involved in drug diversion for profit.

\textsuperscript{141} See, e.g., Andrew Rosenblum et al., Opioids and the Treatment of Chronic Pain: Controversies, Current Status, and Future Directions, 16 EXPERIMENTAL CLINICAL PSYCHOPHARMACOLOGY 405, 406-07 (2008).

\textsuperscript{142} Id. at 409-10; see also infra Part III.A-C.

\textsuperscript{143} 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.

\textsuperscript{144} See, e.g., SAMHSA 2012, supra note 34, at 28-29; Frey-Revere & Do, supra note 129, at 199.

\textsuperscript{145} See, e.g., SR Lieber et al., Power and Control: Contracts and the Patient-Physician Relationship, 65 INT'L J. CLINICAL PRAC. 1214, 1214-17 (2011).

\textsuperscript{146} See SAMHSA 2012, supra note 34, at 16-17; NATIONAL FINDINGS 2012, supra note 80.
A. Suicidality

A mostly overlooked consequence of undertreated pain is the substantial risk of suicide.\(^{147}\) The rate of comorbid suicidality in patients with CP ranges from 17%-to-66% of the population,\(^ {148}\) but even at the lowest estimates of 17%, it far exceeds the approximate 4% rate in the general adult population.\(^ {149}\) In fact, pain and disability perception (belief that one is disabled) are two important risk factors for suicide;\(^ {150}\) in patients with CP, disability perception coupled with a preference for death over disability is a significant predictor of suicidality.\(^ {151}\) 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.\(^ {152}\)

Individuals with certain types of CP syndromes may be at higher risk.\(^ {153}\) 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.\(^ {154}\) Many other studies have “demonstrated a link between chronic pain and suicidal ideation, planning and attempts.”\(^ {155}\) Patients who have two or more painful conditions are also much more likely to attempt suicide.\(^ {156}\) First person accounts by patients with CP are infused with references to suicidal-

\(^{147}\) Mark A. Ilgen et al., Noncancer Pain Conditions and Risk of Suicide, 70 JAMA PSYCHIATRY 692, 696-97 (2013); Kathryn E. Kanzler et al., Suicidal Ideation and Perceived Burdensomeness in Patients with Chronic Pain, 12 PAIN PRAC. 602, 602-04 (2012).

\(^{148}\) Kanzler et al., supra note 147, at 602-03 (citing David A. Fishbain, The Association of Chronic Pain and Suicide, 4 SEMINARS IN CLINICAL NEUROPSYCHIATRY 221, 221-27 (1999)).


\(^{150}\) 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, 553 (2012).

\(^{151}\) Id. at 559.

\(^{152}\) Kanzler et al., supra note 147, at 602.

\(^{153}\) 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 GEN. HOSP. PSYCHIATRY 437, 437-41 (2014).

\(^{154}\) Ilgen et al., supra note 147; 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 persistent headaches to have attempted suicide in the last twelve months).

\(^{155}\) Ilgen et al., supra note 147, at 693; see also IOM, RELIEVING PAIN IN AMERICA, supra note 6, at 692 (citing to eight previous studies).

\(^{156}\) Id. at 89 (stating that people having two or more types of chronic pain were almost three times more likely to report a suicide attempt than those without pain).
ity and the fact that for some patients, opioids are the only treatment that has prevented their suicide. Yet, there are no current suicide prevention efforts that focus on pain as an independent risk factor.

Approximately 90% of individuals who attempt or die by suicide have one or more MIs, whether or not they received a formal diagnosis or care for the MI. Although many suicidal individuals did not receive mental health care in the year before death, the majority of them saw primary care and non-psychiatric specialty providers; the same specialists likely to see patients with CP. MI is prevalent in patients with CP as well, with rates ranging from 30-60%. Therefore, primary care and specialty providers are well suited, and 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. The harms associated with suicidality are more serious than those associated with SUD; however, there are no practice recommendations or calls for universal suicide screenings of patients in pain beyond a handful of articles. Further study of the relationship between pain and suicidality as well as urgent development of effective screening tools should be part of coherent practice and policy recommendations.

157 See, e.g., Craig L. Winberg, Comment on Food & Drug Administration, Physicians for Responsible Opioid Prescribing—Citizen Petition (Aug. 30, 2012), 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 Petition (Oct. 18, 2012), http://www.regulations.gov/#!documentDetail;D=FDA-2012-P-0818-0522 (“[I]f the pain had continued the way it was, I did not plan to continue to live.”).
158 Id. (77% 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, https://www.afsp.org/understanding-suicide/key-research-findings (last visited Nov. 27, 2015).
159 About 50% of them had a formal diagnosis before the attempt of death. 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. 870, 870-77 (2014).
160 See infra Part V.
161 See generally, IOM, RELIEVING PAIN IN AMERICA, supra note 6, at 89.
B. Mental Illness

Another area of concern in practice and policy is the failure to prioritize and address comorbid MI in patients with CP. 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.\textsuperscript{164} 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.\textsuperscript{165} The rates of anxiety disorders are also substantially higher in patients with CP than in the general population.\textsuperscript{166} Addressing comorbid MI in patients presenting with CP is delicate for providers, in part because patients often equate these concerns with being told their pain is imaginary.\textsuperscript{167} Years of theory linking medically unexplained symptoms to somatization (i.e. emotional problems expressed through bodily ailments) worsen these concerns.\textsuperscript{168} Cross training that prepares providers to care for patients with multiple complex problems is rare.\textsuperscript{169} These comorbidities are often difficult to assess and diagnose both because of providers’ lack of training and the patients’ overlapping of symptoms of pain and depression.\textsuperscript{170} It takes a skillful clinician and a thoughtful patient to sort out the problems,\textsuperscript{171} all the while operating in an environment that rewards pro-

\textsuperscript{164} See, e.g., Martin D. Cheatle, Depression, Chronic Pain, and Suicide by Overdose: On the Edge, 12 PAIN MED. S43 (2011).

\textsuperscript{165} 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. HOSP. PSYCHIATRY 99 (2014).

\textsuperscript{166} Howe & Sullivan, supra note 165, at 99.

\textsuperscript{167} This was consistent with my personal experience working as a nurse in a chronic pain practice. See also Fishman & Berger, supra note 122, at 160-67; Cheatle, supra note 164, at S44 ("[P]atients ... “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{168} See, e.g., Foreman, supra note 2, at 100-01; see also Frederick H. Lowy, Management of Persistent Somatizer, 6 INT’L J. PSYCHIATRY MED. 227, 227-39 (1975) (describing the early recognition and “difficulty managing” people who “suffer and complain” without an underlying organic cause).


\textsuperscript{170} See, e.g., Fishman & Berger, supra note 122, at 66-67 (explaining that someone in terrible pain all the time may finds it hard to separate that from the symptoms of depression). See also Ajay D. Wasan et al., Psychiatric Illness, Depression, Anxiety, and Somatoform Pain Disorders, in BONICA’S MANAGEMENT OF PAIN (Scott M. Fishman, Jane Ballantyne & James P. Rathmell eds., 2006).

\textsuperscript{171} Fishman & Berger, supra note 122, at 257-58 (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).
cedures 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.172

Lack of access to or payment for mental health care and integrated multidisciplinary care are significant obstacles to appropriate care. The communication and knowledge barriers to comprehensive assessment compound the problems, leaving many patients with undiagnosed or untreated comorbid MI and, possibly, suicidality,173 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.174

C. Substance Use Disorders (SUD)

"[P]atients with substance use disorders and pain have the right to be treated with dignity, respect, and the same quality of pain assessment and management as all other patients."175

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 behaviors associated with SUD are more likely to lead to criminalization than treatment.176 Moreover, patients in pain tell a near universal story of at some point having their reported level of pain or motivations questioned by providers, with providers suspecting them of drug seeking, or criminal activities associated with drug diversion.177

172 Howe & Sullivan, supra note 166, at 103 (including screenings for anxiety, depression, and SUD with appropriate referrals to improve care).
173 See Cheatle, supra note 164; Howe & Sullivan, supra note 166.
174 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. See Cheatle, supra note 164.
176 The vast problems and failures of U.S. 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 & JUST. 75 (2013).
177 See, e.g., Joseph O. Merrill et al., Mutual Mistrust in the Medical Care of Drug Users: The Keys to the “Narc” Cabinet, 17 J. GEN. INTERNAL MED. 327, 329 (2002) ("Maybe they thought I was coming in ... to get high. I didn't care what they gave. Just a local would have been ok. It's painful to cut into someone's arm like that. [I] thought they would realize that."); Carole C. Upshur, Gonzalo Bacigalupe & Roger Luckman, “They Don't Want Anything to Do with You”: Patient Views of Primary Care Management of
The inclusion of opioids as one tool in the toolbox of pain treatment occupies a unique position in medicine. Physicians often prescribe drugs that are also misused or abused for conditions other than CP and physicians often care for patients engaged in illegal activity. Only in the realm of prescription opioids have providers' obligations transformed from care to criminal investigation. Until law and policy allow providers to embrace the complexity of pain coupled with an obligation to provide care and treatment or referral to patients with SUD, these interactions will not improve. This will require a reexamination of the kinds of prescribing that warrant 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 MacCoun call “use reduction.” Drug use is easier to measure than levels of harm—and only measuring the use of prescription opioids is even easier—but it does not get to the heart of the problems. Use reduction is 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,

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*Chronic Pain, 11 Pain Med. 1791, 1793-94 (2010) (claiming that patients report consistent themes of suspicion and distrust). For example, one patient’s provider said “I’m not losing my license because of you” and another said of her provider “[y]ou know they seem to have a mentality and if they do give you pain medication, it’s like ... you are a drug user ... they don’t take you serious ... they did an MRI and low and behold they found a brain tumor.” *Id.*


179 The process of investigating possible wrongdoing itself is a powerful deterrent to physicians to prescribe opioids even when using due care. For an excellent discussion of this from the shadows effect, see Johnson, *Regulating Physician Behavior, supra* note 39.


181 *Id.* See also Bryan R. Roberts & Yu Chen, *Drugs, Violence, and the State*, 39 ANN. REV. SOC. 105, 105-25 (2013); Food & Drug ADMIN. ET AL., *ROLE OF NALOXONE IN OPIOID OVERDOSE FATALITY PREVENTION 359-60 (2012) (statement of Mr. Scott Burris) (“[A]nother 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.”).
it leads citizens and their representatives to shy away from the part of drug abuse control policy that involves providing services to drug-takers to help them quit, moderate their behavior, or better integrate themselves into the broader society.\textsuperscript{182}

The rejection of a harm reduction model has trickled down into poor access to care and a lack of providers for SUD.\textsuperscript{183} 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.\textsuperscript{184} Changing the approach to address 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.\textsuperscript{185}

Current research suggests the rates of comorbid CP and SUD are variable.\textsuperscript{186} Within this discussion, there are two distinct ways of viewing the degree of 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.\textsuperscript{187} The numbers for the first are well above the rates of pain in the general population.\textsuperscript{188} The numbers of people with CP who develop a SUD without a history of substance

\begin{thebibliography}{188}
\bibitem{182} Kleiman, \textit{supra} note 36, at 221.
\bibitem{185} 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 Reuter & MacCoun, \textit{supra} note 180; Peter Reuter, \textit{supra} note 176, at 78.
\bibitem{186} Kelly E. Dunn et al., \textit{Severity and Interference of Chronic Pain in Methadone-Maintained Outpatients}, 15 \textit{PAIN MED.} 1540, 1545 (2014).
\bibitem{187} See, e.g., id.
\bibitem{188} See, e.g., id. at 1542 (reporting sixty percent of patients in a Methadone maintenance program reported untreated or undertreated chronic pain); \textit{SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., MANAGING CHRONIC PAIN IN ADULTS WITH OR IN RECOVERY FROM SUBSTANCE USE DISORDERS: A REVIEW OF THE LITERATURE} (2012) (citing L.C. Barry et al., \textit{Functional Self-Efficacy and Pain-Related Disability Among Older Veterans with Chronic Pain in a Primary Care Setting}, 104 \textit{PAIN} 131 (2003) (finding that thirty-six percent of patients entering SUD treatment reported also having CP)).
\end{thebibliography}
abuse are around the level of SUDs in 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 patients with a history of substance abuse, physicians are reluctant to address the risks in the context of pain treatment, leading to undertreatment. Work by Joseph Merrill and colleagues indicates 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, use of non-standardized approaches to pain assessment in patients with SUD, and avoidance of patients; patients expressed fears of mistreatment or punishment by providers for their SUD. An integrated care approach for patients with pain and comorbid conditions, such as the one explained by scholars Teresa Jacobson and Gregory Hatchett, is needed to emphasize holistic, contextual assessment, and ongoing care. 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."196

189 See, e.g., Silvia Minozzi et al., Development of Dependence Following Treatment with Opioid Analgesics for Pain Relief: A Systematic Review, 108 ADDICTION 688, 694 (2012) (reporting no significant risk of developing SUD from treatment with opioids for chronic pain).

190 See, e.g., Margo McCaffery & Chris Pasero, Stigmatizing Patients as Addicts, AM. J. NURSING, at 77 (2001); Merrill et al., supra note 177, at 330.

191 Robert N. Jamison et al., Substance Misuse Treatment for High Risk Chronic Pain Patients on Opioid Therapy: A Randomized Trial, 150 PAIN 390 (2010) (testing a counseling intervention added to opioid therapy for patients with a history of SUD and explaining that "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").

192 Merrill, et al., supra note 177, at 329.

193 Id.


195 Id.

196 James DuBois et al., A Humble Task: Restoring Virtue in an Age of Conflicted
There is certainly evidence that many providers are able to work through the complexities and competing concerns involved in treating pain, including prescribing opioids. Patients would rather be heard and deemed trustworthy than receive any particular therapy or treatment. They repeatedly express their desire to be listened to and legitimizd. Bergman and colleagues recently identified frustration among CP patients who felt providers were disengaged, finding many 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.” They are perhaps looking for communication that incorporates elements of Epstein and Gramling’s work on collaborative cognition, which they describe this way,

Engaging patients in constructing preferences in the face of complexity, inadequate evidence, and irreducible uncertainty involves more than 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 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

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Interests, 88 ACAD. MED. 924, 925 (2013).


199 See, e.g., LOUS HESBUSIS, 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 truth. He would listen. And he did.”); see also, Slade et al., supra note 198.

200 Alicia A. Bergman et al., Contrasting Tensions Between Patients and PCPs in Chronic Pain Management: A Qualitative Study, 14 PAIN MED. 1689, 1694 (2013).


202 See, e.g., Pat Croskerry et al., Cognitive Debiasing 1: Origins of Bias and Theory of Debiasing, 22 BMJ QUALITY SAFETY ii58 (2013); Ronald M. Epstein et al., Self-Monitoring
effective for appropriate care.\textsuperscript{203} The IOM also called upon providers to develop care that is patient-centered, comprehensive, and interdisciplinary.\textsuperscript{204}

Individualized, contextual practices reflect providers’ adherence to certain dispositions that advance the ends of medicine and enable providers to prioritize well-being in the context of the patient’s particular vulnerabilities and needs.\textsuperscript{205} In order to achieve those ends, especially in this context, virtue is paramount. DuBois and colleagues explained virtue this way: “[D]ispositions (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{206} In the specific context of pain medicine, James Giordano has argued for what he calls “an agent-based virtue ethics of pain medicine;”\textsuperscript{207} 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{208} 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.

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\textsuperscript{203} Halpern, \textit{Detached Concern}, supra note 202, 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.”). \textit{See also} Hannah Bayne et al., \textit{A Comprehensive Model for Optimizing Empathy in Person Centered Care}, 93 PATIENT EDUC. & COUNSELING 209, 213 (2013) (finding that physicians who worked to understand the patient’s perspective in encounters were “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, or recognize biopsychosocial factors that enable unique treatment plans for each patient”).

\textsuperscript{204} IOM, \textit{Relieving 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.”). For an elegant description of the need to focus on the patient before the disease, see Eric J. Cassell, \textit{The Nature of Clinical Medicine} (2014).

\textsuperscript{205} DuBois et al., supra note 196, at 924.


\textsuperscript{207} Id.
III. 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 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 and policy makers 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."212

Ultimately, both policy and provider level decisions about opioids are in the realm of ethics and moral decision-making, and strongly impact patients with pain or SUD.213 James Rest's interdisciplinary model of moral decision-making includes four distinct but dynamic, non-linear components: 1) awareness or sensitivity (capacity to recognize that a situa-

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211 See, e.g., Croskerry et al., supra note 202 (discussing how to recognize biased decision-making and how to “de-bias” it).
213 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 DU BOIS, ETHICS IN MENTAL HEALTH RESEARCH: PRINCIPLES, GUIDANCE AND CASES (2007).
214 Even drug “use reduction” policies are ultimately unethical when they do not actually reduce the harm to individuals who have SUD. These policies reduce supply to just one kind of abused drug and fail to increase treatment options. Criminalization of the disease of SUD fails to respect those with the condition.
tion 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 of 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 (including those with MI and SUD), as well as my previous work on providers' moral disengagement of patients in pain, particularly when providers do so by sulllying the victim (or patient).

The strongest contributors to moral decision-making overall are social consensus, the magnitude of the consequences, and the probability of effect. 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

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216 Id. at 57.
217 Id.
218 Id.
219 These are collectively understood as components of moral intensity. Id. at 57-60 (citing Thomas Jones, Ethical Decision-Making by Individuals in Organizations: An Issue-Contingent Model, 16 ACAD. OF MGMT. REV. 366 (1991)).
220 Id. at 66 (finding that 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").
221 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 Contreras-Huerta et al., Racial Bias in Neural Empathic Response to Pain, PLOS ONE (Dec. 13, 2013), journals.plos.org/plosone/article?id=10.1371/journal.pone.0084001 (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, PLOS ONE (Nov. 14, 2012), journals.plos.org/plosone/article?id=10.1371/journal.pone.0048546 (finding perceptions that people of lower status felt less pain).
222 See supra Part III.
224 Lincoln & Holmes, supra note 215, at 57.
225 Id.
decisions.\textsuperscript{226} In addition, the extent and likelihood of the perceived consequences of a decision maker’s actions may influence their willingness to act.\textsuperscript{227} For example, if providers fear regulatory scrutiny or even prosecution for prescribing opioids in an uncertain clinical encounter, they are less likely to consider a prescription a viable option.\textsuperscript{228} Likewise, if they are (reasonably or unreasonably) concerned about addiction, the less likely they are to consider an opioid prescription.\textsuperscript{229} The degree of these beliefs, with or without supporting evidence, may contribute to incoherent decision-making.\textsuperscript{230}

Decision-making is part of social cognition.\textsuperscript{231} A wealth of literature exists on theories of decision-making in general\textsuperscript{232} in health law & policy,\textsuperscript{233} and in the context of medical diagnosis.\textsuperscript{234} Unfortunately, very little research exists on decision-making errors in ongoing treatment decisions (as opposed to diagnosis),\textsuperscript{235} in the context of pain,\textsuperscript{236} or on the policy

\begin{itemize}
\item \textsuperscript{226} See, e.g., Johnson, \textit{Regulating Physician Behavior}, supra note 39, at 995-96.
\item \textsuperscript{227} See Lincoln & Holmes, \textit{supra} note 215, at 58-67.
\item \textsuperscript{228} See Johnson, \textit{Regulating Physician Behavior}, \textit{supra} note 39, at 1027; see also, Kelly K. Dineen & James DuBois, \textit{Between a Rock and Hard Place: Can Can Physicians Prescribe Opioids to Treat Pain Adequately While Avoiding Legal Sanction?}, 42 AM. J.L. & MED. 7 (2016).
\item \textsuperscript{229} Johnson, \textit{supra} note 228, at 1006-07.
\item \textsuperscript{230} See Dineen, \textit{supra} note 223, at 166.
\item \textsuperscript{231} See Raymond C. Tait et al., \textit{Provider Judgments of Patients in Pain: Seeking Symptom Certainty}, 10 PAIN MED. 11, 13 (2009).
\item \textsuperscript{232} 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. See, e.g., Joshua D. Wright & Douglas H. Ginsburg, \textit{Behavioral Law and Economics: Its Origins, Fatal Flaws, and Implications for Liberty}, 106 NW. U. L. REV. 1033 (2012). For an excellent overview of the theory of ecological rationality, see Julian N. Marewski & Gerd Gigerenzer, \textit{Heuristic Decision-Making in Medicine}, 14 DIALOGUES CLINICAL NEUROSCIENCE 77, 79 (2012) (claiming that ecological rationality holds that “people use simple strategies, seeking solutions that are good enough with respect to an organism’s goals”).
\item \textsuperscript{235} See Newman-Toker, \textit{supra} note 234 (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.”)
\end{itemize}
decisions surrounding controlled substances, including opioids, and patient care. This is critical because clinical encounters with patients in CP are highly complex, objective findings are often inconclusive, and options are ambiguous.\textsuperscript{237} 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.\textsuperscript{238}

B. Dual Process Models of Decision-making

Decision-making involves complex coordinated neurological computations and processes and decision-making strategies often change through experience.\textsuperscript{239} Dual process theories dominate discussions of decision-making,\textsuperscript{240} as well as theories surrounding the existence of moral intuitions and their relative value.\textsuperscript{241} 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.\textsuperscript{242}

Under DPT, decisions are made in either an intuitive (Type One) or an analytical (Type Two) mode;\textsuperscript{243} “clinical expertise thus depends on the ability to move back and forth between the two modes.”\textsuperscript{244} The default mode, Type One, is unconscious, fast, and efficient;\textsuperscript{245} it is also “character-
ised by heuristics—short-cuts, abbreviated ways of thinking, maxims, 'seen this many times before', ways of thinking." Heuristic use in Type One processing is a function 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 filling in missing information or by saving the mental work of analyzing a large amount of information. Although 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 One decision-making: "[I]mpressionistic thinking using vague gist representations" (impressionistic thinking) and "insightful intuition." Insightful intuition includes knowledge assimilation—such as emergency treatment protocols that through learning and practice transition from Type Two into Type One. Type One may also be responsible for the gut feeling or sense many clinicians describe that can contribute to good care. On the other hand, impressionistic thinking may include the culturally assimilated bias against patients who have a SUD. Thus, the use of Type One processing is neither inherently good nor bad. While Type One processing is indispensable in certain situations, such as lifesaving procedures, other situations call for more reflective reasoning.

Type Two processing is the reflective, analytical mode involving metacognition (thinking about thinking); it is "fairly reliable, safe and effective, but slow and resource intensive." Type Two processing occurs whenever the actor is consciously thinking about what she is doing, such as following a checklist, weighing options, or questioning his or her own as-

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246 Croskerry et al., supra note 202, at ii58 (arguing that the automatic pilot experience is part of these intuitive processing mechanisms).
248 See Sunstein, supra note 241, at 1566.
249 Id.
250 Id.
252 Id. at 180 n.3.
253 Erik Stapler et al., Gut Feelings as a Third Track in General Practitioners' Diagnostic Reasoning, 26 J. GEN. INTERNAL MED. 197, 197 (2010) (describing the role of affect as a heuristic and the value of the alert function).
254 Croskerry et al., supra note 202, at ii61.
255 Id.
256 Id. at ii58.
Using the wrong rules of analysis contribute to decision-making errors in Type Two processing as do factors that contribute to cognitive overload. Errors related to bias are more common in Type One mode; Type Two processing is frequently required for correction.

C. Biases & Heuristic Failure in Decision-Making Errors

Certain situations compound the risk for biased reasoning or failed heuristics, what Wilson and Brekke call "mental contamination." 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, "[e]rrors 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 comorbid conditions." Decisional errors are common when they involve individuals in groups prone to stereotyping, such as patients with CP, SUD, or MI. 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." While no researcher has specifically examined providers’ and policy makers’ cognitive biases and failed heuristic in the context of patients with CP, an examination of some of the potential heuristic errors and biases is warranted.

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257 See Sunstein, supra note 241, at 1565-66 (using the term “System II” in the place of “Type 2”).

258 Pat Croskerry, From Mindless to Mindful Practice—Cognitive Bias and Clinical Decision-Making, 368 NEW ENGL. J. MED. 2445, 2445-48 (2013) (“[O]ther factors come into play, such as cognitive overload, fatigue, sleep deprivation, or emotional perturbations.”). See also, Thompson, supra note 245, at 253-54 (finding that any strain on working memory compromises Type 2 processing).

259 Croskerry et al., supra note 202, at ii61.

260 Id. at ii62 (citing Timothy D. Wilson & Nancy Brekke, Mental Contamination and Mental Correction: Unwanted Influences on Judgments and Evaluations, 116 PSYCHOL. BULL. 117, 117 (1994)).


262 See Croskerry et al., supra note 202, at tbl.1; see also Cayla R. Teal et al., Helping Medical Learners Recognise and Manage Unconscious Bias Toward Certain Patient Groups, 46 MED. EDUC. 80, 81 (2012) (explaining that unconscious bias “interact[s] with the patient’s characteristics … to produce a treatment outcome in which the influence of [unconscious bias] can be magnified when data are ambiguous, when it is unrecognised and unmanaged, [unconscious bias] can lead to health care disparities”).

263 Klein, supra note 57, at 783.
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 One processes and confirmation bias as a consequence of biology: "[O]ur 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 for the actual experience'—and also ignores disconfirming data."

The operation of confirmation bias can jeopardize accurate and appropriate treatment. Anchoring bias is related; it 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 on to salient features of the patient's presentation too early ... and failing to adjust this impression in light of later information."

Rather than just selectively interpreting subsequent evidence to fit the initial impression, as is the case with confirmation bias, decision makers focus all efforts on the initial idea. This, of course, can work in concert with confirmation bias to lead decision makers 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 representativeness 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.\textsuperscript{273} 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 versus non-cancer pain, a dubious distinction at best with no "physiological, pharmacological, or even philosophical [] basis."\textsuperscript{274} This distinction dates back to a time when cancer pain really meant pain at the end of life.\textsuperscript{275} 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{276} Others have advanced compelling examples to illustrate the absurdity of the distinction, such as the exclusion of patients with sickle cell disease (a painful, chronic non-cancer condition),\textsuperscript{277} or patients with painful, terminal non-cancer con-

\textsuperscript{273} Klein, supra note 57 at 782; see also Sunstein, supra note 241, at 1562-63 (explaining the representativeness heuristic and providing examples such as people’s judgments that organic food is better regardless of further details and the role of the representativeness heuristic in the internment of Japanese Americans during WWII).

\textsuperscript{274} Robert K. Twillman, Rescheduling Hydrocodone, LIVESTRONG FOUND. 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., J. Donald Schumacher, Comment on National Hospice and Palliative Care Organization, (Nov. 27, 2012), 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 these non-cancer illnesses is as essential for health and quality of life as it is for those with cancer.").

\textsuperscript{275} See, e.g., Twillman, supra note 274; Norman McCormick, Survival of Cancer Patients, 69 CAN. MED. ASS’N. J. 288, 288 (1953).

\textsuperscript{276} 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., Jeffrey A. Zipper, Comment on the Florida Academy of Pain Medicine (Aug. 25, 2012), 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{277} See, e.g., Sophie Lanzkron, Comment on Physicians for Responsible Opioid Prescribing—Citizen Petition (Sept. 4, 2012), 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 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.").
These kinds of distinctions also illustrate the representative heuristic that may operate in decision makers’ reliance on disease as an entity independent from the patient. 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.” Perhaps a patient appears comfortable and happy when the provider sees him or her sitting in the exam room; when he or she reports severe, even crippling pain after walking to the exam room, the provider may decide he or she is not “on the level” and ignore other information. In reality, this is a typical presentation with lumbar stenosis.

Confirmation and anchoring bias may combine to explain the unfortunate effects of provider, institutional, and regulatory reliance on red flags for diversion. 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.” 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 are 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 “[i]t’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.” Dr. Gary Jay expressed dismay at the negative experiences of some of his long-time patients after Walgreens, a na-

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278 See, e.g., Zipper, supra note 276.
279 See CASSELL, supra note 205.
280 See, e.g., Hinze et al., supra note 134, at 249 (a physician interviewed in this study offered he uses “intuition” to decide whether a patient in pain is “on the level”).
281 Id.
284 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.
285 Davidson County Woman Charged with TennCare “Doctor Shopping”, TENN. STATE GOV’T NEWSROOM (Jan. 2, 2013), https://tn.gov/news/33598. This statement also reflects the unfortunate idea that people with SUD are not “legitimate” patients.
tional drug chain, adopted the use of red flags to deny filling 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, are not subject to the same suspicion as similarly situated 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 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 certifi-

286 Jay, supra note 283.
287 Id.
288 Id. at 84.
289 Id. at 82. This is a DEA created red flag.
290 Timur Kuran & Cass Sunstein, Availability Cascades and Risk Regulation, 51 STAN L. REV. 683, 685 (1999); Croskerry, supra note 270, at 777 ("[T]he 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.").
291 Klein, supra note 57, at 782; see also Ely et al., supra note 269.
292 Ely et al., supra note 270, at 309.
293 Sunstein, supra note 241, at 1560-61.
294 Bergman et al., supra note 200, at 1691 (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").
295 Klein, supra note 57, at 782 (claiming that 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.").
The significant publicity around opioid related deaths may increase the attribution of death to opioid poisoning rather than one of the multiple other drugs or alcohol present in the systems of most victims.296

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 to greater causes of morbidity and mortality may arise, in part, from availability bias.

Poor opioid policy and provider decision 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."297 The social mechanisms of informational and reputational cascades are part of availability cascades.298 Information cascades occur when individuals with incomplete information rely on others (often too with incomplete information) in formulating beliefs.299 Reputational cascades are motivated by social approval needs and occur when individuals choose to indicate, or refrain from rejecting, the beliefs of others.300 These interdependent cascades can snowball and become self-reinforcing for the groups that espouse particular views and "public discourse will rest on flawed judgments,"301 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.302 Availability cascades "constitute a major ... source of the 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. ... [C]ascades force governments to adopt expensive measures without careful consideration of the facts."303

Some of the recent regulatory efforts aimed at reducing opioid use may be incoherent because of availability cascades. As initial policy makers and public health agencies focused on prescription opioids and pain practitioners alone, others adopted their views without a careful examina-
tion of the facts. As time went on, reputational fears may minimize and silence dissenting views, resulting in a one-dimensional, prescription opioid use-reduction approach to the problem. 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 such as patient suffering and even increased use of more dangerous illicit drugs like 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 problems they aim to address, discussed in Part V below, may be products of availability cascades.

3. Framing Errors and Illusory Correlations

The ways in which antecedent conditions of decisions are framed strongly influences subsequent decision-making. For example, the same surgery described two different ways elicits different decisions; 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 opioids as deadly and "causing" overdoses—with little or no mention of the therapeutic utility for some patients in pain—that people are willing to sacrifice pain control for a perceived greater good. Framing polysubstance deaths as OROs instead of deaths from mixing alcohol and multiple classes of drugs only furthers the scapegoating of opioids alone. Most concerning, this may have delayed or decreased critical warnings about the risks of polysubstance use and contributed to untimely deaths. 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

305 See Joanne E. Brady et al., Prescription Drug Monitoring and Dispensing of Prescription Opioids, 129 PUB. HEALTH REP. 139 (2014).
306 See Croskerry, supra note 270, at 777.
307 Sunstein, supra note 241, at 1590.
308 CHIP HEATH & DAN HEATH, DECISIVE: HOW TO MAKE BETTER CHOICES IN LIFE AND WORK 10 (2013) (describing narrow framing/false dichotomies as one of the villains of decision-making).
or a drug-addict, a complete manipulator or a “straight shooter,” deserving or undeserving. Why a patient with SUD or other related conditions is seen as illegitimate or undeserving is hard to understand.\(^{309}\) Pain is also grouped into nonsensical categories, such as cancer and non-cancer pain or surgical and non-surgical pain.\(^{310}\) Finally, the narrow framing and interpretation of the principle of balance in prescribing is illustrative.\(^{311}\)

4. **Visceral Biases: Indignation, Outrage, and Betrayal**

Personal feelings and emotions are powerful drivers of poor decision-making.\(^{312}\) Sunstein describes particularly strong feelings as heuristics in their own right;\(^{313}\) 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.\(^{314}\) 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 at any cost.\(^{315}\) Worse yet, when groups of people prone to share indignation and betrayal deliberate together, the groups “end up more indignant than their median member.”\(^{316}\) 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 deceiving a prescriber to obtain opioid for diversion purposes. Matoka and True described providers’ reactions this way,

[\textit{W}e were struck by how merely noting a research interest in pain (in the most general of terms) often elicited powerfully charged emotion, \textit{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\(^{310}\) See Twillman, \textit{supra} note 274.

\(^{311}\) See infra Part V.

\(^{312}\) See Ogdie et al., \textit{supra} note 234, at 1363 tbl.1.


\(^{314}\) See Sunstein, \textit{supra} note 241, at 1573-74 (explaining 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).

\(^{315}\) See Sunstein, \textit{supra} note 313, at 420.

\(^{316}\) \textit{Id.} at 421 (describing this phenomenon in terms of criminal law).
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.\footnote{317}

If the betrayal and indignation heuristics operate the same way in this context, it could explain why providers believe far more patients are addicted to or are attempting to divert opioids than the evidence supports. It could also explain their willingness to risk unnecessary patient suffering in favor of avoiding any personal 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.\footnote{318}

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.”\footnote{319}

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 patients in pain on therapeutic opioids is bleak. The epidemic metaphor feeds and intensifies availability cascades around prescription opioids; opioids are no longer value neutral tools with positive and negative effects. Value neutral tools are not equated with contagion and plagues: these are things to be avoided at all costs.\footnote{320} There is now what I call an opioid heuristic; opioids are standing in for a host of\

\footnote{317} Crowley-Matoka & True, supra note 136, at 701 (emphasis added).
\footnote{318} Johnson, Test-Driving, supra note 38, at 1480.
possible 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 related to the older concept of opiophobia (fear of opioids); however, the trajectory of opioid-related public discourse has transformed the fear of opioids into a short cut in decision-making. The opioid heuristic is consistently reinforced by the epidemic metaphor as well as the opioid related availability cascades.

For decades, providers have contended that they fear the use of opioids because of potential investigations by the DEA or state boards for prescribing violations.321 This fear is understandable given it is one of the few areas in which prescribers could find themselves embroiled in federal and state criminal, administrative, and even civil proceedings.322 Others fear causing addiction in their patients,323 a fear likely fueled by resurgence of the word “addiction” related to use of opioids in the last five years, in everything from media sources to statements of some provider groups.324 While concerns about diversion and addiction are not unreasonable, they are disproportionate in comparison to other risks and should not obscure the comprehensive evaluation and treatment of patients.325 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 in pain.326

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321 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.”).

322 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 may find themselves facing negligence actions by patients or patients’ family members.

323 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., Minozzi, supra note 189.

324 See, e.g., Physicians for the Responsible Opioid Prescribing, FDA Cracks Down, Finally, on Painkillers, MANSFIELD NEWS J., Nov. 14, 2013 (describing Vicodin as one of the “deadliest drugs in America”).


326 See, e.g., Daniel S. Goldberg, On the Erroneous Conflation of Opiophobia and the Under treatment of Pain, 10 AM. J. BIOETHICS 20, 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.”).
IV. 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.\textsuperscript{327} 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 and reasonable documentation and evaluation practices.

Incoherent policies risk undoing the considerable advancements made in the late 1990s and early 2000s that validated opioids in certain contexts, among other treatments, and did not unduly burden patients in pain or their providers.\textsuperscript{328} Among the policy successes was the use of the regulatory metaphor of balance.\textsuperscript{329} In the regulatory context, balance is an obligation \textit{on governments} to ensure availability of opioids for appropriate medical use while addressing the diversion of opioids for non-medical use.\textsuperscript{330} Unfortunately, the obligation of balance was adopted in an unintended way: \textit{individual providers} began using the metaphor to convey an obligation to balance the well being of their own patients against social concerns surrounding diversion in the community.\textsuperscript{331} This is a perversion of

\textsuperscript{327} See, e.g., Rich, supra note 1.


\textsuperscript{329} See \textit{CARBONE CANCER CTR., supra} note 138 ("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 \textit{FED'N OF STATE MED. BDS., BALANCE, UNIFORMITY, AND FAIRNESS: EFFECTIVE STRATEGIES FOR LAW ENFORCEMENT FOR INVESTIGATING AND PROSECUTING THE DIVERSION OF PRESCRIPTION PAIN MEDICATIONS WHILE PROTECTING APPROPRIATE MEDICAL PRACTICE} 5 (2009).

\textsuperscript{330} This was initiated by the Pain & Policies Study Group decades ago. See, e.g., Scott M. Fishman et al., \textit{Regulating Opioid Prescribing Through Prescription Monitoring Programs: Balancing Drug Diversion and Treatment of Pain}, 5 Pain Med. 309, 310, 321 (2004). See also \textit{CARBONE CANCER CTR., supra} note 138, at 27.

\textsuperscript{331} See e.g., Rollin M. Gallagher & Lisa J. Rosenthal, \textit{Chronic Pain and Opiates}:
a provider's primary obligation. David Brushwood and colleagues quoted Hans Jonas to convey the provider's obligation in this regard.

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 he is under the physician's care.\textsuperscript{332}

The balance metaphor is no longer sufficient for reasons beyond its distortion. The binary, adversarial structure it evokes—pain relief versus diversion prevention—does not adequately reflect or illustrate the complexity of the problems now faced.\textsuperscript{333} Opioids are not simply good for pain and bad for substance abusers. Coupled with the opioid heuristic as a stand in for "opioids as harmful", the balance metaphor is now heavily weighted toward diversion prevention over effective pain treatment. There is an urgent need for models that instead represent the integrated, overlapping, complex approach required to allow for appropriate opioid use and also 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, and relational approach—an approach of what I will call "central coherence"—a term I borrow from psychology literature.\textsuperscript{334} Many current approaches lack

\textit{Balancing Pain Control and Risks in Long-Term Opioid Treatment}, 89 ARCHIVES PHYSICAL MED. & REHABILITATION S77, S77-S82 (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).

\textsuperscript{332} Brushwood et al., supra note 178, at 7 (quoting Hans Jonas, Philosophical Reflections on Experimenting with Human Subjects, 98 DEDALUS 219 (1969)).

\textsuperscript{333} 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, PLOS ONE (Feb. 23, 2011), http://lera.ucsd.edu/papers/crime-metaphors.pdf.

\textsuperscript{334} "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 2 (2014); Katie Lang et al., Central Coherence in Eating Disorders: An Updated Systematic Review and Meta-Analysis, 15 WORLD J. BIOLOGICAL PSYCHIATRY 586, 586-89
central coherence, meaning they attempt to address a fragmented part of the problem while ignoring or even further 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 does not drive incoherent law and policy.

A. Regulating Prescribing at Federal Level

A number of agencies are involved in opioid regulation. At the federal level, the primary agencies are the Drug Enforcement Administration (DEA), a law enforcement agency, and the Food and Drug Administration (FDA), a public health agency. The DEA 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-to-V drugs have medically acceptable uses, are available by prescription only, and have potential for abuse and dependence ranging from high (Schedule II) to low (Schedule V). Most opioid prescription drugs used for pain but also implicated in drug-related morbidity and mortality are in Schedules II or III. Many of the benzodiazepines

(2014).

One example is the focus on reduced OROs without addressing the increase in heroin overdoses.

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 Anti-Narcotics Tax Act, ch.1, 38 Stat. 785 (1914). See, e.g., A. Christopher Bryant, The Third Death of Federalism, 17 CORNELL J.L. & PUB. POL’Y 101, 106-07 (2007).

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. See Drug Enforcement Admin., www.dea.gov (last visited Apr. 8, 2016).

See U.S. FOOD & DRUG ADMIN. (last updated Apr. 8, 2016), www.fda.gov.


Id. See also 21 U.S.C. § 812 (2012).

Id. Examples of Schedule II drugs include morphine, Demerol, oxycodone, Dilaudid, and fentanyl.
implicated in polysubstance abuse, such as Ativan, Valium, and Xanax are Schedule IV drugs. Scheduling is both relevant to the requirements for valid prescriptions and 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 incurred liability. Sometimes that conduct is obviously outside the care relationship, such as exchanging prescriptions for money without conducting a history or examination, 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, but 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

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344 Id. This is the case despite very real concerns surrounding the involvement of benzodiazepines in polydrug overdoses.

345 See 21 C.F.R. § 1306 (1997). State laws often impose additional requirements, such as triplicate forms. See, e.g., Schedules of Controlled Substances: Rescheduling of Hydrocodone Combination Products from Schedule III to Schedule II, 79 Fed. Reg. 49661 (Aug. 22, 2014) (amending 21 C.F.R. § 1308). (“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).


347 See 21 C.F.R. § 1306.04(a) (2005) (“A prescription for a controlled substance ... must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.”); 21 U.S.C. § 829 (2008) (“[N]o controlled substance in schedule II [or III or IV] ... may be dispensed without the written prescription of a practitioner.”).


349 See, e.g., United States v. Kaplan, 895 F.2d 619, 620-21 (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).


351 Id. at 308.
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chilling effect that news of such investigations can create in the physicians, perhaps through availability cascades.\(^{352}\) The DEA can investigate providers for any reason;\(^{353}\) 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.”\(^{354}\) Nonetheless, being arrested and indicted, even if it does not result in a conviction, can destroy a provider’s career.\(^{355}\) Dr. Andrew Ngyuen’s case is illustrative; he was taken into custody and indicted based on a false affidavit.\(^{356}\) 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.\(^{357}\) He suffered millions of dollars in harm in lost patients and reputational damage.\(^{358}\) The charges were eventually dismissed, but the harm was already done.\(^{359}\)

The fact that prescribing scrutiny is disproportionately focused on opioids, rather than on other drugs that result in harm or death, is also problematic.\(^{360}\) For example, physicians do not seem to be prosecuted after a patient overdoses on antidepressants, but are sometimes charged with murder for the same outcome involving opioids.\(^{361}\) 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.”\(^{362}\)

\(^{352}\) 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., M.M. Reidenberg & O. Willis, Prosecution of Physicians for Prescribing Opioids to Patients, 81 CLINICAL PHARMACOLOGY & THERAPEUTICS 903, 903 (2007).

\(^{353}\) United States v. Morton Salt Co., 338 U.S. 632, 642-43 (1950) (noting 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”).

\(^{354}\) Issuance of Multiple Prescriptions for Schedule II Controlled Substances: Proposed Rule, 71 Fed. Reg. 52717 (Sep. 6, 2006). But see, Hoffmann, supra note 339, at 233, for an analysis of recent cases against physicians that reflect aggressive prosecutions.

\(^{355}\) See Reidenberg & Willis, supra note 352, at 904 (finding questionable prosecutions in a large number of physician prosecutions for which the state board never reviewed the prescribing practices before an indictment).

\(^{356}\) See Brushwood, supra note 130, at 157.

\(^{357}\) Id.

\(^{358}\) Id.

\(^{359}\) Id. See also Hoffmann, supra note 339.

\(^{360}\) Reidenberg & Willis supra note 352, at 904.

\(^{361}\) Id. at 905.

\(^{362}\) Id.
2. Rescheduling Controlled Drugs

In 2009, the DEA asked the FDA for a recommendation to re-schedule Schedule III hydrocodone combination drugs, such as Vicodin.\textsuperscript{363} Unless prohibited by state law, Schedule III drugs can be refilled, and in some states, called or faxed into the pharmacy.\textsuperscript{364} This allows providers to manage pain flexibly and remotely while avoiding prescribing unnecessarily large quantities. This is useful, for example, in post-operative care because patients can be sent home on a small supply of Schedule III drugs and receive a refill without another visit if their pain is still significant. In October 2013, the FDA announced, “[d]ue to the unique history of this issue and the tremendous amount of public interest,” they were recommending a recategorization to Schedule II.\textsuperscript{365} This was initiated by Physicians for Responsible Opioid Prescribing (PROP), who argue that there is no reason for the “non-cancer patient” to take opioids.\textsuperscript{366}

Concerns about the unintended consequences of the change are numerous,\textsuperscript{367} 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.\textsuperscript{368} Providers in states that require triplicate forms for Schedule II drugs are concerned about the administrative burden of state law requirements.\textsuperscript{369} Some surgeons have ex-

\textsuperscript{367} See, e.g., John Keilman, Doctors Consider Consequences of New Vicodin Rules, CHI. TRIB. (Oct. 6, 2014) (“The new rules … are meant to cut down [on problems] by making patients jump through more hoops to get the drug[s].”).
\textsuperscript{368} Id.; see also, Comment to Drug Enforcement Administration’s Proposed Rule: Schedules of Controlled Substances: Rescheduling of Hydrocodone Combination Products from Schedule III to Schedule II (Feb. 28, 2014), 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.”).
\textsuperscript{369} See, e.g., Christopher Ziebell, Comment to Drug Enforcement Administration’s Proposed Rule: Schedules of Controlled Substances: Rescheduling of Hydrocodone Combination Products from Schedule III to Schedule II (Mar. 18, 2014), 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
pressed their intention to write larger quantities of hydrocodone for postoperative pain because they can no longer call in a refill for patients who require additional medication.\textsuperscript{370} This is especially problematic for patients in rural areas or those traveling long distances for specialty surgeries.\textsuperscript{371} 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, the DEA finalized the rescheduling.\textsuperscript{372}

3. FDA Actions

The FDA is responsible for regulating the safety and effectiveness of drugs in the United States, approving all labels and labeling changes of drugs, and providing advice on scheduling of controlled substances.\textsuperscript{373} The FDA has taken several actions related to opioids recently. It requested a labeling change for oxycodone products to remove the indication for moderate pain, leaving the only indication as severe pain, although the drug itself 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 Tylenol #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.""). In fact, on September 7, 2015, I spoke with a woman who received a post-operative prescription for an inappropriately mild Schedule III drug after major, invasive surgery because the discharging provider was an Advanced Practice Nurse who could not prescribe Schedule II drugs.


\textsuperscript{371} See, e.g., Andrew Gurman, Comment to Drug Enforcement Administration Proposed Rule: Schedule of Controlled Substances: Rescheduling of Hydrocodone Combination Products from Schedule III to Schedule II (Mar. 13, 2014), 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.").


did not change. The FDA promulgated requirements for Risk Evaluation and Mitigation Strategy (REMS) programs for some drugs approving one and incentivizing the formulation of more abuse-deterrent formulations of opioids, and other activities aimed at solving the opioid epidemic, a term the agency has embraced. 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 programs because of the increased safety, education, and training requirements for providers. Nonetheless, these requirements may be a small price to pay for continued patient access to therapeutic opioids.

Recently, the FDA elicited outrage from groups committed to eliminating opioid use by approving a long-acting hydrocodone product, Zohydro ER. An open letter signed by over a dozen anti-addiction groups called for the resignation of then-FDA Commissioner Margaret Hamburg, and several legislators initiated hearings on the decision. In response,

377 See U.S. FOOD & DRUG ADMIN., What We Do, supra note 373.
378 See Kieran A. Slevin & Michael A. Ashburn, Primary Care Physician Opinion Survey on FDA Opioid Risk Evaluation and Mitigation Strategies, 7 J. OPIOID MGMT. 109 (2011).
379 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 ST. J. (Sept. 4, 2014), blogs.wsj.com/pharmalot/2014/09104/governors-to-hhs-rescind-fda-approval-of-the-zohydro-painkiller/.
three FDA 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 "[t]he risk in singling out a single drug … in this complex, multidrug epidemic is that resulting policy is unlikely to have an effect on the underlying causes."381 This singling out of one drug here may be a product of the opioid heuristic.

B. Regulating Prescribing and Practice at the State Level

"[P]sychological, 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."382 States regulate controlled substances and provider practice through a variety of legal regimes.383 Professional practice is regulated through state medical boards (SMBs).384 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.385 In the past, SMBs have taken action to improve the care of patients in pain, such as instituting rules and advocating for legislation to enhance protections for the good faith treatment of pain.386

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 suffering from chronic pain and related disorders.387

381 Jones, Lurie, & Woodcock, supra note 363, at 1733 (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.").
383 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., Hoffmann & Tarzian, supra note 5.
384 See, e.g., Nadia N. Sawicki, Character, Competence, & the Principles of Medical Discipline, 13 J. Health Care L. & Pol'y 285 (2010).
386 See Carbone Cancer Ctr., supra note 138. See also Fed'n of State Med. BDS., supra note 382.
387 For an overview of state laws in this area, see Nat'l Alliance for Model State Drug Laws & The Nat'l Safety Council, Prescription Drug Abuse, Addiction, &
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. 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.” 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 be reviewed.” At the same time, the Acts acknowledged the important role of disciplinary review for providers who demonstrate carelessness. 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.

In response to OROs, some states are willing to sacrifice those advances for pain treatment. For example, Tennessee’s Intractable Pain Treatment Act, passed in 2001, included a patient’s bill of rights, that acknowledged that some kinds of chronic pain require long term opioids. The law also explicitly continued authority for the state medical board to investigate and discipline careless prescribers. The law was deleted in its entirety as of July 2015. In addition to deleting the entire act, new legislation required the state boards of medicine, osteopathy, and nursing to re-

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390 Id.

391 Id.

392 State-by-state breakdowns of law and regulations are available from several sources. See CARBONE CANCER CTR., supra note 138; FED’N OF STATE MED. BDS., Pain Management Policies, supra note 388.

393 TENNESSEE INTRACTABLE PAIN TREATMENT ACT, TENN. CODE ANN. § 63-6-1101 et seq. (repealed 2015).

394 Id.

395 Id.

peal any rules promulgated under that Act. 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." In addition, they argued the Act had caused undue harm to citizens of Tennessee, that these types of treatments "[were] not needed," and described the use of prescription opioids as a plague. Any earlier state plan had recommended a review and revision—not deletion—of the Tennessee Intractable Pain Treatment Act; even that plan included conclusory language of its own that "the perceived under prescribing of opioids by Tennessee physicians in 2001 has now been replaced by overprescribing." Law enforcement—including the Tennessee District Attorneys and the Bureau of Investigations—supported the deletion of the Act, particularly objecting to the language that required doctors to refer patients to other providers if they refused to prescribe opioids for them. Pain specialists were ostracized and 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 on medical standards, including the fact that blanket abstinence-only approaches are outdated in addiction medicine while chronic-management models and harm reduction models, such as medication-assisted therapy, are endorsed as highly effective for patients with opioid use disorders.\textsuperscript{404}

b. \textit{Redefining and Restricting Pain Management Practices}

A number of states have enacted legislative and regulatory strategies that 1) severely restrict the ability of physicians to practice independently, treading back into dosing-limit regulations, and worse,\textsuperscript{405} 2) actively discourage pain practice,\textsuperscript{406} and 3) curtail primary care providers from treating chronic pain patients.\textsuperscript{407} Some proposed legislation that further scrutinizes prescribing practices of opioids only.\textsuperscript{408} For example, the Texas Pain Management Act, combined with medical board rules, require more than forty specific documentation and care requirements for physicians treating chronic pain.\textsuperscript{409} Maine’s Medicaid program instituted rules that significantly reduced coverage of opioids, requiring those in chronic pain to engage in alternate therapies for a year.\textsuperscript{410} Maine touted the success

\textsuperscript{404} NAT’L CTR. ON ADDICTION & SUBSTANCE ABUSE, supra note 66.

\textsuperscript{405} See, e.g., FLA. STAT. § 456.44 (2012) (mandating pain contracts, substance abuse screening, referrals under certain circumstances, and many other detailed requirements for each patient encounter) (amended 2016).

\textsuperscript{406} 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 (2012 (amended 2016); OHIO ADMIN. CODE § 4731-29 (2011) (requiring among other things, special daily logs of patients).

\textsuperscript{407} See, e.g., § 458.3265, supra note 406 (mandating extension of 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{408} See, e.g., SB. 422 (NM 2015) (proposed legislation) (creating a new administrative oversight board to review the prescribing practices of physicians who prescribe opioids but making no mention of the need to scrutinize polydrug prescribing as well).

\textsuperscript{409} 22 TEX. ADMIN. CODE §§ 170.1–170.3 (2014). See also Louis Leichter, The Texas Intractable Pain Treatment Act and Chronic Pain, TEX. MED. LICENSING LAW BLOG (Mar. 11, 2013), http://www.txmedicallicensinglaw.com/2013/03/articles/texas-medical-board/the-texas-intractable-pain-treatment-act-and-chronic-pain/ (“[W]hile the Intractable Pain Treatment Act required heightened monitoring and more rigorous documentation merely for known drug abusers, the Board’s most recent rules make that standard applicable to all long-term pain management patients.”).

\textsuperscript{410} See, e.g., ME. DEP’T OF HEALTH AND HUMAN RES., MAINECARE BENEFITS MANUAL, Ch.2, §80, (2013); see also Blake Davis, Maine Medicaid Rules Reduce Narcotic
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.” On the other hand, the use of heroin steadily increased over that same time period; a regrettably predictable result of incoherent policies aimed at reducing prescription opioid numbers absent context. These proposals reflect no concern for any of the harms of other classes of drugs, the risks of poly-drug interactions, or the administrative costs required to effect the changes. Instead, they reflect an unfortunate opioid heuristic on the part of decision makers in state legislatures.

Washington State is illustrative. In 2010, despite widespread opposition, the state legislature passed a bill to reverse the increased trend of prescription opioid overdose deaths; the bill applies only to the treatment of chronic non-cancer pain. Washington fully embraced the false dichotomy advanced by Physicians for Responsible Opioid Prescribing of dividing chronic pain into cancer and non-cancer groups. Washington’s State Medical Directors’ Group website has all of their opioid prescribing education in a box entitled “Educational Materials are presented by Physicians for Responsible Opioid Prescribing.”

The state law sets limits on 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 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 of


411 See Blake Davis, supra note 410 (quoting Roy McKinney, Director of Maine’s DEA). Using the raw number of prescriptions is not an appropriate surrogate end-point if the goal of legislation is to reduce substance abuse morbidity and mortality. It also provides no information on the quality of care received by patients in pain.

412 Id.


414 See PHYSICIANS FOR RESPONSIBLE OPIOID PRESCRIBING, About Prop, www.supportprop.org/about-prop/ (last visited Apr. 9, 2016)

415 AGENCY MED. DIRS. GRP., Other Resources, http://www.agencymeddirectors.wa.gov/OtherResources.asp (last visited Apr. 9, 2016) (ironically, this is listed just above of Evidence Based Opioid Prescribing).

416 Id.

hydrocodone/325mg acetaminophen combination pills with instruction of one to two pills every four to six hours as needed for pain.\textsuperscript{418} A patient who follows those directions and takes one pill every four hours receives 30mg of hydrocodone in one day (equivalent of 120mg morphine equivalents).\textsuperscript{419} These are not pain management doses. But recall that the biggest risks involve polysubstance abuse, an issue unaddressed by the law. Thus, it is no wonder providers fear prescribing opioids at all. This is echoed by a Seattle Times article quoting Dr. Peter McGough, chief medical officer for UW Medicine's Neighborhood Clinics, on the impact of the law, "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."\textsuperscript{420}

Of course, Washington already had a shortage of pain management providers,\textsuperscript{421} and some left the area in the wake of the restrictive regulations.\textsuperscript{422} The state health department, realizing that chronic pain patients would not have access, generously suggested they try alternative treatments like "yoga, massages, or acupuncture," although state Medicaid plans do not cover any of those costs.\textsuperscript{423} The Washington law also includes a host of practice requirements such as mandatory treatment agreements, mandatory pain care plans, and rules that make providers responsible for monitoring patient compliance.\textsuperscript{424} An article in the Seattle Times highlighted the real harm to patients with CP, describing the plight of a man with CP who had managed his pain for eight years on a small and steady dose of oxycodone (a generic short-acting opioid).\textsuperscript{425} 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.\textsuperscript{426}

\textsuperscript{418} Id.
\textsuperscript{419} Id. Calculator available at www.agencymeddirectors.wa.gov/files/dosingcalc.xls.
\textsuperscript{422} Heringola, \textit{supra} note 413, at 3.
\textsuperscript{423} Id. (citing Patricia Murphy, \textit{Washington State Pain Management Law Will Take Effect Soon}, KUOW News (June 24, 2011), http://www2.kuow.org/program.php?id=23774).
\textsuperscript{424} Heringola, \textit{supra} note 413, at 2.
\textsuperscript{425} Armstrong & Berens, \textit{supra} note 47.
\textsuperscript{426} Id.
c. Medicaid Fraud as Drug Control

Some states, such as Tennessee, have also committed serious time and resources to fraud investigations. Tennessee Medicaid (TennCare) recipients are aggressively prosecuted for violation of the doctor-shopping statute, 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. The law only applies to Medicaid recipients and the reason for the second prescription may not matter: all prescribers are now required to register prescriptions of opioids, benzodiazepines, 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 database 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, forty-eight other states have PDMPs but their efficacy varies widely from helpful to completely ineffective. Overall, they have not significantly reduced the amount of opioids prescribed, although the value of reduced prescriptions as a surrogate endpoint is questionable. As currently executed, the information included in the majority of PDMPs is incomplete at best. Most states do not require prescribers to consult the database before prescribing or to report their prescriptions under all circumstances. It is therefore unsurprising that prescriber partici---

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427 See, e.g., Hamblen Co. Woman Charged with TennCare Drug Fraud, TENN. DEP’T OF FIN. & ADMIN. (Mar. 3, 2015) https://www.tn.gov/finance/news/14126 (“We hope those that are abusing the TennCare program are getting the message that we are aggressively pursuing TennCare fraud and making arrests statewide. ... We made 22 arrests last month and we have many more cases in the pipeline.”) (quoting Inspector General Manny Tyndall).


429 TENN. CODE ANN. § 53-11-308(e) (2013) (“No prescription for any opioids or benzodiazepines may be dispensed in quantities greater than a thirty-day supply.”); TENN. CODE ANN. § 53-11-308(f) (2013) (“If a prescriber dispenses any opioids, benzodiazepines, barbiturates, or carisoprodol, then the prescriber shall submit the transaction to the controlled substances monitoring database.”).

430 See TENN. CODE ANN. § 53-10-306 (2014) (requiring a case number before accessing the database, as well as some other procedures but nothing approaching probable cause).


432 See Brady et al., supra note 305, at 142-43 (examining data between 1999 and 2008).

433 See id.

pation is highly variable.\textsuperscript{435} Even for those that use PDMPs, the utility can be limited by delays in reporting (many are updated only weekly or monthly).\textsuperscript{436} The level of communication between states also varies.\textsuperscript{437} PDMPs are most promising when they are constructed as a clinical rather than law enforcement tool, where they can allay provider fears and mitigate the chilling effect.\textsuperscript{438} Policies that require use by clinicians and 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;\textsuperscript{439} 2) privacy of the information,\textsuperscript{440} particularly as PDMPs increasingly involve other clinical data, 3) scrutiny of patients on long term opioids,\textsuperscript{441} and 4) the time demands of compliance.\textsuperscript{442} In short, more evidence is needed to determine the impact and utility of PDMPs for improving care and public health.

2. Failure to Reduce Harm

All of these efforts, at best, reduce the number of prescription opioids available for diversion. Historically, the availability of particular drugs of abuse ebb and flow over time with supply and enforcement shifts while the overall rate of substance abuse is stable.\textsuperscript{443} Thus, policies targeting particular drugs rather than the overall harms of substance abuse succeed only

\textsuperscript{435} See Allison Lange et al., \textit{Variability in Opioid Prescription Monitoring and Evidence of Aberrant Medication Taking Behaviors in Urban Safety-Net Clinics}, 156 PAIN 335, 335-40 (2015); Robert K. Twillman et al., \textit{Efforts to Control Prescription Drug Abuse: Why Clinicians Should Be Concerned and Take Action as Essential Advocates for Rational Policy}, 64 CA CANCER J. FOR CLINICIANS 369, 373 (2014) ("One of the most important challenges ... is the generally low adoption of PDMP use by providers.").

\textsuperscript{436} For example, California and Florida only have weekly updates of data. See Nat’l Alliance for Model State Drug Laws, supra note 434.

\textsuperscript{437} Id. Florida, for example, has no interstate sharing and has stringent pain clinic and practice laws, a combination sure to discourage reasonable providers from prescribing opioids.

\textsuperscript{438} Twillman et al., supra note 435, at 372.


\textsuperscript{440} Id. at 3. 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, \textit{Judge Blocks Warrantless Searches of Oregon Drug Database}, REUTERS (Feb. 12, 2014), www.reuters.com/article/us-usa-privacy-oregon-idusBREAlBOOOS20140212.

\textsuperscript{441} Islam & McRae, supra note 439, at 3-4.

\textsuperscript{442} Id. at 4.

\textsuperscript{443} 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., \textit{Rise of the Pills}, 15 UDC/DCSL L. REV. 91 (2011).


In late 2014, the CDC reported, “the death rate from heroin overdose doubled in the 28 states from 2010 to 2012 ... [c]omparing the same years, the death rate from [prescription opioid overdose] declined 6.6%.”\footnote{Rose A. Rudd et al., \textit{Increases in Heroin Overdose Deaths—28 States, 2010 to 2012}, 63 MORBIDITY & MORTALITY WKLY. REP. 849, 850 (Oct. 3, 2014).} 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.\footnote{Id.} 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.\footnote{Hal Johnson et al., \textit{Decline in Drug Overdose Deaths After State Policy Changes—Florida}, 2010-2012, 63 MORBIDITY & MORTALITY WKLY. REP. 569, 570 (July 4, 2014).} At best, the policy changes in Florida may have shifted some people with SUD away from prescription opioids; overall harm reduction is negligible. This 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 side-effect of an already incoherent policy response.

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 which are part of the unfortunately named “universal precautions” for pain treatment.\footnote{The term was borrowed from the infectious disease literature, where it refers to 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 microorganisms does little to reduce the stigma associated with CP. For an overview of the risk stratifications, and other recommendations as part of universal precautions, see Sehgal et al., \textit{supra} note 41, at ES79-80.} Along with the epidemic metaphor, “universal 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 place patients in one of three risk categories: low, medium, and high. The higher risk patients receive less medication and much more scrutiny. Along with longer-standing traditions of urine screening and pain agreements, these strategies have turned to detailed mandates in some states. 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.

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?

Many physicians require treatment agreements for all patients on opioids, especially over the long-term. This practice, while recommended for risk management reasons by a multitude of professional guidelines and state laws, has proven to be both unreliable and inconsistent clinically, a sentiment echoed by even those in strong support of limiting opioid use.

[Agreements are] controversial and questions are raised regarding their intent, elements, language and tone, readabil-

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450 Id.
451 Kentucky, Indiana, and Washington all require 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. ANN. § 218A.172 (2012) and 201 KY. ADMIN. REGS. 9:260 (2013) (requiring ongoing drug screenings that are random and unannounced); 844 IND. ADMIN. CODE 5-6-1 et seq. (2014); WASH. ADMIN. CODE § 246-919-856 (2012) (written agreement for treatment).
452 Mark Collen, Opioid Drug Contracts and Random Drug Testing for People with Chronic Pain—Think Twice, 37 J.L. MED. & ETHICS 841, 843 (2009).
453 Id.
ity, physician responsibility, and legal risk ... [while] [t]he evidence that [opioid treatment agreements] are effective in reducing opioid misuse is relatively weak and [they] have not been proven to improve adherence, improve patient care, or protect the rights of patients or physicians. 455

Nonetheless, 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. 456 Even so, the pain agreement is probably now the standard of care, given the high level of adoption by pain specialists, provider groups, and endorsement or mandate by state legislatures and regulatory agencies. 457 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 document understanding between patient and clinician of the goals and plan of care and to provide informed consent for treatment," 458 there is hope that agreements, when combined with a holistic approach to treatments, will not 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. 459

Regular and random urine drug screenings are usually part of the treatment agreement; 460 these are typically coupled with other screening for substance abuse.

455 Sehgal et al., supra note 41, at ES79.  
456 See Richard Payne et al., A Rose by Any Other Name: Pain Contracts/Agreements, 10 AM. J. BIOETHICS 5, 6-7 (2010).  
458 Cheatle & Savage, supra note 454, at 107.  
460 See Joanna L. Starrels et al., Systematic Review: Treatment Agreements and Urine
abuse or misuse, especially at the beginning of therapy. In addition to testing for illicit drugs, testing for the presence or absence of the prescribed drug is recommended. Even after a series of typical or expected findings, providers are told to test patients at least every six months. Moreover, some states are now requiring urine testing, a mandate now challenged in several jurisdictions as an unconstitutional search and seizure.

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. Here, as with other tools, providers need to carefully interpret the information with the patient in context. 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 overall patient well-being.

When
asked what action they take if a patient’s urine screen reveals an illicit drug, more clinicians surveyed would discharge the patient from their practice without discussion than those who would talk to the patient about the results or refer them for substance abuse treatment.469 This is not an ethically acceptable response. According to Reisfeld and Marschke:

Discharging a patient from a medical practice is virtually never an acceptable response to an inappropriate drug test. The clinician 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.470

Perhaps the most under-addressed problem with urine testing is the significant added associated costs.471 One of the few professional articles to mention the issue does so in one sentence, warning that “[e]ach 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.”472 This statement proved predictive: according to an article in the Wall Street Journal, “some pain doctors are making more from testing than from treating.”473 Described as “roundabout result of the war on pain-pill addiction,”474 Medicare spending on testing for drugs of abuse has increased 1,423% in the last five years.475 This is a serious societal cost and often holds no corresponding benefit for the patient. In practice, patients continue to be tested for risk management purposes even after years of consistent results. Even when results are unusual, providers are reluctant to address issues of substance abuse, preferring to discharge patients. The cost to patients is also significant—Medicare

469 See id. at 126 fig.6.
472 Christo et al., supra note 304, at 136 (emphasis added).
473 See Weaver & Matthews, supra note 471.
474 Id.
475 Id.
coverage is variable and some private payers limit the conditions and the frequency with which urine testing is covered.\textsuperscript{476}

Some doctors have taken advantage of the profit potential and set up services in their offices;\textsuperscript{477} A Wall Street Journal article profiled a doctor who made $1.4 million in one year just for testing his own patients and quoting him as saying, “urine drug testing is how I pay the bills.”\textsuperscript{478} The circumstances under which urine testing is conducted, the justifications for testing, and its effectiveness in improving health and reducing harms requires ongoing study.

3. Continuing Panic

These practices and other opioid related initiatives have advanced quickly,\textsuperscript{479} many without a coherent goal, which may be related to availability cascades. Many advocates for the adequate treatment of patients in pain are pessimistic. For example, Robert Twillman and colleagues worry that

[the quality care gains made in pain treatment that have helped preserve the functional 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.\textsuperscript{480}]

\textsuperscript{476} See, e.g., CTRS. FOR MEDICARE AND MEDICAID SERVS., U.S. DEP’T OF HEALTH & HUMAN SERVS., Local Coverage Determination, Urine Drug Testing, https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=36037&ContrlId=299&ver=13&ContrlVer=1&CntctcrSelected=299*1&Cntctcr=299&name=National+Government+Services%2c+Inc.+(National+Government+Services%2c+Inc.+(13102%2c+A+and+B+and+HHH+MAC%2c+J+K))+&name=National+Government+Services%2c+Inc.+(National+Government+Services%2c+Inc.+(13102%2c+A+and+B+and+HHH+MAC%2c+J+K)))&LCntctcr=299*1&DocType=Active&bc=AgACAAIADAAAAA%3d%3d& (last visited Sept. 14, 2016); BLUECROSS BLUESHIELD OF ALA., Urine Drug Testing in Pain Management, Policy #566, at 3 (Feb. 2016), https://www.bcbsal.org/providers/policies/final/566.pdf (listing as non-covered: “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”).

\textsuperscript{477} See 42 C.F.R. §411.355(b) (2010) (presuming this is accomplished under the in-office ancillary services exception under the Stark Law).

\textsuperscript{478} See Weaver & Matthews, supra note 471 (discussing Dr. Wadley’s practice).

\textsuperscript{479} While between 1999 and 2012, the number of federal legislative actions per year containing the word opioid averaged under 4, in the 113th Congress and 114th Congress, they totaled 24 and 137 respectively. See Opioid, CONGRESS.GOV, https://www.congress.gov/search?q=%7B%22source%22%3A%22legislation%22%2C%22search%22%3A%22opioid%22%7D (last searched Sept. 12, 2016).

\textsuperscript{480} Twillman et al., supra note 435, at 369.
There have been new attempts to discredit the use of opioids in CP altogether; however, some of the reasonable reevaluations of their effectiveness confirmed that opioids are effective in well-selected and evaluated patients. In addition to the restrictive state laws discussed above, a host of federal legislation was proposed, including proposals that would further restrict labeling of oxycodone containing opioids only, create new additional regulatory requirements for the approval and labeling of opioids, create surveillance of opioid prescribers, and create mandatory state surveillance of prescription patterns and notification of all prescribers of suspected patterns of patient misuse. 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 revised its Model Policy for Opioid Prescribing, adding more restrictive language and requirements by which boards of medicine will judge physicians’ opioid prescribing practices.

Clinical policies and provider practices and attitudes have also changed in ways that may be detrimental to patients with pain. A 2013 study by Bergman and colleagues indicates serious reservations by primary care doctors with respect to their patients in pain, lingering disbelief, and

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481 See, e.g., Alec B. O’Connor & Robert H. Dworkin, Treatment of Neuropathic Pain: An Overview of Recent Guidelines, 122 AM. J. MED. S22 (2009) (reaffirming opioids are second line treatments that can be used as first line treatments in certain circumstances); Ewan McNicol et al., Opioids for Neuropathic Pain (2013) (declaring strengthened evidence for intermediate opioid use).

482 See Stop Oxy Abuse Act 2013, H.R. 1366, 113th Cong. (2013). Oxycodone is just one of many of prescription opioids and targeting oxycodone alone makes less sense than targeting prescription opioids without concern about heroin or other illicit opiates.


484 See Prescription Drug Monitoring Act of 2016, S. 3209, 114th Cong. (2016) (requiring at section 3(a)(2) the state prescription drug monitoring program to “provide proactive notification to a practitioner when patterns indicative of controlled substance misuse, including opioid misuse, are detected”).

485 See Rich, supra note 1, at 524-25 (noting that the committee sent letters to the Joint Commission, the Mayday Fund, the Center for Bioethics, and the Wisconsin Pain & Policy Studies Group, among others).

486 This may be a necessary evil in the current environment but it is worth noting that the new policy is twenty-nine pages long while the 2004 policy was five pages long. See FED’N OF STATE MED. BDS., supra note 382 (2013 policy); cf. FED’N OF STATE MED. BDS, Model Policy for the Use of Controlled Substances for the Treatment of Pain, 19 J. PAIN & PALLIATIVE CARE PHARMACOTHERAPY 73, 73 (2005); see also Sandra H. Johnson, Providing Relief to Those in Pain: A Retrospective on the Scholarship and Impact of the Mayday Project, 31 J.L. MED. & ETHICS 15, 16-17 (2003) (detailing some of the policy work contained in the 2004 guidelines).
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 and discourages the use of opioids at all for acute back pain, dental pain, pelvic pain, or migraines; the singling out of those types of pain is concerning, in part, because they are also the patient groups for whom the suicide risk is the highest. Worse yet, multiple visits to an ED for pain alone triggers the recommendation that the patient’s chart be flagged and that they receive a letter informing them that they will not receive opioids for pain again. 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. New York City’s “Discharge Opioid Prescribing Guidelines” 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 without any opioids according to the guidelines. 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.

487 Bergman et al., supra note 200, at 1690-94.
488 Jeffrey A. Glassberg et al., Emergency Provider Analgesic Practices & Attitudes Toward Patients with Sickle Cell Disease, 62 ANNALS OF EMERGENCY MED. 293, 298-301 (2013) (noting that 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).
490 AM. ACAD. OF EMERGENCY MED., supra note 489. 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.
491 Solis, supra note 17, at 91 (describing letters from Wisconsin ED to “frequent flyers” that they would no longer receive pain medication for their pain).
493 See, e.g., Robert A. Bitterman, The Federal Government Blocks South Carolina Hospitals from Posting ’Pain Management Signs’ in their Emergency Departments, ED LEGAL LETTER (July 1, 2013), http://www.ahcmedia.com/articles/6316-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
A 2015 study from the Journal of Emergency Medicine reflects the trends in the ED as well as assumptions and biases about opioid prescribing. The study involved thirteen separate EDs in North Carolina with electronically linked medical records through which over 400 patients with "chronic noncancer pain" who frequently utilized the emergency department were identified for participation in the study. The patients were then assigned to an intervention or control group; those in the control group had no changes implemented. Patients in the intervention group each received a letter with a blanket statement that they "should no longer receive opioid pain medication" for their pain from the ED. The same letter was sent to the patient's community based health provider (if they patient had a community health provider). In addition, an alert was placed in the charts of the patients in the intervention group that stated it was in the patients' best interest to receive treatment for their pain from a community-based provider. The alert continued by recommending that the ED provider should suggest to these patients that they visit a community based primary care provider, pain clinic, or other facility such as a drug treatment or mental health facility. ... The intervention also invited the ED provider not to prescribe opioid medications to the patient, and not to write prescriptions for any medications that the patient reported as lost or stolen.

The stated goals of the study were to determine if interventions (i.e. notifying patients they should not use the ED for pain exacerbations and notifying providers not to prescribe opioids to these patients) would decrease ED visits and opioid prescriptions.

There are a number of problematic assumptions that underlie the study design and execution. First, there is an unquestioned assumption that any and all patients with chronic pain only seek ED care to obtain opioids, the use of opioids in those patients is an unqualified bad, and that there is no medical reason to provide ED care to these patients outside of opioid prescribing—it is a classic example of conflating chronic pain with opioid departments to "educate" patients regarding the ED's restrictions.

494 Chris Ringwalt, et al., A Randomized Controlled Trial of an Emergency Department Intervention for Patients with Chronic NonCancer Pain, 49 J. EMERGENCY MED. 974 (2015).
495 Id. at 975.
496 Id.
497 Id. (emphasis added).
498 Id. at 974-75.
oid use. Second, the study targets this group of patients with interventions directly aimed at decreasing their access to medical care and did so without obtaining any form of informed consent from the patients involved, despite referring to the patients as study subjects and research participants repeatedly. Waiver of consent was justified on the basis that patients not receiving ED care or particular treatments only placed them at minimal risk.

The assessment of minimal risk seems to depend upon several unstated assumptions: 1) that these patients had alternative sources of care and if not, that the ED providers would override the protocol if there was a "real" or legitimate reason for the visit; and 2) denying pain treatment to someone in pain carries no risk of harm because continued suffering is not a harm, treatment is available elsewhere, or perhaps because the underlying narrative of malingering, deceitful, or drug diverting pain patients is accepted. In fact, many in North Carolina—some 400,000 citizens—lack basic access to care, leaving safety net providers, including EDs, as their only option for care. Of those that were seen in the ED during the study period, nearly all were Medicaid recipients, a group that the authors even admitted probably experienced difficulty with access to community based providers. Third, no existing research ties receipt of an opioid prescription in the ED to subsequent diversion or overdose or death or poorer patient outcomes of any kind; therefore, this intervention is classic example of use reduction absent context. In fact, the authors seem surprised that the patients in their study received and used opioids for pain control, stating "we surmise that patient’s primary incentive for continuing ED visits was to receive ... opioids in the ED itself. If so, this finding suggests that the patients...were unlikely to have visited the ED to secure prescriptions for opioids that they subsequently intended to divert." Even if some of these patients have opioid use disorders, decreasing their access to care altogether certainly will not lead them to treatment or improve the public health.

499 See Goldberg, supra note 326.
500 Ringwalt, supra note 494, at 977 (“Because we were primarily interested in changing ED providers' prescribing practices, we secured consents ... only from the CHS' ED providers.”).
501 Id.
503 Ringwalt, supra note 494, at 978 (acknowledging that Medicaid patients may have had “challenges in scheduling outpatient appointments or finding a provider who would accept their insurance”).
504 Id. at 979.
This study, co-authored by professionals from the CDC and funded with public dollars, characterizes the statistically significant reduction in ED visits and opioid prescriptions in the intervention group a success—absent context—while mentioning briefly that they could not exclude the possibility that some of the patients were harmed by a lack of treatment for pain.\footnote{Id. at 980.} What isn’t mentioned is that reducing access to care intentionally also reduces opportunities for assessment of and referrals for related disorders such as SUD and serious MI. It may also discourage patients from seeking ED care for new emergency medical conditions. Leaving any of these conditions untreated is perhaps the most harmful outcome of all. Most concerning, this study is not unique—indeed it represents the typical use reduction approach embraced by many in the public health and policy community.

V. POLICIES THAT REDUCE HARM WHILE PRESERVING GOODS

Some sanity remains in the midst of the incoherent policies. For example, the Centers for Medicare and Medicaid Services blocked South Carolina hospitals from posting the “pain management” signs as a potential Emergency Medical Treatment and Labor Act (EMTALA) violation.\footnote{See Bitterman, supra note 493. Severe pain is a 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 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{Oliver et al., supra note 175, at 171 (“Failure to identify and treat the concurrent conditions of pain and addiction compromises the ability to treat either condition effectively.”).} The American Academy of Pain Medicine has been vocal in terms of advocacy as well.\footnote{Use of Opioids for the Treatment of Chronic Pain, Am. Acad. of Pain Med. (Feb. 4, 2013), http://www.painmed.org/files/use-of-opioids-for-the-treatment-of-chronic-pain.pdf} Even some community leaders understand the need for overall harm reduction; for example, Dr. Wayne Wheeler was quoted as saying, “‘[c]ommunities must change their perception of drug abuse ... [t]hese 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 a community meeting organized by the Ohio Attorney General on curbing drug abuse. See Holly Zachariah, Scioto County Describes How It Cleaned up Drug Abuse, COLUMBUS DISPATCH, Oct. 24, 2013.} Several policy and
practice solutions have emerged that reflect overall concern for harm re-
duction, including the Comprehensive Addiction Treatment and Recovery 
Act (CARA) of 2016.51 Two particular interventions—safe storage and 
disposal and naloxone access—reduce harm and promote public health 
without marginalizing any particular patient group.

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).512 Policy ef-
forts in this area have taken the form of take back initiatives, from the fed-
eral to the local level. In 2010, Congress passed the Secure and Responsi-
ble Drug Disposal Act of 2010.513 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 meth-
ods of collection.514 The DEA has sponsored take-back events since 2010, 
often in conjunction with local law enforcement.515 Over the last four years, 
these events have collected 2,411 tons of unused opioids.516 Although mod-
est, CARA includes several safe disposal provisions: education programs, 
state demonstration projects, and expanded safe disposal sites.517
Safe storage has garnered less attention but is critical given the number of individuals who obtain drugs of abuse from friends or relatives. Patients prescribed opioids for home use should 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. Individual providers and systems may fear providing even inexpensive locks or lock-boxes to patients on prescription opioids or other controlled substances for fear of running afoul of the federal fraud and abuse laws. However, federal enforcement authorities should consider an exception for such a program or one in which drug manufacturers provide secured storage to patients under specific conditions in the interest of harm reduction. 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

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. These symptoms begin approximately one to three hours after consumption of the opioids but progress over an hour or more. Opioid deaths are al-

518 See, e.g., Requirements for Lock Box Use for Methadone, NETWORK FOR PUB. HEALTH LAW (Nov. 21, 2014), 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).

519 Id.

520 The Anti-Kickback Statute prohibits offering remuneration that induces referrals or business, including inducing patient visits through gifts such as waiving copays on a regular basis. 42 U.S.C. § 1320a-7b(b). The Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a, prohibits inducements to beneficiaries, except those of nominal value. See 5 Fed. Reg. 24400, 24410-11 (Apr. 26, 2000) (preamble to the final rule on the Civil Monetary Penalties Law).


522 Twillman et al., supra note 435, at 372.


most completely preventable.\textsuperscript{525} Timely administration of naloxone can prevent death,\textsuperscript{526} further, the ability of laypeople and bystanders to safely administer the drug has been established.\textsuperscript{527}

However, multiple barriers prevent access to, or timely administration of, the drug.\textsuperscript{528} Naloxone is a prescription drug, thus access is limited to authorized prescribers and patients with a provider-patient relationship.\textsuperscript{529} 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{530} Thus, the "[l]aw is a primary driver" of barriers to naloxone use.\textsuperscript{531}

The law can also be a solution, as initiatives in several states and communities have shown.\textsuperscript{532} Most states have taken legislative action to address some or all of these barriers.\textsuperscript{533} 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, and 5) funding for community-based education and training.\textsuperscript{534}

\textsuperscript{525} Corey Davis et al., \textit{Changing Law from Barrier to Facilitator of Opioid Overdose Prevention}, 2013 J.L. MED. & ETHICS 33, 33.

\textsuperscript{526} 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 the time responders arrived. \textit{See id.}

\textsuperscript{527} \textit{See id.} The drug is also now available in nasal spray form for emergency use. \textit{See, e.g.}, Amanda Robinson & Daniel P. Wermeling, \textit{Intranasal Naloxone Administration for Treatment of Opioid Overdose}, 71 AM. J. HEALTH SYS. PHARMACY 2129, 2131-35 (2014) (finding the use of intranasal administration was comparable to IV administration in the prehospital setting).

\textsuperscript{528} \textit{See, e.g.}, Hewlett & Wermeling, \textit{supra} note 524, at 371-76.


\textsuperscript{530} \textit{See id.} at 2.

\textsuperscript{531} \textit{See Corey Davis et al., \textit{supra} note 525, at 33.}

\textsuperscript{532} \textit{Id.} at 33-34. \textit{See also}, Alexander Y. Walley et al., \textit{Opioid Overdose Rates and Implementation of Overdose Education and Nasal Naloxone Distribution in Massachusetts: Interrupted Time Series Analysis}, BMJ (Jan. 31, 2013), www.bmj.com/content/346/bmj.f174 (demonstrating a decrease in opioid overdose death rates after implementation of overdose education and nasal naloxone distribution campaigns).

\textsuperscript{533} For an excellent and comprehensive overview of these laws, see Corey Davis, \textit{supra} note 529. As of June 2016, all but three states had passed some legislation to increase access to naloxone. \textit{See id.}

\textsuperscript{534} \textit{Id. See also}, Corey Davis et al., \textit{supra} note 525, at 34-35.
The idea of reclassifying naloxone as an over-the-counter drug is being explored.\textsuperscript{535} 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 both educate the population about and increase access to naloxone 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 the community, focusing on the loved ones of persons with SUD, law enforcement, patients with CP on opioids, and community groups.\textsuperscript{536} As of December 2014, nearly 200 community-based groups that distribute naloxone are estimated to have prevented 26,000 overdose deaths.\textsuperscript{537} Naloxone access for veterans receiving services at the Veteran’s Administration is also addressed by CARA.\textsuperscript{538}

Despite the incredible potential to significantly reduce harm, these laws have faced criticism by some,\textsuperscript{539} mostly based on theories of risk compensation, essentially arguing that users will consume opioids more recklessly if they feel protected by the availability of naloxone.\textsuperscript{540} Although the objection is not without precedent, previous studies have failed to demonstrate empirical support for the idea in other contexts.\textsuperscript{541} 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.\textsuperscript{542} Naloxone availability reduces harm across the board and can serve as a compelling catalyst for treatment.\textsuperscript{543} In testimony before a combined meeting of the FDA, CDC, National Institute of Drug Abuse, and others, Scott Burris put it this way:

\textsuperscript{535} See FOOD & DRUG ADMIN. ET AL., supra note 181.

\textsuperscript{536} Bridget M. Kuehn, Back from the Brink: Groups Urge Wide Use of Opioid Antidote to Avert Overdoses, 311 JAMA 560, 560-61 (2014).

\textsuperscript{537} Corey Davis, supra note 529, at 2.


\textsuperscript{539} See, e.g., FOOD & DRUG ADMIN. ET AL., supra note 181, at 369-73 (comments of Dr. Madras).

\textsuperscript{540} For a discussion of the role of risk compensation in public health polices, see, e.g., Kristen Underhill, Risk-Taking and Rulemaking: Addressing Risk Compensation Behavior Through FDA Regulation of Prescription Drugs, 30 YALE J. ON REG. 377 (2013).

\textsuperscript{541} Id. at 392-93 (surveying the many areas in which this has been studied).

\textsuperscript{542} See Robinson & Wermeling, supra note 527.

\textsuperscript{543} FOOD & DRUG ADMIN. ET AL., supra note 181, at 333 (comments of Prof. Scott Burris).
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. 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.544

C. Conclusions

Centrally coherent policy solutions for the complex of problems surrounding improper use of opioids are needed. 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 without undue intrusion are critical. 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. Patients in pain should be able to trust providers to treat them appropriately, which may or may not include prescription opioids, and with the understanding that pain is associated with a host of related problems and comorbidities—none of which diminish the patient’s dignity. Patients with SUD require care and support, not criminalization and exclusion. The public health will only improve when we embrace a system that incentivizes care and treatment for all patients, especially those with behaviors and characteristics long subject to cultural and societal based biases and exclusion. This will take deliberate and difficult individual and group action that incentivizes outreach over out-grouping and thoughtful consideration of our underlying assumptions about pain, addiction, and mental illness. Regulatory efforts that focus on opioid use absent context only succeed in shifting rather than reducing harms.

The underlying public health harms associated with opioid misuse are increased morbidity (increased disease burden and decreased function and quality of life from disease or injury) and mortality through untimely deaths. Policy solutions must address those particular underlying problems rather than focusing on prescription opioid use reduction alone. These include addressing the harms of polysubstance use, the relative dangers of certain opioids, the quality of care for pain and related disorders, access to care and treatment for SUD, and concerns about untimely death from suicide. Practice guidelines should include concerns about screening patients

544 Id. at 333-34.
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 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 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 idea 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 1: Common Opioid and Pain Management Policies, Implementers, and Justifications |
|-----------------------------------------------|-----------------------------------------------|-----------------------------------------------|
| Policy                                | Level of Implementation | Conditions necessary to enhance patient wellbeing |
| Mandatory Provider Education | SBM                         | Comprehensive coverage needed of pain, SUD, suicidality, and other comorbid conditions as well as decision making errors and bias; one sided or fragmented mandates are of little use |
| PDMPs                                 | State statutes and regulations, communication may be facilitated through federal channels | Real time reporting, communication with neighboring states, mandatory use by providers and pharmacies, protections for patient privacy |
| ED initiatives, notice of refusal to treat patients with CP with opioids | Local and practice level | No justification for a blanket refusal to treat or blanket exclusion of opioids outside the context of a specific patient encounter. |
| **Naloxone access and immunity provisions** | State statutes; FDA could eventually reclassify as over the counter | 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. |
| **Treatment Agreements** | Practice Level; SBM, state statutes | No justification for state mandated agreements. Use in practice to improve communication and appropriate treatment and not as a justification for discharging patient. |
| **Debiasing Training** | Practice level; SBM | Mandatory CMEs that incorporates debiasing but is not diagnosis specific may improve care to all patients but more research needed. |
| **Urine Screening** | Practice level; SBM | 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. |
| **Safe Storage and Disposal** | Federal (DEA), state & local community, law, regulation, & outreach; practice level | 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. |
| **Opioid dosing and percentage of patients restrictions** | State statutes and SBM | 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. |
| **Data collection** | Federal & state government; private agencies | 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. |