

UNINTENDED CONSEQUENCES OF FEDERAL OPIOID DIRECTIVES: THE NEGATIVE IMPACT OF OPIOID CRISIS RESPONSES ON PALLIATIVE AND END-OF- LIFE CARE PATIENTS

“One of the great mistakes is to judge policies and programs by their intentions rather than their results.”¹

INTRODUCTION²

Alarming statistics of opiate analgesic (“opioid”) overdose deaths has recently captured the attention of Americans. In early 2018, the National Center for Health Statistics reported that drug overdoses killed approximately 70,000 Americans in 2017.³ A New York Times article observed that this report found that the opioid death toll was “higher than the peak yearly death totals from HIV, car crashes, and gun deaths.”⁴ Some scholars have gone as far as to proclaim that the “opioid crisis” is “the deadliest drug crisis the...[United States] has experienced.”⁵ In light of staggering statistical support for the opioid epidemic, one cannot help but wonder how the United States (“U.S.”) found itself “experiencing a drug overdose epidemic of unprecedented magnitude...compared to other high-income countries.”⁶ When it became clear that this swelling problem demanded meaningful and immediate attention, experts and authorities decided to act.

¹ Milton Friedman, *in an interview with Richard Heffman* (1975).

² [Identifying information redacted]

³ National Center for Health Statistics, *Vital Statistics Rapid Release: Provisional Drug Overdose Death Counts*, CENTERS FOR DISEASE CONTROL AND PREVENTION (2019), <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>.

⁴ Margot Sanger-Katz, *Bleak New Estimates in Drug Epidemic: A Record 72,000 Overdose Deaths in 2017*, NEW YORK TIMES: THE UPSHOT (Aug. 15, 2018), <https://www.nytimes.com/2018/08/15/upshot/opioids-overdose-deaths-rising-fentanyl.html?module=inline>.

⁵ Mikayla Foster, *A Lackluster Response to the 64,000 Opioid Overdose Deaths Per Year*, Boston University School of Law: Dome (July 2018), <http://sites.bu.edu/dome/2018/07/10/a-lackluster-response-to-the-64000-opioid-overdose-deaths-per-year/>.

⁶ Jenesse Miller, *U.S. Drug Overdose Death Rates the Highest Among Wealthy Nations, USC Study Finds*, UNIV. S. CAL. PRESS ROOM (Feb. 2019), <https://pressroom.usc.edu/u-s-drug-overdose-death-rates-the-highest-among-wealthy-nations-usc-study-finds/>.

Many legislators, regulators, physicians, researchers, scholars, and laymen have begun working towards understanding where these startling opioid abuse statistics originated.⁷ Unfortunately, it appears the source of this crisis is somewhat ambiguous for opioids are a broad category of drugs⁸ comprised of a broad category of consumers—young, old, sick, healthy, legal and illegal. Each group of opioid consumers holds their own purpose for taking the drugs and identifying who is misusing and who is legitimately taking them for medicinal and pain management purposes is difficult to discern. Specifically, the U.S. government has employed numerous resources and taken important steps to draw attention toward and fight against the current opioid epidemic.

In early 2017, Former Attorney General Jeff Sessions officially announced that the country was in the midst of an opioid crisis.⁹ Soon after, the Department of Justice (“DOJ”) released sweeping agency directives intended to cure the opioid epidemic plaguing our country. While the DOJ’s noble directives may contribute to deterrence in some contexts, they also have proven to functionally undermine necessary healthcare activities in some parts of the healthcare industry. That same year, Former Deputy Attorney General Rod Rosenstein blamed the federal government in part for its role in creating the opioid crisis, saying “[d]rug overdose deaths spiked after federal drug prosecutions fell.”¹⁰ Mr. Rosenstein’s assertion is partially true. In 2011 federal policy re-

⁷ *Id.*

⁸ Opioids consists of “legal and illegal drugs, ranging from prescription painkillers [*i.e.*, oxycodone, morphine, oxytocin, fentanyl] to heroin” and what makes them particularly susceptible to abuse is their dangerous ability to inflict user dependence, tolerance, and addiction. *See* Wagner, L. Bernstein, and J. Achenback, *Trump Declares Opioid Crisis a “National Emergency,” Pledges More Money*, CHI. TRIB. (Aug. 2017), <https://www.chicagotribune.com/news/nationworld/politics/ct-trump-opioids-national-emergency-20170810-story.html>.

⁹ DEPARTMENT OF JUSTICE PRESS RELEASE, Attorney General Jeff Sessions Delivers Remarks on Efforts to Combat Violent Crime and Restore Safety Before Federal, State, and Local Law Enforcement, (Mar. 2017), <https://www.justice.gov/opa/speech/attorney-general-jeff-sessions-delivers-remarks-efforts-combat-violent-crime-and-restore>.

¹⁰ *Id.*

prioritized sentencing adjustments which in turn limited drug prosecutions and supported lower drug sentences across the nation.¹¹ During this period, an increase in opioid addiction statistics seemed to align with the DOJ's decreasing enforcement efforts.¹² Although reprioritization of policy focus is normally within a federal agency's authority, it seems that taking their foot off the gas pedal may have contributed to our current unhealthy opioid environment. Despite this alignment, Rosenstein qualified the government's ownership in contributing to the crisis, reminding the public and regulators that "correlation does not equal causation."¹³ His qualification is appropriate because there are many pain management players in this drug crisis game. Further, the calibration of enforcement efforts is not necessarily the only, or most, effective solution. In fact, taking enforcement too far can and has created life-threatening downstream consequences.

No doubt, the U.S. opioid epidemic is a true crisis. However, certain patient populations are unable to receive necessary pain management treatment because of unintended impacts of restrictive federal regulations related to announced opioid crisis directives. Many healthcare providers attribute their inability to provide effective pain management treatment to patients in cancer, palliative, and end-of-life care settings to the broad federal directives. Therefore, the purpose of this paper is to explore how opioid crisis regulations are causing functional conflicts in providing specific patient populations with pain treatment—namely patients undergoing cancer treatment, palliative care, and end-of-life care.

Part I of this paper explains what the opioid crisis is with important definitions and distinctions. Part II outlines the federal government's response to the crisis through administrative agencies and expanded executive power. Specifically, the federal government has advised and, in some cases,

¹¹*Id.*

¹²*Id.*

¹³*Id.*

mandated, constraining the market supply of opioids and prescription powers. These federal restrictions have been exceedingly prohibitive, creating an overly burdensome regulatory regime on critically ill and elderly patients in true need of pain management. Finally, Part III addresses the unintended consequences caused by the messy federal framework described in Part II. Prescription capability and line drawing issues rise to the forefront as providers struggle to effectively treat critically ill and elderly patients. Part IV reiterates the importance of confronting the effect of opioid regulation so that vulnerable populations most affected by federal directives can gain access to the care that they distinctly need. The U.S. government has recognized the country's opioid problem and continues to query how best to resolve the epidemic. However, vulnerable patient population should not be treated as collateral damage in this pursuit. Instead, critically ill patients should be afforded necessary pain treatment by the healthcare professionals equipped and licensed to employ medical discretion and make key treatment decisions.

I. WHAT IS THE OPIOID CRISIS?

A few terms and classifications must be clarified before analytically discussing the functional problems resulting from federal directive application of opioid regulation in clinical settings. An opioid is “a class of drugs that includes the illegal drug heroin, synthetic opioids such as fentanyl, and pain relievers available by prescription, such as oxycodone, hydrocodone, codeine, morphine, and many others.”¹⁴ In healthcare, opioids can yield beneficial results such as pain relief, functional improvement, and sedation.¹⁵ Opioid use also comes with major risks. They can include: incident

¹⁴ National Institute on Drug Abuse: Opioids (accessed Mar. 2, 2019), <https://www.drugabuse.gov/drugs-abuse/opioids>.

¹⁵ National Academies of Sciences, Engineering, and Medicine, *Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Use* 1, 393 (2017), <https://doi.org/10.17226/24781>. [hereinafter PAIN MANAGEMENT AND THE OPIOID EPIDEMIC]; see also Furlan et. al., *Opioids for Chronic Noncancer Pain: A Meta-analysis of Effectiveness and Side Effects*, 174 CANADIAN MED. ASS'N J. 1589, 1594 (2006), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2711509/pdf/nihms97365.pdf>. (“A meta-analysis of 41 randomized trials involving 6,019 patients found reductions in pain severity and improvement in functional outcomes when opioids were compared with placebo.”).

opioid use disorder, hepatic or renal dysfunction, anxiety disorders, depression, chronic obstructive pulmonary disease, respiratory depression, and, in some instances, death.¹⁶ Because opioids are very effective pain relievers, especially in the short-term,¹⁷ prescribers and patients have traditionally preferred opioids, despite their obvious drawbacks.¹⁸

A. PAIN, OPIOIDS, AND OPIOID USE DISORDER

In the late 1990s, “[u]nderassessment of pain [was] a major cause of inadequate pain management.”¹⁹ During this period, clinicians and scholars adamantly advocated for a better method to recognize, assess, and treat pain.²⁰ Especially in older populations, pain-management advocates expressed concerns that the “consequences of untreated pain can profoundly impact the older person’s quality of life.”²¹ Untreated pain can cause serious “physiologic risks associated...[such as] depression, impaired cognitive function, sleep disturbance, impaired functional abilities, diminished socialization, and increased health care use and costs.”²² In 2001, some clinicians pointed to studies that showed the “lack of assessment, underassessment, and a disparity between the clinician’s and the patient’s ratings of pain intensity are the major causes of

¹⁶ *Id.* See also Lynn R. Webster, *Risk Factors for Opioid -Use Disorder and Overdose*, 125 INTERNATIONAL ANESTHESIA RESEARCH SOCIETY, 1741, 1747 (Nov. 2017), https://journals.lww.com/anesthesia-analgesia/FullText/2017/11000/Risk_Factors_for_Opioid_Use_Disorder_and_Overdose.41.aspx#pdf-link.

¹⁷ See generally Webster *supra* note 16.

¹⁸ See Richard A. Lawhern, *Prescription Opioids and Chronic Pain*, THE ALLIANCE FOR THE TREATMENT OF INTRACTABLE PAIN: A WHITE PAPER (2018), <http://atipusa.org>.

¹⁹ National Pharmaceutical Council and the Joint Commission (formerly the JCAHO), PAIN: CURRENT UNDERSTANDING OF ASSESSMENT, MANAGEMENT, AND TREATMENTS, SECTION II: ASSESSMENT OF PAIN (Dec. 2001), <https://www.npcnow.org/system/files/research/download/Pain-Current-Understanding-of-Assessment-Management-and-Treatments.pdf> [hereinafter “PAIN: CURRENT UNDERSTANDING OF ASSESSMENT, MANAGEMENT, AND TREATMENTS”].

²⁰ *E.g.*, Mitchell Max, *Improving outcomes of Analgesic Treatment: Is Education Enough?* 113 ANN INTERN MED. 885, 885-89 (Dec. 1990).

²¹ Keela Herr, *Assessment and Measurement of Pain in Older Adults*, NIH Public Access 1 (Aug. 2001), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3097898/pdf/nihms286345.pdf>.

²² *Id.*

inadequately controlled pain.”²³ Identifying why pain was being underassessed and treated became a priority of regulators and professional medical societies.

In 2016, Dr. Mitchell Max, the former President of the American Pain Society, wrote an editorial in which he described the underassessment problem and how it emerged. He stated that patients are the “single most reliable indicator of pain”²⁴ as pain “involves a complex interaction between specialized nerves, your spinal cord, and your brain. Pain is both physical and emotional...[and] how you feel and react to pain depends on what is causing it, as well as many personal factors.”²⁵ In addition, “unlike traditional vital signs, pain isn’t displayed in a prominent place on the chart or at the bedside or nursing station.”²⁶ For these reasons, the complex occurrence that we call “pain” is difficult to describe, understand, monitor, and treat. It has become clear that clinical disparity, poor patient communication, financial barriers, and misunderstanding about what pain means or the side-effects of treatment contribute to inadequate under-assessment and under-treatment of pain.²⁷ Due to the many sophisticated and subjective components of the proper assessment to treat pain, experts recognized a need for technical standards to improve patient communication and medical provider pain management—and a movement to develop and implement such standards gained nationwide traction.

Although the problem persisted through the 2000’s, the development of technical pain assessment standards actually began when “the American Pain Society [in 1995] launched their influential ‘pain as the fifth vital sign’ campaign...with intent to encourage proper standardized

²³ PAIN: CURRENT UNDERSTANDING OF ASSESSMENT, MANAGEMENT, AND TREATMENTS, *supra* note 13 at 15.

²⁴ *Id.*

²⁵ The Mayo Clinic, *Understanding Pain* (July 2016), <https://www.mayoclinic.org/understanding-pain/art-20208632>.

²⁶ *Id.*

²⁷ *Id.* at 16.

evaluation and treatment of pain symptoms.”²⁸ To unify the national response, the Joint Commission published official standards “emphasizing the need for organizations to conduct quantitative assessments of pain.”²⁹ The goal of this campaign was to improve pain management and increase general knowledge about treating pain from both the patient and physician perspective. In addition, the Center for Disease Control and Prevention (“CDC”) also advised that when physicians assess their “patient’s pain and function regularly...[a] 30% improvement in pain and function is considered clinically meaningful.”³⁰ While accrediting and authoritative bodies imposed pressure upon health providers and organizations to reach a 30% improvement of the fifth vital sign, health professionals overly promoted quantitative pain measurements in order to assess levels of patient discomfort. As a result, the campaign created and imposed a “rapid institution of strict standards for pain management in hospital systems culminat[ing] in unintended consequences...[such as] a heavy reliance on opioids”³¹ because physicians “were now mandated to provide adequate pain control by the [Joint Commission].”³²

However, not everyone supported this movement. In 2002, the American Medical Association (“AMA”) expressed concern that “requiring all patients to be screened for the presence of pain and raising pain treatment to a ‘patients’ rights’ issue could lead to an increase in pain medication prescribing and, thus, overreliance on opioids.”³³ In 2015, the AMA “brought together 25 physician

²⁸ Mark R. Jones et. al., *A Brief History of the Opioid Epidemic and Strategies for Pain Medicine*, 7 PAIN THER. 13-21, (2018), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5993682/>. [hereinafter BRIEF HISTORY OF OPIOID EPIDEMIC]

²⁹ *Id.* See also David W. Baker, *The Joint Commission’s Pain Standards: Origins and Evolution*, THE JOINT COMMISSION DIVISION OF HEALTHCARE QUALITY EVALUATION (May 5, 2017), https://www.jointcommission.org/assets/1/6/Pain_Std_History_Web_Version_05122017.pdf.

³⁰ CDC, *Assessing Benefits and Harms of Opioid Therapy*, CDC PRESCRIBING GUIDANCE (accessed Mar. 2019), https://www.cdc.gov/drugoverdose/pdf/assessing_benefits_harms_of_opioid_therapy-a.pdf.

³¹ BRIEF HISTORY OF OPIOID EPIDEMIC, *supra* 19 at 24.

³² *Id.*

³³ AMA, *Pain Management Standards and Performance Measures*, REPORT 4 OF THE COUNCIL ON SCIENTIFIC AFFAIRS (2002), <http://www.ama-assn.org/ama/pub/about-ama/our-people/amacouncils/council-science-public-health/reports/reports-topic.page>.

organizations, [seventeen] specialty and seven state medical societies as part of its task force on opioids.” The Task Force to Reduce Prescription Opioid Abuse (“AMA Task Force”) “committed to identifying the best practices to combat the epidemic and to move swiftly to implement these practices across the country.”³⁴ Just a year after its creation, the AMA formally removed pain as a fifth vital sign for medical practitioners in 2016.³⁵ Leaders within the AMA observed that the combination of increasing emphasis on patient satisfaction surveys “that include a focus on the extent to which a patient’s pain is relieved has created a practice environment that likely contributed to an increase in opioid prescriptions.”³⁶ To replace mandatory pain assessment, the AMA’s Task Force issued five recommendations intended to guide physicians in their prescription practices.³⁷ These recommendations were: (1) register for and use your state Prescription Drug Monitoring Programs (“PDMPs”)³⁸ to check your patient’s prescription history; (2) educate yourself on managing pain and promoting safe, responsible opioid prescribing; (3) support overdose prevention measures, such as increased access to naloxone;³⁹ (4) reduce the stigma of substance use disorder and enhance access to treatment, and; (5) ensure patients in pain aren’t stigmatized and can receive comprehensive treatment.”⁴⁰

³⁴ See AMA, *Reversing the Opioid Epidemic*, AM. MED. ASS’N WEBSITE, (accessed Apr. 24, 2019), <https://www.ama-assn.org/delivering-care/opioids/reversing-opioid-epidemic>.

³⁵ See AMA, *Physicians Take Steps to Address Opioid Overdose Epidemic*, AM. MED. ASS’N WEBSITE, (June 2016), <https://www.ama-assn.org/delivering-care/opioids/physicians-take-steps-address-opioid-overdose-epidemic>. [hereinafter AMA PAIN MANAGEMENT RECOMMENDATIONS.]

³⁶ *Id.*

³⁷ *Id.*

³⁸ For more information, see FACT SHEET Office of National Drug Control Policy, *Prescription Drug Monitoring Programs*, (Apr. 2011), <https://www.ncjrs.gov/pdffiles1/ondcp/pdmp.pdf>.

³⁹ “Naloxone is a medication designed to rapidly reverse [an] opioid overdose. It is an opioid antagonist—meaning that it binds to opioid receptors and can reverse and block the effects of other opioids. It can very quickly restore normal respiration to a person whose breathing has slowed or stopped as a result of overdosing with heroin or prescription opioid pain medications.” See National Institute on Drug Abuse, *Opioid Overdose Reversal with Naloxone*, National Institute of Health (revised Apr. 2018), <https://www.drugabuse.gov/related-topics/opioid-overdose-reversal-naloxone-narcan-evzio>.

⁴⁰ AMA PAIN MANAGEMENT RECOMMENDATIONS, *supra* note 26.

As it turns out, AMA was onto something regarding concern over pain assessment—for zeal in assessing and treating pain did, in fact, become a reflex among providers tasked with pain management. As of 2017, “[a]t least two million people ha[d] an opioid use disorder (“OUD”) involving prescription opioids.”⁴¹ OUD is “a problematic pattern of opioid use that leads to serious impairment or distress.”⁴² Now in 2019, the AMA recommendations are being hailed as a step in the right direction. According to the AMA Task Force’s 2018 Progress Report, “opioid prescriptions [have] decreased by more than 55 million—a 22.2 percent decrease nationally”⁴³ and “[a]ll 50 states have seen a decrease in opioid prescriptions over the last five years.” Nonetheless, this paper will soon reveal that reducing general prescribing practices for all patient populations may not be the appropriate target for reform, or benchmark for success.

B. OPIOID TREATMENT EXPLAINED

Not all illnesses are created equal in terms of pain management. Although opioids may be administered in many contexts, the most common use is to treat chronic pain. Generally, opioid use for chronic pain has proven effective in eliminating such pain and producing functional improvements for short periods of time.⁴⁴ Although opioid-receiving patients experience short-term functional and pain relief euphoria, patient dependence grows alongside other negative, long-term physical consequences.⁴⁵ Those long-term physical consequences include the drug’s

⁴¹ PAIN MANAGEMENT AND THE OPIOID EPIDEMIC *supra* note 15.

⁴² Provider’s Clinical Support System, *Opioid Use Disorder: Symptoms and Severity*, PCSS: CLINICAL RESOURCES (Dec. 2017), <https://pcssnow.org/resource/opioid-use-disorder-opioid-addiction/>. (An individual is identified as having OUD if they meet two or more symptoms listed under the following categories: loss of control, social problems, risky use, or pharmacological problems.”).

⁴³ AMA Opioid Task Force 2018 Progress Report, AM. MED. ASS’N (2018), <https://www.end-opioid-epidemic.org/wp-content/uploads/2018/05/AMA2018-OpioidReport-FINAL-updated.pdf>.

⁴⁴ See generally Anna Lembke, et.al., *Weighing the Risks and Benefits of Chronic Opioid Therapy*, AM. ACADEMY OF PHYSICIANS (2016), <https://www.aafp.org/aafp/2016/0615/p982.pdf> (asserting that “[t]he benefit of short-term opioid therapy is supported by multiple clinical trials. However...the risk associated with chronic opioid therapy increase in dose-dependent manner.”).

⁴⁵ AnGe Baldini, et.al., *A Review of Potential Adverse Effects of Long Term Opioid Therapy: A Practitioner’s Guide*, National Library of Medicine: National Institute of Health (2012) (noting that “[d]espite increased use of

addictive potential and development of “ills...such as hyperalgesia,⁴⁶ increasing disability, and a host of other formidable problems, including endocrine and psychological co-morbidities”⁴⁷ that accompany long-term use.

This is a particular concern in the chronic pain context. “In chronic pain patients, it is well known that opioid treatment may initially be part of the solution, but later turn into a substantial part of the problem” for some patients.⁴⁸ Merriam-Webster Dictionary defines “chronic” as “continuing or occurring again and again for a long time.”⁴⁹ Accordingly, chronic patients are likely to experience persisting pain. As such, they are more prone to develop an addiction because of the potential long-term opioid usage.⁵⁰ Therefore, the chronic pain category is precisely the target these federal opioid directives should be aimed at controlling. Government agencies are recommending that nonpharmacologic therapy and nonopioid pharmacologic therapy be the preferred form of treatment for chronic pain.⁵¹

In contrast, outside of chronic pain, “[t]he aggressive use of opioids has long been accepted and strongly promoted for the treatment of pain in patients with cancer or those in end-of-life and palliative care.”⁵² These three forms of care are accompanied by much less controversy because

opioids for long-term management of chronic pain, there remain large gaps in understanding of the basic physiology, efficacy, and side effects of opioid medications, particularly when used over longer periods of time.”).

⁴⁶ “Hyperalgesia is a condition where a person develops an increased sensitivity to pain. What may not hurt most people can cause significant pain in an individual with hyperalgesia.” See Rachel Nall, Hyperalgesia: What you need to know, MED. NEWS TODAY (Aug. 2017), <https://www.medicalnewstoday.com/articles/318791.php>.

⁴⁷ BRIEF HISTORY OF OPIOID EPIDEMIC, *supra* 19 at 29.

⁴⁸ Jette Jojsted, *Addiction to Opioids in Chronic Pain Patients: A Literature Review*, 5 EUR. J. PAIN (2012) (citing J. Eriksen, *Opioids in Chronic Non-Malignant Pain*, 5 EUR. J. PAIN, 231–232 (2001)), <https://onlinelibrary.wiley.com/doi/abs/10.1016/j.ejpain.2006.08.004>.

⁴⁹ Merriam-Webster, (11th ed. 2019), <https://www.merriam-webster.com/dictionary/chronic>.

⁵⁰ Mayo Clinic Staff, *How to Use Opioids Safely*, (May 2018), <https://www.mayoclinic.org/diseases-conditions/prescription-drug-abuse/in-depth/how-to-use-opioids-safely/art-20360373> (“Opioid painkillers are highly addictive. After just five days of prescription opioid use, the likelihood that you'll develop long-term dependence on these drugs rises steeply — increasing your risk of eventual addiction and overdose.”).

⁵¹ See Dowell D, et.al., CDC Guideline for Prescribing Opioids for Chronic Pain—United States, (2016), <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>. [hereinafter 2016 CDC GUIDELINES]

⁵² PAIN MANAGEMENT AND THE OPIOID EPIDEMIC, *supra* note 13 at 62.

opioid prescriptions are for a defined period of time, and are used to treat a more intense form of pain or disease.⁵³ And, further, with intense forms of treatment come with intense forms of discomfort. Thus, patients experiencing these forms of treatment are less likely to benefit from opioid prescribing reform—in fact, restricting their access while they are vulnerable physically and mentally may actually generate harmful effects.

C. DEPENDENCE, TOLERANCE, AND ADDICTION

A final distinction involves the differences among physical dependence, tolerance, and addiction. The medical community asserts that physical dependence occurs when “a patient has received opioids for approximately five days or more and develops withdrawal symptoms...when the drug is withdrawn.”⁵⁴ Dependence is often the patient’s physical reaction to the power of opioids that make a body reliant and accustomed to their effect. As dependence grows, the original prescription dosage becomes less effective, leading to increases in both the dosage frequency and total prescriptive amount.⁵⁵ Thus, even patients taking a legitimate opioid prescription are susceptible to physical dependence. Risks associated with dependence are most concerning in the chronic pain context since this pain is lasting, and not connected to a specific, temporally limited form of closely managed, intense care. In consequence, chronic pain patients are more likely than patients using opioids for other treatments to develop OUD and move into the next category—tolerance.

⁵³ *Id* (“[U]se of opioids for control of pain in cancer and palliative care patients is common and strongly supported by both the available literature and the medical community.”).

⁵⁴ Tracy E. Harrison, M.D., Treating Pain Responsibly in the Midst of an Opioid Epidemic, MAYO CLINIC NEWS, <https://www.mayoclinic.org/medical-professionals/trauma/news/treating-pain-responsibly-in-the-midst-of-an-opioid-epidemic/mqc-20438006> (accessed Mar. 7, 2019).

⁵⁵ See Lembke *supra* note 43.

Tolerance can be explained as a decreasing “susceptibility to the effects of the opioid, which can result in a need for higher and more frequent doses to achieve the same analgesic effect.”⁵⁶ When opioids are utilized for pain management, dependence and tolerance are both expected results because of the drug’s powerful pain relief and euphoric potency. Thus, it is important to manage dosage and duration in patients who are likely to use opioids to the point they may become vulnerable to negative side-effects, as both “duration and dose appear to affect the development of tolerance.”⁵⁷ One way to mitigate tolerance is opioid rotation.⁵⁸ Another effective method is “multimodal pain management [in which] multiple non-opioid drugs can be used in combination with or in place of opioids to target various...pathways...produc[ing] additive and even synergistic effects of the analgesic agents and reduces the adverse effects of opioids.”⁵⁹ Therefore, when opioid administration is properly managed, dependence and tolerance do not necessarily lead to the next, and dangerous, stage of opioid use—addiction.

In contrast to dependence and tolerance, addiction is defined by clinicians as

a primary, chronic disease of brain reward, motivation, memory, and related circuitry. Dysfunction in these circuits leads to characteristic biological, psychological, social and spiritual manifestations...reflected...by [an] inability to consistently abstain, impairment in behavioral control, craving, diminished recognition of significant problems with one’s behaviors and interpersonal relationship, and a dysfunctional emotional response.⁶⁰

Further, “[f]ederal law defines an addict as ‘any individual who habitually uses any narcotic drug so as to endanger the public morals, health, safety, or welfare, or who is so far addicted to the

⁵⁶ J.A. Jeevendra Martyn, MD et.al., *Opioid Tolerance in Critical Illness*, 380 THE NEW ENG. J. OF MED., 365 (Jan. 2019).

⁵⁷ *Id.*

⁵⁸ “Opioid rotation refers to a switch from one opioid to another in an effort to improve the response to analgesic therapy or reduce adverse effects. It is a common method to address the problem of poor opioid responsiveness despite optimal dose titration.” See Knotkova H, Fine PG, Portenoy RK, *Opioid Rotation: The Science and the Limitations of the Equianalgesic Dose Table*, J. PAIN SYMPTOM MANAGEMENT, (Sept. 2009), <https://www.ncbi.nlm.nih.gov/pubmed/19735903>.

⁵⁹ *Id.* at 374.

⁶⁰ PAIN MANAGEMENT AND THE OPIOID EPIDEMIC, *supra* note 13 at 22.

use of narcotic drugs as to have lost the power of self-control with reference to his addiction.”⁶¹ Most experts agree that “the vast majority of people prescribed opioids do not misuse them. However, opioids can [also] produce feelings of pleasure, relaxation, and contentment, leading to [] overreliance[,]. . .misuse and OUD.”⁶² Misuse is precisely the absence of self-control, the presence of uninhibited euphoria, and uncharacteristic behaviors to secure more opioids that led to alarming rates of opioid overuse. Such overuse resulted in increasing rates of misuse, OUD, opioid overdoses, death, and additional harms connected to over-prescribing opioids.

Clarifying differences among dependence, tolerance, and addiction helps shed light on the analysis of federal directives on opioid use. Although dependence and tolerance can lead to addiction, they are not the same as addiction. Dependence and tolerance are natural responses to these powerful pain medications.⁶³ With close monitoring and careful increases or reductions of medication levels, healthcare providers can reduce and manage patient dependence and tolerance.⁶⁴ In contrast, addiction is undesirable because it comes with costs to the patient and society that surpass any benefit of opioid use. Addiction manifests itself in thoughtless use, rash or illicit behavior, and likely overdose or death. Therefore, generally the regulatory directives are targeted at preventing unnecessary prescriptions for opioids, especially in the chronic pain context, in an effort to prevent addiction.

II. THE UNITED STATES GOVERNMENT AND THE OPIOID CRISIS

⁶¹ H. Westley Clark, and Karen Lea Sees, *Opioids, Chronic Pain, and the Law*, 8 J. OF PAIN AND SYMPTOM MANAGEMENT 297, 299 (1993) (*quoting* 21 U.S.C. §802(1)).

⁶² PAIN MANAGEMENT AND THE OPIOID EPIDEMIC, *supra* note 13 at 2.

⁶³ HOW TO USE OPIOIDS SAFELY, *supra* note 39.

⁶⁴ *Id.*

Moving forward, this Part first asks whether pain management should be considered a fundamental right in our insurance based system. After answering this question in the negative, Part II.B then identifies the federal government's role in the regulation of opioid use, explains current federal regulatory initiatives, and addresses concerns related to expanded executive power related to this crisis.⁶⁵

A. THE RIGHT TO PAIN MANAGEMENT?

Managing pain is a problem most naturally understood as a medical or clinical responsibility. However, state and federal governments inevitably have a role in regulating provider and insurer practices, pharmaceutical market supply, and drug research and development. Among other responsibilities the U.S. government serves to guard and protect the rights of its citizens. However, defining the government's role in pain management is no easy task—especially when the rights associated with this pain management are unclear.

A “right” to any form of healthcare—service or payment⁶⁶—has, at best, a shaky legal foundation in the United States.⁶⁷ There are certain pieces of federal legislation dedicated to

⁶⁵ It is important to mention that although the states have a significant role in promoting the “health, safety and welfare” of their citizens, this paper’s primary purpose is to outline and analyze *federal* initiatives, polic[ies], and regulations implemented to fight the opioid crisis. The issue of federalism in terms of regulation creates major coordination incongruity, but this issue is outside the scope of this paper. For more information on the appropriate government regulator *see* Lainie Rutkow, & Jon S. Verick, *Emergency Legal Authority and the Opioid Crisis*, N. ENG. J. OF MEDICINE (Nov. 2017) (arguing that states do not just have a significant role, but the most important role in mitigating the opioid crisis), <https://www.nejm.org/doi/full/10.1056/NEJMp1710862>;

⁶⁶ It is crucial to understand there is a difference between a right to healthcare and a right of payment for healthcare. For further reading on this topic, *see* Health Law Terminology, 20121028 AHLA SEMINAR PAPERS, 121028 Fundamentals of Health Law, Chicago, IL (2012); Walter L. Stiehm, *Poverty Law: Access to Healthcare and Barriers to the Poor*, 4 Quinnipiac Health L.J. 279 (2001); Mahiben Maruthappu, et. al., *Is Health Care a Right? Health Reforms in the USA Upon the Concept of Care*, ANNALS OF MED. AND SURGERY (2013), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4326121/pdf/main.pdf>.

⁶⁷ Whether pain management in the United States or elsewhere is a fundamental human right is a topic outside the scope of this paper. For more information, *see* Frank Brennan, et. al., *Pain Management: A Fundamental Human Right*, 105 PAIN MEDICINE: INTERNATIONAL ANESTHESIA RESEARCH SOCIETY, 205-221 (2007), <https://www.ncbi.nlm.nih.gov/pubmed/17578977>; Linda Farber, et. al., *Pain: Ethics, Culture, and Informed Consent to Relief*, 24 THE J. OF LAW, MEDICINE & ETHICS, 348-59 (1996), <https://journals.sagepub.com/doi/abs/10.1111/j.1748-720X.1996.tb01878.x>; Frank Brennan, et. al., *Access to Pain Management—Still Very Much a Human Right*, 17 PAIN MEDICINE, 1785-89 (2016), <https://academic.oup.com/painmedicine/article/17/10/1785/2270355>.

required healthcare services in specific contexts—usually relating to life-saving or -preserving measures such as delivering a newborn or stabilizing a human in critical condition.⁶⁸ Outside of disability, age, and emergency contexts, there are few federal laws guaranteeing any right to healthcare payment or services. The absence of a broader guarantee exists because in an insurance-based health system, no one is entitled to any and all medically preferable, and sometimes necessary, health services.⁶⁹ No entitlement however does not necessarily equal no access. But the practical implications of such a norm raise important questions regarding the extent of regulatory initiatives and directives

To illustrate, if a patient's private insurance is unwilling to cover an expensive or unnecessary medical treatment, a patient's access to those services may be restricted—or completely barred. In other words, there is no requirement that a provider must administer healthcare treatment to those who need or could benefit from such treatment. For “[t]he medical industry exists almost entirely to serve people who have been rendered incapable of representing their own interest in an adversarial transaction.”⁷⁰ The transaction is adversarial because the interests of insurers and patients are nearly always misaligned.⁷¹ The misalignment occurs when patients “agree[] to a transaction for insurance coverage...[it] means abandoning an unregulated free market for health care...[since] the patient has surrendered their buying power and much of their discretion [in advance] to an entity whose interests are not aligned with their own.”⁷² For insurance companies “don’t bleed...get pregnant...[or] cancer.”⁷³ Instead they have business oriented goals such as

⁶⁸ See 42 U.S.C § 1395DD (2011), EMERGENCY MEDICAL TREATMENT AND LABOR ACT (“EMTALA”) (ensures public access to emergency services regardless of ability to pay).

⁶⁹ See generally Chris Ladd, *There is Never a “Free Market” in Health Care*, FORBES (May 2017), <https://www.forbes.com/sites/chrisladd/2017/03/07/there-is-never-a-free-market-in-health-care/#30f921e71147>.

⁷⁰ *Id.*

⁷¹ *Id.*

⁷² *Id.*

⁷³ *Id.*

quarterly reviews, financial gains, and marketing returns. In consequence, the insurer-patient misalignment, although beneficial in other ways, can result in mis- or under-treatment.

Insurance is not the only regulatory barrier to medical services, however. Even when a patient can afford the treatment they may be inhibited by other regulatory regimes, like that of individualized state legislation that prohibits the entire health care consumer market from enjoying access and benefits of certain available treatment plans and procedures. Although government intervention may be important, restricting access when it is otherwise obtainable by patients with or without their insurers raises the question: should the government be capable of restricting pain management in these instances or should pain management become an entitled “right”?

Unfettered access to pain relief is an untenable position in an insurance-based model. Some pain management experts assert that “[u]nder-treatment of pain is [a] poor medical practice that results in many adverse effects.”⁷⁴ For this reason, among others, international human rights organizations advocate that pain management should be recognized as a fundamental human right. They argue that “[d]omestic opioid laws, policies, and practices that restrict opioid availability, accessibility, and affordability constitute significant discrimination against patients in pain and the dying.”⁷⁵ Although noble in purpose, this argument holds less weight in an insurance-based health system supplemented by limited government subsidization.⁷⁶ Provision of any health service under

⁷⁴ Liu, Spencer, et al., *Pain Management: A Fundamental Human Right*, 105 ANESTHESIA & ANALGESIA: PAIN MED. REV. ART. NO. 1, 205-221 (July 2007), https://journals.lww.com/anesthesia-analgesia/fulltext/2007/07000/Pain_Management__A_Fundamental_Human_Right.37.aspx (arguing that “the unreasonable failure to treat pain is poor medicine, unethical practice, and is an abrogation of a fundamental human right.”).

⁷⁵ Frank Brennan, et. al., *Access to Pain Management—Still Very Much a Human Right*, 17 AM. ACADEMY OF PAIN MED., 1785-89 (2016), <https://academic.oup.com/painmedicine/article/17/10/1785/2270355>.

⁷⁶ See Centers for Medicare and Medicaid Services (“CMS”), MED. REV. AND EDU., (2018), <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/>.

an insurance-based model, including pain management, comes at a cost, and the U.S. addresses health care from a payor perspective.

The payor perspective allows the U.S. to facilitate rational decision making when patients are “in no position to shop for the best provider of [health] services at the most reasonable price.” In consequence, both public and private insurers negotiate ahead of time, design a provider network, and assess whether a critical health event is covered by this network and to what degree payment is owed for covered or non-covered services. If pain management were established as a fundamental right in the U.S. health system, an imbalance in the payment model would arise since it is unrealistic to aim to eliminate pain and suffering altogether. This imbalance would in turn create an unobtainable goal for the payment system, thus fully draining plan resources to address a single problem in a pool of many critical health considerations.

On the other hand, under-treating authentic pain-experiencing patients is a serious concern in an insurance-based model. Similar to arguments put forward by pain advocates, insufficient pain management can result in severe physical, psychological, social, and economic harm.⁷⁷ However, establishing unfettered pain relief as a fundamental part of care ignores the human condition. “The word ‘patient’ itself is derived from [the Latin word] *patiens*, meaning ‘one who suffers.’”⁷⁸ Certainly, patients do not seek health services because they are healthy. Rather, they experience the human being internal alarm system—pain—that alerts them something is physically awry. “[P]ain is part of life and part of medicine...[and] giving sufficient analgesia to eliminate all pain for all patients is a wrong target—but so is treating pain insufficiently.”⁷⁹ Advocates, physicians, patients, and regulators all must acknowledge that pain is intrinsic in the human condition. Modern

⁷⁷ See generally Brennan, *supra* note 55.

⁷⁸ *Id.*

⁷⁹ Thomas H. Lee, *Zero Pain is Not the Goal*, JAMA ONLINE: EDITORIAL (2016), <https://jamanetwork.com/journals/jama/fullarticle/2503504>.

medicine has the tools to manage normative aspects of the human condition, like pain, and these tools should be wielded when appropriate. However, defining pain management as a fundamental right is precarious since pain is incorporated into the human condition, and doing so risks unnecessarily consuming enormous resources in an insurance-based system. Nevertheless, allowing pain treatment to look too much like a privilege opens the door in the U.S. health system for government regulation to potentially inhibit legitimate care when problems like the opioid crisis arise.

B. THE FEDERAL RESPONSE TO THE OPIOID CRISIS

The federal response to the opioid crisis has been multifarious. The legislative and executive branches have publicly acknowledged this crisis and asserted their respective power to address the epidemic. At the direction of President Trump, the DOJ announced in 2017 that it intended to address the opioid crisis in three ways: criminal enforcement, treatment, and prevention.⁸⁰ Several different agencies are leading efforts to integrate these three goals to find an effective national solution. In 2017, the President's Commission on Combating Drug Addiction and the Opioid Crisis (the "Commission") was created as a catalyst for DOJ enforcement efforts.⁸¹ The Commission's research and recommendations were published in November 2017.⁸² The recommendations proposed that legal and policy reforms include "expanded funding for integrated medication-assisted treatments; medical training in appropriate pain management; and waivers of health information privacy regulations that impede access to complete data on fraudulent prescription practices and those who misuse opioids."⁸³

⁸⁰ See DEPARTMENT OF JUSTICE PRESS RELEASE (Mar. 2017) *supra* note 8.

⁸¹ See Gov. Chris Christie, et. al, The President's Commission on Combatting Drug Addiction and the Opioid Crisis, Report of Commissioners (Nov. 2017), https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-15-2017.pdf.

⁸² *Id.*

⁸³ Lainie Rutkow & Jon S. Verick, *Emergency Legal Authority and the Opioid Crisis*, NEW ENG. J. OF MED. (Nov. 2017) available at <https://www.nejm.org/doi/full/10.1056/NEJMp1710862>.

More recently, in January 2019, the Office of the National Drug Control Policy released the National Drug Control Strategy (the “Strategy”). The Strategy prescribed three interrelated elements that sound very similar to those promoted by the Commission: “prevention, treatment and recovery, and reducing the availability of drugs in America.”⁸⁴ In March of 2019, the Government Accountability Office (“GAO”) report⁸⁵ found that the Strategy was inadequate.⁸⁶ While the Strategy’s aims reflect a more holistic approach to the crisis than previous plans, critics of the GAO still claim it is inadequate because the report “doesn’t indicate measures of success for the objectives, doesn’t have a timeline for those objectives, doesn’t have a performance measurement system for the agency, and doesn’t have a five-year projection for program and budget priorities.”⁸⁷ Although it is too early to fully see the effects of this policy, the Strategy, like other executive directives, seems to fall short in terms of operative effectiveness. However, combined with additional exercises of federal power, the Strategy may have the potential to affect important change—hopefully reducing deaths arising from OUD and opioid overdoses.

i. EXPANSION OF FEDERAL POWER: THE HEALTH EMERGENCY DECLARATION

In addition to the directives advanced in the Strategy and the Commission’s reports, President Trump also directed the acting secretary of the Department of Health and Human Services (“HHS”), in March 2017, to declare the opioid crisis a national public health emergency under the Public Health Services Act.⁸⁸ A national emergency declaration “authorizes public health powers, mobilizes resources and facilitates innovative strategies to curb rapidly escalating public health

⁸⁴ James W. Carroll, *National Drug Control Strategy*, REPORT BY THE OFFICE OF NATIONAL DRUG CONTROL POLICY, 1, (Jan. 2019), <https://www.whitehouse.gov/wp-content/uploads/2019/01/NDCS-Final.pdf>.

⁸⁵ GAO Report: Statement of Triana McNeil, Acting Director, Homeland Security, and Justice and Marry Denigan-Maccauley, Acting Director, Health Care, Testimony Before the Committee on Oversight and Reform, House of Representatives (Mar. 2019), <https://www.gao.gov/assets/700/697306.pdf>.

⁸⁶ Shira Stein, *Trump Opioids Strategy Short on Details*, *Lawmakers Say*, BLOOMBERG ONLINE: HEALTH LAW & BUSINESS (Mar. 2019)(observing that the Strategy even lacked “information that was required by statute.”).

⁸⁷ *Id.*

⁸⁸ *Id.*

crisis.”⁸⁹ Emergency declarations are “typical particularly at the local level, for fast spreading diseases, biosecurity threats, and humanitarian disasters.”⁹⁰ But they are uncommon in instances where a problem balloons from patterned behaviors arising over time, as the declaration of an emergency suggests urgency and a need for immediate resolution. The opioid crisis shares more characteristics with the former situation since it emerged over a period of years and its solution—especially in terms of prevention and treatment—may also be a marathon, not a sprint. For “[y]ears of sustained, coordinated, and vigilant effort will be required to contain the present opioid epidemic and ameliorate its harmful effects on society.”⁹¹ Drawing this distinction is important because painting the opioid crisis as a national emergency risks resource-drain on a long-term problem and diminishing devotion as hasty responses create more problems, as opposed to positive, measurable improvements. Thus, the term “emergency,” although accompanied by an opportunity to increase resources, fails to adequately inspire a genuine call to consistent and necessary restorative action.

Although helpful in terms of resource accessibility, the national declaration of a public emergency sent a sense of discordant urgency to the public and regulators. Lawrence Gostin, a faculty director of the O’Neil Institute for National and Global Health, worried “that an emergency declaration could justify paternalistic interventions that deny rights to affected patients or their caregivers.”⁹² As Gostin predicted, federal authorities have responded to the opioid epidemic with unbalanced reactions. In 2016, the CDC released its Guidelines for prescribing opioids for chronic

⁸⁹ Lawrence O. Gostin, et. al., *Reframing the Opioid Epidemic as a National Emergency*, AM. MED. ASS’N: VIEWPOINT (Oct. 2017), <https://jamanetwork.com/journals/jama/fullarticle/2652445>.

⁹⁰ Karen Teber, *Making the Case for Declaring the U.S. Opioid Epidemic a National Public Health Emergency*, O’NEIL INST. FOR NAT’L & GLOBAL HEALTH LAW: NEWS, (Aug. 2017), <http://oneill.law.georgetown.edu/news/making-the-case-for-declaring-the-u-s-opioid-epidemic-a-national-public-health-emergency/>.

⁹¹ See DEPARTMENT OF JUSTICE PRESS RELEASE (Mar. 2017) *supra* note 8.

⁹² See Gostin, *supra* note 78.

pain. For example, some medical experts have said that the 2016 CDC Guidelines,⁹³ announced prior to the emergency declaration, have been misapplied. Specifically, in March of 2019, Health Professionals for Patients in Pain wrote a letter to the CDC, pleading that

[P]atients have endured not only unnecessary suffering, but some have turned to suicide or illicit substance use. Others have experienced preventable hospitalizations or medical deterioration in part because insurers, regulators and other parties have deployed...[a lower] threshold [for opioid prescribing] as both a professional standard and a threshold for professional suspicion. Under such pressure, care decisions are not always based on the best interests of the patient.⁹⁴

Furthermore, others have deemed the declaration's pronouncement to be mere symbolism, or to be a way to allocate extra funds for law enforcement, rather than as concrete to steps counteract the true medical epidemic.⁹⁵ It appears that the true priority of the national public health emergency is law enforcement, not prevention and treatment. More worrisome, the acting director of healthcare at the GAO reported in 2019 that "no public health emergency funds had been used for the opioid crisis since the declaration was made [in 2017]."⁹⁶ Thus, focusing too closely on law enforcement, rather than current and future treatment and prevention practices, risks functionally harming current opioid using patients and inhibiting provider ability to care for a specific patient population.

ii. AGENCY COORDINATION (OR LACK THEREOF)

Although funds from the healthcare emergency declaration have yet to be deployed, these funds and other investment sources could still be wielded to empower federal agency action. As

⁹³ See 2016 CDC GUIDELINES *supra* note 50.

⁹⁴ Health Professionals for Patients in Pain ("HP3"), Professional Call on the CDC to Address Misapplication of its Guidelines on Opioids for Chronic Pain through Public Clarification and Impact Evaluation, (Mar. 2019), https://docs.google.com/document/d/1RzQDSppUKhjiAsEmhW2WbTXIP5V8vJ4M_vBPQLKhK_8/edit.

⁹⁵ John Wagner, et. al., *Trump Declares Opioid Crisis a 'National Emergency' Pledges more Money*, THE CHICAGO TRIBUNE (Aug. 2017), <https://www.chicagotribune.com/news/nationworld/politics/ct-trump-opioids-national-emergency-20170810-story.html>. ("We're not going to arrest our way out of this epidemic.").

⁹⁶ See Stein, *supra* note 39.

of October 2018, the executive branch claimed to be “investing \$320 million into all three parts of the President’s comprehensive plan to end the [opioid] epidemic.”⁹⁷ It is clear that the Commission and Strategy goals show the inevitable entanglement of government agencies. Effective law enforcement requires federal agents, investigators, prosecutors and courts to administer justice against already committed violations of the law. Treatment and prevention, on the other hand, invoke a more clinical and research-based approach. Therefore, not one single agency is capable of handling the sophisticated objectives and necessary expertise required for the overlapping issues associated with the opioid crisis. Thus, a large laundry list of administrative agency actors are employed to help resolve the U.S. opioid problem.

The DOJ, the DHHS, the Center for Medicare and Medicaid Services (“CMS”), U.S. Food and Drug Administration (“FDA”), the CDC, Drug Enforcement Agency. (“DEA”), and the National Institute of Health (“NIH”) are all important agencies in need of resources and power to carry out executive directives and legislative mandates related to the crisis. The problem that emerges, however, is that with many actors come coordination issues. Integrating the goals of the DOJ, DEA, CDC, NIH, and the FDA risks overlap and overregulation. The coordination problem’s negative effect on patients can be demonstrated by comparing the efforts of the CDC, and the FDA.

As mentioned earlier, the CDC published opioid prescription guidelines in 2016 (“CDC Guidelines”).⁹⁸ The non-binding CDC Guidelines apply to primary care physicians prescribing opioids for adults diagnosed with chronic pain. After the publication of the CDC Guidelines, several providers and associations voiced serious concern that the guidelines were likely to have

⁹⁷ DEPARTMENT OF JUSTICE PRESS RELEASE, Justice Department is Awarding Almost \$320 Million to Combat Opioid Crisis, (Oct. 2018), <https://www.justice.gov/opa/pr/justice-department-awarding-almost-320-million-combat-opioid-crisis>.

⁹⁸ 2016 CDC GUIDELINES *supra* note 50.

unintended consequences.⁹⁹ More specifically, industry experts worried that negative government messaging would create a “chilling impact on pain management efforts, even for those groups of patients for whom the guidelines were not intended.”¹⁰⁰ The CDC claimed to incorporate alternative perspectives including these concerns over pain management by incorporating “substantial correspondence” from unique patient types who were being treated with opioids, but these patients expressed concern about the guidelines being “too restrictive for their physicians to properly treat them.”¹⁰¹

However, the CDC’s response was unsatisfactory to many of its critics. The CDC simply emphasized that the guidelines were limited to *primary care* physicians prescribing opioids for patients with *chronic* pain and that the Guidelines were not binding. Further, the CDC said that palliative care, cancer treatment, and end of life patients were not the intended recipients of the guidelines. But even though the 2016 CDC prescribing guidelines are not binding and have a relatively narrow application, they still pose a risk of “limiting access to opioids at local pharmacies” causing “under-treatment of disabling pain in those with serious or advanced illnesses.”¹⁰² Although no relevant studies have been released to date, the current extreme, restrictive framework issued by the CDC lays the groundwork for extreme consequences that revert certain patient populations to the era of pain underassessment.¹⁰³

While it is clear that CDC Guidelines impact daily prescribing behaviors, the FDA also plays a significant upstream role that directly affects prescribing behaviors. In relevant part, the FDA is responsible for approving new drugs, new methods of treatment, and new medical devices for legal

⁹⁹ See Terri Maxwell, *Opioid Guidelines Raise Alarms Among Hospice and Palliative Healthcare Providers*, BECKER’S HEALTHCARE: CLINICAL LEADERSHIP AND INFECTION CONTROL (Mar. 2016) <https://drive.google.com/drive/u/1/folders/1ggnYlrQ46SezF3LdKX6XOqLeeHFVsqsms>.

¹⁰⁰ *Id.*

¹⁰¹ *Id.*

¹⁰² *Id.*

¹⁰³ *Supra* Part I.A.

use on the open healthcare market. In the opioid context, the FDA has undertaken efforts to restrict the supply of available opioids on the pharmaceutical market and to develop alternative pain management remedies. Because the FDA has tightened availability and distribution of opioids approved and released into the market, the effect has limited pharmacy supplies of opioid medication.¹⁰⁴ So even when a prescribing provider writes a legitimate prescription for a patient in need, the pharmacy may not even have the particular medication available in the first place. As a result of the CDC Guidelines¹⁰⁵ and the FDA, supply restrictions are negatively affecting medical practice since prescribers are restricted and necessary pharmaceutical supplies are inadequate. For “over-prescription of opioids has...fallen steeply in recent years...[b]ut during this period, the overdose-death rate has kept climbing: Those 47,600 deaths in 2017 set a new record.”¹⁰⁶ This data suggests that prescribing practices are not the only source of our nation’s opioid crisis, and that efforts to control opioid use should not only focus on physician prescribing habits. For this reason, the FDA and CDC’s joint efforts could unnecessarily restrict patient access, potentially inhibiting providers from treating diagnosed pain needs.

Although the federal government has rightly placed emphasis on the growing problem of opioid abuse, the intense focus has distracted regulators, legislators, providers, and insurers away from a very large population of people whom the opioid industry is intended to serve. Regulator focus is so closely placed on opioid *abusing* patients that any negative consequences tied to *appropriately using* opioid patients are cast to the wayside. In turn, some patients enduring chronic pain, terminal illnesses, intense cancer treatment, or end-of-life care are misunderstood by

¹⁰⁴ Laura DiAngelo & Kelly Brantley, *Limits on Opioid Prescriptions are Becoming More Widespread*, AVALERE INSIGHTS (Apr. 2018), <https://avalere.com/insights/limits-on-opioid-prescriptions-are-becoming-more-widespread>.

¹⁰⁵ See 2016 CDC GUIDELINES *supra* note 50.

¹⁰⁶ Ramesh Ponnuru, *War on Opioid Abuse is Striking the Wrong Target*, BLOOMBERG NEWS: POLITICS AND POLICY (Mar. 2019), <https://www.aei.org/publication/war-on-opioid-abuse-is-striking-the-wrong-target/>.

providers and pharmacies and mistreated in terms of necessary care. The current opioid directive climate is seeking reform and an easy solution. Unfortunately, the federal government's aggressive stance has increased unintended consequences. Aggressive federal involvement can be appropriate, such as within criminal enforcement of illegal opioid use. On the other hand, vulnerable patient populations are functionally suffering from the failure of regulatory agencies to acknowledge the difference in status between an addict and a dying hospice resident.

III. UNINTENDED CONSEQUENCES OF OPIOID CRISIS DIRECTIVES

The Law of Unintended Consequences proclaims that the rational actions of people will always have consequences that are unanticipated or unintended.¹⁰⁷ And while agent intentions—beneficent or improper—are important and suitably attributed to the agent, it is “the actual consequences which happen to proceed from any action, [that] have a very great effect upon our sentiments concerning its merit or demerit, and almost always either enhance or diminish our sense of both.”¹⁰⁸ Adam Smith sophisticatedly points to a phenomenon with which all human actors are presumably familiar—that is, actions by one person can unintentionally impact the actions of other persons.¹⁰⁹ Often economists point to government legislation and regulation as a prime example of this phenomenon. The opioid crisis and the federal government's response to this crisis present a concrete depiction of this law.

Although well intentioned, the federal government response to the opioid crisis has unsuccessfully implemented broad programs that fail to identify or measure true success against the opioid crisis. Small battles have been won, such as reducing opioid prescriptions rates,

¹⁰⁷ Rob Norton, *Unintended Consequences*, THE LIBR. OF ECON. AND L. (accessed Mar. 2019), <https://www.econlib.org/library/Enc/UnintendedConsequences.html>.

¹⁰⁸ Adam Smith, *The Theory of Moral Sentiments*, Edited by Salvio M. Soares, v.1, METALIBRI (2005).

¹⁰⁹ *Id.*

increasing access to substance use disorder treatment, and decreasing market opioid saturation. But the war is far from won—the war being a significant reduction in opioid overdose deaths. From a regulatory standpoint, the previous section showed how the solution to the crisis is less obvious than one might hope. The many directives, studies, guidelines, and recommendations reveal that the opioid crisis is a complicated topic given the diversity of opioid definition, use, and users. Part III now reviews unintended functional consequences related to patient populations in light of the complicate nature of the opioid epidemic and federal reform environment.

A. PRESCRIPTION CONSTRAINTS

Placing restrictions on prescribing methods, volume, and quantity seems to be an obvious solution to the opioid crisis. President Trump said it himself, “[t]he best way to prevent drug addiction and overdose is to prevent people from abusing drugs in the first place. If they don’t start, they won’t have a problem.”¹¹⁰ In line with this reasoning, many state legislatures and commercial pharmacies have imposed prescribing restrictions based on CDC guidelines.¹¹¹ However, the reality of mitigating the opioid crisis is undoubtedly more complex than simply restricting prescription practices. Unfortunately, “some pharmacies and regulatory bodies placed opioid restrictions across the board, thereby reducing access to those with advanced or terminal illnesses.”¹¹² This broad application of intentionally narrow guidelines “presents challenges to pain and symptom management”¹¹³ Removing or severely restricting the ability to prescribe opioids

¹¹⁰ WHITE HOUSE HEALTHCARE FACT SHEET: President Donald J. Trump is Taking Action on Drug Addiction and the Opioid Crisis, (Oct. 2017), <https://www.whitehouse.gov/briefings-statements/president-donald-j-trump-taking-action-drug-addiction-opioid-crisis/>.

¹¹¹ Andrew M. Parker, et. al., *State Responses to the Opioid Crisis*, 46, THE J. OF LAW, MED., AND ETHICS (2018), <https://journals.sagepub.com/doi/10.1177/1073110518782946>.; Susan Scutti and Nadia Kounang, *CVS Will Limit Opioid Prescriptions to 7 Days*, CNN HEALTH + (Sept. 2017), <https://www.cnn.com/2017/09/22/health/cvs-prescription-restrictions-opioids-bn/index.html>.

¹¹² See Maxwell, *supra* note 87.

¹¹³ *Id.*

from a physician's treatment toolbox can inhibit the effectiveness of patient treatment. Thus, there is a

growing concern that increasing restrictions on access to opioids, put into place by many health insurance companies and pharmacies [at the direction of federal and local governments] in an effort to reduce opioids misuse, may inadvertently harm patients with life-limiting illness if those patients are no longer able to receive adequate pain relief because of regulatory barriers or inadequate availability.¹¹⁴

In addition to growing concern over broad guideline application, there is "limited evidence [that] suggests...[that the government] interventions aimed at reducing the supply of prescription opioids in the community...may help curtail access."¹¹⁵ In other words, despite best government efforts, restricting prescription capabilities and reducing pharmacy supplies does not keep addicts from finding alternative opioid sources to sustain their addiction. Moreover, while addicts will venture outside legal opioid supplies to find their next fix, patients with a legitimate medical need for opioid-induced pain relief may have their access unnecessarily reduced, or, at the least, complicated—without legal and effective pain treatment alternatives when regulatory restrictions become overly burdensome. This result impedes healthcare delivery to critically ill patient populations, and risks causing additional physical and psychological harm to their patients. Further, the critically ill patient population is large and growing as baby boomers continue to age.¹¹⁶ Thus, the problem only promises to balloon, and the impact from patchwork federal directives on the form and quality of care that this enlarging patient population receives should not be ignored.

¹¹⁴ Yael Schenker, et. al., *Use of Palliative Care Earlier in the Disease Course in the Context of the Opioid Epidemic*, AM. MED. ASS'N VIEWPOINT (Sept. 2018).

¹¹⁵ *Id.*

¹¹⁶ See generally Mari Siegel, and Suzanne Bigelow, *Palliative Care Symptom Management in the Emergency Department: The ABC's of Symptom Management for the Emergency Physician*, THE J. OF EMERGENCY MEDICINE 1, 25 (2017), <https://reader.elsevier.com/reader/sd/pii/S0736467917307059?token=5447A809462ED4D81070DB8C024E3A0F923013AFB6F283E73C49CF5EEBDB1D8BCDC8280C9F9C2A9AC842FAF14CFB5D34>.

B. LINE DRAWING ISSUES

Recall that the 2016 CDC guidelines expressly exclude palliative care, cancer treatment, and end-of-life care from the guidelines that restricted opioid use.¹¹⁷ This means that patients may eventually transition from strict opioid use constraints as patients seeking care for chronic pain, to looser controls based on their medical status as one of the exempted categories. For patients undergoing cancer treatment, this line is clear since a patient either has a cancer diagnosis and is being treated or they are not. However, for patients receiving palliative or end-of-life care, the line is increasingly unclear.

The World Health Organization (“WHO”) defines palliative care as “an approach that improves the quality of life of patients and their families facing the problem associated with a life-threatening illness, through prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems.”¹¹⁸ Other definitions of palliative care embraced broadening the use to “any stage of serious illness, and...to...care outside the hospital.”¹¹⁹ The goal of palliative care is to enhance the quality of life for both the patient and their families.¹²⁰ Examples of the breadth of disease eligible for palliative treatment are:

[Congestive heart failure] with shortness of breath, [chronic obstructive pulmonary disease] with intractable coughing, or a person with lupus, arachnoiditis, or advanced arthritis where cure is impossible and treatment focuses on symptoms of pain interfering with the enjoyment of life.¹²¹

¹¹⁷ See PAIN: CURRENT UNDERSTANDING OF ASSESSMENT, MANAGEMENT, AND TREATMENTS, *supra* note 13

¹¹⁸ World Health Organization (“WHO”), Definition of Palliative Care (2019), <https://www.who.int/cancer/palliative/definition/en/>.

¹¹⁹ See Schenker *supra* note 100.

¹²⁰ Get Palliative Care, *Palliative Care Can Help You set Goals* (May 2017), <https://getpalliativecare.org/palliative-care-can-help-set-goals/>.

¹²¹ Thomas Kline, *When does Pain Treatment Become Palliative Care Treatment? An Office Approach—Clinical and Reimbursement Guidelines*, Personal Blog (June 2018), <https://medium.com/@ThomasKlineMD/when-does-pain-treatment-become-protected-palliative-care-treatment-339d29024b57>.

The administration of palliative care tends to be in an effort to continue care since the patient's condition remains treatable, or even curable, in order to preserve a functioning quality of life. Pain management is not the only method for maintaining the patient's quality of life, but controlling pain is a significant preservation tool to elongate physical and psychological patient durability.

After palliative treatment ends or fails, the final step in the healthcare system is end-of-life care. End-of-life care is defined as “the support and medical care given during the time surrounding death.”¹²² A primary category of end-of-life care is hospice care. Hospice care “offers medical care toward a different goal [than the goal of palliative care]: maintaining or improving quality of life for someone whose illness, disease or condition is unlikely to be cured.”¹²³ A patient is eligible for hospice when they receive “a prognosis of six months or less.”¹²⁴ Thus, the primary distinction between palliative and end-of-life care is that palliative care patients typically have a longer life expectancy—even if a disease is looming. In contrast, symptom relief, not the pursuit of healing treatment, is the main priority of hospice providers. And as symptom relief rises and life expectancy decreases, pain management becomes more important, while fear of addiction and OUD falls to the wayside since death is more or less imminent.

Definitions for palliative and hospice care are somewhat malleable. Although consensus about patient classification exists, there is movement in and out of the categories based on the patient's response to medical treatment. Malleability, however, is not a positive attribute when opioid regulation applicability is dependent upon patient categorization. Line drawing issues regarding patient categorization can emerge: for example, as opioid restrictions escalate, patients will be

¹²² National Institute on Aging, *What is End-of-Life Care?*, NAT'L INST. OF HEALTH (accessed Apr. 2019), <https://www.nia.nih.gov/health/what-end-life-care>.

¹²³ Hospice Foundation of America, *What is Hospice?*, (accessed Mar. 2019), <https://hospicefoundation.org/Hospice-Care/Hospice-Services>.

¹²⁴ Iia Hughes Broyles et. al., *End-of-Life Care and the Opioid Crisis: Potential Implications and Unintended Consequences*, RTI INTERNATIONAL: INSIGHTS BLOG (June 6, 2018), <https://www.rti.org/insights/end-life-care-and-opioid-crisis-potential-implications-and-unintended-consequences>.

more prone to seek palliative status in order to receive less constrained opioid prescriptions. However, today palliative care clinicians “have limited guidance for appropriate opioid prescribing outside the realm of [a] terminal illness.”¹²⁵ So palliative-care providers have adopted a cautious prescribing approach. Moreover, in some states, local and state governments have imposed CDC opioid prescribing analogs without exempting palliative providers.¹²⁶ Hospice providers are also concerned; “[a]necdotal reports from hospice providers suggest non-terminal patients with chronic pain are seeking care from hospice to obtain access to opioids, despite the requirement that they forgo curative care.”¹²⁷

In either case—palliative or hospice—it is not desirable for patients with a legitimate need for pain management to forage the healthcare system to obtain necessary pain medication. Incentivizing patients to forgo curative treatment (by moving prematurely from palliative care to hospice care) simply to obtain a larger prescription of opioids for pain and life-quality management is not the purpose of healthcare, nor is it the purpose of opioid crisis reform. This runs afoul of the goals of the healthcare system, by diverting specialized provider attention away from patients with pressing palliative or hospice needs to others who simply are seeking a higher prescription for justifiable pain management. This is not to say that any individual should have access to any amount of pain medication that is required in order to manage pain symptoms, because there are reliable studies indicating certain opioid dosages are lethal, regardless of the patient and their tolerance.¹²⁸

¹²⁵ Elizabeth Fehlberg, et. al., *End-of-Life Care and the Opioid Crisis: Potential Implications and Unintended Consequences*, RTI INTERNATIONAL: NEWS AND INSIGHTS (June 2018), <https://www.rti.org/insights/end-life-care-and-opioid-crisis-potential-implications-and-unintended-consequences>.

¹²⁶ See generally Larry Beresford, *Hospice and Palliative Care Providers Eye on Opioid Restrictions Warily*, The California State University: Institute for Palliative Care (accessed Apr. 25, 2019), <https://csupalliativecare.org/opioid-restrictions-2018/>.

¹²⁷ *Id.*

¹²⁸ PAIN MANAGEMENT AND THE OPIOID EPIDEMIC, *supra* note 13 at 22.

Instead, this paper proposed that physicians, not legislative classifications, should dictate when opioid prescriptions may be written within a safe prescribing spectrum. Unlike legislators, physicians are educated and licensed in medicine. The physicians are interacting with the patients and are best positioned to determine when to prescribe and when to pursue alternative forms of treatment. Overregulating physician medical practice with restrictive regulatory directives risks inhibiting a physician's necessary discretion in providing effective medical care. For not two patients are alike and treating them uniformly creates unintended harms.

This proposal does raise another pressing issue, however: drug diversion. Drug diversion occurs when patient friends and family use the patient's prescription for their own purposes. Reported "results of urine drug screens from patients with cancer and in palliative care have provided significant evidence of opioid...diversion."¹²⁹ It is true that palliative, cancer, and hospice patients are less likely to become opioid addicts than those using opioids for longer periods of time to treat chronic pain. Thus, a larger concern than the palliative care patient developing an addiction is that opioids will be inappropriately given to other through drug diversion.

Although diversion and third-party misuse are contributing factors to the growth of the opioid crisis, they remain a small percentage of the larger opioid addiction problem. Combatting drug diversion is a separate inquiry from addressing issues related to those who use opioids with a valid prescription. For third parties never obtained a valid prescription and their diversion is a crime because they are illegally re-directing a valid prescription away from its properly prescribed use and users. Instead, regulators should emphasize both appropriate drug storage and monitoring for the excessive prescription frequency to lessen the chances that prescription opiates find themselves unlawfully inserted into the community by diverting third-parties.

¹²⁹ PAIN MANAGEMENT AND THE OPIOID EPIDEMIC, *supra* note 13 at 62.

IV. CONCLUSION

If nothing else, the most obvious observation is that the opioid crisis is a real and devastating phenomenon plaguing the U.S. Pain assessment and management has become a normative mainstay in our current healthcare system and its primary conduit is opioids. Although opioid use was highly encouraged through the 1990s and into the early 2000s, OUD, addiction, and overdose deaths escalated at unprecedented rates. These statistics raised appropriate concern in the federal government, but unfortunately, this concern has manifested itself in a patchwork quilt of multifarious government directives resulting in both under- and over- inclusive features that undermine appropriate care efforts.

The Law of Unintended Consequences is in full force as critical condition patient populations experience unnecessary and unintentional restriction from pain control mechanisms. The government has engaged in overenforcement— leaving vulnerable cancer, palliative, and hospice patients to pay the price. Instead of relying on uncoordinated regulatory bodies for all the solutions, the federal government should have incorporated a more collaborative opioid solution that included physicians and other medical professionals. By building in physician perspectives and discretion, the federal government might be more effective at achieving realistic and genuine reform, rather than superficial results that do not necessarily indicate success.

The opioid crisis is still alive, and the federal response is not accomplishing its stated goals. It is, unfortunately, harming innocent patient populations. Although access to opioids, or healthcare in general, is not currently an established fundamental right in the U.S., patients do have a right to access certain pain management medications in some circumstances. Contrary to the President's emergency declaration, the opioid crisis takes more than worldwide attention and resources. It

requires all hands on deck to prevent the epidemic from spreading, treat those caught in addiction, prosecute wrongdoers contributing to the problem, and, most crucially, protect those harmed unintentionally by reform.