Definitions Matter: A Taxonomy of Inappropriate Prescribing to Shape Effective Opioid Policy and Reduce Patient Harm

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I. INTRODUCTION

> *We have to be careful to resist reactions that could endanger pain treatment—a fundamental right for all of us—when it is unclear that the proposed solution will succeed in any of its aims or that it even addresses the real locus of the problem.*[1]

Jay Lawrence died by suicide after his providers unilaterally and too rapidly decreased his pain medication.[2] They did so in response to the Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain (CDC Guideline or Guideline),[3] despite the fact that the CDC Guideline is for primary care providers making decisions about beginning opioids in opioid naïve patients.[4] The

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* Assistant Professor and Director, Health Law Program, Creighton University School of Law. I am grateful for the many patients with chronic pain and the array of careful and compassionate providers with whom I have worked in the past, as well as the opportunity to work for and with Sandra H. Johnson, a pioneer in the use of law and policy to improve pain treatment. Those experiences deeply informed this article. As always, Sean Dineen is my champion and best proof-reader—I am grateful for his constant support. Many thanks to John Bergstresser, who provided research assistance for this article and to Dr. Stacey Tovino, Victoria Haneman, and Greg O'Meara for their thoughtful comments. All of them made this article better. Any errors are mine alone. I published an abbreviated form of this article in the Hastings Center Report in 2018. *See* Kelly K. Dineen, *Defining Misprescribing to Inform Prescription Opioid Policy*, 48 HASTINGS CTR. REP. 4, 5–6 (2018).

1. Evan Anderson & Scott Burris, *Opioid Treatment Agreements Are the Answer. What Is the Question?*, AM. J. BIOETHICS, Nov. 2010, at 17.

2. Meredith Lawrence, *How the CDC Guidelines Killed My Husband*, 8 NARRATIVE INQUIRY BIOETHICS 219, 219 (2018); *see also* Meredith Lawrence, *How Chronic Pain Killed My Husband*, PAIN NEWS NETWORK (Sept. 6, 2017), https://www.painnewsnetwork.org/stories/2017/9/4/how-chronic-pain-killed-my-husband [https://perma.cc/AWA6-42PT] ("When the doctor took away Jay's medications, they took away his quality of life. That was what led to his decision. Jay fought hard to live with his pain for a long time, but in the end fighting just was not enough.").

3. Lawrence, *How the CDC Guidelines Killed My Husband*, *supra* note 2, at 219 ("The decision to cut down his medication was based solely on his doctor's misinterpretation of the CDC guidelines.").

4. Deborah Dowell et al., Ctrs. for Disease Control & Prevention, *CDC Guideline for Prescribing Opioid for Chronic Pain—United States,* 2016, 65 MMWR RECOMMENDATIONS & REP. 1, 3 (2016), https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf [https://perma.cc/DB3C-

Guideline did not apply to Jay, who had been on a stable dose of prescription opioids for years,[5] nor did it apply to his providers, who were pain specialists, not primary care providers.[6] Moreover, the Guideline specifically states "[c]linical decision making should be based on a relationship between the clinician and patient, and an understanding of the *patient's clinical situation, functioning, and life context. The recommendations in the guideline are voluntary*, rather than prescriptive standards."[7] In fact, the Guideline is written specifically with the patient context in mind and includes a statement that higher daily doses should be justified by the patient's condition.[8]

Nonetheless, out of fear, misunderstanding, or self-protection, the Guideline was misapplied here and misconstrued by providers, lawmakers, and law enforcement throughout the country, with many states adopting the non-prescriptive daily dosage recommendations as black letter law.[9] Jay's providers made sweeping decisions about every patient in their practice—unilaterally decreasing every patient on prescription opioids to 45mg of morphine milligram equivalents (MME)[10] per day (half the 90mg MME in the CDC Guideline) regardless of their current doses or circumstances, and certainly not in the context of the patient's individual clinical situation.[11] According to Jay's widow,

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T8MW] ("This guideline is intended for primary care clinicians . . . who are considering prescribing opioid pain medication for painful conditions that can or have become chronic.").

5. Lawrence, *How Chronic Pain Killed My Husband*, *supra* note 2.

6. *Id*. I intentionally use the term "provider" throughout this essay. Scholarship in this area too often focuses only on physicians when many types of health care providers (e.g., dentists, advanced practice nurses, psychologists, physician assistants) are authorized by state law and the Drug Enforcement Agency to prescribe opioids.

7. Dowell et al., *supra* note 4, at 2 (emphasis added).

8. *Id.* at 23 ("Most experts also agreed that opioid dosages should not be increased to ≥90 [morphine milligram equivalents]/day without careful justification based on diagnosis and on individualized assessment of benefits and risks.").

9. Kurt Kroenke et al., *Challenges with Implementing the Centers for Disease Control and Prevention Opioid Guideline: A Consensus Panel Report*, 20 PAIN MED., 724 (2019), https://doi.org/10.1093/pm/pny307 [https://perma.cc/L3UY-CY4H]; *see also* Corey S. Davis et al., *Laws Limiting the Prescribing or Dispensing of Opioids for Acute Pain in the United States: A National Systematic Legal Review*, 194 DRUG & ALCOHOL DEPENDENCE 166 (2019) (conducting a national survey and identifying themes of state laws limiting prescriptions through 2017); *Prescribing Policies: States Confront Opioid Overdose Epidemic*, NCSL (Oct. 31, 2018), http://www.ncsl.org/research/health/prescribing-policies-states-confront-opioid-overdose-epidemic.aspx [https://perma.cc/2SDE-CYFG].

10. Daily morphine milligram equivalents are an attempt to standardize the opioid dosing of any prescription opioid medication. *See, e.g.*, Alexandra L. McPherson, *Safety in Numbers or Lack Thereof: Opioid Conversion Calculators*, PHARMACY TODAY, Sept. 2017, at 44. The ways in which CDC calculates daily MME is also the source of significant controversy. *See, e.g.*, Jeffrey Fudin et al., *Safety Concerns with the Centers for Disease Control Opioid Calculator*, 11 J. PAIN RES. 1 (2017).

11. Lawrence, *How the CDC Guidelines Killed My Husband*, *supra* note 2, at 220 ("During his

> Jay was a "model" pain patient. He was seen at a pain clinic at least monthly. He never took more pills than prescribed, and he only received opiates from that clinic. He attempted any treatment alternatives offered by his doctor, his pill counts were accurate at each visit, and he never failed a urinalysis.[12]

Jay was one of the estimated twenty million people in the United States with high-impact chronic pain.[13] After multiple back surgeries, physical therapy, injections, two implanted devices for pain, and myriad alternative treatments, Jay found a daily routine that included opioids that allowed him to function.[14] For Jay, the benefits of opioids outweighed the risks; he showed no signs of an opioid use disorder (OUD), other substance use disorder (SUD),[15] or other adverse effects.[16] There was simply no clinical justification for the decision.

There are a multitude of reasons for providers acting contrary to their ethical and professional obligation to patient well-being; when it comes to

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visit the PA told Jay that as a practice they would be decreasing all of their patients on high dose opioids to under 45 mg a day total."). At that time, Jay was on more than 120 morphine equivalents per day. *Id.* A dose taper to 45mg per day was about a third of his functional dose.

12. *Id.* at 219. Of note, Jay's widow was also charged with assisted suicide because she had purchased the gun Jay used to end his life. *Id.* at 221. She is currently on probation. *Id.*

13. *See id.* at 219–221. High-impact chronic pain limits "life or work activities on most days or every day in the past 6 months." James Dahlhamer et al., *Prevalence of Chronic Pain and High-Impact Chronic Pain Among Adults — United States*, 67 MMWR MORBIDITY & MORTALITY WKLY. REP. 1001, 1002 (2018). *See also* Mark H. Pitcher et al., *Prevalence and Profile of High-Impact Chronic Pain in the United States*, 20 J. PAIN 146, 148 (2019) (analyzing prevalence of high impact chronic pain using a definition of having "pain present on most days or every day over previous 3 months" and having one or more major activity limitation). For a variety of reasons, the prevalence of chronic pain in the United States continues to increase. *See generally* Richard L. Nahin et al., *Eighteen-Year Trends in the Prevalence of, and Health Care Use for, Noncancer Pain in the United States: Data from the Medical Expenditure Panel Survey*, J. PAIN (forthcoming 2019), https://doi.org/10.1016/j.jpain.2019.01.003 [https://perma.cc/R53Z-RZTK].

14. Lawrence, *How the CDC Guidelines Killed My Husband*, *supra* note 2, at 220.

15. 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. Opioid Use Disorder is a subset of SUDs. For more information on the DSM V Criteria for SUD, *see generally* Deborah S. Hasin et al., *DSM-5 Criteria for Substance Use Disorders: Recommendations and Rationale*, 170 AM. J. PSYCHIATRY 834 (2013).

16. Lawrence, *How the CDC Guidelines Killed My Husband*, *supra* note 2, at 219.

opioids,[17] fear of legal and regulatory scrutiny is among them,[18] a recurring theme over decades,[19] but one that is especially salient in the current climate.[20] This coupled with often incomplete understanding of laws and policies,[21] can lead to distorted reactions that cause patients harm.[22]

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17. I use the term opioids throughout this paper to mean prescription and illicit opioid drugs, any drug that interacts with opioid receptors in the body. The term includes both opiates (opioids that are derived from opium) and synthetic or partially synthesized (man-made) opioids, such as fentanyl. I will use the term *prescription opioids* when referring specifically to opioids that have been manufactured via the formal FDA process, legally in the chain of interstate commerce, and dispensed to a patient via a valid prescription. Common prescription opioids include oxycodone, hydrocodone, fentanyl, morphine, codeine, meperidine, Methadone, and hydromorphone. Illicit opioids include heroin, which is a schedule I drug under the Controlled Substance Act and thus is not available on the prescription market in the United States. Illicit opioids also include versions of all prescription opioids that are manufactured on the black market, including illicit fentanyl, which is often laced with heroin. *See generally Opioids*, NIH, https://www.drugabuse.gov/drugs-abuse/opioids (last visited Apr. 17, 2019) [https://perma.cc/54M4-4JQD]; *Controlled Substances Schedules*, DIVERSION CONTROL DIVISION, https://www.deadiversion.usdoj.gov/schedules/#define (last visited Apr. 17, 2019) [https://perma.cc/JJL5-X6PB].

18. *See, e.g.*, April Dembosky, *California Doctors Alarmed as State Links Their Opioid Prescriptions to Deaths*, NAT. PUB. RADIO (Jan. 23, 2019, 2:28 PM), https://www.npr.org/sections/health-shots/2019/01/23/687376371/california-doctors-alarmed-as-state-links-their-opioid-prescriptions-to-deaths [https://perma.cc/WF8B-F2PC] ("Some doctors . . . have been so frightened by the letters that they've lowered their patients' opioid doses or cut them off completely. Some doctors are telling their chronic pain patients to find another doctor, according to the California Medical Association. This carries a whole new set of risks.").

19. *See, e.g.*, Scott M. Fishman, *Risk of the View Through the Keyhole: There Is Much More to Physician Reactions to the DEA Than the Number of Formal Actions*, 7 PAIN MED. 360, 360 (2006) ("It seems that all you may need to change physician behavior is to simply advance intimidating policy statements or even initiate a few physician investigations that begin with a visit from DEA field agents dressed in flak jackets who carry weapons. Physician fear of regulatory scrutiny may not always be based on real threats, but they lead to real changes in prescribing behaviors that can substantially impair the treatment of patients in pain."); Kelly R. Knight et al., *Opioid Pharmacovigilance: A Clinical-Social History of The Changes in Opioid Prescribing for Patients with Co-Occurring Chronic Non-Cancer Pain and Substance Use*, 186 SOC. SCI. & MED. 87, 88 (2017).

20. *See, e.g.*, Sarah M. Hall et al., *INSIGHT: DOJ Opioid Warning Letters—Legitimate Law Enforcement Purpose or Prosecutorial Overreach?*, BLOOMBERG LAW (Feb. 4, 2019, 4:00 AM), https://news.bloomberglaw.com/health-law-and-business/insight-doj-opioid-warning-letters-legitimate-law-enforcement-purpose-or-prosecutorial-overreach [https://perma.cc/35B9-72YJ] (critiquing the practice of some federal prosecutors in sending letters to providers they deem to have problematic prescribing practices even though the prescribers are not the target of an investigation); Cheryl Clark, *Doctors Call California's Probe of Opioid Deaths a 'Witch Hunt'*, KAISER HEALTH NEWS (Jan. 23, 2019), https://khn.org/news/doctors-call-californias-probe-of-opioid-deaths-a-witch-hunt/ [https://perma.cc/6NRB-3LFH] ("Using terms such as 'witch hunt' and 'inquisition,' many doctors said the project is leading them or their peers to refuse patients' requests for painkiller prescription—no matter how well documented the need—out of fear their practices will come under disciplinary review.").

21. *See, e.g.*, Brian K. Yorkgitis et al., *Surgery Program Directors' Knowledge of Opioid Prescribing Regulations: A Survey Study*, 227 J. SURGICAL RES. 194, 197 (2018).

22. *See, e.g.*, Anne Fuqua, *The Other Opioid Crisis: Pain Patients Who Can't Access The Medicine We Need,* WASH. POST (Mar. 9, 2018) ("[M]y doctor chose to leave pain management. He told me he could no longer stand the paperwork and stress involved with being a pain specialist and trying to decide between protecting his ability to provide for his family and protecting his patients.").

Jay's case is not an isolated incident. There are widespread reports of prescribers refusing to see patients in chronic pain (whether or not they use opioids),[23] reflexively reducing patients' opioid prescriptions,[24] or abandoning the use of opioids altogether absent context.[25] One doctor explained to Human Rights Watch:

> There's a lot of talk in the pain medicine world that if you do not get people down to 90 morphine equivalents, you set yourself up for a liability, especially if something were to happen to that patient. It doesn't matter if you did everything appropriately [to prevent abuse]—and we do everything, urine drug testing, prescription monitoring, screening for mental health issues, pill counts. It doesn't feel like enough. We still feel like we're vulnerable to being held liable for patients if they're over that guideline limit, even when you know they're not addicted and they're benefitting [from opioids].[26]

And these reactions are not just limited to the care of patients with non-malignant chronic pain.[27] At a meeting of the American Medical

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23. *See, e.g.*, George Comerci et al., *Controlling the Swing of the Opioid Pendulum*, 378 NEW ENG. J. MED. 691, 691–93 (2018).

24. *See, e.g.*, HUMAN RIGHTS WATCH, "NOT ALLOWED TO BE COMPASSIONATE" 3–4 (2018), https://www.hrw.org/sites/default/files/report_pdf/hhr1218_web.pdf [https://perma.cc/PKW9-A9LU] ("[T]he atmosphere around prescribing for chronic pain had become so fraught that physicians felt they must avoid opioid analgesics even in cases when it contradicted their view of what would provide the best care for their patients. In some cases, this desire to cut back on opioid prescribing translated to doctors tapering patients off their medications without patient consent, while in others it meant that physicians would no longer accept patients who had a history of needing high-dose opioids").

25. *See, e.g.*, Marilyn Serafini, *The Physician's Quandary with Opioids: Pain Versus Addiction*, NEJM CATALYST (Apr. 26, 2018), https://catalyst.nejm.org/quandary-opioids-chronic-pain-addiction/ [https://perma.cc/J24Z-2LB4] ("A 78-year-old woman on the West Coast says she is so terrified of retribution against the physician prescribing her opioids that she won't share her name. She has chronic pain from childhood polio and has had multiple back surgeries. As in other states, the health department where she lives is tracking prescribing, and that has made her physicians nervous, she says. First her primary care clinic ceased all opioid prescribing, then her pain specialist cut her off. Despite the help of patient advocates, multiple pain clinics declined to take her as a patient, while family and friends scraped together excess pills from their medicine cabinets to keep her stable until she found a specialist to prescribe for her. Now, she says, that clinician is fearful of crossing prescribing lines and has told her the clinic may not be around much longer."); David Hanscom, *Limiting Rx Opioids is Making Opioid Crisis Worse*, PAIN NEWS NETWORK (Jan. 14 2019), https://www.painnewsnetwork.org/stories/2019/1/14/how-modern-medicine-pretends-to-treat-pain [https://perma.cc/X8N7-F6G7] ("Instead of exploring ways to implement effective treatments for pain, the government and medical establishment are focusing their efforts on restricting access to pain medications—with most of the focus being on the providers. Physicians are now afraid to prescribe long-term opioids, even though most of us have had patients thrive on a stable opioid regimen.").

26. HUMAN RIGHTS WATCH, *supra* note 24, at iii.

27. I generally do not distinguish between high-impact chronic pain related to cancer or non-cancer diagnoses because of the attendant false dichotomies but do so here for clarity and because nearly all prescribing policies exempt patients with cancer or terminal illness from restriction. For a more in-depth discussion of my reasoning, *see* Kelly K. Dineen, *Addressing Prescription Opioid Abuse Concerns in Context: Synchronizing Policy Solutions to Multiple Complex Public Health*

Association, Dr. McAney shared the story of a patient with severe bone pain from metastatic cancer who was denied his opioid prescription by the pharmacist—"[f]eeling ashamed after the pharmacist called him a 'drug seeker,' he went home, hoping to endure his pain. Three days later, he tried to kill himself. Fortunately, [he] was discovered by family members and survived."[28] No research, guideline, or policy denies prescription opioids to patients with metastatic cancer; stories like these illustrate the extent to which personal fears and decision-making bias may drive disproportionate reactions to situations involving opioids.[29] Those disproportionate reactions are harmful, sometimes fatally so, and all of us involved in opioid policy have a moral obligation to minimize the consequences of policy that is poorly crafted or interpreted perversely.

Much of the policy discourse around prescription opioids has used terms like "overprescribing," "inappropriate prescribing," "misprescribing," or "overutilization" (collectively, inappropriate prescribing) but inconsistently and without definition, what I describe as a failed heuristic.[30] For example, the CDC Guideline does not define inappropriate prescribing at all.[31] A recent report from the National

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Problems, 40 L. & PSYCH. REV. 1 (2016); *see also* Rolf-Detlef Treede et al., *Chronic Pain as A Symptom or A Disease: The IASP Classification of Chronic Pain for the International Classification of Diseases (ICD-11)*, 160 PAIN 19, 22–23 (describing, in part, the various cancer related and cancer treatment related types of painful conditions, some of which remain after treatment when cancer is in remission or cured).

28. Kate M. Nicholson et al., *Overzealous Use of the CDC Opioid Prescribing Guideline is Harming Pain Patients*, STAT (Dec. 6, 2018), https://www.statnews.com/2018/12/06/overzealous-use-cdc-opioid-prescribing-guideline/ [https://perma.cc/FQG7-NNML]. I personally received an urgent text from a colleague recently about the laws in Nebraska after a family member was denied a prescription for opioids by a pharmacy. That individual was obviously cachectic and in the end stages of Stage IV metastatic cancer, had lost her hair, and even showed the pharmacist the multiple intravenous ports in her chest for chemotherapy to no avail.

29. *See* Dineen, *supra* note 27, at 32–46.

30. Some use the term overprescribing to mean prescribing too early from the last prescription. *See, e.g.*, Aileen P. Wright et al., *Strategies for Flipping the Script on Opioid Overprescribing*, 176 JAMA INTERNAL MED. 1, 7 (2016) (telling the story of a patient who received habitually early renewed prescriptions from a less than careful physician). Some use it to mean reflexively prescribing a set amount, such as automatically prescribing for 30 days, after a procedure. *See, e.g.*, Martin A. Makary et al., *Overprescribing Is Major Contributor to Opioid Crisis*, BMJ, Oct. 19, 2017, at 1, 1–2, https://doi.org/10.1136/bmj.j4792 [https://perma.cc/2E22-YB47]. Some use the term to mean continuing to prescribe opioids in the current climate. *See, e.g.*, Fiona Webster et al., *From Opiophobia to Overprescribing: A Critical Scoping Review of Medical Education Training for Chronic Pain*, 18 PAIN MED. 1467 (2017) (identifying a shift in medical education literature from the characterization of not prescribing opioids as opiophobia to prescribing opioids as overprescribing or inappropriate prescribing).

31. A document search showed no matches for inappropriate prescribing or misprescribing. "Overprescribing" appears once without definition: "Across specialties, physicians believe that opioid pain medication can be effective in controlling pain, that addiction is a common consequence of prolonged use, and that long-term opioid therapy often is overprescribed for patients with chronic

Academies of Science, *Pain Management and the Opioid Epidemic*, uses the terms overprescribing and inappropriate prescribing to implicitly describe a host of very distinct prescribing behaviors.[32] A comprehensive policy document by the Aspen Institute uses overprescribing imprecisely.[33] Although many federal and state laws reference inappropriate prescribing, I was unable to locate any that actually defines inappropriate prescribing, overprescribing, or misprescribing.[34]

The lack of definitional clarity for inappropriate prescribing in existing law and policy renders the responses like those of Jay's providers predictable.[35] It also compounds uncertainty in caring for patients with complex health conditions associated with opioids,[36] and sets the stage for decreased quality of care, increased patient avoidance, and increased morbidity and mortality. In the absence of any definitions, providers may logically look to the recommended maximum daily MME and pick a target number under that threshold to demonstrate absolute compliance.[37] This

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noncancer pain." Dowell et al., *supra* note 4, at 3.

32. "Overprescribing" and "inappropriate prescribing" appear in several places throughout the document without definition and in very different contexts. NAT'L ACADS. OF SCIS., ENG'G, & MED., PAIN MANAGEMENT AND THE OPIOID EPIDEMIC (Richard J. Bonnie et al. eds., 2017), https://www.nap.edu/read/24781/chapter/1 [https://perma.cc/UU6K-MVTX].

33. "Overprescribing" appears three times without definition. ASPEN INST. HEALTH STRATEGY GRP., CONFRONTING OUR NATION'S OPIOID CRISIS (2017), https://assets.aspeninstitute.org/content/uploads/2018/01/AHSG-Final-Report-2017_compressed-2.pdf?_ga=2.125457098.1513023905.1550708071-877169743.1550708071 [https://perma.cc/CM9T-8FJH]. Inappropriate prescribing appears once and implicitly means patients obtaining medication in different states—an issue that really does not implicate prescribing behavior unless the prescribers have access to information from other states. *Id.* at 15.

34. A search of Westlaw, Lexis, JSTOR, Google Scholar, and Google for "overprescri!", "over-prescri!", "inappropriate prescribing", "inappropriate prescription", and "misprescri!" garnered a variety of results but the terms were used throughout articles, laws, policy documents, and news reports without explicit definitions. For example, Nevada Assembly Bill 474 (enacted in 2017), includes the term "inappropriate prescribing" fifteen times. Assemb. B. 474, 2017 Leg., 79th Sess. (Nev. 2017). No definitions are provided. *Id.* Washington State has an extremely comprehensive set of medical board regulations around opioid prescribing but does not define overprescribing or inappropriate prescribing. *See* WASH. ADMIN. CODE § 246-919-852 (2019).

35. *See, e.g.*, CTRS. FOR MEDICARE & MEDICAID SERVS., DEP'T OF HEALTH & HUMAN SERVS., CMS-2017-0163, ADVANCE NOTICE OF METHODOLOGICAL CHANGES FOR CALENDAR YEAR (CY) 2019 FOR MEDICARE ADVANTAGE (MA) CAPITATION RATES, PART C AND PART D PAYMENT POLICIES AND 2019 DRAFT CALL LETTER (Feb. 1, 2018), https://www.regulations.gov/contentStreamer?documentId=CMS-2017-0163-0007&contentType=pdf [https://perma.cc/X5Q4-CFXH] ("inappropriate prescribe", "inappropriate prescribing", and "inappropriate prescription" do not appear, "overprescribing" appears once in reference to an FDA policy without definition, "misprescribe" and "misprescribing" do not appear, "opioid overutilization" appears without definition but its implied meaning is based on daily morphine milligram equivalents only).

36. This includes patients with SUDs, chronic pain, serious mental illness, and other common comorbid conditions. For a more detailed discussion, *see* Dineen, *supra* note 27, at 19–29.

37. For a discussion of the role of law or perceived law on norms and behavior, *see* Frederick Schauer, *Awash in a Sea of Norms*, *in* THE FORCE OF LAW (2015).

overreaction to policy is not limited to providers. For example, third party payors overcorrected in response to the Center for Medicare Medicaid Services' (CMS's) guidance to utilize safety warnings for higher doses of opioids. CMS noted:

> [W]e believed that some sponsors implemented these edits beyond their intended use . . . . [They] are not intended as a means to implement a prescribing limit or apply additional clinical criteria for the use of opioids, but instead to give physicians important additional information about their patients' opioid use.[38]

Policymakers and prescribers deserve better and more information as to what inappropriate prescribing means.

This article focuses on opioid prescribing policy and, in particular, on the lack of shared definitions for inappropriate prescribing—a kind of linguistic uncertainty.[39] Even after a century of concern about provider roles in recommending or prescribing certain medications,[40] inappropriate prescribing is about as well defined as hardcore pornography—we know it when we see it.[41] The lack of definitions in this area was recently noticed by federal lawmakers, who added one provision in the Support for Patients and Communities Act (SUPPORT Act).[42] That provision directs the Secretary of Health and Human Services (HHS) to develop a definition of inappropriate prescribing—although it would apply only to new reporting by Medicare Advantage plans to HHS.[43] Although quite limited, this represents the first acknowledgement in law or policy that defining inappropriate prescribing is a necessary antecedent for sanctioning it.

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38. CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 35, at 209; *see also* Kao-Ping Chua et al., *Opioid Prescribing Limits for Acute Pain Potential Problems with Design and Implementation*, 321 JAMA 643, 644 (2019) (describing a situation in Michigan in which the state law limits initial dose for acute pain to 7 days but the largest insurer limits the supply to 5 days).

39. *See, e.g.*, Arnulf Grubler et al., *Coping with Uncertainties-Examples of Modeling Approaches at IIASA*, 98 TECHNOLOGICAL FORECASTING & SOC. CHANGE 213, 215 (2015) ("*Linguistic* uncertainty refers to vagueness or ambiguity in defining the nature and boundary conditions of a particular decision problem at hand . . . .").

40. For a brief history of prescribing regulation in the United States, *see generally* Timothy Atkinson et al., *Opioid Medications: Old Wine in New Bottles*, *in* PRESCRIPTION DRUG DIVERSION AND PAIN: HISTORY, POLICY, AND TREATMENT 1 (John F. Peppin, John J. Coleman, Kelly K. Dineen, and Adam J. Ruggles eds., 2018).

41. Jacobellis v. Ohio, 378 U.S. 184, 197 (1964) (Stewart, J., concurring) (describing the limit of constitutional protection of free expression as "hardcore pornography," defined only as "I know it when I see it.").

42. Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, Pub. L. 115-271, 132 Stat. 3894 (2018).

43. *Id.* § 6063(b)(5)(C)(i) ("[T]he Secretary shall, pursuant to rulemaking—specify a definition for the term 'inappropriate prescribing' and a method for determining if a provider of services prescribes inappropriate prescribing.").

This article will provide guidance on this issue by offering a taxonomy for inappropriate opioid prescribing that is meant to serve as a kind of public choice architecture to reduce decision making errors by policy makers,[44] as well as a debiasing strategy for providers.[45] Part II includes a brief background of the history of recent prescribing policies and examines their impact on opioid related harms. Part III reviews the ways in which policy makers and providers may be prone to decision making errors, identifies and describes the failed misprescribing heuristic, and reviews existing definitions of inappropriate prescribing. Part IV sets out a proposed taxonomy for inappropriate prescribing. In turn, each of the categories will be explained and examined in light of existing empirical research on opioid related harms as well as the possible benefits of existing policies to reduce harms in each category. The modest goal of this taxonomy is that it may help guide policymakers to evaluate and craft better prescribing policy, enhance the predictability and consistency of legal scrutiny of prescribing, and mitigate overreaction by prescribers.

II. THE OPIOID RELATED PUBLIC HEALTH CRISES & PRESCRIPTION OPIOID POLICY

The U.S. is experiencing record levels of morbidity and mortality related to opioids (both prescription and illicit drugs such as heroin and illicitly manufactured fentanyl) as well as other drugs—both prescription and illicit.[46] Drug related morbidity and mortality overlays and intertwines with alarming rates of serious mental illness, suicidality, and chronic pain—all of which are situated in the context of widespread social, cultural, and structural inequities.[47] The root causes of the crisis, or crises,

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44. *See, e.g.*, Adam C. Smith, *Utilizing Behavioral Insights (Without Romance): An Inquiry into the Choice Architecture of Public Decision-Making*, 82 MO. L. REV. 737 (2017) (arguing that "improvement of private choice architecture must be accompanied by careful understanding of public choice architecture in which policies are rendered if behavioral economics is to be a successful foundation for welfare improving policies.").

45. *See, e.g.*, Pat Croskerry, *Cognitive Forcing Strategies in Clinical Decisionmaking*, 41 ANNALS OF EMERGENCY MED. 110 (2003) (describing "cognitive forcing strategies," i.e., "cognitive debiasing" means for avoiding diagnostic errors).

46. *See* Mathew V. Kiang et al., *Assessment of Changes in the Geographical Distribution of Opioid-Related Mortality Across the United States by Opioid Type, 1999-2016*, JAMA NETWORK OPEN, Feb. 2019, https://doi.org/10.1001/jamanetworkopen.2019.0040 [https://perma.cc/E3UJ-SBMJ] (conducting a cross-sectional analysis of all opioid related mortality between 1999 and 2016 by geography and type of opioid involved). *See also* Leo Beletsky & Corey Davis, *Today's Fentanyl Crisis: Prohibition's Iron Law, Revisited*, 46 INT'L J. DRUG POLICY 156, 156–59 (2017).

47. *See generally* Nabarun Dasgupta et al., *Opioid Crisis: No Easy Fix to Its Social and Economic Determinants*, 108 AJPH 182 (2018) (describing the various public health crises and explanatory models).

are myriad and multifactorial.[48] The solutions will need to be myriad and multifactorial as well.

A. Prescription opioid policies

There is no question that opioid related harms in the midst of multiple, overlapping health crises are significant.[49] Careless and sometimes criminal prescribing contributed to the harms,[50] as did aggressive and even criminal practices by drug manufacturers,[51] and a laundry list of concurrent factors.[52] At the same time, prescription opioids are neither inherently good nor evil. They are essential for the treatment of some types of acute pain,[53] necessary to relieve the suffering of patients with pain from active cancer and many terminal conditions, and a critical tool in the treatment of many chronic primary and secondary pain conditions,[54] including those that resulted from prior cancer treatments.[55] In fact, despite widespread rhetoric, there remains "insufficient evidence to either support or refute the efficacy of high-dose opioids in chronic non-cancer pain."[56] A recent review article found small but statistically significant

48. *See generally* Leo Beletsky, *21st Century Cures for the Opioid Crisis: Promise, Impact, and Missed Opportunities*, 44 AM. J.L. & MED. 359 (2018) (providing a comprehensive overview of the complexity of the opioid related public health crises and evaluating the 21st Century Cures Act in light of existing causes and harms).

49. *See id.* at 359–71.

50. *See, e.g.*, James M. DuBois et al., *A Mixed-Method Analysis of Reports on 100 Cases of Improper Prescribing of Controlled Substances*, 46 J. DRUG ISSUES 457, 457–59 (2016); Stacey A. Tovino, *Fraud, Abuse, and Opioids*, 67 U. KAN. L. REV. 901 (2019) (describing the use of fraud and abuse laws to sanction prescribing behavior motivated by personal gain rather than patient well-being).

51. *See, e.g.*, Scott E. Hadland et al., *Association of Pharmaceutical Industry Marketing of Opioid Products with Mortality from Opioid-Related Overdoses*, JAMA NETWORK OPEN, FEB. 2019, at 1, 2, 8–9, https://doi.org/10.1001/jamanetworkopen.2018.6007 [https://perma.cc/D5AW-PW2U]; BETH MACY, DOPESICK: DEALERS, DOCTORS, AND THE DRUG COMPANY THAT ADDICTED AMERICA (2018).

52. *See generally* SUSAN M. ADAMS ET AL., NAT'L ACAD. OF MED., FIRST DO NO HARM: MARSHALLING CLINICAL LEADERSHIP TO COUNTER THE OPIOID EPIDEMIC 7–9 (2017) (discussing the drivers of the opioid epidemic).

53. *See, e.g.*, Richard D. Blondell et al., *Pharmacological Therapy for Acute Pain*, 87 AM. FAMILY PHYSICIAN 766, 770–71 (2013) (discussing how opioids may be properly and effectively prescribed, according to the World Health Organization pain relief ladder, if acetaminophen, aspirin, or other NSAIDs are insufficient to control pain).

54. One example too often left out of any discourse on opioid policy is the use of opioids in the treatment of sickle cell disease. *See, e.g.*, Kelly K. Dineen, *Opioid Prescribing in Special Populations*, *in* PRESCRIPTION DRUG DIVERSION AND PAIN, *supra* note 40, at 190.

55. For an excellent discussion of the evaluation and treatment of patients with chronic pain, *see generally* John F. Peppin et al., *Evaluation and Treatment of the Chronic Pain Patient*, *in* PRESCRIPTION DRUG DIVERSION AND PAIN, *supra* note 40, at 110.

56. Charl Els et al., *High Dose Opioids for Chronic Non-Cancer Pain: An Overview of Cochrane Reviews*, COCHRANE DATABASE SYSTEMIC REVIEWS, Oct. 2018, at 7,

improvements in pain, sleep quality, and physical function with the use of chronic opioid therapy (COT) in some groups;[57] however, the media widely reported that the study showed that opioids do not help at all.[58] At the same time, patients on higher doses of opioids have a greater risk of unintentional poisoning,[59] a risk that must be taken into account by prescribers.[60] Chronic opioid prescribing has decreased dramatically since 2012, with a particularly sharp decrease in daily MME after the release of the CDC Guideline.[61]

In response to rising rates of opioid related morbidity and mortality after 2000, opioid prescribing laws and policies proliferated. Earliest in the response were laws directed at chronic pain treatment with opioids. Some states enacted new requirements aimed at curbing "pill mills," which are criminal operations often set up as pain treatment clinics.[62] Pain

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https://doi.org//10.1002/14651858.CD012299.pub2 [https://perma.cc/B4KM-GU7P].

57. Jason W. Busse et al., *Opioids for Chronic Noncancer Pain: A Systematic Review and Meta-analysis*, 320 JAMA 2448, 2453 (2018).

58. *See, e.g.*, Marlene Lenthang, *New Study Finds Opioids DON'T Work Well for Chronic Pain Despite Millions of Americans Being Prescribed the Drug that Kills 115 People a Day*, DAILY MAIL (Dec. 19, 2018, 1:23 PM), https://www.dailymail.co.uk/news/article-6512875/New-study-finds-opioids-I-work-chronic-pains.html [https://perma.cc/Y5VF-FGA4]; Rachel Rettner, *Opioids Don't Really Do That Much for Chronic Pain, Meta-Analysis Finds,* LIVE SCI. (Dec. 18, 2018, 11:17 AM), https://www.livescience.com/64329-opioids-chronic-pain.html [https://perma.cc/735Y-4859]. *But see* Amy Norton, *Opioids May Help Chronic Pain, But Not Much*, U.S. NEWS & WORLD REP. (Dec. 18, 2018, 12:00 PM), https://www.usnews.com/news/health-news/articles/2018-12-18/opioids-may-help-chronic-pain-but-not-much (acknowledging the findings that there was statistically significant benefit for some patients).

59. I use the word poisoning intentionally because of the inaccuracy of the term overdose and its stigmatizing effect. *See* Edward Xie et al., *Updating Our Language Around Substance Use Disorders*, 189 CMAJ E1566, E1566 (2017) ("The term 'overdose' connotes personal failure and responsibility, and is a remnant of the old psychosocial model of addiction. This term suggests that the patient a) knows the nature of the substance taken and b) has taken more than what she or he was tolerant to or intended to take. 'Overdose' also implies that there is a correct dose, when none exists for use of illicit formulations. . . . [W]e suggest that the more precise terms 'poisoning' or 'intoxication' should be used. . . . With these more accurate terms, providers may be cued to consider and address the two separate health needs present: acute poisoning or intoxication, and the contributory conditions: uncontrolled pain, mental illness, drug dependence or addiction, etc.").

60. *See* Adeleke D. Adewumi et al., *Prescribed Dose of Opioids and Overdose: A Systematic Review and Meta-Analysis of Unintentional Prescription Opioid Overdose*, 32 CNS DRUGS 101, 115 (2018) ("Our study found that chronic users and outpatients are at increased risk of unintentional prescription opioid over-dose. Furthermore, we found that the risk of accidental prescription opioid overdose events becomes apparent from doses as low as 20 MME/day, and there is a dose–response effect relationship between unintentional prescription opioid overdose events and the prescribed dose of opioid analgesic. Therefore, caution should be exercised when patients are prescribed doses above 20 MME/day.").

61. *See* Amy S.B. Bohnert et al., *Opioid Prescribing in the United States Before and After the Centers for Disease Control and Prevention's 2016 Opioid Guideline*, 169 ANNALS INTERNAL MED. 367, 368 (2018).

62. *See, e.g.*, CTRS. FOR DISEASE CONTROL, MENU OF PAIN MANAGEMENT CLINIC REGULATION, intro.–1 (2012) https://www.cdc.gov/phlp/docs/menu-pmcr.pdf [https://perma.cc/

management practices were often collateral damage in these efforts, as many pain management specialists left the specialty or the state because of the significant new regulatory requirements and fear of enhanced scrutiny.[63] Other states focused directly on the use of opioids for chronic pain only and directed regulatory agencies to set prescribing rules as early as 2010.[64] States enacted or enhanced Prescription Drug Monitoring Programs (PDMPs), with more focus on mandatory enrollment of patients receiving prescriptions and requiring prescribers to access PDMPs before prescribing.[65] Beginning in 2016, states passed legislation aimed at limiting prescribing of opioids in acute pain as well.[66] Criminal investigations of prescribers also increased substantially, as did professional board scrutiny.[67]

XUA8-PS3P]; Barbara Andraka-Christou et al., *Pain Clinic Definitions in the Medical Literature and U.S. State Laws: an Integrative Systematic Review and Comparison*, SUBSTANCE ABUSE TREATMENT PREVENTION & POL'Y, Dec. 2018, at 1, 8–9, https://doi.org/10.1186/s13011-018-0153-6 [https://perma.cc/HJQ6-CJZ6].

63. *See, e.g.*, Gary W. Jay, *So Patients Suffer—It's for Their Own Good!!!*, 22 AM. J. THERAPEUTICS 80 (2015) (describing unintended consequences of opioid prescribing regulation); Terrence McCoy, '*Unintended Consequences:' Inside The Fallout Of America's Crackdown On Opioids*, WASH. POST (May 31, 2018), https://www.washingtonpost.com/graphics/2018/local/impact-of-americas-opioid-crackdown/?utm_term=.323a9f16bdbc [https://perma.cc/ZM3V-JXQ6] ("[S]ome physicians, fearful of the financial and legal peril in prescribing opioids, and newly aware of their hazards, have stopped prescribing them altogether."); Matthew Torres, *Concerns Mount Over Pain Clinic Closures In Tennessee*, NEWS CHANNEL 5 NASHVILLE (July 6, 2018, 9:51 PM), https://www.newschannel5.com/news/concerns-mount-over-pain-clinic-closures-in-tennessee [https://perma.cc/D65N-2L3B]. Those that stayed in practice did decrease their daily opioid prescribing modestly, especially in patients at the highest daily dose. *See* Lainie Rutkow et al., *Effect of Florida's Prescription Drug Monitoring Program and Pill Mill Laws on Opioid Prescribing and Use*, 175 JAMA INTERNAL MED. 1642, 1642 (2015).

64. For example, Washington state has been especially aggressive in regulating opioids. They began in 2010 by directing medical quality assurance to repeal all existing rules regarding chronic pain management and issue new rules. *See, e.g.*, Wash. St. Reg. 11-12-025 (Jan. 2, 2012).

65. There is a long history of prescription monitoring by states, but the use of computer or electronic surveillance began in the 1990s. For a full discussion of PDMPs, *see* John J. Coleman, *Monitoring Prescriptions, Third Party Healthcare Payers, Prescription Benefit Managers, and Private-Sector Policy Options*, *in* PRESCRIPTION DRUG DIVERSION AND PAIN, *supra* note 40, at 39. For a modern take on evaluating PDMPs, *see* Rebecca L. Haffajee, *Preventing Opioid Misuse with Prescription Drug Monitoring Programs: A Framework for Evaluating the Success of State Public Health Laws*, 67 HASTINGS L.J. 1621, 1634–87 (2016).

66. *See, e.g.*, *Prescribing Policies: States Confront Opioid Overdose Epidemic*, NCSL (Oct. 31, 2018), http://www.ncsl.org/research/health/prescribing-policies-states-confront-opioid-overdose-epidemic.aspx [https://perma.cc/HEE3-5YBX]. The harms of prescribing too many pills for acute pain, resulting in large numbers of leftover pills that are available for misuse and diversion were well known to public health authorities since at least 2007, but it took nearly ten years to take any action at all on this. *See* Kelly K. Dineen, *supra* note 27, at 47–73.

67. *See, e.g.*, Kelly K. Dineen & James M. DuBois, *Between a Rock and a Hard Place: Can Physicians Prescribe Opioids to Treat Pain Adequately While Avoiding Legal Sanction?*, 42 AM. J.L. & MED. 7, 12 (2016). *See generally* Health Care Compliance Ass'n, *M.D.s are 'Spooked' by Scrutiny of Opioid Prescribing; Documentation Is Best Defense*, REP. ON MEDICARE COMPLIANCE, July 31, 2017, at 1, 1.

Opioid related harms were addressed at the federal level, including three recent federal laws: the Comprehensive Addiction and Recovery Act of 2016 (CARA),[68] the 21st Century Cures Act,[69] and the SUPPORT Act.[70] The Food and Drug Administration (FDA) enacted a Risk Evaluation and Mitigation Strategy (REMS) for prescription opioids[71] and engaged in numerous regulatory strategies to address opioid related harms.[72] The Drug Enforcement Agency (DEA) tightened criteria for drug quotas related to opioids.[73] The Department of Justice and other federal agencies have increased prosecutions against health care organizations and individual providers.[74]

B. Fewer prescriptions, greater harms?

As existing laws and provider reactions have cut the *prescription* opioid supply, persons with SUDs increasingly turn to other prescription drug classes (such as benzodiazepines)[75] and more dangerous illicit

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68. Comprehensive Addiction and Recovery Act of 2016, Pub. L. No. 114-198, 130 Stat. 695 (2016).

69. 21st Century Cures Act, Pub. L. No. 114-255, 130 Stat. 1033 (2016). For an excellent discussion of the 21st Century Cures Act, *see generally* Beletsky, *supra* note 48.

70. Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, Pub. L. No. 115-271, 132 Stat. 3894 (2018).

71. U.S. FOOD & DRUG ADMIN., RISK EVALUATION AND MITIGATION STRATEGY (REMS) DOCUMENT (2012), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Opioid_Analgesic_2018_09_18_REMS_Full.pdf [https://perma.cc/76XK-5279].

72. For a complete list of FDA actions from 1911 through present, *see Timeline of Selected FDA Activities and Significant Events Addressing Opioid Misuse and Abuse*, FDA.GOV https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm338566.htm [https://perma.cc/4GP6-3R5S] (last updated Feb. 13, 2019).

73. *See, e.g.*, Press Release, Drug Enf't Admin., U.S. Dep't of Justice, DEA Propose Significant Opioid Manufacturing Reduction in 2019 (Aug. 16, 2018), https://www.dea.gov/press-releases/2018/08/16/justice-department-dea-propose-significant-opioid-manufacturing-reduction [https://perma.cc/68PN-UXCG]. The SUPPORT Act further tightens the DEA's evaluation of quotas. Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act § 3282.

74. *See, e.g.*, Press Release, U.S. Attorney's Office S. Dist. of Ga., U.S. Dep't of Justice, National Health Care Fraud Takedown Results in Charges Nationwide and in the Southern District of Georgia (June 28, 2018), https://www.justice.gov/usao-sdga/pr/national-health-care-fraud-takedown-results-charges-across-country-and-southern [https://perma.cc/T5CW-MT9W]. *See generally* Tovino, *supra* note 50 (carefully documenting and analyzing the uptick in government enforcement actions involving the federal Anti-Kickback Statute and the federal civil False Claims Act in opioid cases).

75. The coprescribing rate of benzodiazepines with opioids quadrupled between 2003 and 2015, despite evidence of their relationship to opioid related overdoses. Sumit D. Argawal & Bruce E. Landon, *Patterns in Outpatient Benzodiazepine Prescribing in the United States*, JAMA NETWORK OPEN, Jan. 2019, at 1, 6–7 (2019), https://doi.org/10.1001/jamanetworkopen.2018.7399 [https://perma.cc/458Y-K6BF].

drugs.[76] As such, drug poisoning morbidity and mortality continues to climb, with illicit substances—such as heroin, illicitly manufactured fentanyl, cocaine, and methamphetamines—playing an increasing role.[77] Recent research by Cicero and colleagues reveals that heroin is now a more common substance of initiation than prescription opioids;[78] moreover, of those who developed an OUD after receiving prescription opioids from a prescriber (iatrogenic addiction), a significant majority had a previous history of substance misuse.[79] Even a small percentage of people who develop iatrogenic addiction is too many—however, policy efforts should focus proportionately on the sources of harm. To date, disproportionate amounts of media and public policy attention focuses on prescription opioids, primarily in the treatment of chronic pain. A framework for inappropriate prescribing might help make policy efforts and evaluation more proportionate to the harms.

Since the release of the Drug Abuse Warning Network data in 2013, an array of legal and policy initiatives around opioid prescribing were implemented;[80] however, they have done little to reduce overall morbidity and mortality.[81] A recent study by Chen and colleagues used a systems dynamic model to predict the impact of prescribing policies on opioid related mortality through 2025. They concluded that those policies have, at best, a modest impact.[82] According to the authors, their findings "highlight the limitations of preventing prescription opioid misuse alone, and the need to use multiple policy levers simultaneously . . . to alter the projected course of the opioid overdose crisis in the coming years."[83]

Some prescribing policies address the harms associated with opioids

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76. For example, benzodiazepine poisonings have increased substantially, while prescription opioid poisonings have stabilized. *Overdose Death Rates*, NIH.GOV, https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates [https://perma.cc/258Y-DT4L] (last update Jan. 2019).

77. *Id.*

78. Theodore J. Cicero et al., *Increased Use of Heroin as an Initiating Opioid of Abuse: Further Considerations and Policy Implications*, 87 ADDICTIVE BEHAVIORS 267, 269 (2018).

79. Theodore J. Cicero et al., *Psychoactive Substance Use Prior to the Development of Iatrogenic Opioid Abuse: A Descriptive Analysis of Treatment-Seeking Opioid Abusers*, 65 ADDICTIVE BEHAVIORS 242, 242–44 (2017).

80. *See generally* Andraka-Christou et al., *supra* note 62 (surveying state regulations on opioids); Corey Davis et al., *supra* note 9 (conducting a national survey and identifying themes of state laws limiting prescriptions through 2017).

81. *See, e.g.*, Dasgupta et al., *supra* note 47, at 183.

82. Qiushi Chen et al., *Prevention of Prescription Opioid Misuse and Projected Overdose Deaths in the United States*, JAMA NETWORK OPEN, Feb. 2019, at 1, 4–8, https://doi.org/10.1001/jamanetworkopen.2018.7621 [https://perma.cc/W34Q-JT7M].

83. *Id.* at 8.

in isolation, incompletely, or out of proportion to the existing evidence.[84] Others are simply bad—they don't address the harms they purport to and they force providers to act against the interests of their patients.[85] Even well-crafted policies, including much of the CDC Guideline, can be harmful as interpreted and implemented by enforcement agencies, providers, or health care organizations.[86] A recent expert consensus panel emphasized the need for clarification to both policymakers and providers, saying,

> The period following guideline release has seen clinical and policy issues that may have gone beyond what was originally intended by developers of the guideline. *In particular, the appropriate role of regulatory and policymaking bodies, including public and private payers, requires clarification.* The guideline was not meant to be prescriptive but, at times, has been implemented without flexibility, perhaps without full awareness of the guideline's precise content and intent.[87]

State laws that restrict and surveil opioid prescribing have produced predictable but unintended consequences, some of which we are only beginning to realize.[88] These laws have mostly taken the form of supply-side restrictions, focusing too narrowly on prescription opioids alone and ignoring significant issues of concurrent use of other drugs and substances, the consequences of abrupt discontinuation of opioids, and access to treatment for OUDs.[89] In a 2019 systematic review of state prescribing laws, Davis and colleagues explained:

> While we assume these laws to be well-intentioned, it is not clear whether they will be effective in reducing opioid-related harm, *and it is possible that they will increase preventable suffering* among some individuals by leaving pain untreated or encouraging some individuals with opioid use disorder to transition from [prescription opioids] to

84. *See, e.g.*, Kelly K. Dineen, *Defining Misprescribing to Inform Prescription Opioid Policy*, HASTINGS CTR. REP., July–Aug. 2018, at 1, 5–6; Kelly K. Dineen, *supra* note 27, at 8–19.

85. Sandra H. Johnson calls these "the rules are wrong" type of bad law claims. Sandra H. Johnson, *Regulating Physician Behavior: Taking Doctors' "Bad Law Claims" Seriously*, 53 ST. LOUIS L.J. 973, 1005–06 (2009).

86. One example is payors or state lawmakers setting a daily morphine equivalent for all patients, even though those limits are completely incorrect for medication assisted treatment for OUDs. *See* AM. SOC'Y OF ADDICTION MED., PUBLIC POLICY STATEMENT ON MORPHINE EQUIVALENT UNITS/MORPHINE MILLIGRAM EQUIVALENTS (2016), https://www.asam.org/docs/default-source/public-policy-statements/2016-statement-on-morphine-equivalent-units-morphine-milligram-equivalents.pdf?sfvrsn=3bc177c2_6 [https://perma.cc/4DKS-4BP3]. For an excellent description of various bad law claims, *see* Johnson, *supra* note 85.

87. Kurt Kroenke et al., *supra* note 9, at 3 (emphasis added).

88. *See, e.g.*, Beletsky & Davis, *supra* note 46.

89. *Id.*

> potentially more dangerous illicit substances.[90]

Scott Hadland and Leo Beletsky went further, stating,

> [E]ven as policymakers pursue additional regulatory approaches to reduce opioid prescribing—including prescription drug monitoring programs, dose or duration limits on prescriptions, and prescriber sanctions, among others—the overdose crisis will likely worsen so long as supply side interventions are not coupled with evidence based measures to cut demand and reduce harm.[91]

Concerns that some prescribing policies are causing more harm are supported by recent findings. A decade ago, most of the opioid related morbidity and mortality involved prescription opioids, but as policy efforts have compressed their availability, illicit opioids are now more often implicated. This reality is obscured by the traditional reporting that counts illicitly manufactured fentanyl deaths along with prescription opioid related deaths, more than doubling the number attributed to prescription opioids from 17,087 to 32,445 in 2016, for example.[92] A 2018 modeling study by Pitt and colleagues evaluated the impact of eleven policy interventions on opioid mortality and concluded that many of those directed at prescribing "may reduce prescription opioid misuse but increase heroin use, blunting or even eliminating any public health benefit in the short term."[93] Even in the long term, only efforts to reduce acute and transitioning pain prescribing resulted in any projected reductions in opioid related deaths.[94] In 2019, Chen and colleagues concluded,

> We found that under current conditions the opioid overdose crisis is likely to substantially worsen and that interventions such as prescription drug monitoring programs are unlikely to lead to major decreases in the number of deaths from opioid overdose in the near future. Given these findings, policymakers will need to take a stronger and multipronged approach, such as improving access to treatment, expanding harm-reduction interventions, and lowering exposure to illicit opioids, to curb

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90. Davis et al., *supra* at note 9, at 170 (emphasis added).

91. Scott E. Hadland & Leo Beletsky, *Tighter Prescribing Regulations Drive Illicit Opioid Sales*, BMJ, June 13, 2018, at 1, 2, https://doi.org/10.1136/bmj.k2480 [https://perma.cc/4KHX-FGXC].

92. *See* Puja Seth et al., *Quantifying the Epidemic of Prescription Opioid Overdose Deaths*, 108 AJPH 500, 500 (2018).

93. Allison L. Pitt, Keith Humphreys, & Margaret L. Brandeau, *Modeling Health Benefits and Harms of Public Policy Responses to the US Opioid Epidemic*, 108 AJPH 1394, 1396–99 (2018) (separately evaluating reductions in acute pain prescribing, chronic pain prescribing, transitioning pain prescribing, PDMPs, and drug rescheduling and finding that only acute pain and transitioning pain prescribing-reduction policies reduced mortality at all at either 5 or 10 years).

94. *Id.*

the trajectory of the opioid overdose epidemic in the United States.[95]

The reasons that opioid policies sometimes do not address underlying issues, or even cause more harm than good, are complex.[96] Some policies likely fell prey to the intentions heuristic (i.e. the implicit privileging of a policy's good intentions over the actual consequences).[97] Some policies are based on simple misunderstanding and miscommunication of the evidence.[98] Fundamentally, policy makers are prone to the same biases and decision making errors as individuals, which may contribute to incoherent policy enactments.

III. OPIOID RELATED DECISIONS: FAILED HEURISTICS & BIASES

The opioid crisis is too often explained in oversimplified narratives and sound bites. Every decision about opioids is wrapped in robust cultural, moral, and political narratives about the meaning and value of pain and suffering, the nature of addiction, the relationship of the practice of medicine to the treatment of addiction, and the state sanctioned stigmatization of substance use through criminalization. These factors make stakeholders involved in opioid prescribing policies more susceptible to bias and faulty decision making.[99] "[A]s behavioral agents

95. Chen et al., *supra* note 82, at 10 (emphasis added).

96. One reason may be an adherence to the Precautionary Principle, i.e., that "regulators should take steps to protect against potential harms, even if causal chains are unclear and even if we do not know that those harms will come to fruition," which Cass Sunstein has described as "literally incoherent" and providing an "illusion of guidance" only. CASS R. SUNSTEIN, LAWS OF FEAR: BEYOND THE PRECAUTIONARY PRINCIPLE 4–5 (2005).

97. *See, e.g.*, Gary M. Lucas, Jr. & Slavisa Tasic, *Behavioral Public Choice and the Law*, 118 W. VA. L. REV. 199, 218–23 (2015).

98. For example, the media and policymakers continue to spread a narrative in which those harmed by opioids are people who received a prescription from their provider. *See, e.g.*, *Painkillers Driving Addiction, Overdose*, NAT'L SAFETY COUNCIL, https://www.nsc.org/home-safety/safety-topics/opioids [https://perma.cc/688N-4EX3] (last visited Mar. 22, 2019) ("Many adults [are] prescribed opioids by doctors and subsequently become addicted or move from pills to heroin."); Controlled Substances Quotas, 83 Fed. Reg. 17,329, 17,331 (proposed Apr. 19, 2018) (codified at 21 C.F.R. pt. 1303) ("Users may be initiated into a life of substance abuse and dependency after first obtaining these drugs from their health care providers or without cost from the family medicine cabinet or from friends. Once ensnared, dependency on potent and dangerous street drugs may ensue. About 80% of heroin users first misused prescription opioids."). In reality, this is untrue. Approximately 75% of those who report misuse of prescription opioids did not receive a prescription for the medication—instead they steal, borrow, or buy the drugs. *See, e.g.*, Rachel Lapari & Arthur Hughes, *How People Obtain the Prescription Pain Relievers They Misuse*, SAMHSA.GOV (Jan. 12, 2017), https://www.samhsa.gov/data/sites/default/files/report_2686/ShortReport-2686.html [https://perma.cc/XC7M-KB5R].

99. *See* Dineen, *supra* note 27, at 32–46 (applying interdisciplinary literature on decision making to providers and policymakers in Section III); *see also* JUSTIN PARKHURST, THE POLITICS OF EVIDENCE 84–104 (2017), http://eprints.lse.ac.uk/68604/1/Parkhurst_The%20Politics%20of%

themselves, policymakers and regulators are subject to the same psychological biases and limitations as all individuals."[100] The propensity for decision making errors by policy makers may be compounded by public pressures.[101] Measures are needed to assist policy makers that correct for bias in implementing and evaluating opioid prescribing policies.[102] A taxonomy of inappropriate prescribing might serve as a type of public choice architecture or forcing strategy for policy makers.[103]

Providers are also prone to errors in decision-making.[104] No other decisions in medicine risk such a breadth of legal scrutiny as opioid prescribing, which elicits fear and avoidance.[105] Further, the conditions of uncertainty surrounding prescribing, the treatment of pain, the separation of the treatment of SUDs from the rest of medicine and health care, and the long history of stigmatization of opioid related populations all contribute to decision making errors. These factors also fuel strong—and usually negative—emotional reactions, which further heighten the risk of disproportionate and even harmful decisions by providers and policy makers.[106]

20Evidence.pdf [https://perma.cc/2354-LJBG] ("Here we particularly draw on the field of cognitive psychology to explore the ways in which common, yet often unconscious, mental processes may also induce technical and issue bias. As will be shown, many of these instances can be directly linked to our existing values and beliefs, thus making them political in origin.").

100. W. Kip Viscusi & Ted Gayer, *Behavioral Public Choice: The Behavioral Paradox of Government Policy*, 38 HARV. J.L. & PUB. POL'Y 973, 977 (2015) ("Many, although certainly not all, behavioral economics papers focus on the biases and heuristics of ordinary individuals, while seemingly ignoring that regulators are people too and thus subject to the same psychological forces.").

101. *Id. See also* Cass R. Sunstein, *Behavioral Economics and Paternalism*, 122 YALE L.J. 1826, 1826 (2013) ("Official action may fail to respect heterogeneity, may diminish learning and self-help, may be subject to pressures from self-interested private groups (the problem of "behavioral public choice"), and may reflect the same errors that ordinary persons make.").

102. Most of the legal literature focuses in libertarian paternalism, which includes organizing choice architecture in policy to enhance the decisions of those subject to the laws. However, public choice architecture expands that approach to the decisions of policymakers. *See* Thomas A. Lambert, *Two Mistakes Behavioralists Make: A Response to Professors Feigenson et al. and Professor Slovic*, 69 MO. L. REV. 1053, 1053 (2004); Smith, *supra* note 44, at 737–41.

103. Enhancing choice architecture may improve decisions by reducing bias and correcting for decision-making errors. *See, e.g.*, Megan S. Wright, *End of Life and Autonomy: The Case for Relational Nudges in End-of-Life Decision-Making Law and Policy*, 77 MD. L. REV. 1062 (2018) (reviewing choice architecture and applying behavioral economics to end of life decision-making). In the medical literature, a type of debiasing strategy is a forcing strategy, which is intended to force actors into Systems II thinking and reduce the influence of bias. *See, e.g.*, Pat Croskerry, *supra* note 45, at 115 ("[C]ognitive forcing strategies are a specific debiasing technique that introduces self-monitoring of decisionmaking").

104. I have more comprehensively analyzed this problem in a previous article. An in-depth discussion is outside the scope of this article. Dineen, *supra* note 27, at 32–46 (Section III).

105. *See, e.g.*, Dineen & DuBois, *supra* note 67, at 13.

106. *See, e.g.*, SUNSTEIN, *supra* note 96, at 66–85 (discussing the effect of probability neglect and emotions on judgment and decision making); *see also* W. Kip Viscusia & Ted Gayer, *Behavioral*

A. Dual Process Models of Decision-Making, Errors, & Mitigation Strategies

Dual process theories (DPT) of decision-making are ubiquitous across disciplines.[107] DPT divides decisions into intuitive (System 1) and analytical (System 2) poles on a continuum.[108] Neither type is inherently superior—both are essential to decision making.[109] System 1 occupies the majority of our decision-making efforts, in part because of its efficiency.[110] System 1 functions largely through the use of rules of thumb or heuristics that ignore part of the information presented to streamline decision-making, but these heuristics can fail and result in poor decisions because of bias and cognitive error,[111] a focus of much of the work that began in earnest with Tversky and Kahneman.[112] On the other hand, heuristics can effectively simplify decisions and even enhance them in some

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Public Choice: The Behavioral Paradox of Government Policy, 38 HARV. J.L. & PUB. POL'Y 973, 977 (2015) ("Many, although certainly not all, behavioral economics papers focus on the biases and heuristics of ordinary individuals, while seemingly ignoring that regulators are people too and thus subject to the same psychological forces.").

107. *See, e.g.*, Ed O'Sullivan & SJ Schofield, *Cognitive Bias in Clinical Medicine*, 48 J. ROYAL C. PHYSICIANS EDINBURGH 225, 225–28 (2018), https://www.rcpe.ac.uk/sites/default/files/jrcpe_48_3_osullivan.pdf [https://perma.cc/6SNP-EDW6] (discussing "the potential origins of bias based on 'dual process thinking'"); Pat Croskerry, *Clinical Cognition and Diagnostic Error: Applications of a Dual Process Model of Reasoning*, 14 ADVANCES HEALTH SCI. EDUC. 27, 27 (2009) ("[Dual Process Theory] has immediate application to medical decision making and provides an overall schema for understanding the variety of theoretical approaches that have been taken in the past. The model has important practical applications for decision making across the multiple domains of healthcare, and may be used as a template for teaching decision theory, as well as a platform for future research. Importantly, specific operating characteristics of the model explain how diagnostic failure occurs."); Sunstein, *supra* note 101, at 1886 (applying Dual Process Theory to issues of autonomy and paternalism); Adele Diederich & Jennifer S. Trueblood, *A Dynamic Dual Process Model of Risky Decision Making*, 125 PSYCH. REV. 270, 270 (2018).

108. The two types are described in many ways. Type 1 is described as fast, efficient, systems 1, heuristic, autonomous, impulsive, unconscious, and experiential; Type 2 is described as slow, systems 2, deliberative, voluntary, metacognitive, reflective, and rational. *See* Diederich & Trueblood, *supra* note 107, at 271; Carissa Bonner & Ben R. Newell, *In Conflict with Ourselves? An Investigation of Heuristic and Analytic Processes in Decision Making*, 38 MEMORY & COGNITION 186, 186 (2010); Antonio Filippin & Fracesco Guala, *Group Identity as a Social Heuristic: An Experiment with Reaction Times*, 10 J. NEUROSCIENCE PSYCHOL. & ECON. 153, 154 (2017); Dineen, *supra* note 2735–36. For an excellent visual representation of the continuum, *see* Croskerry, *supra* note 107, at 28 (figure 1).

109. *See, e.g.*, Croskerry, *supra* note 107, at 28.

110. Croskerry refers to "the tendency to default to a state that consumes fewer cognitive resources" as the "cognitive miser" function. *Id.* at 30.

111. *See id.* at 28–30, 32.

112. Amos Tversky & Daniel Kahneman, *Judgment Under Uncertainty: Heuristics and Biases*, 185 SCIENCE 1124 (1974). *See also* Cass R. Sunstein, *Moral Heuristics and Moral Framing*, 88 MINN. L. REV. 1556 (2004) (examining the use of heuristics within the context of moral cognition).

circumstances.[113]

System 1 can be further divided into two modes, 1) impressionistic thinking and 2) insightful intuition (including assimilation).[114] "[T]here are two kinds of fast and simple ways of thinking: a stupid kind that represents the most primitive form of thinking and a smart kind that represents the highest form of thinking, insightful intuition."[115] Impressionistic thinking is the mode prone to error because of a long list of biases and other cognitive errors, including representation bias.[116] Long standing values and moral principles also influence impressionistic thinking and can create failed heuristics (rules of thumb that result in decisional errors).[117] System 1 is also impacted by emotion, valence (encoded good or bad distinctions), and other kinds of unconscious but biased information.[118]

In contrast, insightful intuition represents the integration of knowledge and experience to form more accurate and useful heuristics, which lead to fast and frugal decisions.[119] Assimilation is the transfer of what was once System 2 metacognition into System 1 through experience and repetition—for example, with repetition and experience, resuscitation protocols become second nature for health care providers in the emergency

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113. *See* Gerd Gigerenzer & Wolfgang Gaissmaier, *Heuristic Decision Making*, 62 ANN. REV. PSYCHOL. 451, 454–55 (2011).

114. I am synthesizing here work from multiple disciplines in DPT. *See* Valerie F. Reyna & Charles J. Brainerd, *Dual Processes in Decision-Making and Developmental Neuroscience: A Fuzzy-Trace Model*, 31 DEVELOPMENTAL REV. 180, 186 (2011); Mark Kelman, *Moral Realism and the Heuristics Debate*, 5 J. LEGAL ANALYSIS 339 (2013) (providing an enlightening overview of the competing claims about heuristics); Croskerry, *supra* note 107, at 28, 32.

115. Reyna & Brainerd, *supra* note 114, at 186.

116. I have highlighted many of the more common types of error and bias previously in Dineen, *supra* note 27, at 32–46 (Section III). *See also* Jan Schnellenbach & Christian Schubert, *Behavioral Public Choice: A Survey*, (Univ. of Freiburg, Dep't of Econ. Policy & Constitutional Econ. Theory, Freiburger Diskussionspapiere zur Ordnungsökonomik, Working Paper No. 14/03, 2014), https://www.econstor.eu/bitstream/10419/92975/1/777865785.pdf [https://perma.cc/8G83-JYEP] ("All these cognitive errors may be subsumed under one key bias, viz., 'a disposition to lend undue weight to what is readily observed at the expense of appreciating what is below the surface.'" (quoting L. Lomasky, *Swing and a Myth: A Review of Caplan's The Myth of the Rational Voter*, 135 Pub. Choice 469, 471 (2008)).

117. *See, e.g.*, Jonathan C. Corbin et al., *How Reasoning, Judgment, and Decision Making Are Colored by Gist-Based Intuition: A Fuzzy-Trace Theory Approach*, 4 J. APPLIED RES. MEMORY & COGNITION 344, 344–46 (2015).

118. Reyna and Brainerd, *supra* note 114, at 185. Theories of stigma refer to this unconscious information that attributes negative qualities to differences as "negative loading." *See* Norman Sartorius, *Lessons from a 10-Year Global Programme Against Stigma and Discrimination Because of an Illness*, 11 PSYCHOL. HEALTH & MED. 383, 383 (2006).

119. *See* Gigerenzer & Gaissmaier, *supra* note 113, at 454; Reyna & Brainerd, *supra* note 114, at 183 ("Implementation, or how people put together what they perceive about a situation (mental representation) with what they know and value (retrieved from long-term memory), accounts for additional variance in reasoning and decision making").

department.[120] Insightful intuition is less prone to error than impressionistic thinking, with errors stemming from "inadequate knowledge; incomplete gist representations; failure to retrieve relevant knowledge representations, and value . . .; and processing interference."[121]

On the other hand, System 2 is characterized by metacognition and is reflective and analytical. Cass Sunstein described it this way:

> It is deliberative. It calculates. It hears a loud noise, and it assesses whether the noise is a cause for concern. It thinks about probability, carefully though sometimes slowly. If it sees reasons for offense, it makes a careful assessment of what, all things considered, ought to be done. It insists on the importance of self-control. It is a planner as well as a doer; it does what it has planned.[122]

System 2 is far less prone to bias and error, but not immune. Such errors typically reflect cognitive overload by the decision-maker (such as in the case of fatigue) or factual mistakes.[123] Shifting thinking to System 2 can be an effective way to detect and prevent decision-making errors or debias decision-making.[124] Therefore, mechanisms that create a public choice architecture that primes policy makers to utilize System 2 thinking and consider alternative definitions of inappropriate prescribing may be helpful in improving policy evaluation and development.

B. Errors by Policy Makers and Mitigation Strategies

> *[T]he political rhetoric regarding the "opioid crisis" appears to call for immediate answers rather than careful research and measured responses. Policymakers in government and leaders in the nation's medical community need to resist this urge to act too quickly on this topic once again. Instead, all parties involved in these discussions must ensure that all patients are treated individually rather than painted with a broad brush.*[125]

Policy makers are prone to the same decisional errors as individuals,

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120. *See* Croskerry, *supra* note 107, at 30–32.

121. Susan J. Blalock & Valerie F. Reyna, *Using Fuzzy Trace Theory to Understand and Improve Health Judgements, Decisions, and Behaviors: A Literature Review*, 35 HEALTH PSYCHOL. 781, 789 (2016).

122. Cass R. Sunstein, *Is Deontology a Heuristic? On Psychology, Neuroscience, Ethics, and Law* (Harvard Univ. DASH Repository, preliminary draft, Sept. 1, 2013), http://nrs.harvard.edu/urn-3:HUL.InstRepos:13548959 [https://perma.cc/M9TP-44AL].

123. *See generally* Dineen, *supra* note 27.

124. *Id.*

125. Benjamin Pomerance, *Yet Another War: Battling for Reasoned Responses for Veterans Amid the Opioid Crisis*, 11 ALB. GOV'T L. REV. 147, 173 (2018).

and may be even more prone.[126] One example is the tendency to devote risk mitigation resources to more salient but objectively less harmful issues.[127] This is also known as the "availability bias," "availability heuristic," or the "focusing illusion," which "focuses the public's attention on problems that receive significant media coverage, which causes the government to neglect more important but less newsworthy issues."[128] This is true even within a particular area, such as the opioid related crisis. With the often myopic public focus on reducing opioid prescriptions alone, policy makers are likely neglecting a multitude of less salient harms.[129]

According to Michael David Thomas, "policy that reflects policymakers' own goals faces unreliable feedback from within the system and creates a situation of cognitive capture, whereby policy reflects the particular biases of a small group of experts."[130] Policy makers may also be particularly susceptible to reputational cascades and in-group biases.[131] Availability cascades—the concurrent effects of availability bias, reputational bias, and bandwagon effect—likely also play a significant role in prescription opioid policy.[132] This cascade begins when policy-makers focus on the most salient information and neglect other important root causes and sources of harm.[133] As this salient but incomplete information is repeated to other experts and policy-makers, it is often taken as valid without checking underlying facts (i.e. reputation bias).[134] Finally, the desire to preserve in-group norms and personal and professional reputations leads to widespread adoption of incomplete information, leading to over-reaction and incoherent regulation—often with serious

126. *See, e.g.*, Lucas & Tasic, *supra* note 97.

127. *See, e.g.*, Schnellenbach & Schubert, *supra* note 116, at 29.

128. Lucas & Tasic, *supra* note 97, at 211 (further explaining on pages 217–18 that "as a result of focusing illusion, voters and politicians do not evaluate policies globally by considering all angles, including interrelationships among policies. Instead, their analyses are subject to pervasive framing, salience, and vividness effects").

129. These include the known dangers of concurrent use of other drugs and substances, the levels of suicidality, and the need to get patients with SUDs into treatment. *See generally* Dineen, *supra* note 27, at 1–29.

130. Michael David Thomas, *Reapplying Behavioral Symmetry: Public Choice and Choice Architecture*, PUB. CHOICE, July 2018, at 1, 16.

131. *See generally* Jörg Gross, Carsten K. W. De Dreu, *The Rise and Fall of Cooperation Through Reputation and Group Polarization*, 10 NATURE COMM., no. 776, Feb. 2019, https://doi.org/10.1038/s41467-019-08727-8 [https://perma.cc/KQ6V-YALA]; Lucas & Tasic, *supra* note 97.

132. *See* Dineen, *supra* note 27, at 32–46 (Section III).

133. *Id.*

134. *Id.*

unintended consequences.[135] In the end, policy-makers too "frequently fail to see past the superficial effects of government policy, which is why so many policies are undermined by unintended consequences."[136]

A variety of techniques to mitigate decisional errors by decreasing bias have been studied.[137] Debiasing is generally understood "as a strategy (or set of strategies) designed to suppress/mitigate biases, or at least to suppress/mitigate their effects."[138] Providing a taxonomy of inappropriate prescribing may inform the choices of public policy actors by serving as a contextual debiasing mechanism[139] and a restructuring approach—by deconstructing the meanings of "misprescribing" and creating a "consider-the-alternatives" mechanism.[140]

C. The failed "misprescribing" heuristic and limited definitions

> *In practice, overprescribing is an amalgamation of prescribing behaviors encompassing starting dose, number of units in a prescription, dosing schedules, potency, and other factors. A rational approach would treat these as parallel but distinct issues. Yet, the legislative and clinical reaction has included efforts to bring dosage below arbitrary targets or abandon patients who do not conform to clinically arbitrary expectations.*[141]

Heuristics are shortcuts or rules of thumb,[142] but when they cause "mental contamination,"[143] they are appropriately described as failed

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135. *Id.* For a comprehensive explanation of availability cascades, *see* Timur Kuran & Cass R. Sunstein, *Availability Cascades and Risk Regulation*, 51 STAN. L. REV. 683 (1999).

136. Lucas & Tasic, *supra* note 97, at 218.

137. For an excellent overview, *See* Frank Zenker et al., *Reliable Debiasing Techniques in Legal Contexts? Weak Signals from a Darker Corner of the Social Science Universe*, *in* THE PSYCHOLOGY OF ARGUMENT 173 (Fabio Paglieri et al. eds., 2015).

138. Vasco Correia, *Contextual Debiasing and Critical Thinking: Reasons for Optimism*, 37 TOPOI 103, 105 (2018).

139. *See, e.g.*, Mark L. Graber et al., *Cognitive Interventions to Reduce Diagnostic Errors: A Narrative Review*, 21 BMJ QUALITY & SAFETY 535, 535 (2011) (conducting a retrospective review of the literature and categorizing debiasing strategies).

140. *See* Zenker et al., *supra* note 137 (reviewing interdisciplinary literature on bias and error and discussing the effectiveness of debiasing techniques, of which considering the alternatives and deconstructing the issue are among the most promising).

141. Dasgupta et al., *supra* note 47.

142. Shabnam Mousavi & Gerd Gigerenzer, *Heuristics are Tools for Uncertainty*, 34 HOMO OECON 361, 367 (2017). For an excellent discussion of the evolution of the meaning of heuristic, *see* Croskerry, *supra* note 45, at 114–15.

143. Pat Croskerry et al., *Cognitive Debiasing 1: Origins of Bias and Theory of Debiasing*, 22 BMJ QUALITY & SAFETY ii58, ii62 (2013) (quoting TD Wilson & N. Brekke, *Mental Contamination and Mental Correction: Unwanted Influences on Judgments and Evaluations*, 116 PSYCHOL. BULL. 117 (1994)).

heuristics.[144] Heuristics allow decision-makers to use fewer pieces of information, reduce the retrieval of information, simplify the weighting of information, and examine fewer alternatives.[145] They must be carefully tailored in terms of content and context to result in effective decision-making, what is sometimes referred to as "ecological rationality."[146]

Absent ecological rationality, heuristics will fail. One category of heuristics based on recognition can be effective but "incurs bias by searching for only a specific pattern or cue stored in memory and does not aim to assess values of other objects."[147] What I describe below as a misprescribing heuristic may fail, in part, because of this recognition bias. The current state of wide ranging and incomplete definitions may lead policymakers to search and recognize only one or a few patterns that are overrepresented, without consideration of important other categories of recognition. Failed heuristics can combine and create cascades (such as availability cascades), which exacerbate suboptimal and incoherent decisions.[148] Failed heuristics are also steeped in deeply held values and emotions (generally negative and likely to contribute to visceral biases).[149] According to Schnellenbach and Schubert,

> Instead of carefully evaluating all possible alternatives, [policy-makers] will typically use heuristics and follow rules of thumb. While in general, the use of heuristics appears to be a quite efficient strategy . . . , matters may again be different in politics, where rules of thumb tend to be related to stable ideologies, which may not offer very precise guidance to solving policy problems.[150]

What I describe as the "misprescribing heuristic" is a failed heuristic.

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144. There is significant disagreement about the use of the term. I choose to use the term "failed heuristic" to acknowledge that not all heuristics result in bad decisions. Under theories of bounded rationality, heuristics describe biases; however, I am synthesizing the medical literature, the fuzzy trace theory (also a dual process theory), and work on bounded rationality and want to honor the fact that heuristics that develop through experience and skill may be helpful to decision-makers.

145. Gigerenzer & Gaissmaier, *supra* note 113, at 454 (citing AK Shah & DM Oppenheimer, *Heuristics Made Easy: An Effort-Reduction Framework*, 137 PSYCHOL. BULL. 207 (2008)).

146. Mousavi & Gigerenzer, *supra* note 142, at 367 ("The ecological rationality of a decision rule is assessed based on norms that are sensitive to the content of the problem and the context of the situation.").

147. Florian Artinger, Malte Petersen, Gerd Gigerenzer & Jürgen Weibler, *Heuristics as Adaptive Decision Strategies in Management*, 36 J. ORGANIZATIONAL BEHAV. S33, S42 (2015).

148. *See* Dineen, *supra* note 27 (applying availability cascades to opioid related crises responses).

149. *Id.* at 44–45.

150. Schnellenbach & Schubert, *supra* note 116, at 25 (citing Gigerenzer & Gaissmaier, *supra* note 113).

1. The misprescribing heuristic

A misprescribing heuristic impacts policy decisions. A variety of words and phrases—"overprescribing," "misprescribing," "inappropriate prescribing"—are now heuristics (collectively, "misprescribing heuristic") for a range of prescribing behaviors from careful (e.g., a careful prescriber being fooled by a person feigning pain to divert drugs to the market) to criminal (a provider knowingly abandoning their provider role for self-gain).[151] The misprescribing heuristic includes behaviors between careful and criminal prescribing, such as prescribing long term opioids when risks to the patient outweigh the benefits.[152] It also includes prescribing far more pills than a patient will need therapeutically—especially after procedures or for acute pain from injuries—leaving extra pills available for diversion,[153] the primary source of non-medically used opioids.[154] What the misprescribing heuristic does not include is what I will refer to as "underprescribing," including failure to refer patients for appropriate pharmacological therapy (usually referred to as "medication assisted treatment")[155] in whom an SUD is suspected nor does it include too rapid tapering or cold turkey discontinuation of opioids in "legacy patients."[156]

The heterogeneity of prescribing types captured by the misprescribing heuristic, as well as the neglect of some types of inappropriate prescribing, make it ineffective.

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151. *See generally* Dineen, *supra* note 84; Dineen & DuBois, *supra* note 67.

152. *See generally* Jane C. Ballantyne, *Opioids for the Treatment of Chronic Pain: Mistakes Made, Lessons Learned, and Future Directions*, 125 ANESTHESIA & ANALGESIA 1769 (2017).

153. *See, e.g.*, Cornelius A. Thiels et al., *Wide Variation and Overprescription of Opioids After Elective Surgery*, 266 ANNALS SURGERY 564, 564 (2017); Makary et al., *supra* note 30 (using overprescribing to describe surgeon behavior in discharging patients with too many pills).

154. *See* Lapari & Hughes, *supra* note 98.

155. Medication assisted treatment is the tradition terminology and what appears in the federal and state regulations and much of the literature. Nonetheless, I choose to not use that terminology because it adds to the stigma of SUD and furthers the cognitive separation of treatment of addiction from treatment of all other health problems. *See* Sarah E. Wakeman, *Medications for Addiction Treatment: Changing Language to Improve Care*, 11 J. ADDICTION MED. 1, 1–2 (2017).

156. Legacy patients are those patients who have long been treated with opioids for chronic pain, many of whom report functioning best on stable doses. *See* Travis Rieder, *There's Never Just One Side to the Story: Why America Must Stop Swinging the Opioid Pendulum*, 8 NARRATIVE INQUIRY BIOETHICS 225, 228 (2018). Interestingly, at a conference on February 22, 2019, at American University, Thomas Farley, the health commissioner of Philadelphia, explained that the city recently looked for tapering guidelines and found absolutely zero. They subsequently developed a set of guidelines. For information about the conference, *see AUWCL's Health Law and Policy Program Hosts Opioid Crisis Conference*, WCL.AMERICAN.EDU (Feb. 25, 2019), https://www.wcl.american.edu/impact/initiatives-programs/health/events/opioidconference/videos/ [https://perma.cc/Q5BP-4JKT].

2. Implicit and missing definitions of inappropriate prescribing in law and policy

Explicit definitions of inappropriate prescribing are rare. One definition comes from the medical literature in a non-opioid specific context. According to Selic and colleagues:

> Inappropriate prescribing means the use of a drug for which the risk of [adverse drug events] outweighs the clinical benefits, and which could result in harmful effects, either through interactions between drugs or through the non-use of a drug with proven efficiency for patients with sufficiently long life expectancy and a good quality of life.[157]

This definition is excellent because it includes the continued use of drugs when the risks outweigh the benefits, the risks of drug interactions, as well as the failure to use a drug that is appropriate for a particular patient. Each of these are incorporated in the taxonomy of misprescribing below.

In the legal and public policy contexts, no such definitions were discovered. Implicit definitions do exist. In the criminal context, the Controlled Substances Act (CSA) makes exceptions from criminal distribution prohibitions for prescriptions that are for a "legitimate medical purpose" in the "usual course of . . . professional practice."[158] Prescribers who knowingly (including constructive knowledge and willful blindness) deviate from this exception violate the CSA.[159]

The Drug Enforcement Agency's Practitioner Manual further lists criteria indicative of what they call "inappropriate prescribing," a heuristic device to mean criminal prescribing. According to the manual:

> While there are *no criteria* to address every conceivable instance of prescribing, there are recurring patterns that may be indicative of inappropriate prescribing: [a]n inordinately large quantity of controlled substances prescribed or large numbers of prescriptions issued compared to other physicians in an area; [n]o physical examination was given; [w]arnings to the patient to fill prescriptions at different drug stores; [i]ssuing prescriptions knowing that the patient was delivering the drugs

157. Polona Selic et al., *The Effects of a Web Application and Medical Monitoring on the Quality of Medication, Adverse Drug Events and Adherence in the Elderly Living at Home: a Protocol of the Study*, 28 MATERIA SOCIO-MEDICA 432, 432 (2016) (defining inappropriate prescribing in the context of multiple medication use in the elderly rather than in the context of opioid use).

158. 21 C.F.R. § 1306.04(a) (2018). *See also* Dineen & DuBois, *supra* note 67, at 29–48 (reviewing the current standard for criminal violations for misprescribing and recommending a category of corrupt prescribing).

159. Dineen & DuBois, *supra* note 67, at 30–31.

> to others; [i]ssuing prescriptions in exchange for sexual favors or for money; [p]rescribing of controlled drugs at intervals inconsistent with legitimate medical treatment; [t]he use of street slang rather than medical terminology for the drugs prescribed; or [n]o logical relationship between the drugs prescribed and treatment of the condition allegedly existing.[160]

This implicit definition addresses corrupt prescribing only. However, the patterns they list do not necessarily correlate with corrupt or criminal prescribing. In particular, "inordinate" amounts depend upon context and prescriber specialty. On the other hand, some are squarely within the criminal standard, such as exchanging prescriptions for sexual favors or money.

Other federal agencies also only implicitly define inappropriate prescribing. The FDA, a consumer protection agency, focuses more on careless prescribing.[161] For example, the FDA commissioner uses the term frequently, but without definition.[162] *The FDA's Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain* does not define inappropriate prescribing at all.[163] The Center for Medicaid and CHIP Services addresses inappropriate prescribing in terms of misuse by the patient/recipient, tracking recipients that receive opioids "(1) at high dosage, (2) from multiple prescribers and pharmacies, and (3) at high dosage and from multiple prescribers and pharmacies."[164] One problem with this approach is that unless this occurs in a state with a mandatory PDMP with real time reporting, it may not reflect inappropriate prescribing at all. Prescribers are not lie detectors, and other research

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160. OFFICE OF DIVERSION CONTROL, DRUG ENF'T ADMIN., PRACTITIONER'S MANUAL 30 (2006), https://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual012508.pdf#search=inappropriate%20prescribing [https://perma.cc/S5SH-N8TB] (emphasis added).

161. *See* Dineen & DuBois, *supra* note 67, at 28–29 (reviewing the regulation of prescribing by the FDA).

162. *See, e.g.*, Press Release, U.S. Food & Drug Admin., Statement from FDA Commissioner Scott Gottlieb, M.D., on Agency's Approval of Dsuvia and the FDA's Future Consideration of New Opioids (Nov. 2, 2018), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm624968.htm [https://perma.cc/BMW8-XH2B]. *See also* Scott Gottlieb, Comm'r, U.S. Food & Drug Admin., Remarks at the NCCN/ASCO Workshop (Nov. 8, 2018), https://www.fda.gov/NewsEvents/Speeches/ucm625333.htm [https://perma.cc/M67A-P225] (implicitly linking inappropriate prescribing to dose and duration of opioids).

163. *See* U.S. FOOD & DRUG ADMIN., U.S. DEP'T HEALTH & HUMAN SERVS., FDA'S OPIOID ANALGESIC REMS EDUCATION BLUEPRINT FOR HEALTH CARE PROVIDERS INVOLVED IN THE TREATMENT AND MONITORING OF PATIENTS WITH PAIN (2018).

164. CTR. FOR MEDICAID AND CHIP SERVS., U.S. DEP'T OF HEALTH & HUMAN SERVS., BEST PRACTICES FOR ADDRESSING PRESCRIPTION OPIOID OVERDOSES, MISUSE AND ADDICTION 7 (2016), https://www.medicaid.gov/federal-policy-guidance/downloads/cib-02-02-16.pdf [https://perma.cc/QE88-VLTQ].

supports that their chances of detecting dishonesty are only slightly better than chance.[165] These criteria may indicate a condition for which high doses are appropriate, an OUD, or criminal diversion. As such, it lacks the context needed to accurately evaluate prescribing practices.

The Centers for Medicare & Medicaid Services recently expanded its tracking of opioid use by Medicare recipients without cancer. They will measure three criteria: 1) adults who receive equal to or greater than 90 MME for 90 or more days; 2) adults who receive four prescriptions in any MME and from four or more pharmacies in 180 days or less; and 3) the percentage of all adults who received 90 MME or higher daily dose and from four or more prescribers and four or more pharmacies within 180 days.[166] These measures, like many others, track only some areas of concern and focus disproportionately on chronic pain treatment. These measures may also identify patients who may have an OUD. However, there is an alarming paucity of guidance for practitioners in how to assist these patients.[167] Providers may simply discharge these patients instead of referring them to OUD treatment,[168] and there are systematic barriers to access appropriate treatment for opioid use and other SUDs.[169] These tracking criteria also do nothing to address reflexive prescribing after surgeries or procedures; yet, reducing reflexive prescribing is one of the few interventions estimated to reduce overall opioid related poisoning deaths in 5 and 10 years.[170]

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165. *See* Dineen & DuBois, *supra* note 67, at 18–20.

166. CTR. FOR MEDICARE & MEDICAID SERVS., U.S. DEP'T OF HEALTH & HUMAN SERVS., CMS-2018-0154, ADVANCE NOTICE OF METHODOLOGICAL CHANGES FOR CALENDAR YEAR (CY) 2020 FOR MEDICARE ADVANTAGE (MA) CAPITATION RATES, PART C AND PART D PAYMENT POLICIES AND 2020 DRAFT CALL LETTER 136 (Jan. 30, 2019), https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2020Part2.pdf [https://perma.cc/LHQ6-MBDE] (describing their efforts as better aligning with the CDC Guidelines).

167. For an excellent discussion of the significant barriers to adequate treatment for patients who are on opioids, *see* William C. Becker et al., *Management of Patients with Issues Related to Opioid Safety, Efficacy and/or Misuse: A Case Series from an Integrated, Interdisciplinary Clinic*, ADDICTION SCI. & CLINICAL PRAC., Jan. 28, 2016, at 1, 1, https://doi.org/10.1186/s13722-016-0050-0 [https://perma.cc/2GVA-S5L4].

168. *See, e.g.*, Shannon M. Nugent et al., *Substance Use Disorder Treatment Following Clinician-Initiated Discontinuation of Long-Term Opioid Therapy Resulting from an Aberrant Urine Drug Test*, 32 J. GEN. INTERNAL MED. 1076, 1079 (2017) (finding only 43% of the time did providers refer patients with suspected OUD for treatment); Zoe Clancy et al., *The Use of Urine Drug Monitoring in Chronic Opioid Therapy: An Analysis of Current Clinician Behavior*, 9 J. OPIOID MGMT. 121 (2013) (finding more physicians would discharge a patient with a suspicious urine drug screening than even have a discussion with them about substance use disorder).

169. For an excellent discussion of systemic barriers to SUD treatment, *see* Robert D. Ashford et al., *Systemic Barriers in Substance Use Disorder Treatment: A Prospective Qualitative Study of Professionals in the Field*, 189 DRUG & ALCOHOL DEPENDENCE 62 (2018).

170. *See* Pitt et al., *supra* note 93, at 1396–97.

Recent federal laws similarly lack definitions. The SUPPORT Act authorized new evidence-based prevention grants, which includes projects that use PDMPs to detect inappropriate prescribing; however, inappropriate prescribing is not defined.[171] Section 6902 of the SUPPORT Act is aimed at inpatient hospital care and directs the U.S. Department of Health & Human Services to develop guidance to hospitals on, among other things, identifying overprescribing.[172] Again, no definitions are provided. The Comprehensive Addiction and Recovery Act of 2016, mentions inappropriate prescribing only once, requiring the Veteran's Administration to report on how it tracks inappropriate prescribing, yet no definitions or criteria are offered.[173]

Nevada is one of the only states to recognize a need for defining inappropriate prescribing but did so after it passed sweeping legislation significantly limiting opioid prescribing.[174] The Nevada Senate Committee on Health and Human Services noted "[w]hile inappropriate prescribing comes in many forms, generally, it is prescribing outside of the standard of care for a prescriber's practice, specialty or otherwise outside the medical need of the patient. . . . [W]e are placing the responsibility of identifying inappropriate prescribing on the State's licensing boards."[175] As of this writing, "inappropriate prescribing" remains undefined.

A Florida regulation requires continuing education on inappropriate

171. 42 U.S.C. § 280b–1 (Supp. V 2018).

172. SUPPORT Act, Pub. L. No. 115-271, § 6092(c)(5), 132 Stat. 3894, 4001 (2018).

173. Comprehensive Addiction and Recovery Act of 2016 (CARA), Pub. L. 114-198, 130 Stat. 695. Section 913 requires the comptroller general of the United States to report on the VA's efforts to identify "inappropriate prescribing" in (a)(2)(A) and evaluate the VA's process for identifying overprescribing in (a)(2)(C). *Id.* § 913(a)(2)(A), 130 Stat. at 762. There are also surveillance requirements in Section 913(c) that implicitly aim to track inappropriate prescribing but again, they focus on receiving prescriptions from more than one provider, concurrent prescription of opioids and benzodiazepines, and the concurrent filling of ongoing opioid prescriptions while the patient was hospitalized as an inpatient. *Id.* § 913(c), 130 Stat. at 764.

174. Nevada passed a state law limiting opioid prescribing significantly without defining inappropriate prescribing. *See, e.g.*, Megan Messerly, *Opioids in Nevada: How One New Law Attempts to Address the Epidemic and Why Some Doctors Are Pushing Back*, NEV. INDEP. (Jan. 14, 2018, 2:10 AM), https://thenevadaindependent.com/article/opioids-in-nevada-how-one-new-law-attempts-to-address-the-epidemic-and-why-some-doctors-are-pushing-back. The Nevada Senate Committee on Health and Human Services discussed the need to have inappropriate prescribing defined and offered a very general definition in committee. *See* S. Comm. Health & Human Servs., MINUTES, 79th Sess. (Nev. 2017), https://www.leg.state.nv.us/Session/79th2017/Minutes/Senate/HHS/Final/1185.pdf [https://perma.cc/LT8Y-YAGB].

175. S. COMM. HEALTH & HUMAN SERVS., MINUTES, 79th Sess. (Nev. 2017), https://www.leg.state.nv.us/Session/79th2017/Minutes/Senate/HHS/Final/1185.pdf [https://perma.cc/3MYB-3W23].

prescribing but provides no information on what that means.[176] Washington's prescribing regulations were recently changed and address inappropriate prescribing, but again, without definition.[177] Maine adopted the idea that clinical practice guidelines, including the CDC Guideline, provide the needed definition of inappropriate prescribing.[178] A Michigan appropriations bill requires reporting on administration actions against providers for overprescribing, but again provides no guidance or definition.[179] Texas regulations use the term "non-therapeutic prescribing" and implicitly define it as prescribing that might "lead to or contribute to abuse, addiction, and/or diversion of drugs."[180]

The inconsistency across agencies and jurisdictions, as well as the outright lack of definitions is problematic—it may fuel overcorrection and fear by providers and other stakeholders. It leaves policy makers, including, but not limited to, institutions, professional board members, and enforcement authorities, without the context needed to evaluate prescribing practices. These inconsistencies may even be deadly; for example, the neglect of significant sources of prescribing related harm, such as outright discontinuation or too rapid tapering, may fuel upticks in illicit opioid use as well as suicides.

IV. A TAXONOMY OF INAPPROPRIATE PRESCRIBING

> *The availability of information alone does not ensure that it will be—or can be—incorporated. Information that . . . lacks a framework that decision makers can readily understand is unlikely to feed into their thinking.*[181]

Previous work has divided *prescribers* into four types—careful,

176. Fla. Admin. Code Ann. r.64B15–13.001 (2019).

177. Wash. St. Reg. 18-23-061 (Jan. 1, 2019) (amending various portions Wash. Admin. Code §§ 246-918 and 919 regarding opioid prescribing by physicians, physician assistants, and advance practice nurses).

178. 02-380-021 Me. Code R. § 1, 5 (LexisNexis 2019).

179. Michigan Senate Bill 800 (2015), Article XIII § 517 (enacted) ("the department shall submit a report to the subcommittees that includes all of the following: (a) Number of administrative actions taken against prescriber licenses related to opioid prescribing, including the location of where the prescriber practiced and any specialty certifications that prescriber has held since 2010. (b) The number of prescribers who were identified as overprescribing. (c) The actions taken to notify those prescribers who were overprescribing").

180. 22 TEX. ADMIN. CODE §170.1 (2019). To their credit, at least abuse, addiction, and diversion are defined in § 170.2. *Id.* § 170.2. Texas lawmakers also clarified that inappropriate prescribing under regulations for pain clinics includes non-therapeutic prescribing. S.B. 315, sec. 5, 85th Legis., 2017–2018 Sess. (2017).

181. Elisabeth A. Graffy, *Meeting the Challenges of Policy-Relevant Science: Bridging Theory and Practice*, 68 PUB. ADMIN. REV. 1087, 1094 (2008).

careless, corrupt, and compromised by impairment.[182] This classification is consistent with an empirical analysis of 100 cases of misprescribing.[183] Careless prescribers may engage in qualitative overprescribing, quantitative overprescribing, or multi-class misprescribing (described below). This is less common in cases of misprescribing by providers who are compromised by their own impairments—such as an SUD—as they tend to obtain prescription drugs for their own use rather than harming patients.[184] Corrupt prescribers, on the other hand, are those who have abandoned their practice so completely that they can no longer be described as within the bounds of professional practice, either by knowingly trading prescribing privileges for personal gain or through carelessness that has crossed the threshold into corrupt prescribing through the exercise of willful blindness.[185]

Particularly within the category of careless prescribers, more contextual information is required.[186] Focusing on character of the prescribing behavior itself, rather than simply describing the prescriber types, is necessary to further guide evaluation of prescribing practices. This is particularly true in the highly complex and value-laden areas around prescribing drugs that are controlled substances. The highly charged area of opioid prescribing requires careful categorization to guide all stakeholders in the position of evaluating the appropriateness of these prescriptions. Opioid prescriptions must be evaluated in context. As explained by Travis Rieder:

> [I]t may become obvious that no number of pills or of morphine equivalents—and that includes the number zero—should be the aim as we seek to change practice. It is not the case that the risk of overprescribing means we should aim to eliminate opioids. What I propose, rather, is prescribing an appropriate amount of opioids,

182. *See generally* Dineen & DuBois, *supra* note 67 (reviewing and rejecting the long-standing classification of misprescribers—Dated, Duped, Disabled, & Dishonest—in light of evidence and suggesting a new framework of careless, corrupt, and compromised by impairment).

183. *See* DuBois et al., *supra* note 50 (reviewing 100 cases of misprescribing and describing the facts statistically associated with misprescribing related sanctions—including being male, having little oversight—such as a solo practice, having an underlying personality disorder—and describing the types of misprescribing as fitting within the careless, corrupt, and compromised by impairment categories).

184. *See id.* at 16–19; Dineen & DuBois, *supra* note 67, at 49.

185. Dineen & DuBois, *supra* note 67, at 40–50 (providing multiple example cases and a full discussion of what constitutes each category).

186. For example, PDMP data is often analyzed by number of prescriptions only. Only recently have some researchers examined the important of tracking the number of pills, the total morphine equivalents, and the specialty of prescribers. *See* Scott G Weiner et al., *Opioid Prescriptions by Specialty in Ohio, 2010–2014*, 19 PAIN MED. 978, 978 (2018).

whatever that turns out to be.[187]

The taxonomy of misprescribing includes corrupt prescribing, inadvertent overprescribing, qualitative overprescribing, quantitative overprescribing, multi-class misprescribing, and underprescribing. Each category is described below.

A. Corrupt Prescribing

Prescribers who abandon their provider role in favor of personal profit comprise this category.[188] Although this represents a very small portion of providers and a smaller portion yet of misprescribing, it is salient because it is an affront to the trust placed in health care providers and the privileged role they occupy.[189]

The boundaries of corrupt prescribing should be clear to policymakers and providers: it applies when providers abandon their professional obligations and engage in prescribing that poses palpable harm to others for personal gain. Corrupt prescribing is not about poor practice, malpractice, or carelessness. Federal courts have consistently held that a deviation from the standard of care is not sufficient to meet the mens rea requirement of knowledge under the controlled substance act. Instead, pursuant to *Feingold*, providers must depart from being even a "bad doctor" to "a 'pusher' whose conduct is without a legitimate medical justification."[190] Nonetheless, providers continue to fear criminal investigation and sanction; moreover, prosecutorial overreach is in no short supply in the current climate.[191]

Ample regulatory tools already exist for sanctioning corrupt prescribing, from federal and state criminal laws to professional board

187. Travis N. Reider, *Opioids and Ethics: Is Opioid-Free the Only Responsible Arthroplasty?*, 15 HSS J. 12, 12 (2018), https://doi.org/10.1007/s11420-018-9651-3 [https://perma.cc/4N2Y-HGTU].

188. For a detailed examination of corrupt prescribing, *see* Dineen & DuBois, *supra* note 67, at 42–48. *See also* DuBois et al., *supra* note 50, at 16–19.

189. These cases tend to have damning facts that clearly indicate a departure from medical standards. *See, e.g.*, Tom Winter et al., *Feds Charge 5 New York Doctors with Prescribing 8.5 Million Opioid Pills*, NBC NEWS (Oct. 11, 2018, 10:57 AM), https://www.nbcnews.com/news/crime-courts/feds-charge-5-new-york-doctors-prescribing-8-5-million-n918966 [https://perma.cc/4YT2-HJD6](describing doctors meeting patients in the middle of the night, prescribing for cash only, and without appointments).

190. United States v. Feingold, 454 F.3d 1001, 1007 (9th Cir. 2006).

191. *See, e.g.*, Bill Rankin, *Prosecutors Notify 30 Doctors About Excessive Opioid Prescribing*, ATLANTA J.-CONST. (Oct. 5, 2018), https://www.ajc.com/news/crime—law/prosecutors-notify-doctors-about-excessive-opioid-prescriptions/fXSbsKBg8XiMc9y7wj3wPN/ https://perma.cc/U444-C8KY] (describing prosecutors sending letters to doctors they judge to be outliers in prescribing without any evidence of criminal behavior).

scrutiny to tort remedies.[192] Other policies, such as Pill Mill Laws, were designed to eliminate such corrupt prescribing.[193] Once corrupt providers are sanctioned at the criminal level, administrative and civil remedies are likely to follow.

B. Inadvertent Overprescribing

Careful prescribers will generally write appropriate prescriptions, with the exception of what I call "inadvertent overprescribing." Inadvertent overprescribing occurs in a very narrow set of circumstances. It occurs when, despite the exercise of care by the prescriber, an individual feigning pain obtains prescriptions for opioids or other controlled substances. Providers are not lie detectors, nor does experience improve their odds of lie detection.[194] This "provider as lie detector" mythology must be put to rest.[195] This category acknowledges that there are times when careful prescribers will inadvertently overprescribe. Sanctions are inappropriate if due care is exercised.

Interventions such as PDMPs or urine drug monitoring *may* be useful in preventing inadvertent overprescribing.[196] For example, in circumstances where PDMPs are accurate and up-to-date, a careful prescriber may identify a problematic pattern of prescriptions for a particular patient before prescribing. Urine drug monitoring may indicate an underlying SUD by identifying non-prescribed substances.[197] It may also indicate a patient who is diverting prescription opioids for money rather than taking them.[198]

What happens next is critical and unfortunately poorly addressed in

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192. *See, e.g.*, Dineen & DuBois, *supra* note 67, at 21–40. *See also* Y. Tony Yang & Rebecca L. Haffajee, *Murder Liability for Prescribing Opioids: A Way Forward*?, 91 MAYO CLINIC PROC. 1331, 1331–34 (2016).

193. *See, e.g.*, Andraka-Christou et al., *supra* note 62, at 8–9.

194. *See* Dineen & DuBois, *supra* note 67, 18–20.

195. For an example of the way this mythology appears in policy, *see Don't Be Scammed by a Drug Abuser*, DIVERSION CTRL. DIV. (Dec. 1999), https://www.deadiversion.usdoj.gov/pubs/brochures/pdfs/recognizing_drug_abuser_trifold.pdf [https://perma.cc/NH85-XJ97].

196. It *may* be useful if the PDMP is accurate, up to date, and the patient is using their own name or a consistent name at encounters; however, serious concerns exist about whether PDMPs are being used as a health care tool or as a law enforcement mechanism. *See, e.g.*, Jennifer D. Oliva, *Prescription Drug Policing: The Right to Protected Health Information Privacy Pre- and Post- Carpenter*, 69 DUKE L.J. (forthcoming 2019) ("PDMPs are largely criminal and regulatory law enforcement tools dressed up in public health promoting rhetoric").

197. *See, e.g.*, Anand C. Thakur, *Pain Management Assessment Beyond the Physician Encounter: Urine Drug Monitoring and Patient Agreements*, *in* PRESCRIPTION DRUG DIVERSION AND PAIN, *supra* note 40, at 219.

198. *See id.* at 219, 231.

practice, particularly when a SUD is suspected.[199] In a study by Hagemeier and colleagues, a group of physicians discussed this reality:

> MD1: Usually they'll fail the drug screen or the prescriber database and that takes care of it. We discharge from the practice. Now *the one thing I don't think we do* is say 'Hey here are some treatment centers,' do we?
> MD2: No *we don't*
> MD1: We probably ought to say here's some options . . .
> MD2: Here's some options for treatment. We just . . . I don't know.
> MD3: But you're *too ticked off* at them.[200]

Similarly, a study by Clancy and colleagues found that doctors were more likely to discharge a patient than discuss the urine drug test results with a patient after a positive urine screening result for a non-marijuana, illicit drug.[201]

Although some recent research exists on the need to deal with concerns about SUDs or diversion holistically, recommendations for communication and referral to treatment are not often followed in practice. Authors in one study acknowledged that their holistic recommendations are "in contrast to contemporary clinical practice, in which providers may feel compelled to make major decisions abruptly (e.g., taper or discontinue opioids) due to state or local policies or licensure concerns, regardless of whether these decisions are warranted."[202] In contrast, a recent news story on a town's successful, comprehensive harm reduction approach to the opioid crisis demonstrates the appropriate provider approach. According to Dr. Bell:

> If you find a person's urine has a bunch of meth and not their pain meds, you make the assumption they are selling their pain meds to get meth . . . . But we don't kick them out of our clinic. We say, 'OK, what is going on? Do you need help?' Then we get them into treatment.[203]

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199. There is wide variation in how providers deal with concerning PDMP information, with some having discussions and providing referrals and some discharging (or "firing") patients with questionable PDMP findings. *See, e.g.*, Gillian J. Leichtling et al., *Clinicians' Use of Prescription Drug Monitoring Programs in Clinical Practice and Decision-Making*, 18 PAIN MED. 1063, 1063 (2017).

200. Nicholas E. Hagemeier et al., *Prescription Drug Abuse Communication: A Qualitative Analysis of Prescriber and Pharmacist Perceptions and Behaviors*, 12 RES. SOC. & ADMIN. PHARMACY 937, 944 (emphasis added).

201. Zoe Clancy et al., *The Use of Urine Drug Monitoring in Chronic Opioid Therapy: An Analysis of Current Clinician Behavior*, 9 J. OPIOID MGMT. 121, 125–26 (2013).

202. Jessica S. Merlin et al., *Managing Concerning Behaviors in Patients Prescribed Opioids for Chronic Pain: A Delphi Study*, J. GEN. INTERNAL MED. 166, 166–76 (2018).

203. Dan Vergano, *Here's How One Small Town Beat the Opioid Epidemic*, BUZZFEED NEWS

However difficult to effectuate, prescribers do have an ethical and professional obligation to assess the patient for OUD and offer treatment or referral to treatment. This reality is acknowledged in some policy documents.[204] The fact that providers often fail to refer to treatment is likely connected to the recently reported failures of PDMPs to reduce overall opioid related harms, including patients with SUDs shifting to illicit and more dangerous drugs.[205] Prescribers should not be placed in a quasi law enforcement position—a position inapposite to their fiduciary duties to patients and inapposite to the trust needed for effective provider-patient communication.[206]

Sometimes overprescribing is inadvertent and can happen to the most careful providers. Available tools may not detect concerning patterns.[207] Providers are not lie detectors. These realities are often obscured by the over-confidence by providers in their own abilities, self-serving biases, and the pervasiveness of the lie detection mythology in law and medicine.

(Feb. 25, 2019, 9:45 AM), https://www.buzzfeednews.com/article/danvergano/overdose-prevention-little-falls-minnesota [https://perma.cc/GHG6-UYMW].

204. The CDC Guideline states that providers should *not* discharge a patient after a concerning PDMP finding. Dowell et al., *supra* note 4, at 30 ("Experts agreed that clinicians should not dismiss patients from their practice on the basis of PDMP information. Doing so can adversely affect patient safety, could represent patient abandonment, and could result in missed opportunities to provide potentially lifesaving information (e.g., about risks of opioids and overdose prevention) and interventions (e.g., safer prescriptions, nonopioid pain treatment . . . , naloxone . . . , and effective treatment for substance use disorder . . . ."). *See also* Substance Abuse & Mental Health Servs. Admin., U.S. Dep't Health & Human Servs., *Prescription Drug Monitoring Programs: A Guide for Healthcare Providers*, IN BRIEF, Winter 2017, at 1, 8 https://store.samhsa.gov/system/files/sma16-4997.pdf [https://perma.cc/92FQ-KR88] (recommending that providers assess and refer to treatment rather than discharging them); NAT'L ALLIANCE FOR MODEL STATE DRUG LAWS, COMPONENTS OF A STRONG PRESCRIPTION MONITORING PROGRAM 3 (2015) https://namsdl.org/wp-content/uploads/Components-of-a-Strong-Prescription-Monitoring-Program.pdf [https://perma.cc/Q2VQ-EWL8] (PDMP data "should initially be provided to a patient's prescriber(s) and/or dispenser(s) with the goal of referring such patient to treatment, if such prescriber or dispenser deems it necessary, rather than referring the PMP information to law enforcement in the absence of clear evidence of illegal activity.").

205. *See, e.g.*, Pitt et al., *supra* note 93, at 1396–97; Hadland & Beletsky, *supra* note 91, at 1–2.

206. *See, e.g.*, FED'N OF STATE MED. BDS., PRESCRIPTION DRUG MONITORING PROGRAMS (PDMPS) (2018), http://www.fsmb.org/siteassets/advocacy/policies/prescription-drug-monitoring-programs—-adopted.pdf [https://perma.cc/6R74-G6BQ] (unfortunately, this policy document does not recommend or even acknowledge the issue of referral to treatment as the preferred option). *See generally* Dineen & DuBois, *supra* note 67 (discussing the conflict between the ends of medicine and the ends of law enforcement).

207. An example stands out from my time in nursing. One of our patients received fentanyl patches for high impact chronic pain. He never missed an appointment and his urine drug screening tests were always consistent with the medications prescribed. After treating him for more than a year, I received a call from his spouse who told me the patient had a serious opioid use disorder. I discovered he would fill the monthly prescription, save one patch for the day before his next appointment, and then orally consume the rest over a few days. There was simply no reasonably or careful way we could have detected what was really going on.

C. Qualitative Overprescribing

The category of misprescribing that has occupied the lion's share of attention is qualitative overprescribing. Qualitative overprescribing occurs when providers prescribe or continue to prescribe opioids when risks to the patient outweigh the benefits. This tends to happen in the context of chronic pain and with ongoing prescribing. It occurs when prescribers are not carefully assessing risks and benefits of the drug or dose to the patient.[208] This can also happen when the provider is not vigilant in tracking prescription dates and amounts. [209]

Qualitative overprescribing has been the implicit focus of the majority of practice and policy efforts. Most clinical practice guidelines focus on qualitative overprescribing.[210] A long list of so called risk mitigation strategies also fall in this category, primarily in terms of detecting underlying SUDs or diversion.[211] If actually used as a clinical tool to identify new risks to patients from SUD, they are appropriate. Instead, if they are used as a pseudo law enforcement mechanism, they will fail to reduce overall opioid related harms.

Until very recently, legal enactments focused almost solely on this category. "Pill mill" or pain clinic legislation was focused on both corrupt prescribing and on qualitative overprescribing, while ignoring significant harms associated with other classes of misprescribing. State prescribing laws and regulations singled out opioid prescribing for chronic pain, while ignoring completely the palpable harms of other drug classes and practices that left significant numbers of pills available for diversion.[212] In fact, this area is likely over-regulated. The focus on this area may be contributing to the neglect of other important sources of prescription opioid related harms. It may also be creating additional provider avoidance of patients with chronic pain, as well as avoidance of appropriately addressing co-morbid conditions such as SUD.

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208. For a comprehensive overview of treating chronic pain, *see* Martin D. Cheatle, *Biopsychosocial Approach to Assessing and Managing Patients with Chronic Pain*, 100 MED. CLINICS N. AM. 43 (2016).

209. Wright et al., *supra* note 30, at 7 (2016) (telling the story of an emergency department patient whose primary care doctor provided a 90-day supply of opioids approximately every month through carefully timed appointments and selective use of pharmacies).

210. *See, e.g.*, Dowell et al., *supra* note 4; FED'N OF STATE MED. BDS., GUIDELINES FOR THE CHRONIC USE OF OPIOID ANALGESICS (2017) http://www.fsmb.org/siteassets/advocacy/policies/opioid_guidelines_as_adopted_april-2017_final.pdf [https://perma.cc/9HVN-2LL9]; Judith A. Paice et al., *Management of Chronic Pain in Survivors of Adult Cancers: American Society of Clinical Oncology Clinical Practice Guideline*, J. CLINICAL ONCOLOGY (2016).

211. *See, e.g.*, Dineen *supra* note 277, at 8–13; 47–73.

212. *See, e.g.*, *id.*

D. Quantitative Overprescribing

Quantitative overprescribing occurs when providers prescribe more opioids than a patient is likely to need, leading to large quantities of leftover pills. This most commonly happens after hospitalization, surgeries,[213] or dental procedures.[214] Despite long standing evidence of the contribution of leftover pills to the opioid crisis,[215] relatively little effort has been directed at this problem. There remain wide variations in prescribing practices and paucity of clinical guidelines.[216] Only very recently have states started passing laws and promulgating regulations aimed at this issue.

Quantitative overprescribing is primarily a problem of reflexive prescribing coupled with the general misprescribing heuristic, which overemphasizes prescribing for chronic pain. Research indicates it is difficult for providers to abandon established practices.[217] There is interesting work in choice architecture to reduce prescribers' tendencies to follow old patterns through electronic default rules.[218] Some recent studies have found that state laws and institutional policies can reduce the number of post-procedure prescriptions.[219] In a comprehensive study by Pitt and

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213. *See, e.g.*, Karsten Bartels et al., *Opioid Use and Storage Patterns by Patients after Hospital Discharge Following Surgery*, PLOS ONE, Jan. 29, 2016, at 1, 1, https://doi.org/10.1371/journal.pone.0147972 [https://perma.cc/SKA4-KLVX]; Maureen V. Hill et al., *Guideline for Discharge Opioid Prescriptions After Inpatient General Surgical Procedures*, 226 J. AM. C. SURGEONS 996, 996 (2018); Heidi N. Overton et al., *Opioid-Prescribing Guidelines for Common Surgical Procedures: An Expert Panel Consensus*, 227 J. AM. C. SURGEONS 411, 411 (2018).

214. *See, e.g.*, Niodita Gupta et al., *Opioid Prescribing Practices from 2010 Through 2015 Among Dentists in the United States: What Do Claims Data Tell Us?* 149 J. AM. DENTAL ASS'N 237, 237 (2018).

215. *See, e.g.*, Dineen *supra* note 277, at 8–13.

216. *See, e.g.*, Ahmed I. Eid et al., *Variation of Opioid Prescribing Patterns Among Patients Undergoing Similar Surgery on the Same Acute Care Surgery Service of the Same Institution: Time for Standardization?* 164 SURGERY 926 (2018).

217. *See, e.g.*, Daniel J. Niven et al., *Effect of Published Scientific Evidence on Glycemic Control in Adult Intensive Care Units*, 175 JAMA INTERNAL MED. 801, 801 (2015) ("Among patients admitted to adult ICUs in the United States, there was a slow steady adoption of tight glycemic control following publication of a clinical trial that suggested benefit, with little to no deadoption following a subsequent trial that demonstrated harm. There is an urgent need to understand and promote the deadoption of ineffective clinical practices.").

218. *See, e.g.*, Kara Zivin et al., *Implementing Electronic Health Record Default Settings to Reduce Opioid Overprescribing: A Pilot Study*, 20 PAIN MED. 103, 103 (2019) (finding setting default number of opioid pills to 15 in the electronic prescribing system in two health systems led to changes in prescribing patterns, although most interviewed prescribers believed the change had no impact on their practices).

219. *See, e.g.*, Charles D. MacLean et al., *Impact of Policy Interventions on Postoperative Opioid Prescribing*, PAIN MED., Nov. 8, 2018, at 1, 1, https://doi.org/10.1093/pm/pny215 [https://perma.cc/T2XG-XX6Y].

colleagues, interventions aimed at acute pain prescribing were one of the few interventions predicted to reduce overall death rates at both five and ten years.[220] Enhanced policy efforts directed at reducing quantitative overprescribing are warranted.

E. Multiclass Misprescribing

Multiclass misprescribing is dangerous and sometimes deadly.[221] For far too long, the dangers have been ignored, overshadowed, and downplayed because of the misprescribing heuristic.[222] Multiclass misprescribing occurs when opioids are prescribed carelessly along with other drugs known to increase the risk of harm, including the risk of opioid poisonings, without significant clinical justification. It may also occur when opioids are prescribed carelessly to patients who may have alcohol or other substance use disorders or without warning patients of the dangers of taking opioids along with alcohol and illicit substances.[223]

Benzodiazepines are among the most dangerous co-prescribed drugs;[224] however, concerns are emerging about other drugs frequently used to treat pain but that also potentiate the effects of opioids, such as gabapentin and pregabalin.[225] One recent study found 26% of opioid related poisoning decedents also had gabapentin in their system.[226]

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220. Pitt et al., *supra* note 93, at 1396–97.

221. In one study, co-prescription of benzodiazepines was associated with a ten-fold increase in mortality. Nabarun Dasgupta et al., *Cohort Study of the Impact of High-Dose Opioid Analgesics on Overdose Mortality*, 17 PAIN MED. 85, 85–98 (2016). It is also associated with a higher risk of eventual fatal poisoning. *See* Mark Olfson et al., *Risks of Fatal Opioid Overdose During the First Year Following Nonfatal Overdose,* 190 DRUG & ALCOHOL DEPENDENCE 112, 112–19 (2018).

222. *See, e.g.*, Dineen, *supra* note 27, at 19–20.

223. *See, e.g.*, Karlyn A. Edwards et al., *Co-use of Alcohol and Opioids*, 4 CURRENT ADDICTION REP. 194, 194–99 (2017).

224. The chemical mechanisms that enhance morbidity and mortality of combined benzodiazepines and opioids is still not fully understood but the combination is far more dangerous than opioids alone. *See, e.g.*, Neville F. Ford, *An Opioid-Benzodiazepine Interaction: Benzodiazepines as Opioids*?, 9 J. PHARMACOLOGY & PHARMACOTHERAPEUTICS 165, 165–66 (2018).

225. Gabapentin (brand name Neurontin) is FDA approved to treat epilepsy and post-herpetic neuralgia and off label for neuropathic pain and other painful conditions. Pregabelin (brand name Lyrica) is approved for multiple uses, including seizures, neuropathic pain, and fibromyalgia. They are not controlled substances but may be substances of misuse nonetheless. *See generally* Alyssa M. Peckham et al., *All-Cause and Drug-Related Medical Events Associated with Overuse of Gabapentin and/or Opioid Medications: A Retrospective Cohort Analysis of a Commercially Insured US Population*, 41 DRUG SAFETY 213 (2018); Kirk E. Evoy et al., *Reports of Gabapentin and Pregabalin Abuse, Misuse, Dependence, or Overdose: An Analysis of the Food and Drug Administration Adverse Events Reporting System (FAERS)*, RES. SOC. & ADMIN. PHARMACY, June 28, 2018, https://doi.org/10.1016/j.sapharm.2018.06.018 [https://perma.cc/92PK-GZ85].

226. Svetla Slavova et al., *Prevalence of Gabapentin in Drug Overdose Postmortem Toxicology Testing Results*, 186 DRUG & ALCOHOL DEPENDENCE 80, 80 (2018).

Gabapentin and pregabalin are implicated in many intentional and unintentional poisoning deaths, with or without opioids.[227] This is the likely related to both their chemical action and the overlap between the rate of suicides and use of these drugs in patients with chronic pain. Prescribers may ignore these dangers because of the focus on opioid dosage alone.

Significant co-prescribing of opioids and benzodiazepines continues to occur.[228] Co-prescribing of benzodiazepines and opioids is more dangerous than prescribing either opioids or benzodiazepines alone;[229] and risks are particularly acute in the first 90 days of concurrent prescription.[230] The rate of combined benzodiazepine and opioid deaths continues to rise, even as prescription opioid mortality stabilizes.[231] There are, of course, some clinical contexts in which co-prescribing is still appropriate, primarily in patients with complicated co-morbid psychiatric conditions. Any changes or tapering must be handled with extreme care;[232] however, "long term use for chronic pain has poor scientific support and should be discouraged and avoided."[233]

The disproportionate focus on opioids may lead prescribers to underappreciate the risks of benzodiazepines. Benzodiazepine prescribing

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227. *See* Evoy et al., *supra* note 225.

228. *See, e.g.*, Joseph A. Ladapo et al., *Physician Prescribing of Opioids to Patients at Increased Risk of Overdose from Benzodiazepine Use in the United States*, 75 JAMA PSYCHIATRY 623, 623 (2018), https://doi.org/10.1001/jamapsychiatry.2018.0544 [https://perma.cc/QKP7-YC6E].

229. *See, e.g.*, Eric J. Hawkins et al., *New Opioid and Benzodiazepine Co-Prescribing and Mortality Among Veteran Affairs Patients with Posttraumatic Stress Disorder: A Retrospective Cohort Study* (Preprints with The Lancet, 2018), https://ssrn.com/abstract=3235664 [https://perma.cc/B53U-739C]. Co-prescribing is also associated with non-poisoning morbidity, such as fall and emergency department visits. *See* Bobbi Jo H. Yarborough et al., *Correlates of Benzodiazepine Use and Adverse Outcomes Among Patients with Chronic Pain Prescribed Long-term Opioid Therapy*, PAIN MED. (Sept. 10, 2018), at 1, 1–8, https://www.ncbi.nlm.nih.gov/pubmed/30204893 [https://perma.cc/SST9-NGY6] (finding 25% of a veteran population on chronic opioid therapy were co-prescribed benzodiazepines and that factor alone contributed to increased falls and emergency department visits).

230. Inmaculada Hernandez et al., *Exposure-Response Association Between Concurrent Opioid and Benzodiazepine Use and Risk of Opioid-Related Overdose in Medicare Part D Beneficiaries*, JAMA NETWORK OPEN (June 2018), at 1, 1, https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2685628 [https://perma.cc/M9VZ-R674] (finding a five-fold risk of overdose in the first 90 days of treatment which dropped to a 1.87 increased risk thereafter).

231. *See Overdose Death Rates*, *supra* note 76.

232. Co-prescribing may be appropriate for patients with anxiety disorders, post-traumatic stress disorder, or other psychiatric co-morbidities. *See, e.g.*, Benjamin J. Oldfield et al., *Multimodal Treatment Options, Including Rotating to Buprenorphine, Within a Multidisciplinary Pain Clinic for Patients on Risky Opioid Regimens: A Quality Improvement Study*, 19 PAIN MED. S38, S43 (2018) ("While. . . guidelines suggest tapering benzodiazepines in patients prescribed [opioids], tapering requires caution and can be particularly difficult among veterans with post-traumatic stress disorder (PTSD), for whom tapering can be compounded by PTSD exacerbations.").

233. Peppin et al., *supra* note 55, at 126.

has increased over the last decade, even as rates of opioid prescribing decline.[234] According to Argawal and Langdon:

> [A]s opioids lose favor among prescribers, we must remain cognizant that this *might lead to increased use of other potentially dangerous drugs* such as benzodiazepines, especially because evidence for their use in conditions such as back pain is limited.[235]

Recent research on the impact of the CDC Guideline on prescribing indicates that, while opioid prescribing reductions are significant, benzodiazepine prescribing changes are minute.[236] This remains true despite the CDC Guideline specifically recommending avoidance of co-prescribing;[237] of course the subject of the CDC Guideline is opioids, which may cause neglect of the benzodiazepine information.

At least one group of physician researchers have recommended guidelines aimed directly at reducing benzodiazepine prescribing.[238] A few cities have published benzodiazepine specific prescribing guidelines,[239] rather than simply including the risk in opioid focused guidance.[240] Separate guidance for benzodiazepine prescribing is increasingly needed as individuals with OUDs shift to illicit opioids and as the dangers of co-use of alcohol become more clear. At a minimum, separate guidance for benzodiazepine prescribing may prompt providers to warn patients of the risk of concurrent use of opioids that they do not prescribe, as well as initiate communication about substance use and

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234. Sumit D. Agarwal & Bruce E. Landon, *Patterns of Outpatient Benzodiazepine Prescribing in the United States*, JAMA NETWORK OPEN (Jan. 2019), at 1, 1, https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2722576 [https://perma.cc/4JE6-P95G].

235. *Id.* at 8 (emphasis added). *See also* Scott M. Fishman, *Risk of the View Through the Keyhole: There Is Much More to Physician Reactions to the DEA Than the Number of Formal Actions*, 7 PAIN MED. 360, 361 (2006), https://doi.org/10.1111/j.1526-4637.2006.00194.x [https://perma.cc/8PAM-Q247] ("[I]t is well established that when physicians are faced with barriers to prescribing a certain type of medication they will often prescribe around that barrier, turning to drugs that are perceived to be less scrutinized, even if they are less efficacious and/or potentially harmful. This pattern is known as the substitution effect.") (internal citations omitted).

236. Bohnert et al., *supra* note 61, at 371.

237. Dowell et al., *supra* note 4, at 31–32 (Recommendation 11).

238. Matthew E. Hirschtritt et al., *Outpatient, Combined Use of Opioid and Benzodiazepine Medications in the United States, 1993–2014*, 9 PREVENTATIVE MED. REP., 49, 51–53 (2018).

239. *See, e.g.*, The N.Y.C. Dep't of Health & Mental Hygiene, *Judicious Prescribing of Benzodiazepines*, 35 CITY HEALTH INFORMATION 13 (2016), https://ndews.umd.edu/sites/ndews.umd.edu/files/Benzodiazepines%20CHI.pdf [https://perma.cc/V526-42UU]; COMMUNITY BEHAVIORAL HEALTH, CLINICAL GUIDELINES FOR THE PRESCRIBING AND MONITORING OF BENZODIAZEPINES AND RELATED MEDICATIONS (2018), https://dbhids.org/wp-content/uploads/2018/07/Clinical-Guidelines-for-Prescribing-and-Monitoring-Benzodiazepines.pdf [https://perma.cc/L7XS-ZFTK] (Community Behavioral Health contracts with the city of Philadelphia).

240. *See, e.g.*, Dowell et al., *supra* note 4.

SUDs. This approach may help correct for the availability bias induced by the narrow focus on opioids alone.

F. Underprescribing & Opioid Related Abandonment

> *So, what amount of prescribing is appropriate? This represents a difficult question since one size does not fit all. A particular type or dose of one medication may be appropriate for one patient and condition and wholly inappropriate for someone else. Yet despite the medical necessity of tailoring treatments to the individual, the tendency today is for an across-the-board reduction in prescription opioid availability.*[241]

The most universally ignored category of misprescribing is underprescribing. It may be a serious contributor to overall morbidity and mortality, for example by contributing to suicides or unintentional poisonings.[242] Underprescribing means withholding appropriate opioids (including too rapidly or arbitrarily tapering or discontinuing opioids), refusing to consider opioids at all (blanket exclusions) and failing to provide or refer patients to treatment for opioid use or other substance use disorders.[243] This is particularly problematic for legacy patients, who are among the most neglected and vilified in the current climate around opioids.[244]

It is almost inconceivable that after more than a decade of public concern about long-term opioids use, and after several decades of inappropriately liberal prescribing practices, there remains almost no guidance to prescribers as to how, when, and if to taper patients off of opioids. Patients with chronic pain and related conditions are already highly stigmatized and report feeling dismissed, discounted, and ignored by clinicians, family, friends, and in public policy. Existing law, policy, and guidance on opioids has rendered these patients essentially invisible

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241. Michael E. Schatman & Stephen J. Ziegler, *Pain Management, Prescription Opioid Mortality, and the CDC: Is The Devil in the Data?,* 10 J. PAIN RES. 2489, 2491 (2017).

242. Dr. Thomas Kline has assembled an informal list of patients with chronic pain that died by suicide after abrupt or too rapid tapering. Thomas Kline, *#OpioidCrisis Pain Related SUICIDES Associated with Forced Taper*, MEDIUM (Jan. 23, 2019), https://medium.com/@ThomasKlineMD/opioidcrisis-pain-related-suicides-associated-with-forced-tapers-c68c79ecf84d [https://perma.cc/ZU7T-7FLB].

243. Ironically, while the evidence is strong that appropriate pharmacotherapy for addiction, such as with buprenorphine, is effective and lifesaving, law enforcement may further discourage its use by providers. *See, e.g.*, Maia Szalavitz, *The Feds Are Raiding the Offices of Doctors Who Prescribe Addiction Medication*, TONIC (June 26, 2018, 2:44 PM), https://tonic.vice.com/en_us/article/8xevwb/dea-raids-addiction-doctors [https://perma.cc/B894-7WPX].

244. For a range of first-person experiences of legacy patients and those with both pain and opioid use disorders, *see* Kelly K. Dineen & Daniel S. Goldberg, *Living in Pain in the Midst of the Opioid Crisis*, 8 NARRATIVE INQUIRY BIOETHICS 189 (2018), https://muse.jhu.edu/article/712000/pdf [https://perma.cc/XG3L-EHG7].

except as an object of blame and suspicion; guidance focuses instead on when starting opioids may be appropriate, maximum doses, and risk mitigation techniques to prevent opioid diversion from the particular prescriber.

If anything, the obligations to legacy patients are heightened—more than anyone, prescribers (usually in good faith and under mistaken beliefs about the relative benefits and risks of opioids) put them in the position they are in now. At a minimum, providers are morally obligated to compassionately help patients reduce or discontinue opioids when appropriate. And providers need the space from policymakers and enforcement officials to do so. By ignoring the compassionate and appropriate treatment of legacy patients, policymakers implicitly communicate that those patients are less deserving than others who might today be spared opioids in the first place.

When discontinuation is directed by policy, it is usually done without any information on how to do so carefully and appropriately.[245] According to Frank and colleagues, a 2017 systemic review of opioid tapering explained:

> There is *little evidence to guide clinicians* in the process of opioid tapering, especially in primary care settings, where most opioid therapy is prescribed. In addition, little is known about the risks and benefits of opioid tapering. . . . The effects of opioid tapering on patient outcomes have not been systematically reviewed.[246]

The absence of evidence has not stopped some policymakers. In 2018, Oregon proposed a mandatory reduction to zero opioids for all Medicaid beneficiaries over twelve months.[247] This blunt approach is an affront to patient centered medical care and based on little more than deeply held bias or an inability to understand the public health and medical evidence.

Little has changed as of 2019, as the option to reduce or discontinue opioids pervades opioid prescribing guidelines, law, and policy with

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245. The Veterans Administration is the only group to take these risks seriously and to have implemented a national program. *See, e.g.*, Elizabeth M. Oliva et al., *Development and Applications of the Veterans Health Administration's Stratification Tool for Opioid Risk Mitigation (STORM) to Improve Opioid Safety And Prevent Overdose and Suicide*, 14 PSYCHOL. SERV. 34 (2017).

246. Joseph W. Frank et al., *Patient Outcomes in Dose Reduction or Discontinuation of Long-Term Opioid Therapy*, 167 ANNALS INTERNAL MED. 181, 181 (2017).

247. *See, e.g.*, *Oregon's Medicaid Program Weighs Cutting Off Chronic Pain Patients from Opioids*, APHA (Aug. 16, 2018), https://www.pharmacist.com/article/oregons-medicaid-program-weighs-cutting-chronic-pain-patients-opioids [https://perma.cc/N8FY-67VH]; *see also* Maia Szalavitz, *Forcing Pain Patients Off Their Meds Won't End the Opioid Crisis*, TONIC (Aug. 21, 2018, 5:42 PM), https://tonic.vice.com/en_us/article/7xqa44/forcing-pain-patients-off-their-meds-will-not-end-the-opioid-crisis [https://perma.cc/SZ7D-8PFS].

virtually no information on how to do so carefully. This representation of the misprescribing heuristic totally ignores the sometimes-deadly harms of doing so inappropriately. According to Darnell and colleagues,

> [C]ountless "legacy patients" with chronic pain who were progressively escalated to high opioid doses, often over many years, now face additional and very serious risks resulting from rapid tapering or related policies that mandate extreme dose reductions that are aggressive and unrealistic.[248]

There is certainly no appetite by regulators to sanction prescribers for the equally harmful practice of too rapid or involuntary tapering. In fact, significant potential harms—from increasing suffering to death by suicide—have been ignored by every major policy document and prescribing law. An international group of stakeholders has called for urgent attention to this issue saying,

> *New and grave risks now exist because of forced opioid tapering*: an alarming increase in reports of patient suffering and suicides within and outside of the Veterans Affairs Healthcare System in the United States. Reports suggest that forced tapering is also occurring in patients on opioid doses below the Centers for Disease Control and Prevention Opioid Guideline threshold of 90 morphine equivalent daily dose. These patients too are at risk of harm from overly aggressive tapering.[249]

The considerations for legacy patients are different than for deciding about beginning opioids in the first place. Opioid tapers must be patient centered and supportive, without threats of abandonment. Simply, no data exists to support involuntary tapering or "to drastically low levels without exposing patients to potentially life-threatening harms."[250] What information does exist reveals that 1) most patients are tapered for behaviors seen as indicative of misuse, 2) few are referred for substance use disorder evaluation and treatment, and 3) perceptions of heightened monitoring are associated with non-follow-up by the patient.[251] "Once the

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248. Beth D. Darnell et al., *International Stakeholder Community of Pain Experts and Leaders Call for an Urgent Action on Forced Opioid Tapering*, 20 PAIN MED. 429, 430 (2019).

249. *Id.* (emphasis added).

250. *Id.*

251. *See, e.g.*, Jawad M. Husain et al., *Reasons for Opioid Discontinuation and Unintended Consequences Following Opioid Discontinuation Within the TOPCARE Trial*, PAIN MED., Jun. 27, 2018, at 1, 4–7. Concerns are not limited to the United States. Canadian physicians reported similar concerns after guidance was published on safely prescribing opioids but neglected any mention on safe opioid tapering. *See* Ruth Dubin et al., *The Risks of Opioid Tapering or Rapid Discontinuation,* CANADIAN FAM. PHYSICIAN (Dec. 5, 2017), http://www.cfp.ca/news/2017/12/05/12-05 [https://perma.cc/F8YM-S4QQ] ("The 2017 guideline focuses entirely on reducing opioid doses, yet

decision is made to stop the chronic opioid use, the patient must be counseled and educated on the reasons behind the decision. It must be made clear to the patient that the *therapy is being abandoned, not the patient*."[252]

A promising option for assisting legacy patients exists at some VA facilities, where patients receive multidisciplinary care, tapering, or tapering off and onto buprenorphine.[253] Failure to consider something like buprenorphine is classic underprescribing—buprenorphine is broadly effective for both pain and opioid use disorder while being less harmful than other opioids, and it may be more effective than other opioids in certain patients.[254] Oldfield and colleagues describe their approach to tapering this way:

> We strive to express empathy and a reassurance to the patient about non-abandonment. Patient preference is the main driver determining next steps; however, patients with very high opioid doses . . . , those who are co- prescribed benzodiazepines or other sedatives, and those who are already experiencing opioid-related harms . . .are counseled that changes to their regimen need to start immediately.[255]

Yet, practices are trending more toward aggressive tapering, with multitudes of anecdotal reports that legacy patients are either abandoned outright or less than gently coerced into aggressive tapers by providers, who are shouldering the burden of the blunt instrument of law enforcement.[256] Providers understand that scrutiny is not created equally.

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makes no mention of the risks of opiate withdrawal. By adopting the guideline as a standard of practice, prescribers might taper people too rapidly or cut them off entirely. Many family MD's have refused to prescribe opiates or even take chronic pain patients into their practices. Nor do they have training in how to recognize withdrawal symptoms or manage the risks associated with the adrenergic and autonomic overdrive of opiate withdrawal.").

252. Mark S. Wallace & Alexander Papp, *Opioid Withdrawal*, *in* CHALLENGING CASES AND COMPLICATION MANAGEMENT IN PAIN MEDICINE 17 (Magdalena Anitescu et al.eds., 2018) (emphasis added).

253. Oldfield et al*., supra* note 232, at S39. For a discussion of the use of methadone and buprenorphine and the legal separation of those treatments from every other treatment in medicine, *see* Andrew J. Saxon et al., *Medication-Assisted Treatment for Opioid Addiction: Methadone and Buprenorphine*, 21 J. FOOD & DRUG ANALYSIS S69 (2013).

254. *See, e.g.*, Jonathan Daitch et al*., Conversion of Chronic Pain Patients from Full- Opioid Agonists to Sublingual Buprenorphine,* 15 PAIN PHYSICIAN ES59 (2012).

255. Oldfield et al*., supra* note 232 at S39.

256. For example, the North Carolina Medical Board surveyed its members and found that a significant number had stopped seeing patients in chronic pain altogether and 26% stopped prescribing opioids altogether; abandonment is a fair assessment. *See, e.g.*, Taylor Knopf, *Hundreds of N.C. Doctors Say They've Stopped Prescribing Opioids,* N.C. HEALTH NEWS (Oct. 15, 2018), https://www.northcarolinahealthnews.org/2018/10/15/nc-doctors-stop-prescribe-opioids/ [https://perma.cc/MGR7-S5GJ].

A death that might involve a prescription opioid raises far more alarm than a suicide death by another means, such as Jay's in this article's introduction. For example, state law enforcement agents are rapidly adopting a practice of notifying prescribers of patient deaths, but in narrow and incoherent circumstances. Massachusetts is one example, where the Attorney General is sending letters to prescribers if they prescribed opioids within 60 days of a patient's death.[257] The focus is only on opioids. A provider who abruptly discontinues opioids would receive no such letter. Nor would providers who prescribed, for example, high doses of benzodiazepines, a drug also associated with suicide risk.[258] This is illustrative of the misprescribing heuristic. Dr. Lynn Webster has written about the harms that can result from the push to reduce even therapeutic opioid doses out of regulatory concerns, telling the story of his patient Jack. Jack's suicide note said he "couldn't live with the pain anymore."[259] Dr. Webster said,

> I had to ask myself if my concern for my freedom and licensure had led to this tragedy. This was a moral dilemma for me. I could have continued to prescribe a high dose of opioid, but if he had died, even from a natural cause, the medical examiner might have said the death was an unintentional overdose from opioids. Jack might have even intentionally overdosed and no one would know. *Deaths from opioids have become red flags for investigations. By contrast, Jack's death by suicide was not widely recognized by anyone beyond his family and me.*

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257. *See, e.g.*, Steve LeBlanc, *US Attorney Warning Doctors About Prescribing Opioids*, U.S. NEWS & WORLD REP. (Nov. 29, 2018, 5:20 PM), https://www.usnews.com/news/best-states/massachusetts/articles/2018-11-29/us-attorney-warning-doctors-about-prescribing-opioids (describing a program in which prescribers are sent a letter if any patient died within 60 days of an opioid prescription).

258. *See, e.g.*, Tyler J. Dodds, *Prescribed Benzodiazepines and Suicide Risk: A Review of the Literature*, 19 PRIMARY CARE COMPANION CNS DISORDERS, no. 2, 2017, at e1, e1, https://www.psychiatrist.com/PCC/article/Pages/2017/v19n02/16r02037.aspx [https://perma.cc/6FXG-KG27].

259. Lynn Webster, *Pain and Suicide: The Other Side of the Opioid Story*, 15 PAIN MED. 345, 345 (2014). This is not an isolated incident. There are many reports, obituaries, and discussions about suicide by patients cut off of care. *See, e.g.*, Tony Messenger, *Messenger: The Opioid Dilemma Catches Wildwood Couple in its Web*, ST. LOUIS POST-DISPATCH (Feb. 28, 2016), http://www.stltoday.com/news/local/columns/tony-messenger/messenger-the-opioid-dilemma-catches-wildwood-couple-in-its-web/article_a426108b-67b8-514d-bdf7-37c57247a375.html [https://perma.cc/47DU-DBF7] (profiling a man who died by suicide via a gunshot wound after losing access to prescription opioids abruptly); blairhm, Comment to *Are CDC Opioid Guidelines Causing More Suicides?*, PAIN NEWS NETWORK (May 27, 2016), http://accurateclinic.com/wp-content/uploads/2016/10/Are-CDC-Opioid-Guidelines-Causing-More-Suicides-%E2%80%94-Pain-News-Network.pdf [https://perma.cc/ZZ6G-WCFT] ("I am 39 and have chronic pain . . . . I have almost constant deep bone and joint pain . . . . I suffer with this pain every day. I get migraines [and] . . . traditional migraine medicine doesn't work. . . . This is not living; it's just a slower more painful slide towards death. . . . I'm thinking of ending it all tonight. I just can't live like this anymore. Again, this is NOT living.").

> I was tormented by the thought that he might have died because I was unable to help him escape extreme pain.[260]

Prescribing policy must begin addressing the ultimate goal of reducing overall morbidity and mortality. "Every dollar spent on enforcement is a dollar not spent on treatment, harm reduction, or prevention. As we failed to invest in what works, the crisis has mutated into something far more deadly."[261] The misprescribing heuristic is likely to continue shifting the sources of harm and driving more providers to act against their patients' interests. In particular, the focus on a few kinds of prescribing behaviors is causing increased suffering and may contribute to the shift to illicit opioids and suicidality.

Suicidal ideation is particularly acute when someone is experiencing withdrawal, which occurs with abandonment and too rapid tapering. Sometimes this can happen simply from a lack of expertise. Travis Rieder told his story about withdrawal after spending months on opioids following a serious, crushing trauma, which required five major surgeries. He experienced suicidality for the first time in his life. Some the best doctors in the world (at John Hopkins) had no idea how to properly taper him off of opioids. He wrote:

> No one will be surprised to hear that I was angry. Angry at myself, angry at my doctors, angry at the medical community. Just- *angry*. I had been hit by a van and undergone five surgeries, yet *the worst part of the experience was my month in withdrawal hell.* How could it be that my doctor's best tapering advice led to that experience? And how could it be that not one of my more than ten doctors could help?[262]

Serious concerns about suicide in patients with pain is poorly addressed in larger policy discussions, despite the extremely high risk it presents.[263] Pain is an independent risk factor for suicide—a connection noted for centuries.[264] Plato counted painful illness as one of three

260. Webster, *supra* note 259, at (emphasis added).

261. Beletsky & Davis, *supra* note 46, at 158.

262. Travis N. Rieder, *In Opioid Withdrawal, With No Hope in Sight*, 36 HEALTH AFF. 182, 183 (2017) (emphasis added).

263. *See, e.g.*, Pat Anson, *Are CDC Opioid Guidelines Causing More Suicides?*, PAIN NEWS NETWORK (May 27, 2016), http://www.painnewsnetwork.org/stories/2016/5/27/are-cdcs-opioid-guidelines-causing-more-suicides [https://perma.cc/Z5FP-PEAF].

264. *See, e.g.*, Pliny the Elder, *What Diseases are Attended with the Greatest Pain, in* THE ETHICS OF SUICIDE: HISTORICAL SOURCES 118 (Margaret Pabst Battin, ed., 2015) ("It would seem almost an act of folly to attempt to determine which of these diseases is attendant with the most excruciating pain, seeing that everyone is of the opinion that the malady with which for the moment he himself is afflicted, is the most excruciating and insupportable. The general experience, however, [is] . . . that the most agonizing torments are those . . . resulting from calculi of the bladder; . . . maladies of the

exceptions to his general moral prohibition of suicide.[265] While suicide was historically condemned and even punished as a crime,[266] the chronic pain of the deceased was often a mitigating circumstance.[267] Under old English law, when chronic pain was an underlying condition in death by suicide, surviving family members faced lesser property losses than in cases without this mitigating condition.[268] The same was true for 18th Century France, where chronic pain was a documented underlying reason for many suicides.[269] Chronic pain was often seen as an exculpatory factor for the crime of suicide, and juries often declared the cause of death was not suicide but actually the underlying illness.[270]

Today, the association remains between pain and suicide by any means and may be growing stronger.[271] The rate of suicide in patients with chronic pain is also increasing.[272] This is also true for adolescents with

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stomach; and . . . those caused by pains and affections of the head; for it is more generally in these cases . . . that patients are tempted to commit suicide.") (statement from sometime between 23 and 79 A.D.).

265. *See* GEORGES MINOIS, HISTORY OF SUICIDE 45 (Lydia G. Cochrane trans., 1999) (describing Plato's thinking on suicide and listing his exceptions which included condemnation and the "miseries of fate" in addition to painful and incurable illness).

266. A review of the historical legal treatment of all suicide is outside the scope of this article. For an historical overview and the authority of the state to act, *see* Kate E. Bloch, *The Role of Law in Suicide Prevention: Beyond Civil Commitment—A Bystander Duty to Report Suicide Threats*, 39 STAN. L. REV. 929 (1987); *see also* ELIZABETH PRICE FOLEY, THE LAW OF LIFE AND DEATH 153–58 (2011); BRUCE BONGAR, THE SUICIDAL PATIENT: CLINICAL AND LEGAL STANDARDS OF CARE (2d ed. 2002) (Chapters 1 and 2 focus on the multidisciplinary and legal background.).

267. *See, e.g.*, Wilbur Larremore, *Suicide and the Law*, 17 HARV. L. REV. 331, 334 (1904) ("There is just one condition which safely may be tolerated by public opinion as a justification of suicide. . . . If a person be facing certain death, which must be preceded by excruciating physical pain, his suicide may be viewed without reproach.").

268. William E. Mikel, *Is Suicide Murder?*, 3 COLUM. L. REV. 379, 379 (1903) (explaining that while punishment for suicide generally included forfeiture of all property, in the case of chronic pain, the decedent's lands still passed to his heirs while only the chattles were confiscated by the government).

269. *See* MINOIS, *supra* note 265, at 279–80 ("*1 February 1773* Michel Talouard, who was in intolerable pain from rheumatism and sciatica, hanged himself . . . ." and "*Early September 1787* . . . [A] man forty years old who suffered terrible headaches and whose mind sometimes wandered, hanged himself . . . .").

270. *Id.* at 284 (describing a case in which a man's death was declared a natural death despite the fact that he had used a knife to cut the artery in his neck "because he could no longer endure the pain he suffered due to various chronic illnesses").

271. *See, e.g.*, Maria A. Oquendo & Nora D. Volkow, *Suicide: A Silent Contributor to Opioid Overdose Death*, 378 NEW ENG. J. MED. 1567 (2018); Mélanie Racine, *Chronic Pain and Suicide Risk: A Comprehensive Review*, 87 PROGRESS NEUROPSYCHOPHARMACOLOGY & BIOLOGICAL PSYCHIATRY 276 (2018); Mark A. Ilgen et al., *Noncancer Pain Conditions and Risk of Suicide*, 70 JAMA PSYCHIATRY 692 (2013); Kathryn E. Kanzler et al., *Suicidal Ideation and Perceived Burdensomeness in Patients with Chronic Pain*, 12 PAIN PRAC. 602 (2012).

272. *See* Emiko Petrosky et al., *Chronic Pain Among Suicide Decedents, 2003 to 2014: Findings from the National Violent Death Reporting System*, 169 ANNALS INTERNAL MED. 448, 453 (2018) (finding the rate of suicide in patients with chronic pain increased between 2003 and 2014).

chronic pain, in whom duration rather than severity of pain presents the greatest risk.[273] There may be a further association between chronic pain, suicidality, and opioid use (either current or previous). One study suggests that opioid dose is associated with *suicide by any means* in patients with chronic pain.[274] In 2017, more than 40% of suicide and poisoning deaths involved opioids.[275] Between 2003 and 2014, of those with chronic pain that died by suicide, nearly 54% used a firearm while nearly 30% died from poisoning (just over half of those attributed to opioids).[276] Of all of the decedents with chronic pain who were tested, 51.9% had opioids in their system and 47.2% had benzodiazepines.[277] In general, the rates of intentional (suicidal) poisoning deaths are drastically undercounted, with some researchers estimating the rate is closer to 20-30%, or even higher, of all poisonings.[278] According to Rockett and colleagues, "suicide is plausibly the most underestimated manner of death in both clinical medicine and public health."[279]

Yet, assessing the risk of suicidality is a mere afterthought in most guidelines and laws, if it appears at all.[280] "Considering that approximately 1 patient out of 4 reports at least some form of suicidal thoughts, the development of a suicide prevention intervention to be included in chronic pain management programs is clearly justified."[281] This is especially important around times of change in opioid doses or duration. Only a few have explicitly called for attention to suicide in patients with chronic

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273. Bernadette Lewcun et al., *Predicting Suicidal Ideation in Adolescents With Chronic Amplified Pain: The Roles of Depression and Pain Duration*, 15 PSYCH. SERVICES 309, (2018) (identifying "the need for pediatric pain specialists to closely screen and monitor depression and suicidality throughout treatment, particularly for those adolescents with longer pain histories. . . . [I]t is not necessarily those who are reporting the worst physical pain who are at greatest risk.").

274. Mark A. Ilgen et al., *Opioid Dose and Risk of Suicide,* 157 PAIN 1079, 1079 (2016).

275. Amy S.B. Bohnert & Mark Ilgen, *Understanding Links Among Opioid Use, Overdose, and Suicide*, 380 NEW ENG. J. MED. 71, 71–72 (2019).

276. Petrosky et al., *supra* note 272, at 452.

277. *Id.*

278. Oquendo & Volkow, *supra* note 271, at 1569.

279. Ian H.R. Rockett et al., *Variable Classification of Drug-Intoxication Suicides Across U.S. States: A Partial Artifact of Forensics?*, PLOS ONE, Aug. 21, 2015, at 1, 2–3, https://doi.org/10.1371/journal.pone.0135296 [https://perma.cc/Y9LQ-XBAA] (explaining that coroners must determine that the injury was both self-inflicted and that the victim intended death and that factors such as any history of substance abuse will tip in favor of accidental death determination).

280. The only substantive exception is at the Veterans Administration, where they are trying to address this issue. This is also the only context in which the risk appears in the law. *See* Comprehensive Addiction and Recovery Act of 2016, Pub. L. No. 114-198, § 912(c)(2)(A)(ii), 130 Stat. 695, 761 (2016) (requiring that VA guidelines for opioid prescribing be updated to consider the "treatment of patients with current acute psychiatric instability or substance use disorder *or* patients at risk of suicide") (emphasis added).

281. Racine, *supra* note 271, at 276.

pain.[282] One section of the SUPPORT Act does draw attention to this problem but outside the context of tapering or involuntary discontinuation.[283]

There is a disproportionate focus in policy and guidance on screening to prevent diversion (which may or may not be directly harmful) at the expense of the serious suffering and life-threatening nature of suicidality. To the extent policy documents mention suicide, they frame the problem as one of serious mental illness; of course, co-morbid mental illness compounds the risks, but pain is an independent risk factor for suicidality. The American Society of Interventional Pain Physicians guidelines only mention suicide in the context of serious psychiatric comorbidities and without specific guidance to assess for suicide risk.[284] The FSMB's 2017 Model Guidelines for the Chronic Use of Opioid Analgesics mention the word suicide only once and makes no recommendations about assessing patients for suicidality.[285] The CDC Guideline mentions the word "suicide" three times, always in the context of co-morbid mental illness or previous suicide attempts;[286] there are no recommendations regarding suicide screening. In contrast, the word "abuse" appears ninety-two times, "urine drug testing" appears thirty-eight times, "overdose" appears 181 times, "substance use disorder" appears thirty-two times, and "risk mitigation" appears fourteen times.[287] Simply put, policy is more focused on ameliorating the indignation of providers who may feel fooled—or the indignation of regulators—than addressing palpable harms to individual patients.

Much more work is needed to provide guidance to providers about

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282. Parvaz Madadi & Nav Persaud, *Suicide by Means of Opioid Overdose in Patients with Chronic Pain*, 18 CURRENT PAIN & HEADACHE REP. 460, 462 (2014) ("[P]atients receiving opioids require continuous monitoring and surveillance throughout the course of treatment. However, opioid management tools for clinicians . . . have been created for assessing the risk of addiction, opioid misuse, and aberrant drug behaviors. . . . From our work and others, assessing prior history of suicide attempts should be included in this assessment.").

283. SUPPORT Act, Pub. L. No. 115-271, § 6086, 132 Stat. 3894, 3997–99 (2018) (directing, in part, the secretary of HHS to report to Congress on services and barriers to multidisciplinary pain treatment and improving treatment strategies for patients who are at risk for suicide).

284. Laxmaiah Manchikanti et al., *Responsible, Safe, and Effective Prescription of Opioids for Chronic Non-Cancer Pain: American Society of Interventional Pain Physicians (ASIPP) Guidelines,* 20 PAIN PHYSICIAN S3 (2017) ("suicide" appears only twice in the text at page S53, in contrast, "abuse" appears 203 times).

285. FED'N OF STATE MED. BDS., GUIDELINES FOR THE CHRONIC USE OF OPIOID ANALGESICS (2017), http://www.fsmb.org/siteassets/advocacy/policies/opioid_guidelines_as_adopted_april-2017_final.pdf [https://perma.cc/3VW9-3G7N] ("suicide" appears on page 13 as a possible risk of not dealing with aberrant behavior but no recommendations follow).

286. Dowell et al., *supra* note 4 (suicide appears on pp. 14 and 27).

287. *Id.*

safe tapering and discontinuation plans, increase comfort levels with buprenorphine prescribing, and assessing patients for suicidality. Regulators must provide the space providers need to do this compassionately and effectively. Dr. Weeks published the story of his sister, a legacy patient who died from acute withdrawal after she was abruptly discontinued from opioids when her long-term prescriber retired.[288] She was unable to find another prescriber to continue or carefully taper her opioids or transition her to buprenorphine. He wrote, "I worry that recent efforts to address the opioid crisis by the Centers for Disease Control and Prevention, state boards of medicine and the administration may have the unintended consequence of producing more heroin use, or outcomes like the one my sister had."[289] He has since become a buprenophrine prescriber and tries to help legacy patients like his sister.[290] According to Dr. Weeks,

> The profession needs not only to reduce initial and profligate use of opioids, but also needs to recognize and approach opioid addiction as an iatrogenic illness for patients who have already been prescribed substantial quantities of opioids. Professionals need to stop labeling [and] provide compassionate care . . . .[291]

There are some bright spots for legacy patients. Tapering patients off of opioids requires significant support, and some promising research has shown that interventions such as weekly supports and multidisciplinary care are promising.[292] For patients in chronic pain there may be particular opportunities to reduce harm. For example, Petrosky and colleagues found "a history of suicidal thoughts, plans, and attempts and disclosure of suicidal intent were more common among decedents with chronic pain than those without it, indicating that opportunities for intervention may have been available."[293] In other words, patients with chronic pain may talk about their intentions more often than others, providing a space for prevention and intervention.

In the end, policy makers must understand that underprescribing poses distinct harms. Currently no law or regulation addresses these harms.

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288. William B. Weeks, *Hailey*, 316 J. AM. MED. ASS'N 1975 (2016).

289. *Id.* at 1976.

290. *Id.*

291. *Id.*

292. Mark D. Sullivan et al., *Prescription Opioid Taper Support for Outpatients with Chronic Pain: A Randomized Controlled Trial*, 18 J. PAIN 308, 308 (2017) (finding that opioid tapering support programs may allow patients to reduce opioid doses without increasing overall pain intensity or interference with daily activities).

293. Petrosky et al., *supra* note 272, at 453.

V. CONCLUSION

> *[I]t is still important both to recognize how regulation of the use of opioids in medical practice is exceptional, and to try to understand whether the public health and public policy rationales offered for this regulation are persuasive reasons to depart from the norm. It may be, for example, that the regulations as enacted are not as narrowly or wisely tailored as they might be to fulfill the articulated policy and public health goals.*[294]

To date, no policy, law, or guidance defines inappropriate prescribing. This leads to policy development and evaluation not guided by evidence but by bias and oversimplification. The SUPPORT Act is the first major law to seek such a definition. This article advances an initial framework for such a definition, one that may provide a behavioral public choice architecture to address the biases of regulators. Through such a device, policy development may progress in ways more likely to align regulation and enforcement to prescribing related harms.

294. Nathan Guevremont et al., *Physician Autonomy and the Opioid Crisis,* 46 J.L. MED. & ETHICS 203, 205 (2018).