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A LITTLE LESS REGULATION: WHY FEDERAL PAIN MANAGEMENT LAWS ARE HURTING STATE EFFORTS TO COMBAT THE OPIOID EPIDEMIC

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I. INTRODUCTION

Dan Baker was a healthy, athletic, young man when he first enrolled at the University of St. Thomas in Saint Paul, Minnesota.[1] Instead of drinking or partying, Dan spent his time playing baseball and hockey.[2] While enrolled, he suffered a minor back injury and was prescribed opioid painkillers.[3] At that time, he had no idea about the addiction and substance abuse that would ensue.

Dan's parents first became aware there was a problem when his girlfriend expressed concern that Dan was shutting himself in his room and not attending class.[4] Soon after, Dan's parents began accompanying him to follow-up doctor's visits, only to discover that Dan had been "doctor shopping,"[5] a process whereby opioid addicts see different physicians to get the quantity and type of pain pills they desire.[6] Dan's family tried to help with his addiction, but they were unsuccessful. When Dan was no longer able to obtain prescriptions, he began to buy pills off the street.[7]

Dan eventually enrolled in a rehab center in Granite Falls, Minnesota, where he found sobriety and employment; he later got a

1. Jon Collins, *Son's Overdose Death Drives This Minnesota Legislator's Work*, MPR NEWS (Apr. 18, 2016), http://www.mprnews.org/story/2016/04/18/opioid-profiles-dave-baker.

2. *Id.*

3. *Id.*

4. *Id.*

5. *Id.*

6. *See* Neha Casturi, Comment, *A Modern Day Apocalypse: The Pill Mill Epidemic, How It Took Texas by Storm, and How Texas Is Fighting Back*, 14 TEX. TECH. ADMIN. L.J. 445, 447 (2013) (quoting Cindy Horswell, *"Pill Mill" Crackdown Nears Legislative Approval*, HOUS. CHRON. (May 26, 2011, 5:30 AM), http://www.chron.com/news/houston-texas/article/Pill-mill-crackdown-nears-legislative-approval-1603524.php) (defining "pill mills" as large networks of doctors and pharmacists who fill prescriptions for "doctor shoppers," who are individuals who "fraudulently acquire large doses of dangerous controlled substances from multiple clinics for use at the same time without disclosing the other prescriptions").

7. Collins, *supra* note 1.

room at a halfway house in Rochester, Minnesota.[8] This newfound sobriety was short-lived, however, because soon thereafter Dan was laid off from his new job and began experimenting with heroin.[9] Dan re-enrolled in the rehab center but was kicked out after sharing medication with his roommate.[10]

Dan's family was vacationing in California when he called to inform them he had been kicked out of rehab, but he assured them he would be okay until the family returned home.[11] Unfortunately, Dan was wrong. That evening, Dan and a friend bought heroin in Minneapolis and returned to the friend's home in Maplewood, a nearby suburb.[12]

The next morning, Dan's parents flew back to Minnesota and, upon their arrival, received a message that Dan had died of a heroin overdose.[13] A few years later, Dan's father, Dave Baker, was elected to the Minnesota House of Representatives, where he is currently working to expand opioid addiction programs as a memorial to his son.[14]

Another Minnesotan recently died of an opioid overdose; only this time, his death garnered national attention. In April 2016, the famous musician Prince was found dead in his home due to an overdose on the opioid fentanyl.[15] Fentanyl is a dangerous drug, more potent than both heroin and morphine.[16] Further, investigators have learned from family members that Prince had a decades-long history of opioid abuse, mainly Percocet, "to help him deal with the rigors of performing."[17] Investigators revealed that pills containing fentanyl were found in a bottle marked hydrocodone,

8. *Id.*
9. *Id.*
10. *Id.*
11. *Id.*
12. *Id.*
13. *Id.*
14. *Id.*
15. Stephen Montemayor, *Pills Seized from Paisley Park Contained Illicit Fentanyl, Same Drug That Killed Prince*, STAR TRIB. (Aug. 21, 2016, 9:15 PM), http://www.startribune.com/pills-seized-from-paisley-park-contained-illicit-fentanyl-same-drug-that-killed-prince/390816101/ (stating that although investigators believe Prince unknowingly took the drug, they are still uncertain).
16. *Id.*
17. *Id.*

and they believe the mislabeling caused Prince to unknowingly ingest the opioid.[18]

Unfortunately, stories similar to Dan's and Prince's have become increasingly common across Minnesota and the nation. Since 1999, deaths from opioid overdoses have steadily risen and show little sign of slowing down.[19] At the same time, the amount of opioid prescriptions has quadrupled, and in 2014, for the first time, deaths from opioid overdoses surpassed deaths from car crashes.[20]

Why has this become a problem? For one, opioids are extremely addictive.[21] Opioids increase dopamine levels in the brain, causing a person to experience more cravings.[22] Overdoses occur when someone takes a dosage his or her body is not used to, which is why buying prescription opioids off the street is particularly dangerous, since no one can be certain of the dosage or purity of the drug.[23] When an overdose occurs, an individual's respiratory system shuts down, essentially causing the body to forget to breathe.[24]

State and federal governments responded to this crisis with legislation aimed at curbing opioid abuse.[25] Though well-intended, the current legislation may have developed a perfect storm for a crisis. This Note begins by providing a history of opioid usage throughout the world and outlining opioid regulations in the United States during the past century.[26] Next, this Note examines statistics demonstrating the current state of opioid abuse.[27] This is followed

18. *See id.*

19. *See* Jon Collins, *Here's Why Minnesota Has a Big Problem with Opioid Overdoses*, MPR NEWS (Apr. 18, 2016), http://www.mprnews.org/story/2016/04/18/opioid-overdose-epidemic-explained.

20. *See* Rose A. Rudd et al., *Increases in Drug and Opioid Overdose Deaths—United States, 2000–2014*, 64 MORBIDITY & MORTALITY WKLY. REP. 1378, 1379, 1381 (2016).

21. *See* Collins, *supra* note 19.

22. *See id.*

23. *See id.*

24. *See id.*

25. *See What Is the Federal Government Doing to Combat the Opioid Abuse Epidemic?: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 114th Cong. 45–53 (2015) (statement of Nora D. Volkow, Director, Nat'l Inst. on Drug Abuse) [hereinafter Volkow], http://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2016/what-federal-government-doing-to-combat-opioid-abuse-epidemic (outlining some of the programs governments have undertaken to address opioid abuse).

26. *See infra* Sections II.A–B.

27. *See infra* Section II.C.1.

by an examination of the pain management standards from The Joint Commission on Accreditation of Healthcare Organizations (TJC),[28] the recent guidelines from the Centers for Disease Control and Prevention (CDC),[29] and the effect of the Affordable Care Act (ACA) on the opioid abuse epidemic.[30] This Note then discusses current federal and state combative measures[31] and analyzes the effectiveness of the patient satisfaction survey requirement under the ACA and TJC's pain management standard.[32] Finally, this Note will look at the effectiveness of both state prescription drug monitoring programs (PDMPs)[33] and naloxone distribution programs.[34] In sum, this Note argues that although current combative measures have had a positive impact on decreasing prescription opioid abuse, major change will not occur until patient satisfaction surveys are removed from the ACA altogether or penalties from low scores are lessened and TJC's pain management standard is clarified.[35]

II. FROM GENERAL ACCEPTANCE TO HEAVY REGULATION: HOW THE HISTORY OF OPIOID USE HAS SHAPED OPIOID REGULATION TODAY

Opioids have been used as pain relievers for thousands of years, and their addictiveness was known even to early users.[36] This Part provides a general history of opioid use and abuse in order to provide a foundational perspective on today's regulatory environment surrounding opioids.

A. Early History of Opioid Use Around the World

The first recorded uses of opium were found in ancient Mesopotamia around the end of the third millennium B.C.[37]

28. *See infra* Section II.C.2.
29. *See infra* Section II.C.3.
30. *See infra* Section II.C.4.
31. *See infra* Section II.C.5.
32. *See infra* Sections III.A–D.
33. *See infra* Section III.E.1.
34. *See infra* Section III.E.2.
35. *See infra* Part IV.
36. *See The Birth of a Stereotype*, NAT'L ALLIANCE ADVOCS. FOR BUPRENORPHINE TREATMENT, https://www.naabt.org/education/birth_of_a_stereotype.cfm (last visited May 18, 2017) (mentioning that early literature used the term "opium sickness" to describe the addictiveness of the drug).
37. *See* Michael J. Brownstein, *A Brief History of Opiates, Opioid Peptides, and Opioid*

However, it was not until the later part of the nineteenth century that society began to notice high rates of addiction to the popular opium derivative morphine.[38] Since that time, healthcare providers have struggled with balancing high rates of addiction to opioids with the patient pain relief the drugs provide.[39]

Scholars have had difficulty determining when the opium poppy was first cultivated because ancient authors were often ambiguous regarding drug use and abuse; nonetheless, it is generally thought that the Sumerians in ancient Mesopotamia (modern-day Iraq) first cultivated the poppy toward the latter half of 3000 B.C.[40] The Sumerians referred to the opium as "gil" or "joy" and called the poppy "hul gil," meaning "plant of joy."[41] Opium usage then spread to the Assyrians and later to the Egyptians.[42]

Opium eventually spread to the Greeks.[43] Sometime between 460 and 357 B.C., Hippocrates, the "father of modern medicine,"[44] described the white, fire-red, and black poppy and acknowledged each one's usefulness in treating certain diseases.[45] Around the same time, Alexander the Great introduced opium to India when he and his army took poppy with them to war.[46]

Receptors, 90 PROC. NAT'L ACAD. SCI. U.S. 5391, 5391 (1993), http://www.pnas.org/content/90/12/5391.full.pdf.

38. *Id.*

39. *See generally Opium Throughout History*, PBS, http://www.pbs.org/wgbh/pages/frontline/shows/heroin/etc/history.html (last visited May 18, 2017) (providing a timeline on the history opium and its derivatives).

40. *See* Brownstein, *supra* note 37, at 5391.

41. *Id.*

42. *See id.*

43. *See generally* P.G. Kritikos & S.P. Papadaki, *The History of the Poppy and of Opium and Their Expansion in Antiquity in the Eastern Mediterranean Area*, U.N. OFF. ON DRUGS & CRIME BULL. ON NARCOTICS (Jan. 1, 1967), https://www.unodc.org/unodc/en/data-and-analysis/bulletin/bulletin_1967-01-01_3_page004.html#bf001 (presenting research regarding poppy and opium use amongst ancient Greeks).

44. Christos Yapijakis, *Hippocrates of Kos, the Father of Clinical Medicine, and Asclepiades of Bithynia, the Father of Molecular Medicine*, 23 INT'L J. EXPERIMENTAL & CLINICAL PATHOPHYSIOLOGY & DRUG RES. 507, 508 (2009) (arguing that Hippocrates pioneered medicine based on rational conclusions instead of religious or magical beliefs, which was the common practice at the time).

45. *See id.*

46. *Id.* It should be noted that Alexander the Great did not introduce the poppy to India, but it is believed he introduced opium as a derivative from poppies. *See id.*

Around the fourth century A.D., opium had reached China through Arab traders, but accounts of opium use there had been noted even earlier.[47] Sometime between 200 and 264 A.D., a renowned Chinese surgeon, Hua To, is said to have had his patients ingest opium before undergoing surgery.[48]

Little was written in Western literature about opioid usage during the first two hundred years of the early modern era, roughly between 1300 and 1799; however, towards the latter half of this period, the modern opioid pill was created.[49] Beginning around 1300, references to opium disappeared from the historical record, most likely due to the Holy Inquisition happening in Europe at the time: opium was from the "East," and anything from the East was thought to be linked to the devil.[50]

In 1527, Paracelsus, a Swiss-German alchemist and the founder of toxicology, created opium pills and prescribed them as painkillers.[51] He derived a specific compound of opium that was effective in reducing considerable amounts of pain and called this element laudanum, a drug still available by prescription in the United States today.[52]

Innovations in medicine dramatically increased opioid usage in the nineteenth century. In 1806, German chemist Friedrich Wilhelm Adam Sertürner isolated morphine from opium.[53] After its introduction into U.S. medicine, morphine became a "mainstay" in chronic pain treatment and was used to treat all sorts of ailments.[54]

47. *Opium—Poppy Cultivation, Morphine and Heroin Manufacture*, THE VAULTS OF EROWID, https://www.erowid.org/archive/rhodium/chemistry/opium.html (last visited May 18, 2017).

48. *Id.*

49. *Opium Throughout History*, *supra* note 39; Purdue Pharma, *A Brief History of Opioids: Pain, Opioids and Medicinal Use*, THE ATLANTIC, http://www.theatlantic.com/sponsored/purdue-health/a-brief-history-of-opioids/184 (last visited May 18, 2017).

50. *Opium Throughout History*, *supra* note 39.

51. *See id.*; Purdue Pharma, *supra* note 49.

52. Purdue Pharma, *supra* note 49.

53. Brownstein, *supra* note 37, at 5391.

54. Renata Ferrari et. al., *Risk Factors in Opioid Treatment of Chronic Non-Cancer Pain: A Multidisciplinary Assessment*, *in* PAIN MANAGEMENT: CURRENT ISSUES AND OPINIONS 419, 420 (Gabor B. Racz & Carl E. Noe eds., 2012), www.intechopen.com/books/pain-management-current-issues-and-opinions/risk-factors-in-opioid-treatment-of-chronic-non-cancer-pain-a-multidisciplinary-assessment (stating that opium was used to treat pain, anxiety, and respiratory problems, as well as "consumption" and "women's ailments").

By the 1850s, the invention of the hypodermic needle allowed for opium to be used in minor surgical procedures.[55] Physicians found that injecting opium reduced the amount of chloroform needed for surgical anesthesia.[56] Morphine was also used on soldiers during the U.S. Civil War, and morphine addiction became so common among veterans that it became known as "soldier's disease."[57]

Morphine addiction alarmed physicians, so many years were spent trying to find a safer, less addictive alternative.[58] An alternative was thought to be found in 1898, when scientists synthesized heroin, a drug "more potent than morphine and free from abuse liability."[59] Clearly this was not true, however, as opioid addicts frequently abuse heroin today.[60]

B. Opioid Use and Regulation in Recent American History

Opium regulation began in the early twentieth century during the Progressive Era.[61] In 1909, Congress passed the Opium Exclusion Act, barring opium imports for smoking purposes.[62] This Act only applied to opium used for smoking, a practice favored by the new Chinese immigrants; it did not apply to medicinal uses of opium.[63]

In 1914, Congress imposed further regulations on opioids with the passage of the Harrison Narcotics Tax Act.[64] The original

55. Brownstein, *supra* note 37, at 5391.

56. *Id.* Claude Bernard first discovered this use of morphine by using it to premedicate animals. *Id.*

57. *See* Amy Davidson, *The "Soldier's Disease,"* THE NEW YORKER (Nov. 11, 2010), http://www.newyorker.com/news/amy-davidson/the-soldiers-disease.

58. Brownstein, *supra* note 37, at 5391.

59. *Id.*

60. As of 2015, approximately 591,000 Americans age twelve and older had a substance abuse problem involving heroin. *Opioid Addiction: 2016 Facts and Figures*, AM. SOC'Y OF ADDICTION MED., http://www.asam.org/docs/default-source/advocacy/opioid-addiction-disease-facts-figures.pdf (last visited May 18, 2017).

61. *See A History of Opiate Laws in the United States*, NAT'L ALLIANCE OF ADVOCS. FOR BUPRENORPHINE TREATMENT, https://www.naabt.org/laws.cfm (last visited May 18, 2017) (explaining that the 1909 Smoking Opium Exclusion Act was the first time the federal government banned the non-medical use of a substance).

62. Dale Gieringer, *The Opium Exclusion Act of 1909*, COUNTERPUNCH (Feb. 6, 2009), http://www.counterpunch.org/2009/02/06/the-opium-exclusion-act-of-1909/. Some believe the passage of this act was the unofficial beginning of the War on Drugs. *See id.*

63. *Id.*

64. *See* David T. Courtwright, *The Hidden Epidemic: Opiate Addiction and Cocaine Use in the South, 1860–1920*, 49 J. SOUTHERN HIST. 57, 57–58 (1983),

interpretation of the Act only required physicians and pharmacists to approve the distribution of opioids, but the Supreme Court expanded the breadth of the statute.[65] In *Webb v. United States*, the Court ruled that under the Harrison Act, a physician could not continually supply an addict solely to maintain that patient's addiction.[66] In the aftermath of *Webb*, addicts were denied a legal source of opioids, forcing many of them to turn to the black market.[67] In an effort to mitigate illegal drug purchases, local municipalities established narcotics clinics, which supplied drugs—and sometimes treatment—to addicts.[68] However, the federal government, relying on the *Webb* rule, forced many of these clinics to close.[69]

While physicians were being blamed for creating morphine dependence and manufacturers were pulling heroin-laced products from the shelves, scientists were again attempting to create a non-addictive pain-relieving alternative to opioids.[70] The New York Medical Journal described "morphinism [as] a disease, in the majority of cases, initiated, sustained and left uncured by members of the medical profession."[71] By 1916, due to its known harmful effects and addiction, Bayer pharmaceuticals stopped using heroin in cough suppressants.[72] That same year, German scientists first synthesized oxycodone, hoping that it would retain the same pain-relieving effects as morphine and heroin but without the addiction.[73]

The 1920s and 1930s brought even more regulation of prescription opioids and heroin.[74] In 1924, Congress passed the Heroin Act, effectively banning the importation, manufacture, and possession of heroin.[75] The Act also made medicinal heroin illegal

https://www.unf.edu/~dcourtwr/documents/The%20Hidden%20Epidemic.pdf.

65. *See A History of Opiate Laws in the United States*, *supra* note 61 (discussing the Supreme Court rulings upholding the Harrison Act).

66. *See* 249 U.S. 96, 99–100 (1919).

67. *See* Courtwright, *supra* note 64, at 58.

68. *Id.*

69. *Id.*

70. *See* Purdue Pharma, *supra* note 49.

71. Foster Kennedy, *The Effects of Narcotic Drug Addiction*, 100 N.Y. MED. J. 20, 20 (1914).

72. Purdue Pharma, *supra* note 49.

73. *Id.*

74. *Id.*

75. *Id.*

for the first time.[76] In 1938, Congress authorized one of the largest regulations of drug monitoring in history by creating the United States Food and Drug Administration (FDA), under the Food, Drug, and Cosmetic Act (FDCA), to oversee the safety of drugs before they were sold.[77] The FDA did not outlaw the use of opioids already sold—codeine, morphine, and oxycodone—so physicians could still prescribe these drugs to patients.[78]

During the 1950s and 1960s, there were large increases in the usage of both prescription opioids and heroin.[79] In 1950, access to oxycodone expanded when the FDA approved Percodan, a mix of the opioid oxycodone with aspirin.[80] With the wide availability of oxycodone came widespread dependence on the drug, which is still a problem today.[81] In the 1960s, there was a resurgence in illegal heroin smuggling into the country, which was attributed to the ongoing Vietnam War.[82] Finally, in 1969, the World Health Organization stated that medicinal morphine does not necessarily lead to dependence and for the first time distinguished between tolerance and physical dependence on the one hand and drug dependence on the other.[83]

In 1970, Congress responded to increased opioid and drug use with the passage of the Controlled Substances Act, which placed all prescription narcotics and opioids into five so-called schedules.[84] The opioids placed in Schedule I were considered the most dangerous and were no longer allowed to be prescribed.[85] By the mid-1970s, President Nixon had created the Drug Enforcement Agency (DEA) and officially declared the War on Drugs.[86]

76. *Id.*

77. *See* Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938). *See generally* Katharine A. Van Tassel, *Slaying the Hydra: The History of Quack Medicine, the Obesity Epidemic, and the FDA's Battle to Regulate Dietary Supplements Marketed as Weight Loss Aids*, 6 IND. HEALTH L. REV. 203, 223–25 (2009) (providing a general overview of the passage of the FDCA, which gave rise to the FDA).

78. Purdue Pharma, *supra* note 49.

79. *See id.*; *Opium Throughout History*, *supra* note 39.

80. *See* Purdue Pharma, *supra* note 49.

81. *See id.*

82. *See Opium Throughout History*, *supra* note 39.

83. Purdue Pharma, *supra* note 49.

84. *See* 21 U.S.C. § 812(b) (2012).

85. *See id.* § 812(b)(1).

86. *See* Letter from President Richard Nixon to Congress (June 17, 1971), http://www.presidency.ucsb.edu/ws/?pid=3048.

A phenomenon occurred in clinics and hospitals across the country during the 1980s that had a huge effect on the standard of care for treating patient pain in the following decades.[87] This phenomenon was called "opiophobia," which meant a physician's fear to prescribe opioids—even in cases of terminal illness.[88] There have been many theories about what led to the rise of opiophobia, ranging from unfounded fears (that any opioid prescription would cause addiction) to blatant racism (where many physicians refused to prescribe opioids to African Americans because of the racist belief that African Americans were more likely to become drug addicts).[89] Despite the rise of opiophobia, however, some physicians did begin to use prescription opioids to treat pain unrelated to terminal illness, a practice that many believe contributed to the opioid abuse epidemic today.[90]

A consequence of opiophobia from the 1980s was an epidemic of pain undertreatment in the 1990s.[91] Throughout the decade, many clinicians and organizations lobbied federal and state legislators to allow increased use of opioids to treat all pain, not just pain associated with terminal illness.[92]

While physicians and pain societies were busy lobbying Congress, opioid manufacturers were researching more efficient ways to manage pain.[93] Scientists invented extended-release opioids, which were more effective in managing pain because the pill's soothing effects were slowly released over time rather than all at

87. *See* Timothy J. Atkinson et al., *The Damage Done by the War on Opioids: The Pendulum Has Swung Too Far*, 201 J. PAIN RES. 265, 265 (2014) (describing how "the American pain medicine landscape was characterized by opiophobia, the fear to prescribe opioids").

88. *Id.*

89. *See* Annemarie Daly Linares, *Opioid Pseudoaddiction: A Casualty of the War on Drugs, Racism, Sexism, and Opiophobia*, 15 QUINNIPIAC HEALTH L.J. 89, 104–06 (2012).

90. *See generally* Sujata S. Jayawant & Rajesh Balkrishnan, *The Controversy Surrounding OxyContin Abuse: Issues and Solutions*, 1 THERAPEUTICS & CLINICAL RISK MGMT. 77 (2005) (discussing how OxyContin has been used to treat severe pain, not just pain associated with terminal cancers).

91. *See* Ben A. Rich, *A Prescription for the Pain: The Emerging Standard of Care for Pain Management*, 26 WM. MITCHELL L. REV 1, 2 (2000) (describing how healthcare scholarship has documented a serious and persistent problem—the undertreatment of pain and the failure to effectively address suffering in the clinical setting).

92. *See* Atkinson et al., *supra* note 87, at 265.

93. *See* Purdue Pharma, *supra* note 49.

once, as was done in the past.[94] Marketers took advantage of both this new technology and increased consumer demand and began to heavily advertise the use of extended-release prescription opioids.[95] By 1999, around 2.6 million Americans age twelve and older were misusing prescription pain relievers.[96]

In the first decade of the new millennium, both healthcare leaders and legal scholars began to push for pain management to be heavily considered in a physician's applicable standard of care.[97] During this time, TJC began to incorporate these new standards of care, calling pain the "fifth vital sign."[98]

Concurrently, prescription opioid abuse continued to increase, with the rates of abuse doubling between 1998 and 2008.[99] By the mid-2000s, pharmaceutical companies were researching ways to make opioids harder to abuse, but none of the new formulas prevented oral abuse.[100] The FDA also implemented educational programs warning providers about opioid abuse.[101]

C. Opioid Abuse Today

1. The Modern Opioid Epidemic

The United States suffers from an opioid abuse epidemic unseen in previous decades. In 2014, 21.5 million Americans age twelve or older had a substance abuse disorder.[102] Of that 21.5 million, 1.9 million were addicted to prescription pain relievers, and 586,000 were addicted to heroin.[103]

94. *Id.*

95. *Id.*

96. *Prescription Drug Abuse Statistics*, BAYSIDE MARIN (Nov. 19, 2016), http://www.baysidemarin.com/prescription-drugs/abuse-statistics/.

97. *See* Rich, *supra* note 91, at 2–3.

98. Atkinson et al., *supra* note 87, at 265.

99. Purdue Pharma, *supra* note 49; *see* Rudd et al., *supra* note 20, at 1378 (discussing the overall increase of opioid drug abuse, specifically focusing on overdose deaths in the United States since 2000).

100. Purdue Pharma, *supra* note 49.

101. *Id.*

102. SARRA L. HEDDEN ET AL., SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., BEHAVIORAL HEALTH TRENDS IN THE UNITED STATES: RESULTS FROM THE 2014 NATIONAL SURVEY ON DRUG USE AND HEALTH 2 (2015), https://www.samhsa.gov/data/sites/default/files/NSDUH-FRR1-2014/NSDUH-FRR1-2014.pdf.

103. *Id.* at 22, 27.

Opioid overdose death rates have continued to rise.[104] In 2014, more people died of lethal drug overdoses than in any year on record, totaling 47,055.[105] Of those 47,055 lethal drug overdoses, which was more than one-and-a-half times the number of deaths from motor vehicle crashes in the country,[106] 18,893 (or 40% of the total) were from prescription painkillers, and 10,574 (22%) were from heroin.[107] This is a sharp rise from 1999, when there were 16,849 lethal drug overdoses in the United States, with only 4030 (24%) related to prescription painkillers and 1960 (12%) related to heroin.[108] In every year from 1999 to 2014, with the exception of 2012, the number of deaths from prescription painkillers has increased.[109]

The sale of prescription opioids across the United States has also steadily risen since 1999.[110] In 2011, there were 7,200,000 milligrams of prescription opioids sold across the country, compared with 1,800,000 milligrams sold in 1999.[111] Minnesota's opioid abuse pattern mirrors the national abuse trend.[112] From 1999 to 2014, the number of opioid overdoses across the state rose more than 500%, with 319 deaths in 2014, compared to sixty in 1999.[113] As with the national trend, prescription painkillers have been the leading cause of opioid-related deaths from 1999 to 2014, with 1767 deaths, compared to 1495 deaths from non-prescription opioids.[114] Both national and state trends show opioid abuse is growing, and there is little to no sign of these trends slowing down.

2. The TJC Pain Management Standard

The TJC Pain Management Standard, which was introduced in 2001 and encouraged hospitals to create pain assessment policies

104. Rudd et al., *supra* note 20, at 1378.
105. *Id.*
106. *Id.*
107. CTRS. FOR DISEASE CONTROL, NUMBER AND AGE-ADJUSTED RATES OF DRUG-POISONING DEATHS INVOLVING OPIOID ANALGESICS AND HEROIN: UNITED STATES, 1999–2014, http://www.cdc.gov/nchs/data/health_policy/AADR_drug_poisoning_involving_OA_Heroin_US_2000-2014.pdf (last visited May 18, 2017).
108. *Id.*
109. *Id.*
110. Collins, *supra* note 19.
111. *Id.*
112. *Id.*
113. *Id.*
114. *Id.*

and procedures,[115] could be a reason why physicians are overprescribing opioids.[116] The standard may encourage "physicians, dentists, and nurse practitioners—rather than drug cartels and street dealers—[to] play prominent roles in escalating drug use."[117] The standard discusses how pain management is an important part of patient-centered care and requires that certain healthcare providers implement strategies to help the patient fight pain.[118] In July 2015, TJC clarified the two different strategies that providers should use to alleviate pain: pharmacologic and nonpharmacologic.[119] The standard clarifies that the strategies are not exhaustive and that providers and patients should work together in implementing an efficient pain management strategy; it also clarifies that the provider should discuss the risks and benefits of each option with the patient, including the risk of addiction and abuse.[120]

TJC likely clarified its 2001 Pain Management Standard in July 2015 because of the negative attention TJC received regarding its perceived role in the opioid abuse epidemic.[121] Since TJC released this clarification only recently, it may be too early to see if it will have any effect in curbing the number of opioid prescriptions and frequency of abuse.

115. JOINT COMM'N ON ACCREDITATION OF HEALTHCARE ORGS., JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS PAIN STANDARDS FOR 2001, https://www.jointcommission.org/assets/1/6/2001_Pain_Standards.pdf (last visit Apr. 27, 2017) (outlining how healthcare organizations should assess and treat pain).

116. *See* Nathan Trexler, *Developments in Delaware Health Law: Addressing Prescription Drug Abuse*, 14 DEL. L. REV. 29, 29 n.4 (2013).

117. Jeanmarie Perrone & Lewis S. Nelson, *Medication Reconciliation for Controlled Substances—An "Ideal" Prescription-Drug Monitoring Program*, 366 NEW ENG. J. MED. 2341, 2341 (2012).

118. The Joint Comm'n, *Clarification of the Pain Management Standard*, 34 JOINT COMMISSION PERSP. 11, 11 (2014) [hereinafter *TJC 2015 Pain Management Standard*]. This pain management standard applies to "Ambulatory Care, Critical Access Hospital[s], Home Care, Hospital[s], Nursing Care Centers, and Office-Based Surgery Practice Programs." *Id.*

119. *Id.* Nonpharmacologic strategies include "physical modalities (for example, acupuncture therapy, chiropractic therapy, osteopathic manipulative treatment, massage therapy, and physical therapy), relaxation therapy, and cognitive behavioral therapy." *Id.* Pharmacologic strategies include "nonopioid, opioid, and adjuvant analgesics." *Id.*

120. *Id.*

121. *See id.* Medical scholars believe that TJC's pain management standards have led to the "liberalization" of physicians prescribing opioids. Trexler, *supra* note 116, at 29 n.4 (quoting Perrone & Nelson, *supra* note 117, at 2341).

3. New CDC Guidelines

In the face of the mounting crisis, the CDC recently expanded its efforts to combat opioid addiction. In March 2016, the agency published new guidelines for prescribing opioids to patients with chronic pain outside of cancer treatment, palliative care, and end-of-life treatment.[122] The CDC arrived at these recommendations after reviewing scientific data about "the effectiveness, benefits, and harms of long-term opioid therapy for chronic pain"[123] and grouped the recommendations into three categories: "determining when to initiate or continue opioids for chronic pain[;] [o]pioid selection, dosage, duration, follow-up, and discontinuation[;] [and] [a]ssessing risk and addressing harms of opioid use."[124]

The first group of CDC recommendations revolves around when to initiate or continue opioid therapy.[125] The CDC essentially gives two recommendations: first, physicians should prioritize nonopioid therapy; and second, physicians should continually discuss the realistic goals and benefits—as well as the risks—of opioid therapy with the patient.[126] These recommendations complement TJC's clarifications that its standards do not require opioid therapy for pain management and that opioids should only be prescribed when appropriate.[127] Together, the CDC recommendations and TJC clarifications emphasize to physicians that opioid therapies are not ideal and should be avoided when possible, thus potentially helping to curb opioid abuse.

The next four recommendations concern "[o]pioid selection, dosage, duration, follow-up, and discontinuation."[128] Many of the

122. *See* Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, 65 MORBIDITY & MORALITY WKLY. REP. 1 (2016).

123. *Id.* at 8.

124. *Id.* at 15.

125. *Id.* at 16. There are three recommendations for initiating or continuing opioid therapy: (1) nonopioid therapy is preferred; (2) physicians should establish realistic treatment goals with patients; and (3) the physician should continually discuss with the patient the risks and benefits of opioid therapy. *Id.*

126. *See id.*

127. *See* David W. Baker, *Joint Commission Statement on Pain Management*, THE JOINT COMMISSION (Apr. 18, 2016), https://www.jointcommission.org/joint_commission_statement_on_pain_management/.

128. Dowell et al., *supra* note 122, at 15. The four recommendations state that (1) physicians should prescribe immediate-release opioids; (2) patients should be prescribed the lowest effective dose and be carefully evaluated when increasing the dose; (3) patients should only be prescribed opioids for the number of days they

recommendations in this category reflect common sense, such as physicians only prescribing the lowest effective dose and only prescribing opioids for the number of days needed.[129] Recently, states such as Louisiana have passed legislation to limit the number of days physicians can prescribe opioids in accord with the CDC recommendations.[130] As of today, nine states have codified similar limitations, but some still allow pharmacists to prescribe for thirty-day periods, which is far beyond the maximum recommended by the CDC.[131]

The final five recommendations involve assessing the risks and addressing the harms of opioid abuse.[132] The CDC encourages constant monitoring of the patient undergoing opioid therapy, which again parallels TJC's recent clarifications requiring the provider to assess and reassess the patient's pain during opioid

will need them, usually three days or less and seven days in rare circumstances; and (4) physicians should evaluate patients throughout the opioid therapy, and if risks of continued opioid therapy outweigh the benefits, physicians should prioritize nonopioid therapies, taper patients to a lower dosage of opioids, or "taper and discontinue opioids." *Id.* at 16.

129. *Id.*

130. H.R. 192, 2017 Leg., 43d Sess. (La. 2017). *See generally* Elizabeth Crisp, *Legislature Advances Bill to Limit Opioid Prescriptions, Others to Address Opioid "Epidemic,"* THE ADVOC. (Apr. 26, 2017, 6:27 PM), http://www.theadvocate.com/baton_rouge/news/politics/legislature/article_e0407f38-2a96-11e7-b669-a3bbcfc86159.html (discussing opioid legislation in Louisiana).

131. *See generally* CONN. GEN. STAT. ANN. § 20-14o(b) (West, Westlaw through 2017); ME. REV. STAT. ANN. tit. 32, § 2600-C (West, Westlaw through 2017 Reg. Sess. of the 128th Legis.); MASS. GEN. LAWS ANN. ch. 94C, § 19D (West, Westlaw through 2017); N.J. STAT. ANN. § 24:21-15.2(a) (West, Westlaw through 2017); N.Y. PUBLIC HEALTH LAW § 3331 (McKinney, Westlaw through 2017); 35 PA. STAT. AND CONS. STAT. ANN. § 873.3 (West, Westlaw through 2017); 21 R.I. GEN. LAWS. ANN. § 21-28-3.18(l) (West, Westlaw through 2017); 24 DEL. ADMIN. CODE § 9.0 (2016); 13-14-076 VT. CODE R. § 8.1.9 (2017).

132. Dowell et al., *supra* note 122, at 16. The five recommendations suggest that (1) physicians evaluate patients' risk factors for opioid abuse; (2) physicians review state Prescription Drug Monitoring Programs continually to ensure patients are not abusing opioids; (3) physicians conduct urine drug testing throughout opioid therapy; (4) physicians avoid prescribing opioids and benzodiazepines concurrently, as they depress the central nervous system and increase the respiratory drive, placing a patient at a greater risk for overdose; and (5) if a physician concludes a patient has an opioid abuse disorder, the physician should provide the patient with a combination of medication-assisted treatment and behavioral therapy. *Id.* (citing *id.* at 32 and discussing the harms of prescribing opioids and benzodiazepines concurrently).

treatment.[133] This group of CDC recommendations presumes that if a physician consistently monitors a patient throughout opioid therapy, that physician will be able to spot red flags before additional problems develop and can provide the patient the help he or she needs.

The CDC makes clear that these guidelines are just one step in combating opioid addiction and that physicians must make an effort to comply with these guidelines in order to see effective results.[134] The guidelines will be revisited when new evidence regarding their effectiveness comes to light.[135]

4. The Effect of the ACA

The ACA includes a patient satisfaction requirement, which has also incentivized physicians to overprescribe opioids.[136] In October 2012, a portion of the ACA was revised to require hospitals to report data from patient satisfaction surveys.[137] The model survey was developed by the Centers for Medicare and Medicaid Services and the Agency for Healthcare Research and Quality.[138] The survey allows patients to rate the hospital on nine key topics, notably including pain management: "communication with doctors, communication with nurses, responsiveness of hospital staff, pain management, communication about medicines, discharge information, cleanliness of the hospital environment, quietness of the hospital environment, and transition of care."[139] Thirty percent of the hospital's overall quality rating depends on the patient

133. *See* Baker, *supra* note 127.

134. Dowell et al., *supra* note 122, at 33.

135. *Id.* at 35.

136. *See* Alyse Fischer, *Tough Love: Why Patients Should Change Physician Expectations*, 25 ANNALS HEALTH L. ADVANCE DIRECTIVE 97, 103–04 (2015) ("[P]hysicians admit they have changed their course of practice due to these new provisions under the ACA. One disturbing example of this change is doctors who prescribe stronger drugs than a patient needs just to increase patient satisfaction scores.").

137. *Id.* at 101.

138. *Id.*

139. HOSP. CONSUMER ASSESSMENT OF HEALTHCARE PROVIDERS AND SYS.: CAHPS HOSP. SURVEY, http://www.hcahpsonline.org/ (last visited May 18, 2017). The survey also includes questions about demographic information and patient perspectives on care. *Id.* These other topics do not have an impact on the opioid abuse epidemic. *Id.*

satisfaction survey responses, and a low rating could impact the hospital's Medicare funding.[140]

In an effort to enforce the new ACA provision, the federal government withheld $850 million from hospitals upon implementation, an amount expected to double in 2017.[141] To earn this money back, hospitals must report high patient satisfaction scores.[142] This implementation measure has placed ACA-bound hospitals at risk of losing anywhere between $500,000 and $850,000 annually.[143] As of 2017, all physicians who accept Medicare patients will see their pay linked to responses from these patient satisfaction surveys.[144]

Recent studies have concluded that tying Medicare funding to patient satisfaction surveys has negatively impacted healthcare and contributed to the opioid abuse epidemic.[145] With the new ACA provisions, physicians subscribe to the belief that "[m]ore tests and stronger drugs equal more satisfied patients, and more satisfied patients equal more pay."[146] Now, some hospitals overtreat patients by taking measures such as providing prescription medications to all patients discharged from the hospital.[147] Providing prescription medications in this manner is dangerous practice because the chemical composition of prescription opioids provides pleasurable pain relief, eventually causing individuals to reward themselves through substance abuse.[148]

140. Fischer, *supra* note 136, at 101.

141. *Id.* at 102.

142. *Id.*

143. *Id.*

144. *Id.*

145. *See id.* at 104–06; *see also* Joshua J. Fenton et al., *The Cost of Satisfaction: A National Study of Patient Satisfaction, Health Care Utilization, Expenditures, and Mortality*, 172 ARCHIVES INTERNAL MED. 405, 409 (2012) (finding that higher patient satisfaction correlated with overall increases in healthcare costs, prescription drugs, and increased mortality); William Sonnenberg, *Patient Satisfaction Is Overrated*, 46 KEYSTONE PHYSICIAN 4, 4 (2013), http://www.nxtbook.com/nxtbooks/pafp/keystonephysician_2013fall/index.php?startid=4#/4 (describing how a physician at a medical conference told an audience that he increased his patient satisfaction score by 7% by prescribing an antibiotic to all patients who complained of a cough, sore throat, or sinus headache).

146. Kai Falkenberg, *Why Rating Your Doctor Is Bad for Your Health*, FORBES (Jan. 2, 2013, 9:06 AM), http://www.forbes.com/sites/kaifalkenberg/2013/01/02/why-rating-your-doctor-is-bad-for-your-health/.

147. Fischer, *supra* note 136, at 104.

148. *Opioid Addiction 2016 Facts & Figures*, AM. SOC'Y OF ADDICTION MED. (2016),

5. Current Combative Measures

In recent years, federal and state governments have begun to step up their efforts in combating the opioid abuse epidemic. In May 2015, Nora Volkow, the director of the National Institute on Drug Abuse, gave a speech to Congress outlining specific steps the federal government is taking to combat opioid abuse.[149] She noted the efficiency of several types of interventions, in particular,

> Educational initiatives delivered in school and community settings (primary prevention); [s]upporting consistent use of prescription drug monitoring programs (PDMPs); [i]mplementation of overdose education and naloxone distribution programs to issue naloxone directly to opioid users and potential bystanders; [a]ggressive law enforcement efforts to address doctor shopping and pill mills; [d]iverting individuals with substance use disorders to Drug Courts; [e]xpansion of access to [medication-assisted treatment]; [and] [a]buse-deterrent formulations for opioid analgesics.[150]

This section will analyze four of these approaches: prescription drug monitoring programs,[151] increased naloxone distribution programs,[152] law enforcement efforts to limit doctor shopping and pill mills,[153] and increased access to drug courts.[154]

a. PDMPs

In recent years, most states have enacted prescription drug monitoring programs (PDMPs) to help curb prescription opioid substance abuse.[155] PDMPs allow the government to monitor

http://www.asam.org/docs/default-source/advocacy/opioid-addiction-disease-facts-figures.pdf.

149. Volkow, *supra* note 25.

150. *Id.*

151. *See infra* Section II.C.5.a.

152. *See infra* Section II.C.5.b.

153. *See infra* Section II.C.5.c.

154. *See infra* Section II.C.5.d.

155. *See* KAREN BLUMENSCHEIN ET AL., REVIEW OF PRESCRIPTION DRUG MONITORING PROGRAMS IN THE UNITED STATES 1, 4 (2010), http://chfs.ky.gov/NR/rdonlyres/85989824-1030-4AA6-91E1-7F9E3EF68827/0/KASPEREvaluationPDMPStatusFinalReport6242010.pdf (demonstrating that by June 1, 2010, forty-two states had enacted legislation providing for the formation of PDMPs, and thirty-three states had created functioning PDMPs). *See generally* Volkow, *supra* note 25 (discussing the effectiveness of PDMPs in Florida and

electronic prescription data submitted by healthcare prescribers; state governments typically provide physicians and pharmacists access to this data so the practitioners know what medications patients under their care have been prescribed.[156] In her speech before Congress, Nora Volkow particularly focused on Washington and Florida as examples of effective PDMPs, noting that Washington saw dramatic decreases in opioid deaths between 2008 and 2012 and Florida saw the same between 2010 and 2012.[157]

b. Increased Naloxone Distribution Programs

Naloxone is an opioid-reversal drug that restores normal respiration to a person who has overdosed on prescription opioids or heroin.[158] Traditionally, naloxone has only been available as an injection and only carried by medical emergency personnel.[159] Recently, the FDA authorized an auto-injector of naloxone that can be distributed by caregivers who witness a drug overdose.[160] As of 2014, thirty states and Washington, D.C., have implemented take-home naloxone programs, which have reversed 26,463 drug overdoses.[161]

c. Efforts to Reduce Doctor Shopping and Pill Mills

Doctor shopping and pill mills have also contributed to the current prescription drug crisis.[162] Traditionally, pill mills were "a network of medical doctors and pharmacists who [would] prescribe

Washington state). The PDMP assistance website has profiles on all states describing their action or inaction on PDMPs. *See State Profiles*, PRESCRIPTION DRUG MONITORING PROGRAM TRAINING & TECH. ASSISTANCE CTR., http://www.pdmpassist.org/content/state-profiles (last visited May 18, 2017). Missouri is the only state that does not have legislation enacting a PDMP. *See id.*

156. *Prescription Drug Monitoring Frequently Asked Questions (FAQ)*, PRESCRIPTION DRUG MONITORING PROGRAM TRAINING & TECH. ASSISTANCE CTR., http://www.pdmpassist.org/content/prescription-drug-monitoring-frequently-asked-questions-faq (last visited May 18, 2017).

157. Volkow, *supra* note 25.

158. *Id.*

159. *Id.*

160. *Id.*

161. Eliza Wheeler et al., *Opioid Overdose Prevention Programs Providing Naloxone to Laypersons—United States, 2014*, 64 MORBIDITY & MORTALITY WKLY. REP. 631, 631, 633 (2015).

162. *See* Khary K. Rigg et al., *Prescription Drug Abuse and Diversion: Role of the Pain Clinic*, 40 J. DRUG ISSUES 1, 2 (2010).

and fill controlled substance prescriptions to drug seeking individuals."[163] Today, pill mills are a network of physicians who prescribe opioids to drug-seeking patients, who then "cash in" the prescription at a pharmacy.[164]

Several states have attempted to regulate doctor shopping and pill mills. For instance, Texas passed legislation to allow the state medical licensing board to monitor pain management clinics in an effort to curb the overprescribing of opioids.[165] Some scholars have lauded Texas for its efforts but have noted that the legislation did not go far enough in countering opioid substance abuse.[166] In contrast, Florida's partnership with the federal DEA in raiding pill mills helped the state to witness a dramatic decrease in overdose deaths between 2010 and 2012.[167]

d. Focus on Drug Courts

Recently, states have shifted their focus in the War on Drugs from a statutory and law-enforcement response to a public-health response, focusing on drug addiction and drug-related crime.[168] Many believe that a new focus on drug courts will be more successful than past efforts at combating drug addiction since "drug courts have incorporated successful public health strategies into the criminal law to achieve better outcomes, such as reduced recidivism, cost-effectiveness, and the optimization of public safety."[169]

III. NEXT STEPS: REPEAL, REVISE, AND IMPLEMENT

Despite a plethora of legislation, regulations, and recommendations, the rate of opioid deaths continues to rise each year.[170] Clearly something else needs to occur in order to decrease

163. Casturi, *supra* note 6, at 447.

164. *Id.*

165. *Id.* at 454–56.

166. *See id.* at 466.

167. *See* Volkow, *supra* note 25 (citing Hal Johnson et al., *Decline in Drug Overdose Deaths After State Policy Change—Florida, 2010–2012*, 63 MORBIDITY & MORTALITY WKLY. REP. NO. 26 557, 569–74 (2014)).

168. *See, e.g.*, Stephen Hunter et al., *New Jersey's Drug Courts: A Fundamental Shift from the War on Drugs to a Public Health Approach for Drug Addiction and Drug-Related Crime*, 64 RUTGERS L. REV. 795, 796 (2012).

169. *Id.*

170. *See* Rudd et al., *supra* note 20, at 1378 (stating that between 2000 and 2014, the number of opioid overdose deaths increased by 200%).

the occurrence of stories similar to those of Dan Baker and Prince. There is essentially a two-step process in effectuating significant change in the current opioid abuse epidemic. First, there must be a repeal of the patient satisfaction survey requirement in the ACA and either a repeal or revision of TJC's Pain Management Standard.[171] Second, there must be effective federal and state implementation of the programs discussed in Volkow's speech before Congress.[172]

A. Repeal of Patient Satisfaction Surveys in the ACA[173]

As previously discussed, the ACA has a provision aimed at incentivizing hospitals to provide better care for their patients.[174] A portion of the ACA survey allows patients to rate the hospital on its pain management, which then contributes to the hospital's total score.[175] If the hospital receives a low score, it could lose a portion of its Medicare reimbursement from the federal government.[176] Essentially, this incentivizes hospitals to prescribe more pain medicine to prevent low scores due to patient discomfort.[177]

In addition to incentivizing more opioid prescriptions, this ACA provision does not accurately capture the quality of patient care.[178] A national study found that higher patient satisfaction might not mean greater outcomes.[179] From 2000 to 2007, over 50,000 adults were studied, observing each individual during a two-year cycle.[180] Each survey asked the participants questions about their patient satisfaction and health care expenditures, and the study later analyzed the death rates of the participants.[181] The results showed

171. *See infra* Sections III.A–D.

172. *See infra* Section III.E.

173. This section is based on the ACA as of April 2017. Since Republicans now have a majority in both houses of Congress and the presidency, there is a chance this law could be repealed, making the arguments in this section moot. *See* Alison Kodjak, *Trump Can Kill Obamacare with or Without Help from Congress*, NPR (Nov. 9, 2016, 7:05 AM), http://www.npr.org/sections/health-shots/2016/11/09/501203831/trump-can-kill-obamacare-with-or-without-help-from-congress.

174. *See* Fischer, *supra* note 136, at 101–03.

175. *Id.* at 101–02.

176. *Id.* at 102.

177. *See id.* at 103–04.

178. *See id.* at 103 ("These disturbing findings indicate that patient satisfaction is not a reliable indicator of quality healthcare.").

179. *See* Fenton et al., *supra* note 145, at 409.

180. *Id.* at 406–07.

181. *Id.* at 406.

that individuals with higher patient satisfaction scores had greater odds of hospital admission, greater costs on health care and drugs, and a higher mortality rate.[182] This demonstrates that patient satisfaction might not be the best indicator of quality healthcare.[183]

Some physicians have even resorted to unprofessional and unsafe practices in order to achieve adequate patient satisfaction scores.[184] In another study, researchers investigated whether patient satisfaction surveys had a negative impact on physician practices and patient care.[185] The study showed that these surveys can promote inappropriate clinical care, among other dissatisfying outcomes.[186] The analysis included the following selected quotes from study participants indicating how these surveys can promote inappropriate medical practices:

> Narcotic seekers are another huge problem and they are well aware of the patient satisfaction scores and how they can use these threats and complaints to obtain narcotics.
>
> I give a few pain pills to seekers who I would previously have said no.
>
> [W]e practice bad medicine as a result of [the patient satisfaction] surveys.
>
> Narcotic abuse is the biggest problem because the drug seeker knows the game and threatens to call administration more than any other group.[187]

A common theme of the results of these studies seems to be that the surveys allow some narcotic users to game the system to gain the drugs they seek.

Patient satisfaction surveys have had little effect in efficiently monitoring hospitals.[188] They have been mediocre at best at improving hospital practices, and even studies that report improvements have had contradictory findings.[189] In fact, it seems

182. *Id.* at 405.

183. Fischer, *supra* note 136, at 103.

184. *Id.* at 103–04.

185. *See* Aleksandra Zgierska et al., *Impact of Patient Satisfaction Ratings on Physicians and Clinical Care*, 8 PATIENT PREFERENCE & ADHERENCE 437 (2014).

186. *Id.* at 443. The results also suggested that the surveys can result in job dissatisfaction and attrition, but both are outside the scope of this article. *Id.*

187. *Id.* at 440.

188. *See* Fischer, *supra* note 136, at 106; Rashid Al-Abri & Amina Al-Balushi, *Patient Satisfaction Survey as a Tool Towards Quality Improvement*, 29 OMAN MED. J. 3, 5 (2014).

189. *Cf.* Al-Abri & Al-Balushi, *supra* note 188, at 5 ("[T]here is little published

that patient satisfaction surveys have only led to increased costs for both patients and health care providers.[190] For example, in order to regain their Medicare incentive funding, hospitals have been forced to spend money on "frivolous amenities such as flat screen televisions, live music, valet parking, and custom-order room-service meals."[191] Hospitals have also spent time and money training nurses in bedside manner, even providing them with scripts to rehearse their lines with patients.[192] In short, research has shown that the ACA's patient satisfaction surveys do little to improve the overall quality of care and mainly have the effect of incentivizing hospitals to prescribe more opioids and spend more on frivolous amenities in an effort to improve a very important, yet mostly meaningless score.

B. Repeal of TJC's Pain Management Standards

TJC's pain management standards have a large influence on hospitals throughout the country, in part because many states use the standards to establish a baseline for their own standards of care in medical malpractice actions.[193] In 2001, TJC unveiled new standards for pain management, which were highly exalted by medical scholars at the time.[194] These seven new standards indicated

research on improvements resulting from feedback information of patient surveys."). An article in *The Atlantic* states that if hospitals want to provide their patients with better care, they should focus on hiring nurses "rather than tricking patients into believing they're getting better care." Alexandra Robbins, *The Problem with Satisfied Patients*, THE ATLANTIC (Apr. 17, 2015), https://www.theatlantic.com/health/archive/2015/04/the-problem-with-satisfied-patients/390684/.

190. Fischer, *supra* note 136, at 106.

191. *Id.* at 107.

192. *Id.* In a physician blog that provided different ways to improve patient satisfaction scores, the first option was to "[h]ire sunshine," meaning happy people. Lucien W. Robert, *Six Ways to Improve Patient Satisfaction Scores*, PHYSICIAN'S PRAC. (May 20, 2015), http://www.physicianspractice.com/physician-compensation/six-ways-improve-patient-satisfaction-scores. Of course this means that *Grey's Anatomy* star character Dr. Cristina Yang, a highly qualified yet notoriously difficult heart surgeon, might not have been hired by Seattle Grace Hospital, since she could possibly cause the hospital to lose its Medicare reimbursement. *See Grey's Anatomy* (ABC television broadcast Mar. 27, 2005).

193. *See* Barry R. Furrow, *Pain Management and Provider Liability: No More Excuses*, 29 J.L. MED. & ETHICS 28, 39 (2001).

194. *See id.* ("[TJC] standards finally addressed pain management in hospitals and the need for proper organizational structures to promote such management."); Laura D. Seng, *Legal and Regulatory Barriers to Adequate Pain Control for Elders in Long-Term Care Facilities*, 6 N.Y. CITY L. REV. 95, 108 (2003) (arguing that TJC standards

that pain management should be a top priority for physicians.[195] After the adoption of these standards, there was an astronomical increase in the number of opioid prescriptions.[196] This, in turn, led to a large rise in opioid addiction.[197]

In 2015, TJC clarified the 2001 standards, stating that both pharmacologic and nonpharmacologic therapies should be used in managing pain.[198] In April 2016, David Baker, an Executive Vice President of TJC, released a statement discussing the 2015 clarifications, which clearly stated that the 2001 standards had been misconstrued and TJC was not responsible for today's opioid abuse epidemic.[199]

C. The Effect of TJC's Pain Management Standards on the Standard of Care in Medical Malpractice Actions

This section argues that TJC's standards did indeed have a major influence on today's opioid abuse epidemic. Specifically, TJC's pain management standards, even with the 2015 clarifications, can help a patient establish an advantageous duty of care for a claim against a physician for underprescribing opioids. To avoid this, TJC should limit the application of its standards exclusively to terminally-

encourage better pain assessment protocols).

195. TJC's 2001 pain management standards included:

> 1. the right of patients to appropriate assessment and management of pain;
> 2. assessing the nature and intensity of pain in all patients;
> 3. recording the results in a way that allows regular reassessment and follow up;
> 4. determining and assuring staff competency in pain assessment and management, including in the orientation of all new staff;
> 5. establishing policies and procedures to support appropriate prescription or ordering of effective pain medications;
> 6. educating patients and families about effective pain management; and
> 7. addressing patient needs for symptom management in the discharge planning process.

Furrow, *supra* note 193, at 39 n.160.

196. *See* Collins, *supra* note 19.

197. *See Prescribing Data*, CENTERS FOR DISEASE CONTROL AND PREVENTION, http://www.cdc.gov/drugoverdose/data/prescribing.html (last visited May 18, 2017).

198. *TJC 2015 Pain Management Standard*, *supra* note 118, at 11 (discussing the clarifications to TJC's pain management standards that went into effect January 1, 2015).

199. Baker, *supra* note 127.

ill patients. This limitation better complies with the original intent of the standards, which was to combat opiophobia and stop the needless suffering of terminal patients.

Traditionally, in order to bring a successful medical malpractice claim the patient must establish four elements: (1) the defendant doctor owed a duty of care; (2) the defendant breached that duty of care; (3) the plaintiff suffered actual damage; and (4) the defendant's breach actually caused the plaintiff's damages.[200] Typically, the physician owes the patient a duty of care when they are in a treatment relationship; the standard is what a reasonable physician would do under the same or similar circumstances.[201] Further, courts have clarified that reasonableness is measured by the "degree of knowledge and skill which is ordinarily possessed and exercised by other members of [the] profession in similar circumstances."[202] TJC's pain management standards could affect the way that this knowledge is measured.

A physician's expected knowledge is usually measured by clinical practice guidelines.[203] State or federal statutes do not set these guidelines; rather, these guidelines are the product of thoughts and literature within the medical profession, and such thoughts become a standard practice when they are generally accepted.[204] TJC's pain management standards have become generally accepted because hospitals are required to abide by them in order to be accredited.[205] Therefore, these standards can be used as evidence to determine if a physician was negligent regarding a patient's pain management.[206] It seems logical to conclude that,

200. *See, e.g.*, Paul v. Skemp, 625 N.W.2d 860, 865 (Wis. 2001). Each of the four elements has additional sub-elements; however, for the purposes of this article, only the duty element will be discussed in detail.

201. *See, e.g.*, Bryant v. Oakpointe Villa Nursing Ctr., Inc., 684 N.W.2d 864, 871 (Mich. 2004) (holding that a professional relationship between a doctor and patient is a prerequisite to a medical malpractice action); Palmer v. Biloxi Reg. Med. Ctr., Inc., 564 So. 2d 1346, 1354 (Miss. 1990) (stating that the nationally recognized standard of care for physicians is that which is reasonable and ordinary).

202. *E.g.*, Landeros v. Flood, 551 P.2d 389, 392–93 (Cal. 1976).

203. Furrow, *supra* note 193, at 31.

204. *Id.* at 31–32.

205. *See id.* at 39.

206. Since TJC's standards have codified effective pain management as an integral part of a hospital's accreditation process, a hospital could be liable under a theory of corporate negligence, which extends liability of a hospital to the negligent acts of its employees. *See id.* at 38–39.

based solely on the 2001 standard, a plaintiff could easily prove that a physician acted unreasonably in failing to prescribe opioids to properly manage pain.

It is doubtful that the 2015 clarifications would negatively impact a patient's malpractice suit against a physician or hospital for undertreating pain. The clarification simply states that pharmacologic and nonpharmacologic approaches may be used in the treatment of chronic pain, but it does not state that nonpharmacologic approaches are ideal or mandatory.[207] Therefore, even with the new clarifications, physicians are still highly incentivized to overprescribe opioids to avoid medical malpractice actions. In order to curb overprescription, TJC should limit the reach of its pain management standard to terminally ill patients, who coincidentally were the original subjects behind the legislative push to allow physicians to more liberally prescribe opioids.

D. Reasoning Behind TJC's Pain Management Standard and the Recommended Evolution of That Standard

TJC's 2001 Pain Management Standard was part of a larger effort by pain lobbyists in the 1990s to decrease fears related to opiophobia.[208] During this time physicians were fearful of prescribing opioids to any patient, even those who were terminally ill, out of fear that the patient would become addicted.[209] In response to this growing concern, TJC unveiled the standards to establish a duty for accredited hospitals to adequately treat and manage patient pain.[210]

207. *See TJC 2015 Pain Management Standard*, *supra* note 118, at 11. Of course, as mentioned earlier, the CDC guidelines released in March 2016 state that nonpharmacologic approaches should be prioritized over pharmacologic approaches. *See* Dowell et al., *supra* note 122, at 16. As of this writing, there has not been litigation providing an opportunity for a court to decide which guidelines would establish the proper standard of care.

208. *See* Daniel S. Goldberg & Ben Rich, *Pharmacovigilence [sic] and the Plight of Chronic Pain Patients: In Pursuit of a Realistic and Responsible Ethic of Care*, 11 IND. HEALTH L. REV. 83, 86 (2014). Opiophobia is best defined as "an unreasonable fear of and resultant reluctance to prescribe, administer, or receive opioid analgesics, even for the relief of severe pain which is unresponsive to other available pain management strategies." Rich, *supra* note 91, at 43.

209. *See* Rich, *supra* note 91, at 43. Opiophobia was considered a worldwide problem; however, its effects were particularly felt in the United States due to the open War on Drugs. *Id.*

210. *See* Baker, *supra* note 127.

Admittedly, there was a vast undertreatment of pain by physicians in the 1980s and 1990s due to opiophobia.[211] This led to many patients needlessly suffering because physicians feared the patients would become addicted to the pain medicine, even though opioid therapies were the only known treatment that would work.[212] In its response, however, TJC reversed the problem by incentivizing physicians to overprescribe or risk possible malpractice claims.[213] In order to effectively deter physicians from overprescribing opioids, TJC should limit its pain management standards to apply only to those patients who do not have adequate pain relief from nonopioid therapies. This limitation would likely ease physician concerns that underprescribing opioids would open them up to malpractice suits, and there would therefore likely be a significant decrease in the number of opioid prescriptions.

E. Analysis of Combative Measures

Over the past few years, both state and federal governments have become increasingly concerned about the growing opioid epidemic. There has been significant research nationwide to determine the best measures to combat opioid abuse. PDMPs and the implementation of naloxone distribution programs, in particular, have proven to be extremely effective measures.[214]

1. PDMPs

States have responded to the opioid abuse crisis by implementing PDMPs with the hope that these programs will significantly decrease instances of opioid abuse.[215] As of today, forty-nine states have PDMP legislation, including Minnesota.[216] The

211. *See* Goldberg & Rich, *supra* note 208, at 85.

212. This conclusion is derived from Ben Rich's definition of opiophobia, which is a fear to prescribe opioids even where the severe pain is unresponsive to other known mitigating treatments. *See* Rich, *supra* note 91, at 43.

213. *See generally* Furrow, *supra* note 193, at 39 n.160 (enumerating TJC's seven regulations for managing chronic pain).

214. *See generally* Volkow, *supra* note 25 (giving an overview of the federal government's efforts to combat opioid abuse and highlighting PDMPs and naloxone distribution programs).

215. *See, e.g.*, Jacob O'Brien, Note, *A Review and Evaluation of Indiana's Inspect System and Governing Legislation: Maximizing Potential Impact on Public Health*, 10 IND. HEALTH L. REV. 701, 703 (2013).

216. *Id.*; MINN. STAT. § 152.126 (2016) (Minnesota's PDMP statute).

general consensus among the states that have examined the impact of their PDMPs is that the programs have significantly hindered patients' ability to abuse prescription drugs, especially since they make doctor shopping more readily identifiable.[217] This section will analyze the Minnesota PDMP statute,[218] examine a case study of Indiana's prescription drug monitoring legislation,[219] and compare the two states' laws in order to recommend how Minnesota can most effectively implement its own PDMP.[220]

a. Minnesota's PDMP

The Minnesota Legislature implemented its PDMP through Minnesota Statutes section 152.126 in an effort to curb opioid abuse.[221] Generally, the statute requires participating dispensers to submit certain identifying information to the program, such as the name of the prescriber, the name of the patient, the name of the drug prescribed, and the date.[222] This data is then submitted to the statewide database, which is controlled by the Minnesota State Board of Pharmacy.[223] That data can then be accessed by permissible

217. O'Brien, *supra* note 215, at 714.

218. *See infra* Section III.E.1.a.

219. *See infra* Section III.E.1.b.

220. *See infra* Section III.E.1.c.

221. Glenn Howatt, *Minnesota's Drug Registry Aims to Put a Lid on Prescription Drug Abuse*, STAR TRIB. (Oct. 10, 2015, 8:11 PM), http://www.startribune.com/minnesota-s-drug-registry-aims-to-put-a-lid-on-prescription-drug-abuse/331889251/.

222. *See* MINN. STAT. § 152.126, subdiv. 4(a) (2016). The fourteen specific requirements are as follows:

(1) name of the prescriber;
(2) national provider identifier of the prescriber;
(3) name of the dispenser;
(4) national provider identifier of the dispenser;
(5) prescription number;
(6) name of the patient for whom the prescription was written;
(7) address of the patient for whom the prescription was written;
(8) date of birth of the patient for whom the prescription was written;
(9) date the prescription was written;
(10) date the prescription was filled;
(11) name and strength of the controlled substance;
(12) quantity of controlled substance prescribed;
(13) quantity of controlled substance dispensed; and
(14) number of days supply.

Id.

223. *Id.* § 152.126, subdivs. 1(b), 5(a).

users—prescribers, dispensers, pharmacists, and patients[224]—to identify individuals who either obtain prescriptions from dispensers in a quantity or frequency that is inconsistent with the general standards for those substances or present forged or altered prescriptions for controlled substances.[225] It is important to note that the statute considers possible HIPAA violations by requiring providers to give notice to patients of their reporting requirements and grants immunity from liability to any reporter acting in good faith.[226]

Minnesota's PDMP participation requirements have been subject to debate, resulting in many health providers not participating in the program at all.[227] In 2014, for example, around 30% of the top prescribers in Minnesota did not have a PDMP

224. The statute specifically identifies twelve permissible users:

> (1) a prescriber or an agent or employee of the prescriber to whom the prescriber has delegated the task of accessing the data . . . ;
>
> (2) a dispenser or an agent or employee of the dispenser to whom the dispenser has delegated the task of accessing the data . . . ;
>
> (3) a licensed pharmacist who is providing pharmaceutical care for which access to the data may be necessary . . . ;
>
> (4) an individual who is the recipient of a controlled substance prescription . . . or a guardian of the individual, parent or guardian of a minor, or health care agent of the individual acting under a health care directive . . . ;
>
> (5) personnel or designees of a health-related licensing board . . . or of the Emergency Medical Services Regulatory Board . . . ;
>
> (6) personnel of the board engaged in the collection, review, and analysis of controlled substance prescription information . . . ;
>
> (7) authorized personnel of a vendor under contract with the state of Minnesota who are engaged in the design, implementation, operation, and maintenance of the prescription monitoring program . . . ;
>
> (8) federal, state, and local law enforcement authorities acting pursuant to a valid search warrant;
>
> (9) personnel of the Minnesota health care programs . . . ;
>
> (10) personnel of the Department of Human Services . . . ;
>
> (11) personnel of the health professionals services program . . . ; and
>
> (12) personnel or designees of a health-related licensing board . . . .

Id. § 152.126, subdiv. 6(b).

225. *Id.* § 152.126, subdiv. 5(a).

226. *Id.* § 152.126, subdivs. 4(d) (discussing the reporter's notice requirements to the patient), 9 (granting the reporter immunity from liability).

227. *See* Howatt, *supra* note 221.

account.[228] The most recent PDMP legislation considered this fractured use problem and required every prescriber across the state to participate by July 1, 2017.[229] It will be interesting to see if nonparticipating providers will be subject to the statute's disciplinary provision.[230] The two most common concerns providers have regarding mandatory participation are the cost of implementation and the potential diminishing of on patient privacy.[231]

b. Indiana's PDMP

Indiana created a PDMP in 2004, much earlier than when Minnesota created its program in 2010.[232] A 2013 article published in the *Indiana Health Law Review* analyzed Indiana's program and offered recommendations to maximize its potential.[233] Many of the limitations in Indiana's program mirror possible limitations in Minnesota's program, so Minnesota legislators should learn from Indiana's experience when analyzing Minnesota's own PDMP.

Indiana calls its program INSPECT, and it requires all schedule II–V drugs to be reported.[234] Non-scheduled substances need not be reported.[235] Similar to the Minnesota statute, Indiana's law limits the authorized users who can request information from the program, and the authorized users can easily access the information by simply searching an individual's name within the database.[236]

Overall, the *Indiana Health Law Review* article concludes that the Indiana program has been successful in collecting data about potential prescription drug abuse and has the potential to curb

228. *Id.*

229. *See* MINN. STAT. § 152.126, subdiv. 6(c).

230. *See generally id.* § 152.126, subdiv. 7 (providing that a dispenser who knowingly fails to distribute information to the board will be subject to disciplinary action).

231. *See* Howatt, *supra* note 221.

232. *Compare* Minn. STAT. § 152.126 subdiv. 2 (stating that the Minnesota State Board of Pharmacy shall establish a PDMP by January 1, 2010), *with* IND. PROF. LICENSING AGENCY, http://www.in.gov/pla/inspect/2338.htm (last visited May 18, 2017) (stating that INSPECT'S current form was created in 2004). *See generally* IND. CODE ANN. §§ 35-48-7-2.5–17 (West, Westlaw through 2017 Reg. Sess. of the 120th Gen. Assemb.) (describing the INSPECT program).

233. *See generally* O'Brien, *supra* note 215.

234. *See id.* at 715.

235. *Id.* at 715–16.

236. *Id.* at 716–18.

doctor shopping.[237] Specifically, the author identifies two positive aspects of the Indiana program.[238] First, the system considers possible HIPAA violations by limiting both the authorized users of INSPECT and the amount of patient health data such users may see when conducting a search.[239] Second, it shields practitioners acting in good faith from liability for authorized entries, which incentivizes practitioners to make disclosures.[240] Still, there is obvious room for improvement since the number of injuries and deaths arising from opioid abuse has continued to increase across Indiana.[241]

The article highlights five areas of INSPECT that should be changed in order to maximize the program's potential.[242] First, Indiana should increase the use of interoperability agreements with other state PDMPs.[243] An interoperability agreement allows a state to share information from its own PDMP with another state's PDMP, thereby curbing interstate prescription drug abuse through doctor shopping.[244] Since not all states have effective PDMPs, having an interoperability agreement with all fifty states would be unrealistic; however, Indiana could strive for such agreements between states within the region, since that would most likely be the zone where Indiana residents would go for interstate doctor shopping.[245]

237. *See id*. at 723.

238. *Id*. at 724.

239. *See* IND. CODE ANN. § 35-48-7-11.1 (West, Westlaw through 2017 Reg. Sess. of the 120th Gen. Assemb.) (limiting who has access to view INSPECT data); O'Brien, *supra* note 215, at 724; *see also FAQs*, IND. PROF. LICENSING AGENCY, http://www.in.gov/pla/inspect/2371.htm (last visited May 18, 2017) (suggesting that the approval for access and other statutory restrictions limit what users see when conducting a search).

240. O'Brien, *supra* note 215, at 725.

241. *See id*.

242. *Id*. at 728–36 (discussing five recommendations to maximize the effectiveness of Indiana's system: (1) increase the number of interoperability agreements, (2) create a more proactive system, (3) implement independent evaluation, (4) monitor non-controlled substances, and (5) require practitioner participation).

243. *Id*. at 728.

244. *See id*. at 728–29.

245. *See id*. Indiana already has interoperability agreements with all bordering states, creating a great obstacle for interstate doctor shoppers; however, O'Brien believes that all states within the region should be covered, since it would be feasible for opioid abusers to drive a little farther to fall outside of an interoperability agreement. *See id*. at 729.

Second, Indiana should develop a more proactive PDMP.[246] A more proactive system would automatically alert authorized users about a possible abuse problem with a particular patient, as opposed to a reactive system, where authorized users are not alerted to a potential problem unless they search for a particular patient.[247] The author admits that no state has yet to develop a fully proactive system but believes such a system would be possible through analytical software or similar technology that would flag potential abusers based on an individual's characteristics and drug use patterns.[248]

Third, Indiana should create an independent evaluative entity that would measure the program's effectiveness in combating prescription drug abuse within the state.[249] This would comply with the National Alliance for Model State Drug Laws' (NAMSDL) model for an effective PDMP.[250] An independent evaluative entity would strengthen a PDMP because it would allow a non-governmental group to examine the current program, discover possible shortcomings, and make the program more user-friendly.[251]

Fourth, Indiana should expand coverage of INSPECT to monitor the usage of non-scheduled substances, such as "over-the-counter medications and medications that are prescribed to treat medical conditions such as high blood pressure, diabetes, and bacterial infections."[252] There are three possible situations where non-scheduled substances should be monitored: first, where the drug has a high tendency of addiction or abuse; second, where the drug "has significant potential for dangerous drug interaction"; and third, where patients voluntarily agree to have their non-controlled

246. *Id.*

247. *See id.*

248. *See id.*

249. *Id.* at 730.

250. *Id.* NAMSDL has published what it believes to be a model PDMP law, last revised in 2015, and many of the subdivisions found in the model PDMP law are found in both Indiana and Minnesota's programs. *See generally* NAT'L ALL. FOR MODEL STATE DRUG LAWS, MODEL PRESCRIPTION MONITORING PROGRAM ACT (2015), http://www.namsdl.org/library/A72D4573-0D93-65C4-281BD9DB01418276/.

251. *See* O'Brien, *supra* note 215, at 730.

252. *Non-Controlled Substances*, TAKE BACK MEDS, http://www.takebackmeds.org/proper-disposal/non-controlled-substances (last visited May 18, 2017); *see* O'Brien, *supra* note 215, at 731. This expansion is needed because any medication can be abused if taken in high enough doses. Roy R. Reeves et al., *Abuse of Medications That Are Theoretically Without Abuse Potential*, MEDSCAPE (2015), http://www.medscape.com/viewarticle/842222.

substances monitored to better protect themselves against adverse drug reactions.[253]

Fifth, physicians should be required to participate in the INSPECT program.[254] The author concludes that this last limitation is possibly the greatest barrier to INSPECT realizing its full potential and that many of the arguments against a mandatory requirement, such as a diminishing of patient privacy, are unfounded in light of current data.[255] The article ultimately concludes that Indiana's INSPECT system is one of the strongest PDMPs in the country but is still not being used to its full potential.[256] With the implementation of the five suggestions, perhaps Indiana's prescription drug abuse problem could come under control.

c. Is Minnesota's PDMP Reaching Its Full Potential?

This final section compares Minnesota's PDMP statute with the *Indiana Health Law Review* article's five recommendations to maximize the potential of Indiana's INSPECT system. Minnesota has already adopted two of the five recommendations made in the article: evaluation by an independent entity and mandatory participation in the PDMP for providers.[257] However, the other three recommendations remain pertinent for Minnesota to use its PDMP program to its full potential.

First, an effective PDMP should have a larger number of interoperability agreements with different states in order to increase the effectiveness of abuse monitoring and curb doctor shopping.[258] In December 2015, the Minnesota Board of Pharmacy reported that twenty-two states currently exchange data with Minnesota, including its bordering states of North Dakota, South Dakota, Iowa, and Wisconsin.[259] This data is similar to what was found in Indiana, where

253. O'Brien, *supra* note 215, at 731–32.

254. *Id.* at 733.

255. *Id.* at 733–36.

256. *See id.* at 739.

257. *See* MINN. STAT. § 152.126, subdiv. 3 (2016) (outlining an independent evaluating entity for Minnesota's PDMP); *id.* § 152.126, subdiv. 6(c) (requiring that every prescriber who practices in Minnesota maintain an account with the state's PDMP by July 1, 2017).

258. *See* O'Brien, *supra* note 215, at 728.

259. MELISSA WINGER & BARBARA A. CARTER, MINN. BD. OF PHARM., REPORT TO THE LEGISLATURE: INTERSTATE PRESCRIPTION DATA EXCHANGE MN PRESCRIPTION MONITORING PROGRAM 3 (2015),

all border states had entered into interoperability agreements with the state, but not all states that prescription drug abusers could potentially reach are covered.[260] Nebraska is an example of a state that, although not bordering Minnesota, is nearby enough that drug abusers could easily travel there to obtain prescriptions and avoid detection by Minnesota's PDMP.[261] Minnesota also faces a unique obstacle since it sits on an international border. The effectiveness of Minnesota's PDMP could be increased through additional interoperability agreements with other states.

On another note, perhaps the federal government should implement a national PDMP, forgoing the need for interoperability agreements altogether. A national PDMP could be similar to the National Practitioner Data Bank (NPBD), which allows medical professionals to view malpractice payments from physicians.[262] A national program such as this would certainly optimize the federal government's ability to monitor prescription drug abuse and limit geographic disparities in opioid abuse. Further, the federal government should consider implementing monitoring programs with international neighbors, such as Canada. This would be beneficial to states that sit on an international border, like Minnesota, since many residents could simply walk across the border to escape PDMP state monitoring.[263]

https://www.leg.state.mn.us/docs/2015/mandated/151330.pdf. The following states exchange prescription drug monitoring data with Minnesota: Arizona, Arkansas, Colorado, Connecticut, Delaware, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Michigan, Mississippi, Nevada, New Mexico, North Dakota, Ohio, South Carolina, South Dakota, Virginia, West Virginia, and Wisconsin. *Id.*

260. *See* O'Brien, *supra* note 215, at 728–29.

261. As of August 2015, Nebraska does not data share with Minnesota's PDMP. *See* WINGER & CARTER, *supra* note 259; *see also* News Release from Doug Peterson, Neb. Att'y Gen. (Feb. 13, 2017), https://ago.nebraska.gov/sites/ago.nebraska.gov/files/doc/2017-02-13%20Dose%20of%20Reality%20News%20Release_0.pdf (announcing a public awareness campaign regarding the dangers of opioid prescription misuse).

262. *See About Us*, NAT'L PRACT. DATA BANK, https://www.npdb.hrsa.gov/topNavigation/aboutUs.jsp (last visited May 18, 2017).

263. It should be noted that both Canadian provinces that border Minnesota, Manitoba and Ontario, do have their own PDMPs. *See generally* MINISTRY OF HEALTH & LONG-TERM CARE, NARCOTICS MONITORING SYSTEM (NMS): PHARMACY REFERENCE MANUAL (2012); *Manitoba Prescribing Practices Program (MΣP)*, NAT'L ASS'N PHARMACY REG. AUTHORITIES (May 2006), http://napra.ca/Content_Files/Files/Manitoba/current%20web%20site/Manitoba_Prescribing_Practices_Program_May2006.pdf (outlining Manitoba's PDMP).

Second, Minnesota should consider investing in a more proactive PDMP system. The statutory language of Minnesota Statutes section 152.126 indicates that the database must be manually searched in order for a prescriber to see a potential red flag; in other words, there are no automatic alerts to preemptively catch drug abusers and potential overdoses.[264] Analytical software should be used to alert users of a potential opioid abuser without requiring medical providers to perform a manual search. This would likely result in catching more prescription drug abusers and catching them sooner.

Minnesota has already implemented the third suggestion from the *Indiana Health Law Review* article, an independent evaluative entity.[265] Subdivision three of Minnesota's PDMP statute creates an advisory task force consisting of both governmental and non-governmental representatives.[266] The statute outlines the duties of the task force, which mainly consist of evaluating the program and interpreting the data.[267] In this respect, Minnesota seems to meet this recommendation for an effective PDMP.

264. Language such as "directly access" seems to indicate a search is required to obtain the information. *See* MINN. STAT. § 152.126, subdiv. 6(d) (2016).

265. O'Brien, *supra* note 215, at 730.

266. *See* MINN. STAT. § 152.126, subdiv. 3(a). The following entities have at least one representative appointed to the advisory task force by the Minnesota State Board of Pharmacy:

> (1) the Department of Health;
> (2) the Department of Human Services;
> (3) each health-related licensing board that licenses prescribers;
> (4) a professional medical association, which may include an association of pain management and chemical dependency specialists;
> (5) a professional pharmacy association;
> (6) a professional nursing association;
> (7) a professional dental association;
> (8) a consumer privacy or security advocate;
> (9) a consumer or patient rights organization; and
> (10) an association of medical examiners and coroners.

Id.

267. *See id.* § 152.126, subdiv. 3(b).

> The advisory task force shall advise the board on the development and operation of the prescription monitoring program, including, but not limited to:
> (1) technical standards for electronic prescription drug reporting;
> (2) proper analysis and interpretation of prescription monitoring data;

Fourth, an effective PDMP should expand coverage to allow for monitoring of non-scheduled substances.[268] The Minnesota PDMP statute currently only requires reporting of scheduled substances.[269] Minnesota should consider expanding its program to include non-scheduled drugs that have a high potential for abuse or dangerous drug interactions and patients who voluntarily agree to have such information monitored for their own health benefit.[270] This expanded coverage is needed because abuse of non-scheduled substances is also a problem.[271] For example, there have been numerous reports of abuse of antihistamines, sedatives, and muscle relaxants.[272] Since non-scheduled substances have the potential for abuse, Minnesota's own PDMP should monitor those over-the-counter purchases.

Fifth, physicians should be required to participate in the PDMP. Effective July 1, 2017, all prescribers in Minnesota must register and maintain an account with the state's PDMP.[273] However, the wording of the statute might give prescribers a loophole because they are only required to "register and maintain" an account, not enter prescription and patient information.[274] Further, due to the unpopularity of the mandatory requirement, it will be interesting to see if this deadline is in any way enforced.[275]

In conclusion, much like Indiana's INSPECT program, Minnesota's PDMP is strong and effective, but prescription drug abuse within the state continues to increase.[276] In order to maximize

(3) an evaluation process for the program; and

(4) criteria for the unsolicited provision of prescription monitoring data by the board to prescribers and dispensers.

Id.

268. *See* O'Brien, *supra* note 215, at 731.

269. *See* MINN. STAT. § 152.126, subdiv. 1(c) (defining controlled substances as scheduled substances).

270. *See* O'Brien, *supra* note 215, at 731–32.

271. *See generally* Reeves et al., *supra* note 252 (discussing abuse problems with non-scheduled substances).

272. *See id.* (noting a rise in reports of (1) antihistamine abuse, (2) individuals stating that they could not resist the urge to take sedatives, and (3) emergency department visits for muscle relaxant abuse).

273. *See* MINN. STAT. § 152.126, subdiv. 6(c).

274. *Id.*

275. *See* Howatt, *supra* note 221 (discussing how many politicians do not like the mandatory requirement because of the potential cost and privacy violations).

276. *See* Collins, *supra* note 19 (showing that between 1999 and 2014 the number of deaths as a result of opioid overdoses in Minnesota increased by more than

the potential of the state's PDMP, Minnesota should increase interoperability agreements, develop a more proactive system, and expand the statute to allow for monitoring of non-scheduled substances. With these recommendations, hopefully the state's PDMP can have an even more positive effect on decreasing opioid abuse.

2. Benefits and Costs of Increased Naloxone Availability

Naloxone is a powerful, life-saving drug that helps prevent overdose deaths from opioids.[277] Naloxone is not new, as it has been used by emergency rooms and emergency medical technicians (EMT) for decades; however, intranasal administration of naloxone has allowed laypersons outside the emergency department to administer the drug.[278] Since this administration method is relatively new, there is little literature documenting laypersons' use of naloxone in emergency situations.[279] Several barriers do exist to increased naloxone distribution, "including access to products, funding and reimbursement, legal barriers, and the need for education at the level of the patient, the caregiver(s) or family, and provider."[280] These barriers must be overcome in order to maximize the potential of increased naloxone distribution. This section will analyze the benefits and costs of increased naloxone distribution and then explore how Minnesota is combating potential pitfalls of its naloxone distribution program.[281]

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277. *See* Abby M. Bailey & Daniel P. Wermeling, *Naloxone for Opioid Overdose Prevention: Pharmacists' Role in Community-Based Practice Settings*, 48 ANNALS OF PHARMACOTHERAPY 601, 601–02 (2014).

278. *See id.* Traditionally, naloxone has been administered through intravenous, intramuscular, and subcutaneous ways. *Id.* at 602. These traditional ways limit who can administer naloxone, as they are much more invasive and therefore would require greater care than the new intranasal option. *Id.*

279. *Id.*

280. *Id.* Bailey and Wermeling compare many of the issues faced by naloxone distributers to barriers faced by advocates for increased usage of emergency contraceptives. *Id.* This analogy is particularly apposite given the controversial nature of naloxone distribution and the "moral-hazard and medical-legal issues" it entails. *Id.*

281. *See infra* Section III.E.2.a–c.

a. Benefits of Increased Naloxone Distribution

A decrease in opioid overdoses and related deaths is the most obvious benefit of increased naloxone distribution. An opioid overdose occurs when the opioid binds to receptors in the brain stem, essentially causing the body forget to breath, leading to respiratory failure.[282] Naloxone interrupts this process by introducing an opiate antagonist that can reverse the binding mechanisms of many opioids.[283] But there's a catch. With naloxone administration, there is only a brief time period between the start of the overdose and death, typically one to three hours, when the drug can effectively reverse the overdose.[284] Fortunately, studies have shown that usually another person witnesses a drug overdose,[285] so if that person has a way to effectively administer naloxone, then he or she could save a life.

Opponents to increased naloxone distribution might argue that a witness to an overdose event could just call 911 and the EMTs could administer the drug. This would obviously be ideal; however, witnesses usually call 911 as a last resort (only 10% to 56% of the time) because police often arrive with the 911 response team.[286] Many opioid abusers worry about police arrival because of their prior criminal history.[287] Instead of calling 911, witnesses attempt to revive the victim themselves with dubious home remedies, all the while

282. Daniel Kim et al., *Expanded Access to Naloxone: Options for Critical Response to the Epidemic of Opioid Overdose Mortality*, 99 AM. J. PUB. HEALTH 402, 403 (2009).

283. *Id.*

284. *Id.* Some studies have shown an even smaller window of opportunity for effective naloxone distribution. *Id.*

285. *Id.*

286. *Id.* (citing S. Darke & J. Ross, *Overdose Among Heroin Users in Sydney, Australia: Responses to Overdose*, 91 ADDICTION 413 (1996); P.J. Davidson et al., *Fatal Heroin-Related Overdose in San Francisco, 1997–2000: A Case for Targeted Intervention*, 80 J. URB. HEALTH 261 (2003); M. Tracy et al., *Circumstances of Witnessed Drug Overdose in New York City: Implications for Intervention*, 79 DRUG ALCOHOL DEPENDENCE 181 (2005)).

287. *See id.* (stating that many opioid abusers are on parole or have arrest warrants against them such that they are understandably disinclined to invite police involvement). Further, these fears are not unfounded, considering that roughly 42% of those who called 911 for opioid overdoses reported seeing police arrive on the scene in addition to EMTs. *Id.* There have also been reports of searches, interrogations, and the threat of manslaughter charges if the overdose is fatal. *Id.*

wasting valuable time to save the unresponsive drug user from a fatal overdose.[288]

Instead of expecting witnesses of an overdose to call 911, it makes more sense to provide them with adequate training to prevent the victim's death. Indeed, this idea is strongly supported by drug users, who would be the ones directly affected by increased naloxone distribution.[289] Studies in both San Francisco and Rhode Island showed around 90% of drug users wanted to participate in naloxone training or would want a peer to administer naloxone to them in an overdose episode.[290] Increased distribution would give these drug users the opportunity to save a life and would more than likely reduce the amount of opioid deaths.[291]

b. Costs of Increased Naloxone Distribution

There are many issues with increasing the distribution of naloxone, most of which are beyond the scope of this article, such as logistical issues of insurance coverage or ethical issues relating to pharmacists' role in naloxone distribution.[292] Perhaps the most significant legal issue is the potential criminal liability of those who fail to safely distribute naloxone.[293]

Some states have confronted this dilemma by expanding the scope of their Good Samaritan statutes to include provisions protecting naloxone administrators.[294] Good Samaritan laws were a response to the common-law theory that rescuers were not immune

288. *Id.* The following are examples of dubious home remedies: "injecting them with salt, milk, or stimulants like cocaine; immersing them in a cold bath; massaging their hearts; or deliberately inflicting pain." *Id.*

289. *See id.*

290. *Id.*

291. *See id.* (stating that two facts lead to the conclusion that increased distribution of naloxone would likely lead to fewer overdose deaths: the effectiveness of a timely naloxone distribution and the high likelihood of witnesses to an overdose event).

292. Logistical issues include getting the outpatient version of the drug on provider plans and lobbying for naloxone manufacturers to get on state Medicaid reimbursement plans. *See* Bailey & Wermeling, *supra* note 277, at 604. Ethical issues in the pharmacists' role also come into play in two situations: (1) should the pharmacist be in the role of identifying patients for naloxone distribution, and (2) should the pharmacist be involved in clinical outcomes and follow-ups, or is their role limited to education and counseling? *See id.* at 605.

293. *See id.* at 604–05.

294. *See id.*

from liability for their negligent acts or omissions.[295] Since 1959, all states and the District of Columbia have enacted Good Samaritan laws, although there are wide variations in the scope of immunity provided by different states.[296] These laws have been controversial, as many argue they take away restitution for victims of unsuccessful rescue attempts;[297] however, Good Samaritan laws with wide scopes could be beneficial in providing adequate protection to naloxone distributors. Unfortunately, not all Good Samaritan laws protect naloxone administrators,[298] as only eighteen states have expanded their Good Samaritan laws to include naloxone distribution.[299]

States have also attempted to protect naloxone administrators through naloxone access laws.[300] The protections provided by these laws vary in scope, from providing immunity for prescribers alone to extending immunity to laypersons alike.[301] As of May 2017, forty-five states have some form of a naloxone access law.[302] Of these forty-five,

295. *See* Eric A. Brandt, *Good Samaritan Laws—The Legal Placebo: A Current Analysis*, 17 AKRON L. REV. 303, 304 (1983) (noting that at common law "a rescuer could be held liable for negligent acts associated with the rescue").

296. *Id.* at 303. The laws vary between providing immunity only to physicians and providing immunity for anyone who provides emergency care. *Id.*

297. *Id.* at 306.

298. *See* DRUG POLICY ALL., STATE LEGISLATION: OVERDOSE PREVENTION (2016), http://www.drugpolicy.org/sites/default/files/Fact%20Sheet_State%20based%20Overdose%20Prevention%20Legislation%20%28January%202016%29.pdf.

299. The following are the eighteen states that have Good Samaritan legislation for naloxone distribution: California, Connecticut, Delaware, Georgia, Illinois, Kentucky, Massachusetts, Minnesota, Mississippi, Nevada, New Jersey, New Mexico, New York, North Carolina, Pennsylvania, Rhode Island, Vermont, and Washington. *See id.*

300. *See id.*; *see also* Susan P. Weinstein, *Commentary: Naloxone Access and Good Samaritan Overdose Protection Laws Abound in State Legislatures*, PARTNERSHIP FOR DRUG-FREE KIDS (June 24, 2015), http://www.drugfree.org/news-service/commentary-naloxone-access-good-samaritan-overdose-protection-laws-abound-state-legislatures/ (explaining what Naloxone Access Laws are and why states might enact them).

301. DRUG POLICY ALL., *supra* note 298.

302. These states have a Naloxone Access Law: Alabama, Alaska, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, and Wisconsin. *Naloxone Overdose Prevention Laws*, LAW ATLAS PROJECT, http://lawatlas.org/datasets/laws-regulating-administration-of-naloxone (last visited May 18, 2017).

twenty-nine states provide immunity from both civil and criminal liability to laypersons administering naloxone.[303]

c. Minnesota Laws on Naloxone Distribution

Minnesota has both a Naloxone Good Samaritan Law and a Naloxone Access Law.[304] Minnesota's Good Samaritan law permits a layperson to administer naloxone and provides that if the administrator believed in good faith the recipient was suffering from a drug overdose, then the administrator is immune from both civil and criminal liability.[305] The statute also provides immunity from civil and criminal liability to health care professionals.[306] Minnesota's

303. Those twenty-nine states include Alabama, Arkansas, Colorado, Connecticut, Georgia, Hawaii, Idaho, Illinois, Kentucky, Louisiana, Massachusetts, Michigan, Minnesota, Mississippi, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Pennsylvania, Rhode Island, South Carolina, Texas, Vermont, Washington, West Virginia, and Wisconsin. *Id.* Notably, none of these states require the layperson administrator or the naloxone recipient to participate in a naloxone administration program as a condition of immunity. *See id.*

304. MINN. STAT. § 604A.04 (2016) (Naloxone Good Samaritan Statute); *id.* § 151.37, subdiv. 12 (Naloxone Access Law). The Naloxone Access Law defines the individuals who are allowed to administer naloxone, including those trained to recognize the signs of overdose.

305. The applicable statute reads,

> (a) A person who is not a health care professional may possess or administer an opiate antagonist that is prescribed, dispensed, or distributed by a licensed health care professional pursuant to subdivision 3.
>
> (b) A person who is not a health care professional who acts in good faith in administering an opiate antagonist to another person whom the person believes in good faith to be suffering a drug overdose is immune from criminal prosecution for the act and is not liable for any civil damages for acts or omissions resulting from the act.

Id. § 604A.04, subdiv. 2.

306. The Good Samaritan statute provides for immunity as follows:

> A licensed health care professional who is permitted by law to prescribe an opiate antagonist, if acting in good faith, may directly or by standing order prescribe, dispense, distribute, or administer an opiate antagonist to a person without being subject to civil liability or criminal prosecution for the act. This immunity applies even when the opiate antagonist is eventually administered in either or both of the following instances: (1) by someone other than the person to whom it is prescribed; or (2) to someone other than the person to whom it is prescribed.

Id. § 604A.04, subdiv. 3.

Naloxone Access Law essentially provides additional protection from civil and criminal liability to both laypersons and health care professionals.[307]

With both the Naloxone Good Samaritan Law and the Naloxone Access Law, ordinary Minnesotans who administer naloxone to overdose victims need not worry about liability when administering the drug. Minnesota might consider expanding its access law to create training programs for naloxone distribution, as other states have done.[308] States should invest in naloxone distribution training since such training is essential for the drug's success, as administrators would need to be comfortable administering the drug in emergency situations.[309]

To conclude, naloxone is a powerful drug that has the potential to save the lives of many opioid overdose victims. In an effort to save more lives, states have begun distributing naloxone for outpatient use. To maximize the success of these distribution programs, states should pass legislation granting immunity to administrators and invest in product training. With these necessary elements, widespread naloxone distribution could have a significant impact on overall opioid overdose deaths.

IV. CONCLUSION

Despite the successful implementation of PDMPs and naloxone distribution programs, opioid abuse and overdose death rates continue to rise.[310] Federal initiatives, such as the ACA's patient satisfaction surveys and TJC's patient pain standards, though well-intended, have incentivized physicians to overprescribe, which in turn has led to higher rates of addiction and substance abuse. In order to make a significant dent in the prescription drug abuse epidemic, legislation like the ACA's patient satisfaction surveys and TJC's patient pain standards must be repealed or revised because they currently incentivize physicians to overprescribe. Since the ACA's patient satisfaction surveys and TJC's patient pain standards conflict with current state combative measures, such as PDMPs and naloxone distribution programs, these pieces of federal legislation,

307. *See* DRUG POLICY ALL., *supra* note 298.

308. States with such programs include Illinois, Maryland, New Mexico, New York, Vermont, and Virginia. *Id.*

309. *See* Bailey & Wermeling, *supra* note 277, at 604.

310. *See* Collins, *supra* note 19.

regulation, and guidance should either be repealed or revised. Minnesota has the opportunity to be at the forefront of these initiatives. Since Minnesota has historically provided a "first-class healthcare system" to its population,[311] it should provide a first-class opioid abuse initiative as well. These initiatives would be a great memorial to Minnesotans who have lost their lives to opioid abuse, such as Prince and Dan Baker, and perhaps other states and the federal government would look to Minnesota as an example of how to significantly decrease opioid abuse throughout the country.

311. Andy Slavitt, Commentary, *Minnesota Health Care, and Values, Take a Blow in GOP Bill*, STAR TRIB. (May 11, 2017, 6:00 PM), http://www.startribune.com/minnesota-health-care-and-values-take-a-blow-in-gop-bill/422052663/.

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