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Public Health Law—Punishing Pain: Why Treating Chronic Pain with Opioids Needs a New Standard of Care

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PUBLIC HEALTH LAW—PUNISHING PAIN: WHY TREATING CHRONIC PAIN WITH OPIOIDS NEEDS A NEW STANDARD OF CARE

I. INTRODUCTION

"they denied the script im done love you."

Brent Slone texted that to his wife thirty minutes before killing himself.[1] In 2011, Brent survived a horrific car accident.[2] His survival came at a gruesome price—broken ribs, a compressed spinal cord, pelvis fractures, lung collapse, a ruptured bladder, and severe damage to other critical internal organs.[3] It left Brent paralyzed from the waist down and resolved Brent to a life of excruciating chronic pain and depression.[4] A few years after the accident, Brent started seeing doctors for pain management at Kentucky's Commonwealth Pain and Spine ("Commonwealth").[5] Doctors treated Brent's pain with a medicine pump implant and a high dose of opioids to take each day.[6] Brent's dose of 240 morphine milligram equivalents ("MME") worked well for three years.[7]

In 2017, Brent went to California for surgery.[8] Unfortunately, the surgery failed, and Brent lost his pain pump from an infection while in recovery.[9] Brent's California doctors increased his opioid prescription to offset the pain.[10] It took 540 MME, roughly double Brent's previous dose, to give

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1. *$7 Million Awarded to Family of Man who Killed Himself After Pain Medication Denied*, WDRB (Aug. 30, 2021), https://www.wdrb.com/news/7-million-awarded-to-family-of-man-who-killed-himself-after-pain-medication-denied/article_92db6b14-09c0-11ec-b39b-7b711a46b1c7.html.

2. Maia Szalavitz, *What the Opioid Crisis Took from People in Pain*, N.Y. TIMES (Mar. 7, 2022), https://www.nytimes.com/2022/03/07/opinion/opioid-crisis-pain-victims.html.

3. *Id.* Brent also broke his shoulder and knee; the injuries to his internal organs included a ruptured bladder and damages to his colon, spleen, and kidney. *Id.*

4. *Id.*; *Slone v. Commonwealth Pain and Spine*, 25 KY. TRIAL CT. REV., Oct. 2021, Ky. Trial Ct. Rev. LEXIS 37.

5. *Slone v. Commonwealth Pain and Spine*, *supra* note 4.

6. *Id.*

7. *Id.* Converting a dose of an opioid medication to its equivalent dose in MME is a way to compare the strength of different opioid pain medications among patients. *See* Kathleen Adams & Michael Guerra, *Unintended Consequences of United States Chronic Pain Guidelines*, 43 INT'L J. CLINICAL PHARMACY 313, 314 (2021). Methods of MME conversion are not universal, and differences in patients' bodies, pain levels, and side effects will result in different reactions to a certain dose of the same medicine. *Id.* Inaccurate MME conversions during dose tapering can result in patients suffering withdrawals. *Id.*

8. *Slone v. Commonwealth Pain and Spine*, *supra* note 4.

9. *Id.*

10. *Id.*

him some relief.[11] When Brent returned to Kentucky after recovering, Commonwealth refilled Brent's new, higher dose of opioids so Brent would not run out of pain medicine before his next appointment in the middle of August.[12] But at the August appointment, Brent's providers slashed his daily opioid dose by over fifty-five percent.[13] The swift and drastic dose reduction caused him extreme pain and dangerous withdrawal symptoms.[14] He took extra pills to cope with the pain but quickly ran out of all his medicine.[15] Brent and his wife pleaded his doctors for more.[16] His doctors denied the requests and refused to see Brent until his next appointment, effectively cutting Brent's high dose to zero in a matter of weeks.[17] On September 12, Brent's wife made several calls to the clinic, but Brent's doctor had already made up his mind—no early refills.[18] Brent killed himself the same day.[19]

Brent's story is not a one-off tragedy but a theme for those suffering from chronic pain.[20] Jay Lawrence fractured his back when he crashed his eighteen-wheeler into a bridge to keep it from colliding with another car.[21]

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11. Plaintiff's Trial Memorandum at 2, Slone v. Commonwealth Pain Associates, No. 18-CI-005283 (Jefferson Cnty. Cir. Ct., Aug. 27, 2021), https://www.juryverdicts.net/SloneBPTrialMemo.pdf [https://perma.cc/8H2Y-T5LA] [hereinafter Plaintiff's Trial Memorandum].

12. *Id.*

13. *Id.*

14. Andrew Joseph, *Her Husband Died by Suicide. She Sued His Pain Doctors—a Rare Legal Challenge over an Opioid Dose Reduction*, STAT (Nov. 22, 2021), https://www.statnews.com/2021/11/22/her-husband-died-by-suicide-she-sued-his-pain-doctors-a-rare-challenge-over-an-opioid-dose-reduction.

15. *Slone v. Commonwealth Pain and Spine*, *supra* note 4.

16. Plaintiff's Trial Memorandum, *supra* note 11, at 3.

17. *Id.* at 4.

18. *Id.* at 3–5.

19. *Id.* at 4–5.

20. *See* Kelly K. Dineen, *Definitions Matter: A Taxonomy of Inappropriate Prescribing to Shape Effective Opioid Policy and Reduce Patient Harm*, 67 U. KAN. L. REV. 961, 963, 965 (2019). The article explores opioid prescribing policy and proposes a taxonomy of the several definitions of inappropriate prescribing. *See, e.g.*, *id.* at 1001. *See also* Megan Becker-Leckore et al., *Narrative Symposium: Living with Chronic Pain in the Midst of the Opioid Crisis*, NARRATIVE INQUIRY BIOETHICS, Winter 2018, at 193–224. This symposium features stories from chronic pain patients living at the center of the two public health crises: opioid overdose and undertreated chronic pain. *Id*. As Becker-Leckore describes: "People can kill themselves with pills, but they can save themselves too. The stories of people who keep themselves alive, undramatically, with pills they'd rather not take, are the ones you never hear, but they are legion." *Id.* at 196; *see also* Thomas Kline, *SUICIDES associated with forced tapering of opiate pain treatments*, MEDIUM (May 11, 2018), https://thomasklinemd.medium.com/opioidcrisis-pain-related-suicides-associated-with-forced-tapers-c68c79ecf84d (listing chronic pain patients who committed suicide due to forced or rapid tapering of opioid therapy).

21. Maia Szalavitz, *Cracking Down on Opioids Hurts People with Chronic Pain*, VICE (Nov. 6, 2017, 7:00 AM), https://www.vice.com/en/article/8x5m7g/opioid-crackdown-chronic-pain-patients-suicide.

The accident damaged Jay's spinal cord, causing him lifelong debilitating chronic pain.[22] Vertebral fusions, spinal implants, steroid injections, and therapy could not control Jay's pain.[23] After the failed treatments, doctors prescribed Jay daily opioids.[24] They worked. Opioids never cured Jay's pain, but his dose of 120 MME allowed him to do everyday activities and maintain a decent quality of life.[25]

In February 2017, Jay's pain clinic doctor cut Jay's dose down to ninety MME and planned to lower it to thirty MME the following month—a seventy-five percent reduction in only one month.[26] The drop from one hundred twenty to ninety meant Jay now had fewer pills to treat pain he described as fire on "every nerve in [his] body."[27] He tried to fight it, but knew the pain would only get worse.[28] Jay shot himself in the heart the morning before his next appointment, when his doctor planned to drop his dose again.[29] Reflecting on his suicide, Jay's wife noted, "[t]o know that he was finally out of pain was a weight lifted off both of us."[30]

Since 1999, the opioid overdose crisis has killed 932,000 Americans.[31] Though Brent and Jay died by suicide, their deaths share a common factor with overdose deaths: opioids, either too much or too little. However, a closer look suggests prescription opioids are not the problem, but decades of short-sighted and countervailing policy and legislative efforts to help those with untreated pain and end substance abuse and overdose deaths.[32]

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22. Art Levine, *The Government's Solution To The Opioid Crisis Feels Like A War To Pain Patients*, HUFFPOST (Jul. 31, 2018, 08:00 AM), https://www.huffpost.com/entry/government-crackdown-opioid-prescriptions-pain-patients_n_5b51ec57e4b0fd5c73c4a42e.

23. Elizabeth Llorente, *As doctors taper or end opioid prescriptions, many patients driven to despair, suicide*, FOX NEWS (Dec. 10, 2018, 11:29 AM), https://www.foxnews.com/health/as-opioids-become-taboo-doctors-taper-down-or-abandon-pain-patients-driving-many-to-suicide; Dineen, *supra* note 20, at 963.

24. Szalavitz, *supra* note 21 ("He'd become resigned to the fact that he wasn't going to regain function, but on good days he could make Meredith coffee before she went to work and help tend to their menagerie of nine cats and two dogs.").

25. *Id.*; Llorente, *supra* note 23.

26. Szalavitz, *supra* note 21; Dineen, *supra* note 20, at 962 (explaining that Jay's pain clinic decided to decrease all its pain patients' opioid prescriptions to a maximum dose of forty-five MME).

27. Llorente, *supra* note 23.

28. Dineen, *supra* note 20, at 961 n.2; Becker-Leckore et al., *supra* note 20 at 219; Meredith Lawrence, *How Chronic Pain Killed My Husband*, PAIN NEWS NETWORK (Sept. 6, 2017), https://www.painnewsnetwork.org/stories/2017/9/4/how-chronic-pain-killed-my-husband.

29. Llorente, *supra* note 23; Becker-Leckore et al., *supra* note 20, at 221–22.

30. Lawrence, *supra* note 28.

31. *Death Rate Maps & Graphs*, CDC, https://www.cdc.gov/drugoverdose/deaths/index.html (last visited Mar. 25, 2023).

32. *See* Stefan G. Kertesz & Adam J. Gordon, *A Crisis of Opioids and the Limits of Prescription Control: United States*, 114 ADDICTION 169, 171 (2018). The authors suggest

During the 1990s, physicians ramped up opioid prescribing to recognize pain as the fifth vital sign.[33] Liberal opioid prescribing for chronic pain correlated with an increase in overdose deaths, and inappropriate prescribing for chronic pain bore the blame.[34] At the same time, the familiar villains of the opioid crisis appeared. Pharmaceutical companies aggressively touted opioids as a cure-all, but in the interest of profit rather than pain relief.[35] "[O]utlaw doctors" running "pill mills" sold opioids to patients they knew did not need them.[36] Patients feigned symptoms to dupe physicians into prescribing opioids, then illegally diverted them.[37] Though overly simplistic, these narratives about the overdose problem informed solutions that changed the course of opioid prescribing for chronic pain.[38]

Law and policy actors zeroed in on those closest to prescription opioids—prescribers and chronic pain patients. Guidance from public health organizations, like the Centers for Disease Control and Prevention (CDC), recommended restrictions on the number of opioids physicians should prescribe and how long patients could take them.[39] States imposed harsh dose limits and closely watched those writing and receiving prescriptions.[40] Phy-

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that the policy "reflects an imbalance that threatens efforts to address pain and addiction, while endangering patients whose receipt of opioids for pain represents a key part of their care." *Id.* at 169.

33. *See* Paul J. Larkin, Ruan v. United States: *An Important Ruling or Merely 'Sound and Fury'?*, GEO. J.L. & PUB. POL'Y, Aug. 2022, at 11 (noting physicians received pressure from several stakeholders to treat chronic pain with opioids).

34. Bingzi Hu, *At the Intersection of Competing Social Values: Evaluating the Criminal Law Approach Addressing the Opioid Crisis*, 15 L. J. SOC. JUST. 40, 42–43 (2022); *see* Dineen, *supra* note 20, at 966 (explaining inconsistent use of "inappropriate prescribing," "overprescribing," "misprescribing," and "overutilization" in policy and media).

35. Liza Vertinsky, *Pharmaceutical (Re)Capture,* 20 YALE J. HEALTH POL'Y L. & ETHICS 146, 208 (2021).

36. *See* Kelly K. Dineen & James M. DuBois, *Between a Rock and a Hard Place: Can Physicians Prescribe Opioids to Treat Pain Adequately While Avoiding Legal Sanction*, 42 AM. J.L. MED. 7, 42 (2016).

37. *Id.* at 15–16.

38. Taleed El-Sabawi, *The Role of Pressure Groups and Problem Definition in Crafting Legislative Solutions to the Opioid Crisis*, 11 N.E. U. L. REV. 372, 382, 385, 388–89, 394, 398–99 (2019).

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

40. Jennifer D. Oliva, *Dosing Discrimination: Regulating PDMP Risk Scores*, 110 CALIF. L. REV. 47, 47 (2022) ("Law enforcement conducts dragnet sweeps of PDMP data to target providers that the platform characterizes as 'overprescribers' and patients that it deems as high risk of drug diversion, misuse, and overdose."); Nathan Guevremont et al., *Physician Autonomy and the Opioid Crisis*, 46 J.L. MED. & ETHICS 203, 204 (2018) (noting that opioid-related "laws and regulations are extremely specific and restrictive" and "often fall outside the standard regulatory regime, limiting physician discretion to treat individual patients.");

sicians who exceeded the bounds faced criminal prosecution and discipline.[41] As a result, many physicians quit prescribing opioids altogether.[42] Some doctors stopped accepting new chronic pain patients, while others dangerously decreased patients to low doses or suddenly took patients off the medication entirely.[43]

One of the more significant initiatives to limit opioid prescribing came in 2016 when the CDC released its first Guideline for Prescribing Opioids for Chronic Pain ("CDC Guideline" or "Guideline").[44] The Guideline prompted physicians to taper patients to lower doses or suspend opioid treatment altogether.[45] Nothing about the Guideline itself compelled physicians to follow it. Nevertheless, individual states and regulatory bodies enshrined it in law, giving the recommendations "the force of legal mandates."[46]

Over fifty million Americans suffer from chronic pain.[47] Millions of these patients depend on daily prescription opioids to manage pain that noth-

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see generally Andrew M. Parker et al., *State Responses to the Opioid Crisis*, 46 J.L. MED & ETHICS 367, 368 (2018) (providing a catalog of state policy responses to the overdose crisis).

41. *See* Hu, *supra* note 34, at 44.

42. *See FDA identifies harm reported from sudden discontinuation of opioid pain medicines and requires label changes to guide prescribers on gradual, individualized tapering*, FDA (Apr. 9, 2019), https://www.fda.gov/media/122935/download (warning health care professionals not to "abruptly discontinue opioid analgesics in patients physically dependent on opioids"); Brief of Amici Curiae Professors of Health Law and Policy in Support of Petitioner at 16–17, Ruan v. United States, 142 S. Ct. 2370 (2022) (No. 20-1410).

43. Kurt Kroenke et al., *Challenges with Implementing the Centers for Disease Control and Prevention Opioid Guideline: A Consensus Panel Report*, 20 PAIN MED. 724, 725–26 (2019).

44. *See 2016 CDC Opioid Prescribing Guideline*, *supra* note 39.

45. *See* Stefan G. Kertesz et al., *Nonconsensual Dose Reduction Mandates are Not Justified Clinically or Ethically: An Analysis*, 48 J.L. MED. & ETHICS 259, 260–64 (2020) ("The decline in opioid prescribing accelerated after the release of a consensus Guideline from the CDC in 2016."); Travis N. Rieder, *Is Nonconsensual Tapering of High-Dose Opioid Therapy Justifiable?*, 22 AMA J. ETHICS 651, 652–53 (2020) ("The CDC guideline . . . has been widely misinterpreted as a mandate to deprescribe for existing patients—in particular, for *legacy* patients . . . ."); Hannah T. Neprash et al., *Abrupt Discontinuation of Long-term Opioid Therapy Among Medicare Beneficiaries*, *2012-2017*, 36 J. GEN. INTERNAL MED. 1576, 1576 (2021) ("2016 Guideline for Prescribing Opioids for Chronic Pain was leading physicians to indiscriminately curtail [long-term opioid therapy] for patients"); Nadeau et al., *supra* note 47, at 1, 12 ("[T]he CDC . . . by restricting treatment of pain in clinics, has created a second very serious crisis, this one involving 18 million patients in moderate to severe chronic pain."); Adams & Guerra, *supra* note 7, at 314–15; Kroenke et al., *supra* note 43, at 725; Dineen, *supra* note 20, at 961.

46. Brief of Amici Curiae Professors of Health Law and Policy in Support of Petitioner, *supra* note 42, at 16–17; *see* Dineen, *supra* note 20, at 971–73.

47. Nadeau et al., *Opioids and Chronic Pain: An Analytic Review of the Clinical Evidence*, FRONTIERS PAIN RSCH., Aug. 17, 2021, at 1.

ing else can cure.[48] Without effective pain treatment, patients face significant harm, including a doubled risk of death by suicide.[49] Opioid dose reductions or total cut-offs threaten the safety of patients who already take opioids without issue, particularly those who have a history of doing well on a high dose for a long time.[50]

When a provider putatively harms a patient this way, the patient deserves the right to seek legal relief through a medical malpractice claim that the provider's negligent treatment caused the harm.[51] However, "only a few cases of physicians facing individual liability for prescribing opioids exist."[52] Health care liability depends on how expert medical professionals define the standard of care.[53] Experts for both the plaintiff-patient and defendant-doctor will provide opposing views, but the patient cannot win unless they prove the doctor's prescribing practices fell below the accepted standard for a prescribing and caused the patient harm.[54] Without an agreed upon standard of care for chronic pain, health care practitioners and expert witnesses may depend on clinical practice guidelines or mandatory regulations and laws as a proxy for the standard of care.[55]

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48. Stefan G. Kertesz & Allyson L. Varley, *New Data on Opioid Dose Reduction—Implications for Patient Safety*, JAMA NETWORK OPEN (June 13, 2022), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2793299 (noting eight to ten million patients need opioids).

49. Alessandra Constanza et al., *The Role of Demoralization and Meaning in Life (DEMIL) in Influencing Suicidal Ideation Among Patients Affected by Chronic Pain: Protocol of a Single-Center, Observational*, *Case-Control Study*, JMIR RSCH. PROTOCOLS, 2020, at 1 (finding chronic pain increases the prevalence of suicidal ideation by 20% to 40%, suicide attempts by 5% to 14%, and risk of death by 50% as compared to a control group).

50. *See* Dineen, *supra* note 20, at 965, 1003–05.

51. Madeline Orlando, *The Doctor Will See You Now: How the Opioid Crisis Changed the Standard of Care in Medical Malpractice Suits*, 52 U. PAC. L. REV. 231, 233–34 (2020) (detailing examination of opioid prescribing and the standard of care in medical malpractice lawsuits; Orlando ultimately arguing for a new standard of care courts should apply); Mark A. Rothstein & Julia Irzyk, *Physician Liability for Suicide after Negligent Tapering of Opioids: Currents in Contemporary Bioethics*, 50 J.L. MED. & ETHICS 184, 186 (2022).

52. Orlando, *supra* note 51, at 233 (citing Koon v. Walden, 539 S.W.3d 752 (Mo. Ct. App. 2017); Cnty. Comm'n of McDowell Cnty. v. McKesson Corp., 363 F. Supp. 3d 639 (S.D. W. Va. 2017)); *see also* Kelly K. Dineen Gillespie, Ruan v. United States: *"Bad Doctors," Bad Law, and the Promise of Decriminalizing Medical Care*, 2022 CATO SUP. CT. REV. 271, 281 (2022) ("Doctors are almost never held accountable for withholding care when it comes to opioids.").

53. Robert Warner & Timothy R. Deer, *Malpractice and the Practice of Pain Medicine: An Attorney's Perspective*, 9 AM. ACAD. OF PAIN MED. S137, S138 (2008).

54. *Id.* at S137.

55. *Id.* at S137; Orlando, *supra* note 51, at 233, 246–55; Tanya E. Karwaki, *Deprescribing: Legal & Policy Reforms for Safe & Effective Medication Use*, 17 J. HEALTH & BIOMEDICAL L. 209, 231 (2021) (describing how prescribers feel less threatened by potential liability when following opioid prescribing guidelines); Peter M. Durney & Harrison L. Lebov, *The Perils of Prescribing Medication and the Goldilocks Principle: Defending Relat-*

This Note argues that the 2016 CDC Opioid Prescribing Guideline triggered a shift in the standard of care for using opioids to treat chronic pain. Specifically, the Guideline made it nearly impossible to prove physicians fall below the standard when suddenly stopping and involuntarily tapering chronic pain patients from opioids to follow the Guideline's recommendations.[56] Although the CDC revised its prescribing guidelines in 2022 and stressed that policy actors should not use it as the basis for restrictive opioid policy, the 2022 Guideline[57] is unlikely to evolve the standard to sufficiently protect long term chronic pain patients from harmful dose reductions or sudden discontinuation of opioid therapy.[58] Preventing this harm requires explicit legislative action, not simply course-corrective measures by the CDC.

Section II of this Note first explores the fraught relationship between chronic pain, opioids, and the overdose crises. It then introduces the CDC Guideline and patient harm stemming from it.[59] Section III illustrates how the CDC Guideline shaped the medical profession to favor limits and restrictions on using opioids for treating chronic pain and how courts and legislative bodies enforce this standard as law.[60] Section IV argues the CDC Guideline is an unreliable source for the standard of care that effectively shields liability for physicians who follow the Guideline, even when doing so causes patient harm.[61] Section V moves to solutions to fix the standard of care. It first examines how the CDC's 2022 revision to the original opioid prescribing guidelines cannot fix the problem, then urges states to take immediate legislative action to heal the standard before it gets worse.[62]

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ed Claims of Malpractice, 86 DEF. COUNS. J. 1, 6–11 (2019); *see* Kendra Simpson, *The Racial Tension Between Underprescription and Overprescription of Pain Medication Amid the Opioid Epidemic*, 45 N.Y.U. REV. L. & SOC. CHANGE 129, 152, 154–56 (2021).

56. *See infra* notes 293–301 and accompanying text.

57. Deborah Dowell et al., *CDC Clinical Practice Guideline for Prescribing Opioids for Pain—United States, 2022*, 71 MORBIDITY & MORALITY WKLY. REP. 1 (2022) [hereinafter *2022 CDC Opioid Prescribing Guideline*].

58. *See infra* Section V.

59. *See infra* Section II.

60. *See infra* Section III. Medical malpractice case law on this issue is extremely rare; thus, Section III reviews the CDC Guideline's influence on the standard of care in expert depositions, testimonies, and reports, and in other cases defining standards for prescribing opioid therapy.

61. *See infra* Section IV.

62. *See infra* Section V.

II. BACKGROUND

A. Chronic Pain and the Use of Opioid Therapy as Treatment

1. What is Chronic Pain?

Pervasive, persistent, and difficult to cure—chronic pain is a public health crisis.[63] Chronic pain lasts longer than three months.[64] Of the fifty million Americans with chronic pain, eighteen million suffer at moderate-to-severe levels.[65] The crisis is not limited to physical pain—chronic pain can lead to death and lowers a person's quality of life by limiting the ability to perform necessary day-to-day activities.[66]

Further, if left untreated, chronic pain becomes unforgiving and persistent, leading to a "plethora of complications" of the most crucial bodily functions.[67] Living with severe chronic pain is akin to dying from cancer.[68] When poorly treated, chronic pain comes with a host of hardships—trouble working, greater healthcare needs, and loss of mental, physical, and emotional function.[69] Additionally, those who have suffered for long periods of time live with "fears that their pain might never go away" and question "whether their lives would ever be worth living in such extreme pain."[70]

2. Legacy Chronic Pain Patients

Brent and Jay represent legacy chronic pain patients. Legacy patients tend to rely on long-term treatment of higher-dose opioid therapy, and many do not show signs of addiction to opioids but rather symptoms of physical dependence.[71] Distinguishing between addiction and physical dependence helps reduce the stigma portraying pain patients as drug seekers.[72] Physical

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63. Kelly K. Dineen, *Addressing Prescription Opioid Abuse Concerns in Context: Synchronizing Policy Solutions to Multiple Complex Public Health Problems*, 40 L. & PSYCH. REV. 1, 19 (2016).

64. *Resources: Fast Facts About Chronic Pain*, NAT'L PAIN ADVO. CTR., https://nationalpain.org/fast-facts-about-pain (last visited Feb. 10, 2023).

65. Nadeau et al., *supra* note 47, at 1.

66. *Id.*; Paul J. Christo, *Opioid Controversies: The Crisis – Causes and Solutions: Opioids May be Appropriate for Chronic Pain*, 48 J.L. MED. & ETHICS 241, 241–42 (2020).

67. Forest Tennant, *Complications of Uncontrolled, Persistent Pain*, PRAC. PAIN MGMT., Jan. 28, 2012, at 1.

68. *See* Nadeau et al., *supra* note 47, at 6.

69. *Id.*

70. HUM. RTS. WATCH, "NOT ALLOWED TO BE COMPASSIONATE" 4, 11 (2018).

71. Rieder, *supra* note 45, at 652–53.

72. HUM. RTS. WATCH, *supra* note 70, at 2, 33–34; *see* Lise Dassieu et al., *Conversations About Opioids: Impact of the Opioid Overdose Epidemic on Social Interactions for People who Live with Chronic Pain*, 31 QUALITATIVE HEALTH RSCH. 1658, 1665 (2021)

dependence is a normal reaction when taking a medication for a long time.[73] It means the patient's body has acclimated to the dose of a certain drug, so suddenly taking it away could cause withdrawal symptoms.[74] Conversely, addiction leads to "compulsive drug use despite harmful consequences," such as forgoing obligations at work or home and engaging in other destructive behavior to acquire the drug.[75]

Legacy patients often benefit from continued treatment of opioids when the risks do not outweigh the benefits of the treatment.[76] These patients may face severe pain, withdrawals, and other harms when providers reduce, or taper, a patient's opioid therapy, especially without the patient's consent.[77] After the CDC indicated that long-term use of opioids is not safe or effective in treating chronic pain, providers started prescribing opioids less often and at lower doses, even if long-term opioid therapy at a higher dose improved the patient's pain.[78] Patients whose pain has been adequately managed with responsible opioid therapy for a long time, even at high doses, deserve to have their treatment preferences considered.[79] This may include staying at their current dose, trying something else, or seeing if a lower dose provides the same relief.[80] While lower doses or other forms of treatment have their benefits, abruptly terminating opioid therapy, which

("[C]ommunication about the opioid overdose epidemic has entailed both a general climate of fear with regard to these drugs and a stigmatizing image that tends to demonize the persons using them.").

73. HUM. RTS. WATCH, *supra* note 70, at 33–34.

74. *Id.*

75. *Id.*; *see* DANIELLE B. HORN ET AL., RESPONSIBLE CONTROLLED SUBSTANCE AND OPIOID PRESCRIBING (2022), https://www.ncbi.nlm.nih.gov/books/NBK572085/.

76. Adrian Bartoli & Courtney Kominek, *What Do the CDC Guidelines Mean for Patients on Long-Term, High-Dose Opioids?*, PRAC. PAIN MGMT. (Apr. 2019), https://www.practicalpainmanagement.com/resource-centers/opioid-monitoring-2nd-ed/what-do-cdc-guidelines-mean-patients-long-term-high-dose.

77. Rieder, *supra* note 45, at 652–53.

78. *Id.*; *see* HUM. RTS. WATCH, *supra* note 70, at 3–4 (conducting interviews with dozens of physicians to find "the atmosphere around prescribing for chronic pain had become so fraught that physicians felt they must avoid opioid analgesics even in cases when it contradicted their view of what would provide the best care for their patients. . . . [T]his desire to cut back on opioid prescribing translated to doctors tapering patients off their medications without patient consent . . . [or] no longe[r] accept[ing] patients who had a history of needing high-dose opioids.").

79. *Id.*; *see* Frank Brennan et al., *Access to Pain Management as a Human Right*, 109 AM. J. PUB. HEALTH 61, 63 (2019) ("[P]hysicians should be able to make the clinical determination of the best treatment options . . . and patients should have access to them, including opioids.").

80. *See* Travis N. Rieder, *There's Never Just One Side to the Story: Why America Must Stop Swinging the Opioid Pendulum*, NARRATIVE INQUIRY BIOETHICS, Winter 2018, at 227–28.

may be the most effective treatment for some legacy patients, can have serious consequences.[81]

3. Opioid Therapy May be Appropriate for Chronic Pain

Arguments against using opioid therapy in the long-term do not pass muster. Recent evidence and patient reports indicate that opioid therapy may effectively treat chronic pain in certain patients, particularly when alternative treatments fail to offer patients relief.[82] The evidence against the long-term use of opioid therapy not only contributes to stigmatization of patients who need opioids as drug seekers or addicts[83] but also fails to consider the actualities and nuances of the chronic pain patient's experience.

> Unfortunately, by and large, these trials have been marked by failure to accommodate the enormous patient to patient variability in necessary opioid dosage, failure to titrate opioids to achieve adequate control of pain, over rapid drug titration (which magnifies side effects and renders achievement and assessment of dosage adequacy difficult), and lack of recognition of the high prevalence of idiosyncratic side effects. It may take many months to identify an opioid that is well-tolerated by a given patient, gradually titrate dosage to the point of effective control of pain, and effectively treat important comorbidities such as depression.[84]

Some conclusions about long-term opioid therapy, including its ineffective treatment of chronic pain, stem from flawed evidence, lack support, or have been refuted by existing scientific data.[85] To be fair, the evidence at the time did not conclusively establish whether high-dose opioids effectively treated chronic pain.[86] However, it also did not prove the conclusion that opioids are not effective.[87] In fact, it can take several months or years to find the right medication and dosage to treat a patient's chronic pain, but none of the randomized controlled trials[88] testing the efficacy of opioids to treat

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81. *Id.*

82. Nadeau et al., *supra* note 47, at 1; Jason W. Busse et al., *Opioids for Chronic Noncancer Pain: A Systematic Review and Meta-analysis*, 320 JAMA 2448, 2457 (2018); June Oliver & Cathy Carlson, *Misperceptions about the 'Opioid Epidemic:' Exploring the Facts*, 21 PAIN MGMT. NURSING 100, 102 (2020) ("[A] moderate or fair response to long-term opioids is often reported."); Dineen, *supra* note 20, at 970–71; HUM. RTS. WATCH, *supra* note 70, at 13.

83. HUM. RTS. WATCH, *supra* note 70, at 2.

84. Nadeau et al., *supra* note 47, at 2.

85. *Id.* at 11.

86. Dineen, *supra* note 20, at 970–71.

87. *Id.*

88. *See* Nadeau et al., *Opioid Trials: Time for a New Approach? Enriched enrollment randomized gradual withdrawal designs*, 12 PAIN MGMT. 243, 243 (2022) ("Randomized

chronic pain lasted long enough to conclude whether opioids are effective for long-term use.[89] Establishing standards of care recommending against the use of long-term opioid therapy makes little sense without clear evidence, especially when legacy patients report that opioids reduce their pain, enable them to live normal lives, and that their symptoms worsen when they are forced to stop taking the medication.[90] Yet, this did not deter the CDC and, subsequently, many states from drawing bright-line conclusions from these "seriously flawed RCTs characterized by inadequate experimental designs" on how to use—or *not* use—opioid therapy to treat chronic pain, often limiting the doses to a hard ceiling of ninety MME to comply with the CDC Guideline even when a patient saw pain relief at higher doses.[91]

B. Chronic Pain and Opioid Therapy in the Context of the Overdose Epidemic

The chronic pain and opioid overdose epidemics share common threads. Opioid medication remains crucial to both but plays conflicting roles.[92] Bad doctors overprescribing opioids to patients who abuse them receive a fair share of the blame for causing opioid use disorder, addiction, and overdose deaths.[93] While one cannot minimize the significant number of lives lost from drug overdoses, neither can one diminish the lives lost from inadequately managed chronic pain.[94] Federal agencies and state lawmakers responded to increasing overdose deaths with laws and policies designed to curb abuse and overdose by limiting chronic pain patients' access to opioid medication.[95] The basic logic behind these measures reasons that overdose

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controlled trials (RCTs) constitute our most powerful tool for testing the efficacy and safety of therapeutic interventions.").

89. Most studies lasted only a month long, and the longest study lasted only twenty-four weeks. *See* Nadeau et al., *supra* note 47, at 2.

90. Kertesz et al., *supra* note 45, at 262–64.

91. Nadeau et al., *supra* note 47, at 2, 11; *see* Jeffrey A. Singer, *If Lawmakers Really Want to "Follow the Science" They Will Repeal Codified Opioid Guidelines*, CATO INST. (May 24, 2021, 10:31 AM), https://www.cato.org/blog/lawmakers-really-want-follow-science-they-will-repeal-codified-opioid-guidelines.

92. *See* Kate Nicholson & Deborah Hellman, *Opioid Prescribing and the Ethical Duty to Do No Harm*, 46 AM. J.L. & MED. 297, 303–04 (2020).

93. *See* Hum. RTS. WATCH, *supra* note 70, at 2; *see also* Dineen, *supra* note 20, at 996.

94. *See* Christo, *supra* note 66, at 241. According to the CDC, almost 263,000 Americans died of overdoses involving prescription opioids from 1999 to 2020. *Drug Overdose*, CDC, https://www.cdc.gov/drugoverdose/deaths/prescription/overview.html (last visited Jan. 8, 2023).

95. Dineen, *supra* note 20, at 990 (noting how many laws and regulations focused on opioid prescribing for chronic pain); Michael Waldrop, *A Little Less Regulation: Why Federal Pain Management Laws are Hurting State Efforts to Combat the Opioid Epidemic*, 43 MITCHELL HAMLINE L. REV. 881, 884–88 (2017); HUM. RTS. WATCH, *supra* note 70, at 22.

deaths would slow if the country reduced the prevalence of opioids by lowering the amount of prescriptions, reducing the number of available pills, and monitoring prescribing practices.[96] Overdose deaths did not slow, but increased, and the policies took away a crucial tool to treat chronic pain.[97] Chronic pain patients lost the treatment that freed them, even temporarily, from the afflictions of chronic pain.[98] Non-opioid treatments could not provide the same relief.[99] Out of fear of potential liability, some physicians felt they could not ignore the Guideline and had no choice to taper, despite their desire to offer individualized care to patients who depended on opioids.[100]

Opioid policies also influenced the accepted standards of practice—that is, the standard of care—for using opioid therapy to treat chronic pain.[101] While the CDC and policy actors use the overdose epidemic to justify these standard-of-care-changing measures, they did not appreciate the extent to which prescription opioids might have had on the overdose epidemic.[102]

1. Common Misperceptions Influencing the Standard of Care

A common misperception surrounding the overdose epidemic is that prescription opioids primarily led to the incalculable loss of life.[103] Recent statistics show that prescription opioids for chronic pain treatment are not the main drivers of the overdose epidemic in the United States, but rather the epicenter of the epidemic lies with synthetic opioids derived from illicitly manufactured fentanyl as well as heroin and methamphetamine.[104] Opioid

96. Karwaki, *supra* note 55, at 238–41; Dineen, *supra* note 20, at 975–76.

97. Kertesz & Varley, *supra* note 48, at 1 ("[P]rescribing of opioids for pain reached its peak in 2011 to 2012. By 2020, prescribing per capita had decreased to levels last seen in 1993."); Brief of Amici Curiae Professors of Health Law and Policy in Support of Petitioner, *supra* note 42, at 16–17.

98. *See* HUM. RTS. WATCH, *supra* note 70, at ii–iv, 35–37, 42, 63–64.

99. *See* Christo, *supra* note 66, at 242 (discussing examples of alternative treatments); *see also Resources: Fast Facts About Chronic Pain*, *supra* note 64.

100. HUM. RTS. WATCH, *supra* note 70, at 4, 28 (describing how providers "felt that the only way to protect themselves from liability was to stay rigidly at or below the CDC Guideline's 90 [MME] threshold and to disregard the emphasis on individualized patient care and respect for patient consent.").

101. Nicholson & Hellman, *supra* note 92, at 306; Lars Noah, *State Regulatory Responses to the Prescription Opioid Crisis: Too Much to Bear?*, 124 DICKINSON L. REV. 633, 646 (2020).

102. Dineen, *supra* note 20, at 976–77.

103. Jeffrey J. Bettinger et al., *Misinterpretation of the "Overdose Crisis" Continues to Fuel Misunderstanding of the Role of Prescription Opioids*, 15 J. PAIN. RSCH. 949, 949–50 (2022) ("[T]here continues to be a disturbing and disproportionate narrative pertaining to the involvement and overall influence of opioid prescribing"); Oliver & Carlson, *supra* note 82, at 101.

104. *See generally* Christine L. Mattson et al., *Trends and Geographic Patterns in Drug and Synthetic Opioid Overdose Deaths—United States, 2013-2019*, 70 MORBIDITY &

prescribing has declined by almost fifty percent over the last decade, yet overdoses have soared to record highs.[105] Further, the American Medical Association reports "reductions in opioid prescribing have not led to reduction in drug-related mortality."[106] Courts have recognized this by refusing to hold pharmaceutical companies liable for overdose deaths stemming from illicit fentanyl.[107] Recently, a court in California ruled "medically appropriate prescriptions" did not cause the "adverse downstream consequences" related to the overdose epidemic.[108]

Opioid overdose death reports distort the number of overdose deaths caused by prescription opioids.[109] CDC analysts acknowledged that over a decade's worth of reports wrongly overstated prescription opioid overdose deaths.[110] The erroneous reports stem from bad data analysis: the CDC mislabeled deaths involving illegal, black-market fentanyl as prescription opioid overdose deaths.[111]

Additionally, if someone dies, for example, to an overdose of Tylenol or heroin, but the coroner detects a small amount of oxycodone in this person's system, the death still is recorded "as a prescription opioid death."[112]

MORTALITY WKLY. REP. 202, 202–06 (2021) (finding that deaths involving synthetic opioids, such as illicitly manufactured fentanyl, increased 1,040% from 2013 to 2019); Oliver & Carlson, *supra* note 82, at 101; John D. Lilly, *Estimating the Actual Death Rate Caused by Prescription Opioid Medication and Illicit Fentanyl*, 23 J. AM. PHYSICIANS & SURGEONS 20, 22 (2018) ("Searching the CDC Wonder database reveals that the recent spike in deaths is primarily due to illicit fentanyl."); Kertesz & Gordon, *supra* note 32, at 171 ("Since 2013, illicitly manufactured synthetic opioids such as fentanyl have played a rising role in [overdose] deaths").

105. AM. MED. ASS'N, 2021 OVERDOSE EPIDEMIC REPORT: PHYSICIANS' ACTIONS TO HELP END THE NATION'S DRUG-RELATED OVERDOSE AND DEATH EPIDEMIC—AND WHAT STILL NEEDS TO BE DONE 3 (2021).

106. *Id.*

107. *See generally California and Oklahoma Courts Say Drug Companies Aren't Liable Under a Public Nuisance Theory for the Opioid Epidemic*, CROWELL (Nov. 30, 2021), https://www.crowell.com/NewsEvents/AlertsNewsletters/all/California-and-Oklahoma-Courts-Say-Drug-Companies-Arent-Liable-Under-a-Public-Nuisance-Theory-for-the-Opioid-Epidemic; Brian Mann, *A California Court Says Drug Companies Aren't Liable for the State's Opioid Crisis*, NPR (Nov. 2, 2021, 8:38 AM), https://www.npr.org/2021/11/01/1051321580/california-judge-drug-companies-opioid-crisis-allergan-endo-johnson-teva.

108. *See* People v. Purdue Pharma L.P., No. 30-2014-00725287-CU-BT-CX, 2021 WL 5227329, at *7 (Cal. Super. Nov. 01, 2021).

109. *See* John F. Peppin & John J. Coleman, *CDC's Efforts to Quantify Prescription Opioid Overdose Deaths Fall Short*, 10 PAIN THERAPY 25, 25–26 (2021).

110. *Id.* ("[F]our senior analysts of the Centers for Disease Control and Prevention (CDC), including the head of the Epidemiology and Surveillance Branch, acknowledged for the first time that the number of prescription opioid overdose deaths reported by the CDC in 2016 was erroneous. . . . The [CDC] erroneously reported prescription opioid overdose deaths in 2016 and for more than a decade before.").

111. *Id.*

112. Oliver & Carlson, *supra* note 82, at 100–01.

The data used to blame the overdose crisis on overprescribing opioid pain medicine does not appreciate whether the presence of opioids caused the deaths at all.[113] Therefore, physicians who use the overdose crisis as justification for their arguably negligent tapering of patients off pain medication, when no other reason for the taper exists, fail to treat their patients' individual and unique needs.[114] Tapering or reducing patients who have historically benefitted from long-term, higher-dose opioids and have taken the medicine as prescribed without any complications or risk of addiction will not end America's overdose crisis.[115] An assessment of the current scientific evidence reveals that opioids may be appropriate to treat chronic pain and many patients and providers agree.[116] Consequently, if the prevailing standard of care recommends against using opioids to treat chronic pain, then the standard misses a crucial, lifesaving treatment for some patients.

Using opioid therapy to treat chronic pain is not a novel treatment, nor is it inherently risky.[117] New research suggests opioid doses that exceed the CDC's ninety MME threshold have fatality rates lower than one percent.[118] Furthermore, the risk of addiction hovers around only eight percent or less.[119] Recently, an expert witness testified that addiction occurs in one in four patients, but the court shot her down, relying on scientific evidence.[120] Nevertheless, these baseless claims, often by high-level lawmakers, changed how physicians treat chronic pain.[121]

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113. *Id.*

114. The New Hampshire Board of Medicine reprimanded a physician who cut a patient's dose to follow the CDC Guideline despite the patient's symptoms of withdrawals and increased pain. *See* Jacob Sullum, *State Regulators Punish Doctor for Cutting a Pain Patient's Opioid Dose and Dropping Him After He Became Suicidal*, REASON (July 10, 2019, 12:45 PM), https://reason.com/2019/07/10/state-regulators-punish-doctor-for-cutting-a-pain-patients-opioid-dose-and-dropping-him-after-he-became-suicidal/.

115. *See* Oliver & Carlson, *supra* note 82, at 103 ("There is a nonlinear relationship between opioid prescribing rates and opioid death rates.").

116. Christo, *supra* note 66, at 244.

117. Nadeau et al., *supra* note 47, at 6.

118. *Id.* at 3 (identifying a 0.25% patient fatality rate for doses greater than 100 MME compared to 0.5% for doses over 400 MME). Another study of over two million people revealed a less than .022% risk of overdose death from opioids. Nabarun Dasgupta et al., *Cohort Study of the Impact of High-Dose Opioid Analgesics on Overdose Mortality*, 17 PAIN MED. 85, 89 (2016).

119. Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain—Misconceptions and Mitigation Strategies*, 374 NEW ENG. J. OF MED. 1253, 1259 (2016).

120. People v. Purdue Pharma L.P., No. 30-2014-00725287-CU-BT-CX, 2021 WL 5227329, at *17 (Cal. Super. Nov. 01, 2021) ("As Defendants point out, the studies relied upon by Dr. Lembke for that conclusion are inadequate to support it. The more reliable data would suggest less than 5%, rather than 25%. Under either number, addiction based solely on the patient having been prescribed opioids does not occur in 'most of these patients.'").

121. *See generally* Dineen, *supra* note 20, at 974–75; HUM. RTS. WATCH, *supra* note 70, at 71–72.

2. Mainstream Opioid Litigation

In addition to pain medication, other factors characterize the opioid epidemic and chronic pain crisis. Litigation has swallowed the opioid epidemic; over 3,000 state and municipal governments have filed lawsuits against pharmaceutical giants Purdue Pharma, Johnson and Johnson, and others—blaming these companies for the epidemic causing unnecessary deaths.[122]

Advocates for chronic pain have taken up arms in the courtroom, filing class action lawsuits against CVS, Costco, and Walgreens, because the companies' pharmacies have declined to fill patients' valid prescriptions for pain medicine.[123] Without access to medicine, chronic pain patients not only suffer harm in the pharmacy but also experience harm in the doctor's office when trying to receive treatment for chronic pain.[124] Much of this harm is not the fault of individual prescribers,[125] but rather it stems from national opioid prescribing recommendations for chronic pain in the CDC Guideline.[126]

C. The CDC Guideline for Prescribing Opioids for Chronic Pain

Responding to the overdose epidemic and confusion about how physicians should use opioid therapy to treat chronic pain, the CDC sought to

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122. *See Opioids*, NAT'L ASSOC. ATTY'S GEN., https://www.naag.org/issues/opioids/ (last visited Jan. 1, 2023); *see also* Nat'l Prescription Opiate Litig. v. Purdue Pharma L.P. (*In re* Nat'l Prescription Opiate Litig.), No. MDL No. 1:17-cv-02804, 2018 U.S. Dist. LEXIS 176260 (N.D. Ohio Oct. 5, 2018) (a consolidated action of lawsuits filed by cities and counties alleging opioid manufacturers deceived medical professionals to prescribe opioid drugs, resulting in addiction and overdose in America).

123. *See* Fuog v. CVS Pharmacy, Inc., No. 20-337 WES, 2021 U.S. Dist. LEXIS 183035, at *1–2 (D.R.I. Sept. 24, 2021); Smith v. Walgreens Boots All., Inc., No. 20-cv-05451-CRB, 2021 U.S. Dist. LEXIS 21734, at *2–3 (N.D. Cal. Feb. 3, 2021).

124. *See infra* Section II.D.

125. On one hand, the physicians can hardly be blamed. After all, they taper in response to a nation struggling with a catastrophic number of overdose deaths and they must practice medicine with federal agencies and medical boards breathing down their necks; in fact, many providers face the real concerns of losing their practices or medical licenses, or even prison time, for prescribing opioids resulting in overdoses and addiction. *See* Dineen & DuBois, *supra* note 36, at 7; *see also* Julia MacDonald, *"Do No Harm or Injustice to Them": Indicting and Convicting Physicians for Controlled Substance Distribution in the Age of the Opioid Crisis*, 72 ME. L. REV. 197, 201–02 (2020). But, on the other hand, cowering to societal pressure and poor mandates and reducing a patient's opioid dose—despite the fact it will cause the patient harm—is clearly an unethical, uncompassionate model of professional practice and pain management; some propose this practice does not have clinical justification, and it should not have justification under the law, either. *See* Kertesz et al., *supra* note 45, at 264–65.

126. *See 2016 CDC Opioid Prescribing Guideline*, *supra* note 39.

direct prescribing practices through a series of recommendations.[127] By and large, the CDC Guideline recommends against using opioid therapy as a first-line treatment for chronic pain.[128] Instead, it encourages providers to use alternative treatments before opioid therapy, followed only by conservative opioid therapy after a provider assesses the risks and benefits of the treatment.[129] If a provider chooses to proceed with opioid therapy, it recommends only at a low dose for a short amount of time.[130]

Specifically, the agency advised physicians to avoid prescribing opioids at doses higher than ninety MME and warned against increasing doses.[131] The CDC also urges revaluation when considering a dose higher than ninety MME.[132] While the CDC also recommends physicians reassess treatment and offer opportunities for tapering off opioids if a patient already takes a dose of ninety MME or greater, the CDC did not offer comprehensive guidance on how to manage such patients.[133] However, the Guideline—despite its unintended consequences to the contrary—does not recommend physicians force patients to taper or end patients' treatment against their will, but instead tells physicians to work with patients to lower dosages, terminate opioid therapy, or make tapering decisions.[134]

At first glance, the CDC's recommendations do not seem very radical. It encourages collaborating with patients to assess the risks and benefits of continued treatment and recognize that opioid therapy is appropriate for certain patients.[135] However, the CDC Guideline had a significant influence.[136] Many legislatures and physicians strictly apply the CDC's recommendations, resulting in harm and increased pain to chronic pain patients when prescribers taper or discontinue patients' pain medications, dismiss

127. *Id.*

128. Kertesz & Gordon, *supra* note 32, at 172.

129. *Id.*

130. Nicholson & Hellman, *supra* note 92, at 306 (explaining the Guideline's recommendation to prescribe opioids "at the lowest effective dose for the shortest effective duration.").

131. Kertesz et al., *supra* note 45, at 260; HUM. RTS. WATCH, *supra* note 70, at 24.

132. Kertesz & Gordon, *supra* note 32, at 172.

133. Kertesz et al., *supra* note 45, at 260.

134. *Id.*; Kertesz & Gordon, *supra* note 32, at 172; HUM. RTS. WATCH, *supra* note 70, at 25; Dineen, *supra* note 20, at 1001–03; Heather Tick et al., *Comment from the Academic Consortium for Integrative Medicine & Health on the CDC Clinical Practice Guideline for Prescribing Opioids–United States, 2022*, 11 GLOB. ADV. MED. 1, 1 (2022) ("[T]he 2016 Guideline had an unintended consequence: some opioid prescribers were overly enthusiastic in reducing opioid prescribing thereby forcing patients into rapid tapers or even 'abandoning' patients on long-term opioids.").

135. HUM. RTS. WATCH, *supra* note 70, at 24–25.

136. *See* Nicholson & Hellman, *supra* note 92, at 306–07; Noah, *supra* note 101, at 646.

patients receiving long-term opioid therapy, or refuse to treat chronic pain patients altogether.[137]

D. Harms to Chronic Pain Patients and Opioid Therapy Tapering

The CDC Guideline and restrictive opioid policies reduce patients' access to legitimate opioid therapy by compelling physicians to act against their interests and the interests of patients hoping to live without pain and suffering.[138] While these laws and policies intended to mitigate opioid misuse, they "limit access to needed pain treatment and inadvertently increase harm" to pain patients.[139] Many patients describe the CDC Guideline, along with laws and regulations derived from it, as having the prescriptive and chilling effect of forcing patients off successful opioid therapy.[140]

For example, Stephanie Miller said her high dose of opioids gave her enough relief to do the dishes, but she could no longer shower without help after her doctor reduced her dose.[141] In her words, it "felt like a ticking clock for when my life was going to end."[142] Bob Green's doctor lowered his dose without consent because the doctor feared punishment from federal law enforcement.[143] The change drastically impacted Bob's ability to function. He said that he went from "working at 110%" with the help of opioid therapy to living "about 10% of a life."[144] Similarly, Marty Revolloso shattered his spine and needed opioids at a dose of 180 MME to manage the pain.[145] The medicine helped him work part-time and make progress with his pain that he did not believe was possible.[146] But after a Texas Medicaid policy forced his doctor to taper him down to ninety MME to match the CDC's recommendation, Marty said, "I was flat on my back from the pain. I couldn't eat,

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137. Mark A. Rothstein et al., *Doctors and Pain Patients Avoid "Ruan" in the Supreme Court*, 50 J.L. MED. & ETHICS (Mar. 2023); Rieder, *supra* note 45, at 652; Neprash et al., *supra* note 45, at 1576; Robert L. "Chuck" Rich, *Prescribing Opioids for Chronic Pain: Unintended Consequences of the 2016 CDC Guideline*, 101 AM. FAM. PHYSICIAN 458, 458 (2020) ("[P]olicies that limit the duration of opioid therapy or that require abrupt tapering or discontinuation of opioid therapy have resulted . . . in physicians' offices limiting or dismissing patients who are seeking or already receiving these medications").

138. Dineen, *supra* note 20, at 975.

139. Corey S. Davis & Amy Judd Lieberman, *Laws Limiting Prescribing and Dispensing of Opioids in the United States, 1989-2019*, 116 ADDICTION 1817, 1826 (2019); *see also* Dineen, *supra* note 20, at 975.

140. *See infra* notes 132–146 and accompanying text.

141. HUM. RTS. WATCH, *supra* note 70, at 31–32.

142. *Id.* at 32.

143. *Id.* at 34.

144. *Id.*

145. *Id.*

146. *Id.*

couldn't get up, couldn't bathe, I stank."[147] Jennifer Vinnard's doctor unilaterally cut her prescription by over fifty percent to follow the CDC Guideline, despite knowing that Jennifer's pain responded well to the higher dose.[148] Jennifer later discovered that her doctor felt she had to follow the CDC Guideline, otherwise the clinic would close.[149] The lower amount did not treat Jennifer's pain and left her unable to do simple daily activities.[150]

To the CDC's credit, the Guideline does not call for involuntarily discontinuing patients from opioid therapy or forcing patients to taper the dose down to a certain level.[151] However, while the CDC Guideline does recommend tapering plans, it does not describe the plans to ensure providers can taper while continuing to treat a patient's pain effectively.[152] Many legacy patients experience severe consequences—including death—when, in response to legal requirements, incentives, or the CDC Guideline, providers decide to taper or discontinue patients' opioid therapy, refrain from taking on legacy patients, or stop writing patients opioid prescriptions altogether.[153]

In the wake of the CDC Guideline, patients on long-term opioid therapy experienced widespread medication tapering at alarming rates, and sometimes providers tapered patients abruptly or used tapering methods harsher than those advised by clinical guidelines.[154] Abrupt tapering and cutting patients off from the critical tool of opioid therapy leads to inconceivable

147. HUM. RTS. WATCH, *supra* note 70, at 35.

148. *Id.* at 36.

149. *Id.*

150. *Id.*

151. Kertesz & Gordon, *supra* note 32, at 172.

152. Joseph V. Pergolizzi et al., *Three Years Down the Road: The Aftermath of the CDC Guideline for Prescribing Opioids for Chronic Pain*, 36 ADVOC. THERAPY 1235, 1235 (2019).

153. Kertesz et al., *supra* note 45, at 260.

154. *See* Neprash, *supra* note 45, at 1576, 1580–81 ("[T]he . . . 2016 Guideline for Prescribing Opioids for Chronic Pain was leading physicians to indiscriminately curtail [Long Term Opioid Therapy (LTOT)] for patients . . . . [T]he vast majority of patients were discontinued abruptly from LTOT, falling 'off a cliff' of over 50% their daily dose . . . . [T]he majority of patients on very high MME doses, even over 200 daily MME, had an abrupt discontinuation."); *see also* Joshua J. Fenton et al., *Trends and Rapidity of Dose Tapering Among Patients Prescribed Long-Term Opioid Therapy, 2008-2017*, 2 JAMA NETWORK OPEN 1, 8 (2019) ("[T]he percentage prescribed long-term opioids undergoing dose tapering has increased substantially in recent years, particularly after the publication of the 2016 CDC opioid prescribing guideline and among patients prescribed daily doses exceeding 90 MMEs. . . . [O]ver 1 in 4 patents tapered at a rate faster than 40% per month, and 5% of patients . . . faster than 95% per month."); Yuhua Bao et al., *Robust Prescription Monitoring Programs and Abrupt Discontinuation of Long-Term Opioid Use*, 60 AM. J. PREV. MED. 537, 543 (2021) ("This study draws attention to the very high rate (>80%) of LTOT discontinuation without tapering, . . . largely inconsistent with current guidelines. . . . The substantial proportion who were receiving a high dose . . . and the high proportion who discontinued without tapering suggest a serious burden of uncontrolled pain and potential adverse outcomes related to abrupt discontinuation.").

harms, including frequent patient suicide, uncontrolled pain, extreme withdrawal symptoms, various kinds of mental health crises, and mortality, among many other harms.[155] When patients experience harm because of a provider's negligent dose tapering or inappropriate prescribing, a standard of care—influenced by arguably incomplete guidelines and uncompassionate professional practice—should not hinder a patient's medical malpractice claim.

III. THE STANDARD OF CARE

Medical malpractice strives to minimize patient harm from the negligent practice of medicine.[156] Not only does it attempt to compensate harmed patients and hold negligent physicians accountable but also it works to prevent patient harm in the first place.[157] Crucial to a medical malpractice claim is the standard of care.[158]

The CDC Guideline's ubiquity, authority, and influence helped bring about the practice of limiting access to opioid therapy that appears to be the standard of care in the United States.[159] Though the Guideline only offered recommendations, it carried the weight of law.[160] The CDC Guideline alone does not constitute the standard of care or define the "course of professional practice."[161] However, the CDC Guideline does not stand alone. Although *not* mandatory, the CDC Guideline is persuasive and has a far-reaching impact on measures influencing the standard of care for treating chronic pain in the United States:

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155. HUM. RTS. WATCH, *supra* note 70, at 39; Jocelyn R. James et al., *Mortality After Discontinuation of Primary Care-Based Chronic Opioid Therapy for Pain: A Retrospective Cohort Study*, 34 J. GEN. INTERNAL MED. 2749, 2755 (2019); Alicia Agnoli, et al., *Association of Dose Tapering with Overdose or Mental Health Crisis Among Patients Prescribed Long-Term Opioids*, 326 JAMA 411, 417 (2021).

156. Karwaki, *supra* note 55, at 230; Joseph S. Kass & Rachel V. Rose, *Medical Malpractice Reform—Historical Approaches, Alternative Models, and Communication and Resolution Programs*, 18 AMA J. ETHICS 299, 299 (2016) ("[P]atients might reasonably expect medical malpractice law to serve as a deterrent to the improper practice of medicine and to compensate—through a negotiated settlement or a trial—patients who are victims of physician negligence.").

157. Kass & Rose, *supra* note 156, at 300.

158. *See* Orlando, *supra* note 51, at 242–43.

159. *See infra* Section III.

160. Nicholson & Hellman, *supra* note 92, at 306 ("The Guideline provides a standard that is non-mandatory guidance, though coming from the CDC, it carries significant weight"); *accord* Brendan LoPuzzo, *A Bitter Pill to Swallow: The Need for a Clearly-Defined Course of Professional Practice When Prescribing Opioids for the Legitimate Medical Purpose of Treating Pain*, 47 HOFSTRA L. REV. 1397, 1425 (2019).

161. LoPuzzo, *supra* note 160, at 1425.

> While the guidelines are not legally binding, they set up the criteria for an evolving standard related to the use of opioids. From a legal context, any medical expert witness, medical licensing board, judge, or court of law can interpret the guidelines as the standard for what a reasonably prudent practitioner might do in the same or similar circumstances. To ignore these recommendations would be a serious mistake.[162]

Experts, lawmakers, and policy advisers have used the CDC Guideline too rigidly to define the standard of care for opioid therapy and chronic pain.[163] The standard of care described in this Section essentially shields providers from liability by altering treatment to conform with the CDC Guideline, even if the treatment causes a patient harm.

A. Experts' Definition of the Standard of Care

Despite its unintended consequences of harming chronic pain patients, the CDC Guideline has unquestionably influenced how medical professionals and courts define the standard of care.[164] Various court cases, expert reports, and testimonies suggest that the medical community subscribes to a standard of care limiting legacy patients from accessing opioid therapy to treat chronic pain.

1. Deference to the CDC Guideline

In *O'Brien v. Saha*, a deliberate indifference case, the defendant's medical providers successfully requested the court take judicial notice of the authenticity and contents of the CDC Guideline.[165] The court recognized the CDC Guideline "strongly warn[s] against the use of opiates . . . in the treatment of chronic non-cancer pain."[166] The providers discontinued the plaintiff's opioid medications, reasoning that opioids are not the appropriate

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162. Jennifer Bolen, *A Legal Interpretation of the CDC Opioid Prescribing Guidelines*, PRAC. PAIN MGMT. (Apr. 29, 2019), https://www.practicalpainmanagement.com/resource-centers/opioid-monitoring-2nd-ed/legal-interpretation-cdc-opioid-prescribing-guidelines; *see* Nicholson & Hellman, *supra* note 92, at 306 (explaining that state lawmakers, pharmacies, insurance companies, law enforcement, and others have implemented the CDC's opioid prescribing recommendations into laws and policies as a rigid, easy-to-apply rule instead of a flexible standard).

163. *See* Nicholson & Hellman, *supra* note 92, at 306.

164. *See infra* Section IV.

165. O'Brien v. Saha, No. 19-cv-01957-JLS (JLB), 2021 U.S. Dist. LEXIS 18731, at *31 n.12 (S.D. Cal. Jan. 30, 2021).

166. *Id.* at *31. The prison used the CDC Guidelines as the basis for its internal prescribing guidelines. *Id.* at *35.

treatment for chronic pain, and the defendant's expert found the treatment "medically acceptable under the circumstances."[167]

The court agreed to take judicial notice of the CDC Guideline's contents and authenticity, signifying the court's willingness to treat the Guideline's non-mandatory recommendations as indisputable and authentic evidence of the standard of care.[168] The court gave the CDC Guideline significant weight after its authors revealed it does not support "discontinuation of opioids already prescribed at higher dosages, yet it has been used to justify abruptly stopping opioid prescriptions."[169] Additionally, it shows the court relied on the expert's erroneous belief that the Guideline represents an authoritative statement of the standard of care. This sends a strong message to potential medical malpractice plaintiffs: physicians do not prescribe below the standard of care when altering opioid prescriptions to match the recommendations in the CDC Guideline.[170]

In a similar case, *In re Johnson*, a registered nurse who treated chronic pain patients with opioid therapy at levels over the CDC's ninety MME ceiling lost her license to practice for "failing to conform to standards" of practice.[171] The court compared the nurse's patients' daily doses to the CDC's recommendations, quoting it directly.[172] The nurse argued against using it as evidence of the standard of care, but opposing expert evidence persuaded the court that the CDC Guideline "inform[s] and summarize[s] standards of practice."[173] The court affirmed the license-revoking board's use of "the CDC Guidelines as evidence of the standard of care."[174] Comparing MME levels to the CDC's ninety MME dose threshold recommendation ignores

167. *Id.* at *61–63.

168. *See id.*; *see also* Lynn Webster et al., *Drug Trafficking, Good Faith, and Legal Standards to Convict: How the United States Supreme Court is About to Affect Every Prescriber in America*, 18 J. OPIOID MGMT. 203, 203 (2022).

169. Kertesz et al., *supra* note 45, at 261; *see* Dowell et al., *No Shortcuts to Safer Opioid Prescribing*, 380 NEW ENG. J. MED. 2285, 2286 (2019) [hereinafter *No Shortcuts*].

170. *See* Gilah R. Mayer, Berman v. Chin: *Why an Elder Abuse Case Is a Stride in the Direction of Civil Culpability for Physicians Who Undertreat Patients Suffering from Terminal Pain*, 37 NEW ENG. L. REV. 313, 344 (2002) ("[W]hen clinical practice guidelines developed by nationally recognized experts in the field exist, those guidelines can and should be recognized as the medical standard of care."); Karwaki, *supra* note 55, at 231 ("Prescribers often feel more secure prescribing medications in accordance with clinical guidelines, increasing the likelihood that prescribers will comply with the standard of care.").

171. *In re* Johnson, No. A17-1571, 2018 Minn. App. Unpub. LEXIS 599, at *3, *13 (Minn. Ct. App. July 16, 2018).

172. *Id.* at *4.

173. *Id*. at *4 n.2.

174. *Id.*

case-by-case patient care in favor of an objective test.[175] Imposing a maximum dose tells opioid prescribers to toe the line or risk deviating from the standard of care.[176]

2. Disallowance of Other Standards

In a disciplinary action against a pain management physician for negligence and failure to exercise due care, the Michigan Court of Appeals affirmed the revocation of David Jankowski's medical license.[177] Jankowski's violations stemmed from prescribing opioids for chronic pain at doses higher than the CDC Guideline's ninety MME threshold.[178] When evaluating Jankowski's conduct, experts testifying against the physician relied extensively on the CDC Guideline as an "authoritative statement" of the standard of care while rejecting Jankowski's alternative standard.[179] Basing its decision on the opinion of an expert witness who did not specialize in treating pain, the court found an "[administrative law judge's] analysis was consistent with the use of the CDC Guideline as a benchmark to evaluate [the physician's] conduct."[180] The court concluded that "the CDC Guideline were the accepted standard of care regarding prescribing pain medication" despite the fact the CDC Guideline did not even exist during the time when the provider treated several of his patients.[181]

Jankowski's expert, a pain medicine specialist, argued against strict adherence to the CDC Guideline to establish the standard of care.[182] He noted chronic pain treatment varies from patient to patient, emphasized the non-compulsory nature of the recommendations in the CDC Guideline, and argued the CDC Guideline's ninety MME dose limit was not universally accepted in the industry.[183] The court found the argument futile and instead relied on the CDC Guideline, stating the standard practice of pain management has evolved "toward caps on pain medication."[184] Jankowski's rejected standard of care called for "working through the risks and benefits of the

175. *See* Jan Hoffman, *C.D.C. Proposes New Guidelines for Treating Pain, Including Opioid Use*, N.Y. TIMES (Feb. 10, 2022), https://www.nytimes.com/2022/02/10/health/cdc-opioid-pain-guidelines.html; *see also* HUM. RTS. WATCH, *supra* note 70, at 28.

176. *See* Maia Szalavitz, *When the Cure Is Worse Than the Disease*, N.Y. TIMES (Feb. 9, 2019), https://www.nytimes.com/2019/02/09/opinion/sunday/pain-opioids.html.

177. *In re* Jankowski, No. 348760, 2020 Mich. App. LEXIS 7731, at *25–26 (Mich. Ct. App. Nov. 19, 2020).

178. *Id.* at *2–3.

179. *Id.* at *4.

180. *Id.* at *4, *19–20.

181. *Id.* at *19.

182. *Id.* at *9–10.

183. *Jankowski,* 2020 Mich. App. LEXIS 7731, at *8–10.

184. *Id.* at *19, *25.

prescription for the patient" and "incorporating drug therapy into a comprehensive plan," as well as various kinds of other therapies, procedures, and even non-opiate medication.[185] Furthermore, the expert testified the standard of care embraced individualized treatment and argued "finding a balance that worked for each patient was more important than the level of morphine equivalent dosing prescribed."[186]

While this case furthers the message that compliance with the CDC Guideline does not qualify as a deviation from the standard of care, it goes a couple of steps further. In addition to using the CDC Guideline as a litmus test for appropriate prescribing, the court rejected an alternative standard of care and deferred to the CDC Guideline, notwithstanding evidence that the CDC Guideline may not have a sound basis in scientific evidence.[187]

3. Emphasis on Non-Opioid Treatment

Other cases expressing the standard of care for chronic pain management emphasize the restriction of opioid therapy for pain management. In *Mazza v. Austin*, the expert conflated the CDC Guideline with the standard of care and found the physician's decision to taper and not prescribe opioid medications did not deviate from the standard.[188] The expert admitted the standard of care was influenced by "state and federal guidelines" and "policy to reduce the risk from opiate overdoses."[189] Furthermore, the court found the expert's testimony persuasive and found, as a general rule, the risks of prescribing opioid medication for chronic pain outweighed the benefits because the rule is "consistent with the consensus of authoritative medical experts reflected in the CDC Guideline."[190] Contrary to the court's rule, the CDC Guideline endorses a risk-benefit assessment and says physicians should consider opioid therapy only when the risks do not outweigh the benefits.[191] The court's categorical finding that the benefits of opioid therapy do not outweigh the risks constitutes a blatant misapplication of the CDC Guideline, and it endorses the view that opioid therapy is not a viable treatment option for chronic pain.[192]

185. *Id.* at *8.
186. *Id.* at *12.
187. *Id.* at *8–10.
188. Mazza v. Austin, No. 2:14-cv-0874 TLN AC P, 2020 U.S. Dist. LEXIS 110905, at *62 (E.D. Cal. June 23, 2020).
189. *Id.*
190. *Id.* at *84.
191. HUM. RTS. WATCH, *supra* note 70, at 24.
192. *See Mazza*, 2020 U.S. Dist. LEXIS 110905, at *84 (summarizing that the general rule supports the decision not to prescribe opioid medications for chronic pain).

Other courts have made similar assertions. For example, in *Kelly v. Talbot*, a provider tapered a patient off opioid therapy, despite the patient's complaints of continued pain.[193] Several doctors and the court concluded that "opioids are not appropriate for chronic pain management."[194] Similarly, in *State v. Christensen*, an expert witness testified the standard of care for chronic pain management embraces "non-opioid medications as much as possible."[195]

4. Justifying Tapering and Staying Within the CDC Guideline

Other experts justify tapering and use the Guideline as indicative to explain the standards they follow in practice.[196] Expert Daren Subnaik emphasized the CDC's "heavy push" to taper patients down to the CDC's recommendations of ninety MME per day and noted that he follows the Guidelines to wean his patients' doses down to "try to be within the CDC Guideline."[197] Likewise, Matthew Grimm established a causal connection between the Guideline and dose tapers, noting he attempted to "wean patient[s] off of reliance of opiate medications and therefore [is] following CDC guidelines."[198] Milton Landers, an expert witness testifying against a physician in a jury trial, used the CDC Guideline to argue that the physician prescribed a high dose that fell outside the course of professional practice.[199] Jack Gomberg used the CDC Guideline as the touchstone for the standard of care for chronic pain, finding a physician engaged in inappropriate prescribing that deviated from the standard by not following the recommendations in the Guideline.[200] Gomberg cited the CDC Guideline as the sole support for his expert opinion.[201] Other experts spoke more generally about the standard of care, offering expert opinions like "[t]here has been a significant clinical movement away from the use of chronic opioids,"[202] or "the pain manage-

193. Kelly v. Talbot, No. 1:15-cv-01529-TWP-TAB, 2018 U.S. Dist. LEXIS 113260, at *21 (S.D. Ind. July 9, 2018).

194. *Id.* at *23.

195. State v. Christensen, 472 P.3d 622, 635 (Mont. 2020).

196. Deposition Transcript of Daren Subnaik at 42, Hurst v. Preble, No. 2015-CA-000881-09MK (Fla. Cir. Ct. Sept. 29, 2017).

197. *Id.* at 31, 42.

198. Expert Report of Matthew P. Grimm at 3, Cipriano v. Extell West 57th Street, LLC., No. 152119/2013 (N.Y. Sup. Ct. Nov. 28, 2017).

199. Expert Report of Milton H. Landers at 5, United States v. Gerber, No. 3:18-cv-01908 (N.D. Ohio Aug. 13, 2018).

200. Expert Affidavit of Jack Gomberg at 3, Maria Angeles Liberatore v. David Greuner, No. 162511/2015 (N.Y. Sup. Ct. Mar. 24, 2016).

201. *Id.*

202. Expert Report of William S. Rosenberg at 37, Nevro Corp. v. Bos. Sci. Corp., No. 3:16-cv-06830 (N.D. Cal. Jan. 18, 2018) (citing the CDC Guideline to support his position on the standard of professional practice).

ment doctor is now encouraged to utilize the CDC guidelines."[203] Finally, although the CDC Guideline did not exist during the time of the alleged harm in the lawsuit, expert Rick Chavez supported his testimony with the CDC Guideline and handed a copy to the attorneys during his deposition.[204]

The CDC Guideline and related testimony clearly have considerable sway in courts.[205] Experts use the Guidelines as an analog for the standard of care in different ways. Many consider the CDC Guideline's recommendations as hard-and-fast rules and use them to size up other physicians' prescribing patterns in court.[206] Some use the Guidelines to justify taking patients off opioids, while others find non-compliance with the recommendations as a deviation from the standard of care.

B. The CDC Guideline's Influence on State Laws and Policies

Even if a court does not use the CDC Guideline as evidence of the standard of care, a plaintiff alleging a physician committed malpractice by tapering or discontinuing opioid therapy altogether faces other legal barriers in proving the physician deviated from the standard of care due to the laws and policies limiting opioid prescribing.[207] After the CDC published its Guideline, several states used its recommendations as a model for their own opioid limitation laws: "many states adopt[ed] the [Guideline's] non-prescriptive daily dosage recommendations as black letter law."[208]

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203. Deposition Transcript of John Michael Powers at 21, Schwartz v. King, No CV2014-003484 (Ariz. Super. Ct. Apr. 28, 2016).

204. Deposition Transcript of Rick Chavez at 142, Christopher v. Active Life Physical Med. Pain Ctr., No. CV2014-013532 (Ariz. Super. Ct. June 15, 2016).

205. *See supra* Section III.A.

206. *See* Webster et al., *supra* note 168, at 203. Courts occasionally allow standard of care testimony from non-physician expert witnesses, as well as testimony about the expert's personal beliefs about opioid therapy. *See* Deposition Transcript of Paul Deutsch at 45–47, Thomas v. Alitalia-Compagnia Aerea Italiana, No. 14-20668-CV (S.D. Fla Oct. 22, 2015). A non-physician expert expressed deep concern and total disagreement with opioid therapy for pain treatment, especially long-term opioid therapy, and equated the standard. *Id.* The expert seemed to couple the CDC Guidelines with the standard of care, asserting a prescriber does not do anything wrong if his or her actions meet "the standards of care *and* the clinical practice guidelines. *Id.* at 45–47 (emphasis added). The expert also hinted at how federal agencies are "trying to set a different standard" that gives patients with "horrific pain" great trouble filling prescriptions. *Id.* at 47.

207. *See* Rothstein et al., *supra* note 137, at 2, 7–8 ("[T]he Guideline has been adopted and applied more broadly by state legislatures, state medical boards, and private institutions.").

208. Dineen, *supra* note 20, at 962; *accord* Allison Petersen et al., *State Legislative Responses to the Opioid Crisis: Leading Examples*, 11 J. HEALTH & LIFE SCI. L. 30, 35–40 (2018); Noah, *supra* note 101, at 646 ("The CDC's effort appears to have had an impact, in part thanks to state decisions to codify parts of these guidelines.").

The number of laws limiting the amount or duration of opioids providers may prescribe quadrupled after 2016, the year the CDC released its guidelines.[209] As of 2019, thirty-nine states enacted laws restricting opioid prescribing, and fourteen states imposed statutory limits on the maximum daily dosage of opioids a provider can prescribe.[210] Furthermore, from 2016 through 2018, the federal and state opioid-related policies totaled 527, with 171 of those policies imposing opioid prescribing limits.[211] The laws either restrict how long providers can treat patients with opioid therapy or impose maximum dose ceilings, and some laws do both.[212] Additionally, all fifty states have prescription drug monitoring laws that track and document all controlled substance prescriptions.[213] Although designed to fetter out corrupt prescribers running "pill mills," this oversight stoked a fear of potential criminal liability in physicians, even for appropriate and compassionate efforts to treat patients with severe chronic pain.[214]

Many of the laws aligned with provisions in the CDC Guideline, and some of them referenced the document directly.[215] According to the CDC and Human Rights Watch, forty-six states established guidelines, laws, or policies aligned with the CDC's recommendations in the CDC Guideline.[216] Certain states used the CDC Guideline as direct justification for the laws, while others implemented its recommendations.[217]

For example, Maine's law requires tapering patients down to a maximum dose of 100 MME, justifying the limit with the CDC Guideline.[218] Texas and South Dakota also incorporated the CDC Guideline into their laws, requiring physicians to reduce opioid therapy doses to either one hundred or ninety MME.[219] According to one study, policymakers in twenty-five states referred to or incorporated the guidelines in thirty-five policies, while another one hundred seventy-one state policies placed limits on opioid prescribing, created dose limits, and mandated daily supply limits "often based on recommendations in the Guideline."[220] To sum up with a stark ex-

209. Davis & Lieberman, *supra* note 139, at 1824 (conducting a systematic legal review of individual state laws limiting the amount or duration of opioids medical providers may prescribe).

210. *Id.* at 1823–24.

211. Duensing et al., *An Examination of State and Federal Opioid Analgesic and Continuing Education Policies: 2016–2018*, J. PAIN RSCH. 2431, 2440 (2020).

212. *See* Rothstein et al., *supra* note 137, at 7.

213. *Id.*

214. *Id.* at 8.

215. Adams & Guerra, *supra* note 7, at 314.

216. HUM. RTS. WATCH, *supra* note 70, at 26.

217. *Id.* at 66; Waldrop, *supra* note 95, at 896.

218. HUM. RTS. WATCH, *supra* note 70, at 26; Kertesz & Gordon, *supra* note 32, at 172.

219. HUM. RTS. WATCH, *supra* note 70, at 26, 68.

220. Duensing et al., *supra* note 211, at 2440.

ample, Oregon's Medicaid policy does not take adequate pain treatment into account: it mandates an obligatory tapering to zero opioids for all Medicaid recipients with chronic back or spine conditions.[221]

IV. FLAWED GUIDELINE AND A FLAWED STANDARD OF CARE

The CDC Guideline does not deserve the authority courts and expert witnesses afford to it when defining the standard of care.[222] The agency admitted the CDC Guideline has significant shortcomings.[223] Courts must recognize this before authorizing its use as evidence of the standard of care. This Section examines the CDC Guideline's most notable shortcomings and misapplication to argue intentional measures are needed to divorce the CDC Guideline as representative of the standard of care.

A. Vetting the CDC Guideline

If a court scrutinizes the CDC Guideline, it will discover the document has serious flaws.[224] The Guideline's flaws make it a problematic and less convincing source of evidence to define the standard of care for treating legacy chronic pain patients who already take opioids above the Guideline's dose threshold.[225] This Subsection puts the CDC Guideline to the test by evaluating it against the criteria that courts and scholars typically consider when assessing a clinical practice guideline ("CPG") as evidence of the standard of care in a malpractice claim.[226]

1. Reliability of Evidence Used in the CDC Guideline

The quality of evidence used to support recommendations in the Guideline make it an inappropriate basis for the standard of care.[227] If a court per-

221. HUM. RTS. WATCH, *supra* note 70, at 68.

222. *See* Webster et al., *supra* note 168, at 203.

223. Nicholson & Hellman, *supra* note 92, at 307, 307 n.56 (describing the CDC's response to how policy actors implemented mandates stemming from portions of the Guideline based in low-quality evidence); *see No Shortcuts*, *supra* note 169 at 2287.

224. *See, e.g.*, Jason W. Busse et al., *Addressing the Limitations of the CDC Guideline for Prescribing Opioids for Chronic Noncancer Pain*, 188 CMAJ 1210, 1210 (2016); Alan L. Gordon & Seamus L. Connolly, *Treating Pain in an Established Patient: Sifting Through the Guidelines*, 100 R.I. MED. J. 41, 41 (2017); Bettinger et al., *supra* note 103, at 952.

225. *See* Nadeau et al., *supra* note 88, at 6; Bettinger et al., *supra* note 103, at 954.

226. *See id.*; *see also* Sira Grosso, *What is Reasonable and What Can Be Proved as Reasonable: Reflections on the Role of Evidence-Based Medicine and Clinical Practice Guideline in Medical Negligence Claims*, 27 ANNALS HEALTH L. 74, 76, 95 (2018).

227. Bettinger et al., *supra* note 103, at 954; Patricia R. Recupero, *Clinical Practice Guideline as Learned Treatises: Understanding Their Use as Evidence in the Courtroom*, 36 J. AM. ACAD. PSYCHIATRY L. 290, 294 (2008).

mits a jury or expert witness to use a CPG's portrayal of the standard of care to gauge whether a provider deviated from the standard and committed malpractice, then "only good quality, and thus, reliable guidelines must be selected."[228] To avoid misleading juries, courts should preclude standard of care evidence from CPGs that lack scientific merit.[229]

Courts can assess the quality of a CPG by looking at its sources.[230] Though the CDC is a relatively trustworthy authority for public health information, a CPG's sources can threaten its reliability.[231] Such is the case for the 2016 CDC Guideline for Prescribing Opioids for Chronic Pain. The CDC made surprisingly strong recommendations, but explicitly noted "the clinical scientific evidence informing the recommendations is low in quality."[232] Further, it based *all but one* of its recommendations merely on observations or studies with severe limitations—the weakest types of scientific evidence.[233]

Many opioid-related cases consider whether the physician prescribed opioids at excessive dose levels, thus falling outside acceptable practice.[234] Often prescribing opioids at doses greater than the CDC's ninety MME recommendation raises red flags suggesting negligent or criminal practice.[235] Many prescribers responded with inappropriate tapers to bring patients within the Guideline, risking harm to long-term patients who need a higher dose.[236] Yet, the CDC's dose limit of ninety seemingly developed out of thin air without evidence to back it up.[237] The CDC modeled its guideline on the Washington state guidelines, which had a 120 MME limit.[238] One of the developers of the Washington guidelines and a peer reviewer for the CDC

228. Grosso, *supra* note 226, at 98.

229. Recupero, *supra* note 227, at 294.

230. Grosso, *supra* note 226, at 98.

231. Recupero, *supra* note 227, at 295.

232. *2016 CDC Opioid Prescribing Guideline*, *supra* note 39, at 34; *see* Adams & Guerra, *supra* note 7, at 314.

233. Kertesz & Gordon, *supra* note 32, at 172; *see* Singer, *supra* note 91; Faruque Ahmed et al., U.S. ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP) HANDBOOK FOR DEVELOPING EVIDENCE-BASED RECOMMENDATIONS 7 (2013) (highlighting that portions of the CDC Guideline is largely based on type 4 evidence).

234. *See supra* Section III.

235. *See* Pergolizzi et al., *supra* note 152, at 1238; *see* HUM. RTS. WATCH, *supra* note 70, at 58–64.

236. HUM. RTS. WATCH, *supra* note 70, at 32–57.

237. *See* Pergolizzi et al., *supra* note 152, at 1237 ("This cutoff rate does not appear to be supported by evidence but is an arbitrarily set value. It may not meet the needs of many long-term opioid patients."); *see* David Tauben, *Interview with David Tauben: University of Washington, Chief Division of Pain Medicine*, 7 PAIN MGMT. 223, 234 (2017).

238. Bobbi Nodell, *CDC's Opioid Rx Guidelines Follow Washington's Lead*, UW MED. (Apr. 7, 2016), https://newsroom.uw.edu/story/cdc-opioid-rx-guidelines-take-washingtons-lead.

Guideline admitted they did not base the ninety MME cutoff on scientific evidence, or for that matter, any evidence at all:

> The very first question that was put to [the Opioid Prescription Guideline committee] was 'is there a dose (of opioids) at which patients start to do badly?' We had *no published data available* at that time either in the form of randomized trials or epidemiological studies. There were suggested dose limits that had been proposed but again they were just *consensus driven*. . . . *I just proposed a number*: I said 'above 80 milligrams of morphine *I think* my patients start doing worse not better.' . . . [Our guidelines] were roundly and profoundly denounced . . . [T]he complaint was: how dare you come up with a dose limit when you do not have any data? Lawsuits were filed against us.[239]

Before the CDC agreed to publish the Guideline, an organization attempting to curb opioid use—Physicians for Responsible Opioid Prescribing ("PROP")—tried to lobby the FDA to add labels to opioids with a daily dose limit of 100 MME.[240] The FDA rejected PROP's recommendation because "the scientific literature does not support establishing a maximum recommended dose of 100."[241] Additionally, the FDA had no evidence that the dose ceiling marks the line between safe and unsafe prescriptions.[242]

Evidence of the CDC's arbitrary ninety MME dose cutoff can oversimplify the standard of care and may mislead the jury.[243] It is also not "based on sufficient facts or data" as required by the Federal Rules of Evidence.[244] The CDC's failure to support its claims with quality evidence seriously weakens its reliability.[245] Blind deference to the CDC Guideline as the standard of care is irrational and irresponsible.[246]

2. Defects in Development, Bias, and Conflicts of Interest

Not only must CPGs be based on high-quality evidence, but defects in its development or conflicts of interest among the authors can weaken a

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239. Tauben, *supra* note 237, at 234 (emphasis added).

240. Chad Kollas, *PROP's Disproportionate Influence on the U.S. Opioid Policy: The Harms of Intended Consequences*, PALLIMED (May 3, 2021), https://www.pallimed.org/2021/05/props-disproportionate-influence-on-us.html (citing Letter from Janet Woodcock, Director, Ctr. for Drug Evaluation & Rsch., to Andrew Kolodny, President, Physicians for Responsible Opioid Prescribing (Sept. 10, 2013)).

241. *Id.*

242. *Id.*

243. *See* Grosso, *supra* note 226, at 97–98.

244. FED. R. EVID. 702.

245. *See* Grosso, *supra* note 226, at 97–98.

246. *Id.* at 94; *see* Webster et al., *supra* note 168, at 203.

CPG's use as an objective source of the standard of care.[247] Courts should refrain from admitting an expert's opinion about the standard of care if it relies on CPGs riddled with accountability issues, conflicts of interest, or bias. The CDC Guideline has all three.[248]

First, the CDC initially refused to reveal the identities of the expert consultants assisting with the Guideline, but a leak revealed several consultants, as well as one of the CDC Guideline's principal authors, were affiliated with PROP—the same organization advocating for Congress to reduce the use of opioid therapy for several years.[249] PROP members also served as peer reviewers and on other CDC advisory panels.[250] For years, PROP and its members have lobbied to restrict access to opioids and reduce reliance on opioids use for chronic pain, so the PROP-heavy roster might mean the CDC Guideline suffers from an ideological bias.[251] The CDC's advisors hardly included providers who actually treat chronic pain: it had only one pain management clinician, who later became the president of PROP.[252] Critics felt the group's composition of vocal critics of opioid prescribing swayed the recommendations of the CDC Guideline in a way that "seems devoid of empathy for patients who need legally-prescribed opioid medications for relief from serious and long-lasting pain that compromises their

247. Recupero, *supra* note 227, at 294–95, 297–99; Lars Noah, *Medicine's Epistemology: Mapping the Haphazard Diffusion of Knowledge in the Biomedical Community*, 44 ARIZ. L. REV. 373, 422, 425, 456–57 (2002).

248. *See* Kollas, *supra* note 240; Chad Kollas et al., *Roger Chou's Undisclosed Conflicts of Interest: How the CDC's 2016 Guideline for Prescribing Opioids for Chronic Pain Lost Its Clinical and Professional Integrity*, PALLIMED (Sept. 17, 2021), https://www.pallimed.org/2021/09/roger-chous-undisclosed-conflicts-of.html; Michael E. Schatman & Stephan J. Ziegler, *Pain Management, Prescription Opioid Mortality, and the CDC: Is the Devil in the Data?,* 10 J. PAIN RSCH. 2489, 2489–90 (2017).

249. Schatman & Ziegler, *supra* note 248, at 2489 (discussing how after the leak revealed the identifies of these experts, stakeholders raised concerns that some experts might have biases against using opioids to treat pain); Rich Samp & Wash. Legal Found. (WLF), *CDC Bows to Demands for Transparency and Public Input on Draft Opioid Prescribing Guidelines*, FORBES (Dec. 15, 2015, 4:01 PM), https://www.forbes.com/sites/wlf/2015/12/15/cdc-bows-to-demands-for-transparency-and-public-input-on-draft-opioid-prescribing-guidelines/?sh=5aa7a3a0135b.

250. Pat Anson, *PROP Helped Draft CDC Opioid Guidelines*, PAIN NEWS NETWORK (Sept. 21, 2015), https://www.painnewsnetwork.org/stories/2015/9/21/prop-helped-draft-cdc-opioid-guidelines.

251. Kollas, *supra* note 240; *see generally* Andrew Kolodny, *Opioids Are Rarely the Answer*, N.Y. TIMES (Feb. 9, 2016, 11:34 AM), https://www.nytimes.com/roomfordebate/2012/02/15/how-to-curb-prescription-drug-abuse/opioids-are-rarely-the-answer (claiming that "opioids are rarely the answer" for "[u]ntreated chronic pain.").

252. Kollas, *supra* note 240. This individual also worked with Tauben on the Washington guideline. *See* Nodell, *supra* note 238.

quality of life and independence."[253] Additionally, the CDC restricted public input on its draft guideline, did not answer any questions, and allowed public comments for only two days.[254] This questionable behavior during the guideline's development subjected the CDC to allegations it violated the Federal Advisory Committee Act.[255] Pressure from Congress persuaded the CDC to allow public comments for an additional thirty days.[256]

Furthermore, potential financial conflicts of interest undercut the credibility of the CDC Guideline and its use to set the standard of care.[257] Many affiliated with both PROP and the CDC Guideline serve as well-paid expert witnesses in malpractice cases and for states seeking to hold pharmaceutical companies liable in opiate litigation across the country.[258] National guidance issued by a federal agency warning against the use of opioid therapy could certainly resolve contested issues in the litigation, so perhaps the guideline's authors published it eyeing these future opportunities.[259] This kind of conflict of interest suggests those writing the CDC Guideline might have had ulterior motives, and courts have rejected expert testimony about CPGs if it suspected the CPG was developed "with litigation concerns in mind."[260] While the allegations range from questionable to damning, they raise concerns about the CDC Guideline's validity because an expert witness's affiliation with a CPG casts doubt on an expert's credibility:

> [I]n a setting where [the expert witness] is living handsomely . . . from the fruits of his work as an expert witness on behalf of defendants in medical malpractice cases, his involvement in setting clinical standards and then pointing to such standards in support of his expert opinions inevitably implicates concerns about credibility.[261]

For expert testimony in opiate litigation in Oklahoma, a co-founder of PROP and member of the CDC Guideline's stakeholder review group re-

253. Kollas, *supra* note 240 (quoting Patient Quality of Life Coalition, Letter to Hon. Lamar Alexander, Chairman, Comm. of Health, Ed., Lab. & Pensions, U.S. Senate, (Nov. 13, 2015) (on file with Chad Kollas)).

254. Schatman & Ziegler, *supra* note 248, at 2489.

255. *Id.*

256. *Id.*

257. *See* Kollas et al., *supra* note 240; Samp & Wash. Legal Found., *supra* note 249; Pat Anson, *How Opioid Critics and Law Firms Profit from Litigation*, PAIN NEWS NETWORK (June 21, 2019), https://www.painnewsnetwork.org/stories/2019/6/21/opioid-critics-and-law-firms-profiting-from-the-overdose-crisis.

258. Anson, *supra* note 257.

259. Telephone interview with Claudia Merandi, President & CEO, Dr. Patient F., Founder of Don't Punish Pain Rally (Nov. 13, 2021).

260. Recupero, *supra* note 227, at 294.

261. Trowbridge v. United States, 703 F. Supp. 2d 1132, 1136 (D. Idaho 2010).

ceived several hundred thousand dollars.[262] Conflicts of interest in clinical guidelines raise serious bias concerns that could improperly influence how a jury determines the standard of care.[263]

3. Relevance of the CDC Guideline to Specific Cases

For a CPG to be of any use for setting the standard of care in a malpractice case, it needs to be relevant "to the claim it allegedly supports."[264] Generally, a relevant CPG will make a fact more or less probable than it would be without the CPG, so CPGs concerning the treatment of the patient-plaintiff's medical condition are generally admissible.[265] The CDC Guideline for Prescribing Opioids for Chronic Pain obviously seems to relate to how providers should treat chronic pain with opioids, but its relevance—especially its relevance to patients prescribed opioid therapy at levels higher than ninety MME—breaks down at the margins.

An expert may use a CPG to support opinions on the standard of care only if the CPG actually supports the expert's claim.[266] As discussed, experts have used the CDC Guideline to argue opioids are not appropriate treatment for chronic pain and that providers should not use opioid therapy in doses exceeding ninety MME for extended periods of time.[267] However, the CDC Guideline does not cite evidence to support either claim.[268] The CDC Guideline recommended against using high-dose opioid therapy for chronic pain because there was an *absence of evidence* showing it works well for chronic pain.[269] With this logic, the CDC suggests the lack of reliable evidence showing opioids work for chronic pain means opioids *do not* work for chronic pain, but the CDC makes its argument from ignorance.[270] An ab-

262. The Oklahoman, *Opioid Trial – Day 13: Afternoon Session*, YOUTUBE (June 13, 2019), https://www.youtube.com/watch?v=4rncKWv7Ctc (3:06:00–3:17:46).

263. *See* Noah, *supra* note 227, at 422.

264. Recupero, *supra* note 227, at 295.

265. Grosso, *supra* note 226, at 98; FED. R. EVID. 401.

266. Recupero, *supra* note 227, at 295.

267. *See supra* Section III.

268. *See* Pergolizzi et al., *supra* note 152, at 1235–37; Bettinger et al., *supra* note 103, at 954; *see supra* Section IV.A.1 and accompanying text for an analysis of the evidence used in the CDC Guideline.

269. *See* CDC, *Contextual Evidence Review for the CDC Guideline for Prescribing Opioids for Chronic Pain – United States*, *2016*, MMWR RECOMMENDATIONS & REP., Mar. 18, 2016, at 1, 6 ("Studies examining the efficacy of high-dose opioids for chronic pain outside of end-of-life care were not identified."). *But see supra* Section II.A.3.

270. Bettinger et al., *supra* note 103, at 954 ("[T]here has not been a single, randomized controlled trial directly assessing the effectiveness of chronic opioids in the management of chronic pain with a duration of greater than a year. This is important in that the claim often made pertains to how opioids are not effective when used long-term, although there is no actual empirical evidence to support such a claim"). One randomized control trial is some-

sence of evidence is not evidence of absence—the CDC's lack of evidence of efficacy is very different from claiming there is no efficacy.[271] The weak link between the recommendations and supporting scientific data raises concerns about whether the CDC erred in conducting a comprehensive clinical review, or whether the authors relied on personal prescribing preferences to inform the recommendations about long-term opioid therapy.[272]

Similarly, the ninety MME dose limit, arguably leading to the most patient harm, has no evidentiary backing and does not consider significant variabilities between patients that influence the effective dosage of a medicine.[273] Most notably, the CDC Guideline does not supply very practical guidance on how to manage chronic pain patients who *already* depend on high-dose, long-term opioid therapy, instead it focuses mainly on the initial decision to prescribe opioids.[274]

When a CPG does not support an expert's claim or an expert conflates its recommendations, courts consider them irrelevant.[275] The Sixth Circuit did not allow an expert witness's claim about the plaintiff's harm from a chemical in a toxic tort case because the CPG the expert used to base his claim did not have "scientific literature or studies supporting" his theory.[276] In *Woods*, the court did not allow an expert to conflate testimony about the amount of blood loss because the CPG the expert quoted did not actually test how much blood someone in the plaintiff's specific condition would lose.[277] Like in these cases, the CDC Guideline does not provide recommen-

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times used to support claims of opioids ineffectiveness, but the study has serious limitations such that reliance on it is "negligent" and "a glaring ineptitude and likely bias of those that wield it to further their agendas." *Id.*

271. *See* Lynda Ware, *Teapots and unicorns: absence of evidence is not evidence of absence*, EVIDENTLY COCHRANE (Feb. 22, 2022), https://www.evidentlycochrane.net/teapots-and-unicorns-absence-of-evidence-is-not-evidence-of-absence/ (warning against bold assertions that a treatment is ineffective because the evidence relied upon may be unreliable).

272. *See* John D. Ayres, *The Use and Abuse of Medical Practice Guideline*, 15 J. LEGAL MED. 421, 427, 430–31 ("[Some guidelines] are outdated or may be based on inadequate data or suspect conclusions. . . . [P]arameters simply may reflect the practice customs of the developers [in the absence of] high-quality clinical trials or other studies").

273. Nadeau et al., *supra* note 47, at 2.

274. *See* Busse et al., *supra* note 224, at 1210; Gordon & Connolly, *supra* note 214, at 41.

275. *See* Recupero, *supra* note 227, at 295–96 ("While citing relevant CPGs may strengthen an expert's testimony when the CPGs support the expert's opinion, stretching the relevance of a text merely to footnote one's testimony may weaken credibility."); Conde v. Velsicol Chem. Corp., 24 F.3d 809, 811 (6th Cir. 1994); Woods v. United States, 200 Fed. App'x 848, 855 (11th Cir. 2006).

276. *Conde*, 24 F.3d at 813.

277. *Woods,* 200 Fed. App'x at 855 ("But the ASA report only purports to describe the effect of a *transfusion* of *one unit* of whole blood or red blood cells on hematocrit and hemoglobin levels in a typical *nonbleeding* adult. Nothing in the ASA report suggests that the same rules of thumb can be used as Woods proposes, to accurately determine the volume of blood lost by a bleeding adult who has lost more than one unit of blood.").

dations for the specific situations of long-term chronic pain patients' need for higher-dose opioid therapy to treat pain adequately.[278] Even though the Guideline provides some evidence of the standard of care for prescribing opioids, it does not accurately reflect the standard for using opioid therapy in the specific case of treating legacy patients whose chronic pain patients has been effectively managed with long-term opioid therapy.[279]

B. Misapplication and the Impossible Standard of Care

The misapplication of the CDC Guideline exacerbated the chronic pain crisis in the United States.[280] Though perhaps well-intended, it emphasized restraining the use of opioids and cautioned against dose increases, making its implementation harmful to those who depend on opioid therapy to treat their pain.[281] However, stakeholders criticized the Guideline for its medical and legal implications, the harm it has caused chronic pain patients, and the Guideline's considerable influence despite its apparent pitfalls.[282]

Policymakers enacted restrictive laws and regulations based on the recommendations in the CDC Guideline to induce physicians to cut back on opioid prescribing.[283] Prescribers faced discipline from medical boards and/or prosecution for exceeding the bounds.[284] Notably, the Guideline's suggested daily dose cutoff of ninety MME, although unsupported by sufficient evidence,[285] received "inflexible application" from legislatures and other policy actors that codified them as "hard limits."[286] The oversight influenced physicians to rapidly cut opioid dosages, end opioid treatment entirely, or abandon pain patients.[287] After intense criticism, misinterpretation, and patient plight, the authors of the CDC Guideline admitted these laws gave many of its recommendations a rule-like effect.[288]

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278. *See* Bettinger et al., *supra* note 103, at 954.

279. *See generally,* Michelle M. Mello, *Of Swords and Shields: The Role of Clinical Practice Guideline in Medical Malpractice Litigation*, 149 U. PA. L. REV. 645, 663–64 (2001).

280. *See supra* Section III.C.

281. HUM. RTS. WATCH, *supra* note 70, at 28.

282. *See generally* Adams & Guerra, *supra* note 7, at 314.

283. Nicholson & Hellman, *supra* note 92, at 306–07.

284. *Id.*

285. Pergolizzi, *supra* note 152, at 1235–37.

286. *No Shortcuts*, *supra* note 169, at 2285; *see* Bettinger et al., *supra* note 103, at 952 ("Another unfortunate consequence of the Guideline has been shifting federal and state opioid-related policies and health insurer and community pharmacy limitations on opioid prescribing, particularly among those attempting to define [maximum morphine equivalent daily dose]").

287. *No Shortcuts*, *supra* note 169, at 2285; *see* Bettinger et al., *supra* note 103, at 952.

288. *No Shortcuts*, *supra* note 169, at 2285.

When applied by medical providers and legislatures, the CDC Guideline restricted patients from accessing opioid therapy to treat pain, including legacy pain patients.[289] Restricting opioid therapy from legacy patients who seriously need the medications to live an acceptable quality of life "diverge[s] from compassionate, rational use of opioids to a swift restriction of access. . . ."[290] This practice arguably violates human rights—"UN human rights officials [stated] that the failure to ensure access to controlled medicines for the relief of pain and suffering threatens the protection of persons from cruel, inhuman, and degrading treatment."[291] Physicians especially owe legacy patients the duty not to cause harm by subjecting patients to the risks of abrupt or forced opioid cessation; as argued by Professor Kelly Dineen:

> Underprescribing means withholding appropriate opioids (including too rapidly or arbitrarily tapering or discontinuing opioids), refusing to consider opioids at all (blanket exclusions) and failing to provide or refer patients to treatment for opioid use or other substance abuse disorders. This is particularly problematic for legacy patients, who are among the most neglected and vilified in the current climate around opioids. . . . If anything, the obligations to legacy patients are heightened—more than anyone, prescribers (usually in good faith and under mistaken beliefs about the relative benefits of opioids) put them in the position they are in now. At a minimum providers are morally obligated to compassionately help patients reduce or discontinue opioids when appropriate. . . . By ignoring the compassionate and appropriate treatment of legacy patients, policymakers implicitly communicate that those patients are less deserving than others who might today be spared opioids in the first place.[292]

Casting the Guideline into law turned the CDC's dose limit recommendations for opioid prescribing into a legal requirement. These rigid statutory dose limits tell medical professionals what the law considers acceptable.[293] Naturally, the profession changed practices to fall within the law's acceptable limits.[294] Doing so removes flexibility from the standard of care calculus.[295] Essentially, dose restrictions shift the central question from "did the

289. Dineen, *supra* note 20, at 971.
290. Christo, *supra* note 66, at 243.
291. Brennan et al., *supra* note 79, at 62.
292. Dineen, *supra* note 20, at 1001–02.
293. *See* Guevremont et al., *supra* note 39, at 215.
294. *Id.*
295. Pat Anson, *Revised CDC Opioid Guideline Gives Doctors More Flexibility*, PAIN NEWS NETWORK (Feb. 10, 2022), https://www.painnewsnetwork.org/stories/2022/2/10/revised-cdc-opioid-guideline-gives-providers-more-flexibility. Christopher Jones, Acting Director of the CDC's National Center for Injury Prevention and Control, stated, "We certainly have learned and recognized the harm that has resulted when aspects of the 2016 guideline have been applied as inflexible, rigid standards that really go beyond the intent of what we wanted to occur." *Id.*

defendant treat *this patient* correctly under *these particular conditions*" to "did the defendant prescribe opioids in a way the law allows?" The combined effect makes it difficult for patients to argue a dose reduction falls below the standard of care: after all, the prescriber only reduced the dose to match the statutory limits.[296] Likewise, when a physician reduces or cuts off a pain patient from opioids to obey legislative fiats or national guidelines, a jury will likely find the physician followed the standard of care in the profession, making a deviation from the norm in a medical malpractice claim essentially impossible to prove.[297] When law or policy requires physicians to taper pain medication, it becomes the standard of care.[298]

A standard of care should reduce patient harm, not increase it. The standard of care for treating chronic pain falls short: it harms legacy patients.[299] Much of this harm stems from physicians, courts, and legislatures' reliance on the CDC Guideline to define the standard of care.[300] If experts use this Guideline to help define the standard of care for long-term chronic pain management, but the application of the Guideline harms some chronic pain patients, then the law fails to meet its goal of protecting these patients from substandard medical care, thus revealing the need to reevaluate the standard of care in the context of chronic pain.[301]

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296. *See* Nicholson & Hellman, *supra* note 92, at 305–08 (describing how physicians, pharmacists, and others treated the standard in the CDC Guideline as a rule); Stefan G. Kertesz et al., *Promoting Patient-Centeredness in Opioid Deprescribing: A Blueprint for De-implementation Science*, 35 J. GEN. INTERNAL MED. 972, 974 (explaining how government actors rigidly used and enforced the CDC's dose recommendations in a way that stunted patient care); Brief for Amicus Curiae National Pain Advocacy Center in Support of Petitioners at 9, Ruan v. United States, 142 S. Ct. 2370 (2022) (Nos. 20-1410, 21-5261) ("[The CDC's recommended daily dose limit] was interpreted as a mandate rather than guidance and misused by regulators—including law enforcement—as a proxy for inappropriate prescribing. As a result, providers who prescribed above the dosage threshold were subjected to scrutiny, and healthcare workers began to rapidly taper patients down to the CDC's dose threshold.").

297. LoPuzzo, *supra* note 160, at 1427.

298. Anson, *supra* note 295; *see 2022 CDC Opioid Prescribing Guideline*, *supra* note 57, at 6 ("This clinical practice guideline should not be applied as inflexible standards of care across patient populations by healthcare professionals; health systems; pharmacies; third-party payers; or state, local, or federal organizations or entities.").

299. *See* Brief for Amicus Curiae National Pain Advocacy Center in Support of Petitioners, *supra* note 283, at 8 ("Recent attempts by public health agencies to articulate a standard of care for opioid prescribing have backfired, requiring the agencies to course correct. The CDC, for example, stated publicly that key provisions in its 2016 Guideline for Prescribing Opioids for Chronic Pain had been misapplied as one-size-fits-all mandates by policy actors in ways that risk patient harm."); *see No Shortcuts*, *supra* note 169, at 2287.

300. *See, e.g.*, Dineen, *supra* note 20, at 961.

301. *See generally* Mello, *supra* note 266, at 684 (identifying problems with and arguing against the use of clinical practice guidelines to define the standard of care in medical malpractice cases).

Using the CDC Guideline to establish the standard of care for using opioids to treat chronic pain creates an easy, one-size-fits-all rule to avoid running afoul of the standard of care and potential liability for patient harm.[302] However, bringing legacy chronic pain patients down to the Guideline's dose threshold comes with the likelihood of unintended harms, including increased pain and devastating withdrawal symptoms.[303] The risk of causing unnecessary harm to patients, coupled with the CDC Guideline's deficient recommendations for treating patients who have taken higher doses of opioids for a long time, makes the CDC Guideline an unreliable benchmark for the standard of care. Additionally, reliance on the guidelines to define the standard of care is further misplaced because clinical practice guidelines, without more, do not set the standard of care.[304] The problem, however, is that the CDC Guidelines have been widely accepted and carry considerable weight in law, policy, and practice.[305] Guidelines with wide acceptance over time, no matter how flawed, often shape the "standard practice" in the profession or the standard of care.[306]

V. FIXING THE STANDARD OF CARE

At all levels of government, policies to end the overdose crisis devoted too much attention to cutting back on opioid prescribing.[307] Though the efforts failed, they changed the medical profession's attitudes about using opioids to treat pain.[308] The new standard of care for treating pain, laced either directly or implicitly with the CDC's recommendations, hurt chronic pain patients in the process.[309] Fixing the standard of care requires purging the CDC's recommendations from health policy.[310] The CDC and state legislatures can take immediate action to do so.

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302. *See* Dineen, *supra* note 20, at 465; Webster et al., *supra* note 168, at 203 (discussing that the U.S. Department of Justice has deemed some opioid prescriptions unlawful for nonadherence with the 2016 CDC Guideline).

303. *See* Rieder, *supra* note 45, at 652.

304. Karwaki, *supra* note 55, at 231.

305. *Id.*

306. Barry R. Furrow, *Pain Management and Provider Liability: No More Excuses*, 29 J.L. MED. & ETHICS 28, 31 (2001).

307. Rothstein & Irzyk, *supra* note 51, at 184.

308. *See* Kate M. Nicholson, *Undoing Harm in Chronic Pain and Opioid Prescribing*, 112 AM. J. PUB. HEALTH 18, 18–19 (2022).

309. *Id.*

310. *See infra* notes 331–332

A. The 2022 Guideline: An Insufficient Step in the Right Direction

The implementation of the 2016 CDC Guideline had unforeseen consequences for chronic pain patients. To be sure, the CDC likely did not intend any of this. The agency made this much clear in 2019 when it acknowledged how misapplications of the Guideline harmed patients.[311] But nothing changed after the CDC acknowledged those harms.[312] Three years later in 2022—six years since the release of the original guideline—the CDC finally took deliberate steps to mitigate this harm by releasing a new version of its Opioid Prescribing Guideline.[313] Although the 2022 Guideline makes significant improvements, it leaves much to be desired.[314]

The 2022 Guideline makes repeated, worried warnings that stakeholders—including doctors and lawmakers—should not use the Guideline to inform laws or as an inflexible standard of care.[315] It weaves these warnings throughout the entire document. The new Guideline also eliminates specific dose thresholds, like the ninety MME limit.[316] It cautions against forcing patients off of opioids without consent.[317] It emphasizes treating chronic pain should not take a one-size-fits-all approach, but rather a patient-forward one that relies on good clinician judgment.[318] The CDC makes it abundantly clear the recommendations in the 2022 Guidelines are voluntary, not "absolute limits of policy or practice."[319]

While an improvement, the 2022 Guideline still raises concern. It stresses prescribers should use opioid therapy only when necessary and encourages non-opioid therapies wherever possible.[320] It still harps on alterna-

311. *See No Shortcuts*, *supra* note 169 at 2287.

312. Sally Satel & Kate M. Nicholson, *How Rochelle Walensky Can Improve the CDC's Pain Guidelines*, WASH. MONTHLY (Mar. 24, 2022), https://washingtonmonthly.com/2022/03/24/how-rochelle-walensky-can-improve-the-cdcs-pain-guidelines/.

313. *See 2022 CDC Opioid Prescribing Guideline*, *supra* note 57, at 1.

314. Will Stone & Pien Huang, *CDC issues new opioid prescribing guidance, giving doctors more leeway to treat pain,* NPR (Nov. 3, 2022, 4:22 PM), https://www.npr.org/sections/health-shots/2022/11/03/1133908157/new-opioid-prescribing-guidelines-give-doctors-more-leeway-to-treat-pain; Shravani Durbhakula & Joshua Sharfstein, *HHS Needs to Step up so CDC's New Guidelines Won't be 'a Bridge to Nowhere' for Most Americans Living with Chronic Pain,* STAT (Apr. 29, 2022), https://www.statnews.com/2022/04/29/cdc-guidelines-bridge-to-nowhere-chronic-pain-patients/; Szalavitz, *supra* note 2.

315. *See* Maia Szalavitz, *'Entire Body Is Shaking': Why Americans With Chronic Pain Are Dying*, N.Y. TIMES (Jan. 3, 2023), https://www.nytimes.com/2023/01/03/opinion/chronic-pain-suicides.html.

316. Stone & Huang, *supra* note 314.

317. *Id.*

318. Alvin Powell, *New CDC Guidelines a 'corrective' for opioid prescriptions, specialist says*, HARV. GAZ. (Nov. 21, 2022), https://news.harvard.edu/gazette/story/2022/11/new-cdc-guidelines-a-corrective-for-opioid-prescriptions-specialist-says/.

319. Stone & Huang, *supra* note 314.

320. *Id.*

tive, nonopioid treatments, which *can* be effective but not for everyone.[321] Additionally, access to alternative treatments is spotty and often uncovered by insurance.[322] And even though it removed dose thresholds or limits, the CDC still recommends individual doses as "guideposts."[323] Specifically, the guidepost cautions providers before prescribing over fifty MME, lower than the 2016 Guideline's ninety MME threshold.[324] The guidepost-threshold distinction might easily be lost on those who try to implement the 2022 recommendations.

An obvious issue with the 2022 Guideline is how it seems to skirt responsibility for the harms from the 2016 Guideline and attributes blame to how states and other actors misapplied the recommendations.[325] Even with the 2022 Guideline's explicit warnings, it is still possible policies and laws will misapply its recommendations or ignore the revisions entirely.[326]

Some states have already rejected the improvements in the 2022 Guideline or disregarded the CDC's plea that its recommendations should not be codified. For example, Florida's Deputy Secretary for Health rejected the 2022 Guideline, stating the revision "takes a step backward" and that "the general public shouldn't be told they are 'essential' for pain management."[327] New York's Attorney General called on the CDC to adopt stronger guidelines with numeric dose thresholds and attributed rising overdose deaths to prescription opioids.[328] A Missouri lawmaker proposed a bill for the state's health department to promulgate rules and regulations "consistent with the most recent guidelines for prescribing opioids."[329] A bill introduced in West Virginia tells health care practitioners to exercise judgment for

321. *See* Dowell et al., *Prescribing Opioids for Pain — The New CDC Clinical Practice Guideline*, 387 NEW ENG. J. OF MED. 2011, 2013 (2022).

322. Jeannie Baumann, *CDC Opioid Guidelines Encourage Use of Alternatives for Pain*, BLOOMBERG LAW (Nov. 3, 2022, 2:34 PM), https://news.bloomberglaw.com/pharma-and-life-sciences/cdc-opioid-guidelines-call-non-opioids-just-as-effective-for-acute-pain.

323. *See 2022 CDC Opioid Prescribing Guideline*, *supra* note 57, at 30.

324. Leo Beletsky & Kate M. Nicholson, *CDC's Updated Opioid Guidelines Are Necessary, but Not Sufficient*, MEDPAGE TODAY (Nov. 18, 2022), https://www.medpagetoday.com/opinion/second-opinions/101825.

325. *See* Dowell et al., *supra* note 321, at 2012 ("Concurrently, new laws, regulations, and policies, in some cases *purportedly* derived from the 2016 guideline, went beyond — and were inconsistent with — its recommendations.") (emphasis added).

326. Christine Vestal, *States Likely to Resist CDC Proposal Easing Opioid Access*, PEW (Mar. 1, 2022), https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2022/03/01/states-likely-to-resist-cdc-proposal-easing-opioid-access.

327. *Now is Not the Time for the CDC to Relax Opioid Prescription Guidelines*, FLA. HEALTH (Nov. 22, 2022, 5:01:54 PM), https://www.floridahealth.gov/newsroom/2022/11/20221122-cdc-relax-opioid-guidelines.pr.html.

328. *See* Letter from N.Y. Attorney Gen. Letitia James to CDC Director Rochelle P. Walensky (Apr. 11, 2022), https://ag.ny.gov/sites/default/files/nyag_comment_on_proposed_2022_cdc_opioid_guideline_as_filed.pdf.

329. H.B. 320 102d Gen. Assemb., 1st Reg. Sess. (Mo. 2023).

treating pain "in accordance with the most current" CDC Opioid Prescribing Guideline, but the text of the bill emphasizes nonopioid treatment and makes no special exception for those who already need opioid medication.[330]

The point is: publishing a new Opioid Prescribing Guideline is unlikely to resolve lingering problems from the 2016 Guideline.[331] The fact the agency *updated* its Opioid Prescribing Guideline without rescinding the 2016 Guideline it knows caused harm is a case in point.[332] The CDC needs to take an active role to control the misapplication of the 2016 Guideline and prevent possible misapplication of the 2022 Guideline. To do so, the agency should first publicly rescind its 2016 Guideline and consider rescinding the 2022 Guideline as well. While the CDC cannot change laws, it can certainly influence them. Therefore, the agency must also work with every state legislature and explicitly request it amend any laws, policies, or regulations purportedly or directly influenced by the 2016 Guideline. The message must be clear: any law based on 2016 Guideline does not slow overdose deaths but instead causes the harm to chronic pain patients who need opioids to function.

B. State Legislative Action

States must take enact legislation to mend the standard of care across the country and ensure pain patients receive the care they need.[333] To start, state legislatures need to amend or repeal existing laws and medical licensing board regulations that rely on recommendations in the 2016 CDC Guideline. This includes prescription limits, trainings, prescribing guidelines, disciplinary standards, and other statutory or regulatory restrictions.[334] Removing the laws based on the defunct and deficient CDC Guideline is a necessary first step.

States must also enact legislation that (1) unequivocally restricts the CDC Guideline's influence on the standard of care and physician practice; and (2) specifically protects chronic pain patients who depend on a higher dose of opioid therapy in the long-term. Rhode Island, Minnesota, and Oklahoma supply good examples of provisions states should enact.

Rhode Island recently enacted legislation that promotes a more compassionate, individualized, and evidence-backed, comprehensive approach

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330. S.B. 598 86th Leg., 1st Reg. Sess. (W. Va. 2023).

331. *See* Szalavitz, *supra* note 315.

332. *See* Mark A. Rothstein & Julia Irzyk, *The CDC should rescind, not 'update,' its 2016 opioid guideline*, THE HILL (Feb. 18, 2022, 11:31 AM ET).

333. Telephone interview with Claudia Merandi, President/CEO of The Doctor Patient Forum and founder of Don't Punish Pain Rally (Nov. 13, 2021).

334. *See* Guevremont et al., *supra* note 40, at 207–10 (evaluating state opioid laws and regulations impacting physician autonomy).

to treating chronic or intractable pain.[335] Rhode Island's new law defines chronic or intractable pain[336] and permits healthcare providers to practice medicine according to professional practice that includes prescribing opioid therapy "without regard to the 2016 CDC Guideline for Prescribing Opioids for Chronic Pain."[337] Furthermore, the laws must require providers to consider the "individualized needs of patients" and permit practitioners to manage pain using "their best judgment notwithstanding any statute, rule, or regulation to the contrary."[338]

New legislation should recognize that opioid therapy affords many patients significant quality of life improvements and pain relief, and specifically prohibit stopping or lowering a patient on stable, effective medication, absent clear evidence of diversion or misuse.[339] For example, Minnesota's 2022 Intractable Pain statute provides:

> [Prescribers] treating intractable pain by prescribing, dispensing, or administering [opioid analgesics] must not taper a patient's medication dosage solely to meet a predetermined morphine milligram equivalent dosage recommendation or threshold if the patient is stable and compliant with the treatment plan, is experiencing no serious harm from the level of medication currently being prescribed or previously prescribed, and is in compliance with the patient-provider agreement as described in subdivision 5.[340]

A state can further enhance this provision by specifying involuntary tapers are not the standard of care. Oklahoma's Anti-Drug Diversion Act serves as a good model:

> Nothing in the Anti-Drug Diversion Act shall be construed to require a practitioner to limit or forcibly taper a patient on opioid therapy. The standard of care requires effective and individualized treatment for each patient as deemed appropriate by the prescribing practitioner without an administrative or codified limit on dose or quantity that is more restrictive than approved by the Food and Drug Administration (FDA).[341]

All states should pass this legislation to further prevent chronic pain patients from experiencing harm caused by the CDC Guideline. These laws

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335. *See* 2021 R.I. Pub. Laws 38.
336. 5 R.I. Gen. Laws § 5-37.4-2 (2022).
337. 21 R.I. Gen. Laws § 21-28-3.20.1 (2022).
338. *Id.*
339. *See* Richard A. Lawhern & Stephen E. Nadeau, *How to Fill the Holes in the CDC Opioid Prescribing Guideline Revisions*, PRAC. PAIN MGMT. (Nov. 02, 2021), https://www.practicalpainmanagement.com/treatments/pharmacological/opioids/commentary-how-fill-holes-cdc-opioid-prescribing-guideline-revisi.
340. MINN. STAT. § 152.125 (2022).
341. OKLA. STAT. tit. 63, § 2-309I (2022).

afford physicians more liberty to treat chronic pain according to their best medical judgment, not according to the recommendations in the CDC Guideline. Changing physician practice this way will eventually change the standard of care in medical malpractice cases, but more importantly, help chronic pain patients get the treatment they need.

VI. CONCLUSION

CaSonya Richardson Slone, Brent's wife, won her case.[342] She won her rare legal challenge suing the clinic and doctors who denied and reduced her husband's pain medication, resulting in his suicide.[343] The jury—seeing that taking away someone's high-dose, long-term, and effective opioid therapy can result in serious harms—awarded CaSonya and her daughter seven million dollars.[344] Unlike Brent's tragic death, this is a one-off legal victory, but the victory is a sign of what may come—a new standard of care that, along with a handful of victories like CaSonya's, gives chronic pain patients proper care instead of punishing their pain.

The CDC Guideline established a standard of care for treating chronic pain management. The standard, though seriously flawed, served as the basis for sweeping policy decisions, and many states adopted laws and regulations limiting opioid prescribing. The CDC Guideline and the laws relying on it defined a new standard of care, but the standard led to patients being forced off their medication or dangerously tapered to an ineffective dose. The standard also made it difficult for chronic pain patients to use malpractice as redress for those harms. Fixing the standard of care requires a diligent effort by the CDC and state legislatures, and the solution can address both untreated pain and opioid misuse, thus preventing further harm to Americans suffering from chronic pain, opioid use disorder, or on the brink of overdose.

*Robert Stodola**

342. *See* Joseph, *supra* note 14. For more details about Brent and CaSonya's story, see *supra* notes 1–13 and accompanying text.

343. Joseph, *supra* note 14.

344. *Id.*

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