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We think of pain as a symptom. But in . . . patients [with chronic pain], the pain is the disease.

—Clifford J. Woolf, director of the F.M. Kirby Neurobiology Center at Boston Children's Hospital and neurology professor at Harvard Medical School[1]

INTRODUCTION

Shortly before receiving yet another lidocaine needle in the back of his neck, Staff Sergeant Josh Kisner, an Army veteran who suffers from severe headaches and chronic neck pain, confessed:

> I don't know why it is starting up again. It had calmed down to a tolerable level. It's the stupidest things like reaching into the closet to grab a shirt. For a while, I just lived on

[1] Lenny Bernstein, *For some with chronic pain, the problem is not in their backs or knees but their brains*, WASH. POST (Sept. 23, 2019, 7:26 PM), https://www.washingtonpost.com/national/health-science/for-some-with-chronic-pain-the-problem-is-not-in-their-backs-or-knees-but-their-brains/2019/09/23/80538660-5d5c-11e9-842d-7d3ed7eb3957_story.html. *See also* OWEN D. JONES ET AL., LAW AND NEUROSCIENCE 344 (2014).

> Percocets. It was the only way to do it. That's why I hate that drug and if they give it to me after surgery, I am going to beg for something else.[2]

This was just another day "along recovery" for Kisner, who avoided medical evacuation despite experiencing symptoms of traumatic brain injury ("TBI"), while deployed in Baqubah, Iraq in 2007.[3] Fellow Army veteran Justin Springer made Kisner's story accessible to the public through his documentary, *Along Recovery*, which bravely and respectfully follows four wounded soldiers whose lives changed dramatically after returning from Iraq and Afghanistan and captures their treatment experiences at Brooke Army Medical Center in San Antonio, Texas.[4] Springer describes the health conditions faced by soldiers returning from overseas combat deployments: severe headaches, chronic pain, sleeplessness, depression, and memory and concentration issues, among others.[5] It is frustrating because "you can have all these problems but there's no real way to pinpoint why you are having them."[6] When doctors give soldiers an MRI, "it almost always comes back negative and they can't really see why you are having any problems."[7]

As Sean Hollins, a soldier suffering from a TBI explained, he would contemplate withholding how he felt from the hospital because "they say[,] hey[,] let's give you some more medication,"[8] and he is "not a big fan of medications."[9] The initial instinct of doctors to prescribe to soldiers opioids as part of their treatment plan, without more, leads to opioid misuse and

[2] *Along Recovery*, (Gravitas Ventures May 20, 2012), https://www.amazon.com/Along-Recovery-Justin-Springer/dp/B00GDF77AM. 49:11-49:40.
[3] *Along Recovery*, *supra* note 2, at 17:10-17:16.
[4] *Id*. at 17:10-17:16.
[5] *Id*. at 20:28-20:56.
[6] *Id*. at 20:28-20:56.
[7] *Id*. at 20:28-20:56.
[8] *Id*. at 28:00-28:32.
[9] *Id*. at 30:50-31:02.

addiction.[10] This sad reality highlights how the treatment process affects people suffering from chronic pain and comorbid conditions.[11] Witnessing how these soldiers struggled through Springer's eye-opening documentary footage frames the need to re-assess the current treatment protocols for the disease of chronic pain.

This paper argues that there is a disconnect between our understanding of chronic pain and the legal infrastructure surrounding treatment of the disease. The healthcare delivery system currently limits or denies patients access to evidence-based alternatives that demonstrably alleviate chronic pain. This paper proceeds as follows. Part I provides a brief overview of the addicted brain and the opioid crisis and explains how these topics connect with chronic pain. Part II examines the efficacy of evidence-based treatment methods, existing guidelines on chronic pain treatment, and the importance of integrating alternative treatment methods into a pain patient's multidisciplinary treatment plan. It then addresses problems under current law, including the lack of insurance coverage for evidence-based alternative pain treatments. Part III proposes legal reforms to bridge these gaps. Specifically, it recommends that the Department of Health and Human Services ("HHS") condition state funding for chronic pain—in connection with opioid-related funding—on state medical boards' implementation of a mandated 15-week evidence-based alternative treatment plan in place of opioid therapy or, where medically necessary, in conjunction with prescription

[10] *See* Jennifer D. Oliva, *Son of Sam, Service-Connected Entitlements, and Disabled Veteran Prisoners*, 25 GEO. MASON L. REV. 302, 303 n.7 (2018) (citing sources that reference veterans facing addiction, including Andrew Golub & Alexander S. Bennett, *Introduction to the Special Issue: Drugs, Wars, Military Personnel, and Veterans*, 48 SUBSTANCE USE & MISUSE 795, 796 (2013)).

[11] Josh Roe, *One veteran tells the story of his struggles trying to manage chronic pain*, ABC NEWS CHANNEL (Sept. 11, 2019), https://newschannel9.com/features/price-of-freedom/one-veteran-tells-the-story-of-his-struggles-trying-to-manage-chronic-pain (describing veteran Scott McConathy struggles because for 12 years doctors gave him 60 mg of Morphine 3 times per day, lowered to 40 milligrams of hydrocodone, then cut him off).

opioids. It further contends that HHS ought to require evidence of protocols implementing individualized plans that integrate any combination of sessions in therapies including, but not limited to, cognitive behavioral therapy, yoga, acupuncture, and physical therapy. In additional, federal law should require insurance companies to cover these evidence-based alternatives.

Part IV examines some potential problems that could result from the solutions proposed in Part III. Those include the additional demands required of doctors and other practitioners treating patients for pain, namely focusing additional time and resources on these patients, as well as demands on insurance companies that have thus far failed to provide coverage for alternatives. Part IV responds to these concerns and the resistance to change in several ways. It argues that: (i) chronic pain already costs our country because people are suffering and dying from the misuse of opioids; (ii) this country has spent billions of dollars on this public health crisis already with limited progress; (iii) the cost of alternative treatments is not measurable without attempting to effectively implement a program to fill the known gaps in chronic pain treatment; and (iv) these alternatives are cost- and resource-effective. This paper concludes by reiterating the need for mandatory, individualized evidence-based alternative treatment plans for chronic pain patients.

I. BACKGROUND

A. The U.S. Opioid Misuse and Overdose Public Health Crisis: Brain Effects and Relevant Statistics

The United States is facing a substance use disorder and drug overdose public health crisis.[12] In the United States, over 130 people die each day after overdosing on opioids according

[12] Puja Seth et al., *Overdose Deaths Involving Opioids, Cocaine, and Psychostimulants — United States, 2015–2016*, 67 MORBIDITY & MORTALITY WKLY. REP. 1, 1 (2018).

to the National Institute of Health ("NIH").[13] In 2017, opioid use disorder resulted in 47,600 drug-overdose deaths.[14] Advances in neuroscience show the effects of drugs on neural pathways and differences in brain-wiring between people suffering from opioid use disorder and those that do not.[15] The CDC published opioid prescribing guidelines in 2016, which recommend dosage limitations and the satisfaction of certain threshold requirements prior to prescription renewal.[16] While the guidelines are useful, there was controversy surrounding their implementation[17] and they are insufficient standing alone. Neuroscience research demands a change in our approach to treating the underlying disease of pain due to its effects on brain circuitry and quality of life. If we intend to overcome the opioid crisis, it is critical that we reassess our view of the addicted brain, especially in the context of chronic pain.

B. The connection between chronic pain and opioid use disorder

Chronic pain and opioid use disorder are interrelated. The Institute of Medicine *Report on Pain* ("IOM Report") suggests that 100 million Americans suffer from pain.[18] "The medical

[13] NATIONAL INSTITUTE ON DRUG ABUSE, *Opioid Overdose Crisis*, https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis (last visited Nov. 21, 2019).
[14] *See* U.S. DEP'T OF HEALTH & HUMAN SERVS., CTRS. FOR DISEASE CONTROL & PREVENTION, *Overview of the Drug Overdose Epidemic: Behind the Numbers*, https://www.cdc.gov/drugoverdose/data/ (last visited Nov. 12, 2019). (citing Lawrence Scholl et al., *Drug and Opioid-Involved Overdose Deaths — United States, 2013–2017*, 67 MORBIDITY & MORTALITY WKLY. REP. 1419, 1419 (2019)).
[15] Alan I. Leshner, *Addiction is a Brain Disease, and It Matters*, 278 SCIENCE 45, 45 (1997), in OWEN D. JONES ET AL., LAW AND NEUROSCIENCE 592 (2014).
[16] Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain*, 65 MORBIDITY & MORTALITY WKLY. REP. 1, 30 (2016), https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fmmwr%2Fvolumes%2F65%2Frr%2Frr6501e1er.htm.
[17] *See infra* notes 74-76 and accompanying text.
[18] Position Statement, American Academy of Pain Medicine, Use of Opioids for the Treatment of Chronic Pain (Mar. 7, 2013), https://painmed.org/about/position-statements/use-of-opioids-for-the-treatment-of-chronic-pain (citing Institute of Medicine, Committee on Advancing Pain Research, Care and Education, *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research*, WASHINGTON (DC): NATIONAL ACADEMIES PRESS (US) (2011) [hereinafter IOM REPORT]).

blunder of casually prescribing opioids for acute and chronic pain is partly to blame for the addiction crisis that has taken more than 400,000 lives over the past 20 years."[19] Many who suffer from chronic pain are either not receiving adequate treatment or relying on opioids.[20] Critically, the relief from opioids is temporary, so opioids are not effective at managing patients' pain.[21] When the opioids wear off, the pain becomes prevalent.[22] This, in turn, causes pain to affect patients like a debilitating disease, resulting in the patient's need for more opioids and ongoing dependency, with limited relief.[23] Change is on the horizon, but before this paper discusses current developments, it provides some background on chronic pain and the legal framework.

C. The law's understanding of chronic pain and the disconnect reflected by legal framework

Chronic pain is pain that persists past the end of the injury-related healing process, which differentiates chronic pain from acute pain.[24] Chronic pain generally is pain that lasts more than three months.[25] Pain results from neurological changes, affecting the central nervous system and peripheral nerves; it does not have to be the product of something else.[26] In other words, "you can have an injury that heals and still have pain [or] you can have no specific injury and have pain . . .

[19] *See* Bernstein, *supra* note 1, at 1 (observing that casually prescribing opioids plays a role in opioid-related deaths).
[20] Puja Seth et al., *supra* note 11, at 1.
[21] *Id*. at 1.
[22] *Id*. at 1.
[23] Matt Seidholz & Allison Young, *Can Cognitive Behavioral Therapy Help Reduce Pain Better Than Opioids?*, EVERYDAY HEALTH (Nov. 21, 2018), https://www.everydayhealth.com/opioids/can-cognitive-behavioral-therapy-help-reduce-pain-better-than-opioids/.
[24] OWEN D. JONES ET AL., LAW AND NEUROSCIENCE 344 (2014).
[25] Jennifer L. Murphy et al., *Cognitive behavioral therapy for chronic pain among veterans: Therapist manual* 11, U.S. DEPARTMENT OF VETERANS AFFAIRS, https://www.va.gov/PAINMANAGEMENT/docs/CBT-CP_Therapist_Manual.pdf (last visited Nov. 21, 2019).
[26] Amanda C. Pustilnik, Address at the Mass General Hospital Center for Law, Brain & Behavior Public Symposium: The Pain Brain in Evidence and Policy—Visible Solutions: How Neuroimaging Helps Law Re-Envision Pain (June 30, 2015).

[The pain] *is in the brain*." [27] Chronic pain, as experienced by an individual, results from a combination of physical, psychological, and environmental factors, and thus pain is subjective and difficult to quantify objectively.[28]

The law relies on an outdated conceptualization of pain, which affects the evaluation of pain and legal compensation for it. *Carradine v. Barnhart* depicts chronic pain and how courts historically have approached pain.[29] Here, Carradine slipped and fell and her pain endured.[30] The court denied her request for disability benefits, finding a lack of "objective evidence" to support her alleged pain.[31] The appellate court reversed, reasoning that back surgery and taking painkillers were objective measures she took to lessen her pain.[32] However, the court went on to point to the psychosomatic aspect of her pain, by proclaiming that her back was fine, and her complaints show that the pain is all "in her head."[33] Such reasoning demonstrates the law's lack of understanding of pain and its effect on the framework for providing relief for pain patients.[34]

Law professor Amanda C. Pustilnik pointed out the abovementioned holes in the legal analysis in *Carradine*.[35] She poignantly noted that "the Social Security Administration said in 1984 that they wanted to reconsider their pain reg[ulations], and we are still in the same place. It might be easier to reach judges and change the law interstitially through interpretation."[36] This paper

[27] *Id*. at 10:26-10:30 (emphasis added).
[28] Daniel J. Gabler, *Conscious Pain and Suffering Is Not a Matter of Degree*, 74 MARQ. L. REV. 289, 296 (1991).
[29] *See* Carradine v. Barnhart, 360 F.3d 751 (7th Cir. 2004).
[30] *Id*. at 753.
[31] *Id*. at 751.
[32] *Id*. at 754.
[33] *Id*. at 754.
[34] Pustilnik, *supra* note 25, at 03:15-04:02.
[35] *Id*. at 05:05-08:28.
[36] *Id*. at 50:48-51:38.

argues that it is beyond time to make such changes, but it is important to take a look at the research on evidence-based alternatives prior to delving into that discussion.

II. THE EVIDENCE-BASED ALTERNATIVES AND MULTIDISCIPLINARY TREATMENT PLAN CHRONIC PAIN PATIENTS DESERVE FOR TREATING THEIR DISEASE

Studies on non-pharmacological alternatives for treatment of chronic pain repeatedly deem such treatment methods effective.[37] This section looks at broad studies and trends and then delves into specific research that demonstrates the efficacy of cognitive behavioral therapy, physical therapy, and acupuncture as examples of the need for implementation of evidence-based alternatives. It then chronicles several recent recommendations to treat pain patients with evidence-based treatment alternatives to opioids, the need for a multidisciplinary patient-centric individualized treatment plan, problems under current law (including lack of insurance coverage for evidence-based alternatives), and findings from brain imaging related to chronic pain.

A. Studies on the efficacy of evidence-based alternatives

Studies exploring evidence-based alternatives for treatment of chronic pain demonstrate the effectiveness of such alternative treatments in improving patient outcomes, with an important caveat—that certain evidence-based alternatives work better than others for specific chronic pain conditions.[38] One 2007 study explored the effectiveness of chiropractic, meditation, hypnosis, yoga, biofeedback, and acupuncture in treating chronic pain.[39] It suggests that these alternative

[37] Luca Scascighini et al., *Multidisciplinary treatment for chronic pain: a systematic review of interventions and outcomes*, 47 RHEUMATOLOGY 1, 11 (2008).
[38] Andrea C. Skelly et al., *Noninvasive Nonpharmacological Treatment for Chronic Pain: A Systematic Review*, 209 AGENCY FOR HEALTHCARE RESEARCH & QUALITY 1, 40 (2018), https://www.ncbi.nlm.nih.gov/books/NBK519958/.
[39] Gabriel Tan et al., *Efficacy of selected complementary and alternative medicine interventions for chronic pain*, 44 J. REHAB. RESEARCH & DEV. 195, 195 (2007).

treatment modalities have varying levels of efficacy, and clinicians should become familiar with these non-pharmacological methods and consider incorporating them into treatment plans.[40]

Separately, trends became apparent in soldiers, who suffered from injuries in training or in combat. As a result of injuries, soldiers experienced tremendous pain, compounded by PTSD and traumatic brain injury, and sadly, they showed little response to the treatment methods health care practitioners implemented.[41] Due to a high rate of psychological illnesses, suicide, drug and alcohol addiction, the Army Surgeon General's Pain Management Task Force ("PMTF") came about in 2009 to create a "comprehensive pain management strategy that was holistic, multi-disciplinary and multi-modal in its approach."[42] The PMTF published a formal report in 2010, which included over 100 recommendations for practice, education, research, and organizational changes at all levels.[43] The abovementioned IOM Report followed.[44] Both reports recommended and endorsed evidence-based alternatives for pain patients and a patient-centered, multimodal treatment plan.[45] The next section examines the efficacy of specific evidence-based alternatives to prescription opioids—cognitive behavioral therapy, physical therapy, and acupuncture.

1. Efficacy of Cognitive Behavioral Therapy for chronic pain

Cognitive Behavioral Therapy ("CBT") is a form of psychotherapy focused on present circumstances and emotions and uprooting negativity.[46] In the context of chronic pain, successful

[40] *Id*. at 208.
[41] Eric Schoomaker & Chester Buckenmaier, *Call to Action: 'If Not Now, When? If Not You, Who?'*, 15 PAIN MEDICINE S4, S5 (2014).
[42] *Id.* at S5.
[43] *Id*. at S5.
[44] *See* Schoomaker & Buckenmaier, *supra* note 40, at S5; IOM REPORT, *supra* note 17, at 93.
[45] *Id*. at S5.
[46] David A. Hanscom et al., *Defining the Role of Cognitive Behavioral Therapy in Treating Chronic Low Back Pain: An Overview* 5 GLOB. SPINE J. 496, 496 (2015).

CBT helps patients recognize the role that negative emotions and cognition play in influencing pain perception and recategorize pain by viewing it as a brain state, whereby the patient sees herself or himself as a well person who has pain.[47] CBT decreases the individual's obsession with pain, his or her constant urge for medical help, and, thereby, assists patients in managing their diseases.[48]

Studies show that CBT improves chronic pain.[49] One study compared patients with chronic pain to a healthy control group.[50] The results established that, "[a]fter 11 weeks of CBT, patients with chronic pain had gray-matter volumes in the bilateral dorsolateral prefrontal, posterior parietal, anterior cingulate, and orbitofrontal and sensorimotor cortices similar to those found in a healthy control group."[51] This study showed tremendous implications for the impact of CBT on chronic pain, particularly through the evidence that neural pathways modified by pain can be uncoupled when pain begins to subside and patients begin to conceptualize pain differently.[52]

A 2012 Cochrane Database Systemic Review found that CBT had "small to moderate positive effects on pain, disability, and mood immediately after treatment compared with treatment as usual."[53] Other reviews of CBT supported that finding, demonstrating that the treatment helps with both pain and depression.[54] A randomized clinical trial found that patients who participated

[47] *Id*. at 497.
[48] Murphy, *supra* note 24, at 26.
[49] *Id*. at 10.
[50] David A. Seminowicz et al., *Cognitive behavioral therapy increases prefrontal cortex gray matter in patients with chronic pain*, 14 J. PAIN 1, 5 (2013), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3874446/pdf/nihms532417.pdf.
[51] *Id*. at 2.
[52] *Id*. at 6.
[53] Amanda Williams et al., *Psychological therapies for the management of chronic pain (excluding headache) in adults*, 11 COCHRANE DATABASE SYSTEMATIC REVIEW 1, 2 (2012), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6483325/pdf/CD007407.pdf.
[54] Dawn M. Ehde et al., *Cognitive-behavioral therapy for individuals with chronic pain: efficacy, innovations, and directions for research*, 69 AM. PSYCHOLOGIST 153, 159 (2014).

in CBT or other mindfulness-based therapy had better outcomes after 26 weeks than those who did not receive these treatments.[55] A study conducted by a team at Group Health Research Institute in Seattle compared different chronic low back pain treatment methods and concluded that 8 weeks of CBT can improve back pain over 6 months.[56] Thus, research suggests that CBT can improve outcomes in patients with chronic pain.

2. How Physical therapy can effectively alleviate chronic pain

Physical therapy ("PT") utilizes exercises and physical manipulation to preserve, restore, and improve range of motion and physical function after impairment caused by an injury, disease, or disability.[57] Physical therapy has benefits for certain types of chronic pain patients, including some who take prescription opioids.[58] However, insurance companies routinely place limitations on the number of PT visits and reimbursement, and this interferes with treatment efficacy.[59]

Physical therapy is an integral component of chronic pain treatment; it helps improve physical functionality and quality of life by enhancing a patient's ability to engage in various

[55] Daniel C. Cherkin et al., *Effect of mindfulness-based stress reduction vs cognitive behavioral therapy or usual care on back pain and functional limitations in adults with chronic low back pain: a randomized clinical trial*, 315 THE J. OF THE AM. MED. ASS'N 1, 8 (2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4914381/pdf/nihms781082.pdf.
[56] Harrison Wein, *Meditation and cognitive-behavioral therapy ease low back pain*, NATIONAL INSTITUTES OF HEALTH (Mar. 29, 2016), https://www.nih.gov/news-events/nih-research-matters/meditation-cognitive-behavioral-therapy-ease-low-back-pain (citing Daniel C. Cherkin et al., *supra* note 54, at 8 (2016)).
[57] Physical Therapy Definition, Merriam-Webster Dictionary, *available at* https://www.merriam-webster.com/dictionary/physical%20therapy.
[58] Per the CDC press release following misapplication of the guidelines, these evidence-based alternatives are not appropriate as the front-line approach for conditions like oncology and terminal illnesses. *See* Press Release, Centers for Disease Control and Prevention, CDC Advises Against Misapplication of the Guideline for Prescribing Opioids for Chronic Pain (Apr. 24, 2019), https://www.cdc.gov/media/releases/2019/s0424-advises-misapplication-guideline-prescribing-opioids.html [hereinafter CDC PRESS RELEASE].
[59] Erik Carvalho et al., *Insurance Coverage, Costs, and Barriers to Care for Outpatient Musculoskeletal Therapy and Rehabilitation Services*, 78 N.C. MED. J. 1, 1 (2018).

activities.[60] A JAMA Network Open study observed patients experiencing pain in four categories (back, knee, neck, or shoulder pain).[61] This study analyzed outcomes of 88,985 patients with private insurance who either received PT within 90 days of their initial doctor visit or did not receive such PT treatment.[62] The data, collected at 91 and 365 days, found that a visit to a physical therapist early on can eliminate patients' need for opioids and reduce the number of pills for those who do need to take prescription opioids for all 4 conditions assessed.[63] Thus, the benefits of physical therapy for chronic pain are clear and widely recognized.

3. Acupuncture as an efficacious treatment for chronic pain

Acupuncture helps chronic pain more than traditional treatment methods, according to studies.[64] Acupuncture involves stimulating specific points on the body by techniques, including insertion of thin metal needles through the skin.[65] Ten million acupuncture treatments are administered in the United States annually.[66] Three million American adults receive acupuncture each year; chronic pain is the leading reason for treatment.[67] Acupuncture's analgesic effect can happen almost immediately for pain patients, but the mechanism for how it works is unclear.[68]

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[60] Eric Sun et al., *Association of Early Physical Therapy With Long-term Opioid Use Among Opioid-Naive Patients With Musculoskeletal Pain*, 1 THE J. OF THE AM. MED. ASS'N NETWORK OPEN 1, 7 (2018).
[61] *Id*. at 1.
[62] *Id.* at 3.
[63] *Id.* at 6.
[64] Dionysios Trigkilidas, *Acupuncture therapy for chronic lower back pain: a systematic review*, 29 ANNALS OF THE ROYAL C. OF SURGEONS OF ENGLAND, 595, 596 (2010).
[65] *Mayo Clinic*, ACUPUNCTURE, https://www.mayoclinic.org/tests-procedures/acupuncture/about/pac-20392763 (last visited Nov. 21, 2019).
[66] Jason Jishun Hao & Michele Mittelman, *Acupuncture: Past, Present, and Future*, 3 GLOB. ADVANCES IN HEALTH AND MED. 6, 6 (2014).
[67] Andrew J. Vickers et al., *Acupuncture for chronic pain: individual patient data meta-analysis*, 172 ARCHIVES OF INTERNAL MED. 1444, 1444 (2012).
[68] Kenji Kawakita & Kaoru Okada, *Acupuncture therapy: mechanism of action, efficacy, and safety: a potential intervention for psychogenic disorders?*, 8 BIOPSYCHOSOCIAL MED. 1, 2 (2014).

In a systematic review with meta-analysis, acupuncture was associated with greater, immediate relief of chronic pain compared to sham acupuncture or analgesic injection.[69] In a meta-analysis on the long-term impact of acupuncture, 90% of acupuncture benefits persisted 12-months after the conclusion of the course of treatment.[70] Another study conducted by researchers from the University of York and Hull York Medical found that acupuncture impacts particular neural structures.[71] Their research showed that acupuncture "deactivates" brain areas associated with processing pain.[72] The many studies and reviews show that acupuncture reduces chronic pain.

B. How efficacy of evidence-based alternatives has led to changes in guidelines and the clinical framework

1. CDC Guidelines and their recommendation of using non-opioids to treat chronic pain

The efficacy of non-pharmacological evidence-based alternatives in comparison with opioids has resulted in changes to guidelines for clinicians.[73] The Centers for Disease Control and Prevention ("CDC") released guidelines that recommend non-drug approaches as the preferred treatment methods for chronic pain and use of non-opioids over opioids.[74] Opioids should only be used (i) in combination with non-pharmacological evidence-based alternatives, and (ii) if the "expected benefits for both pain and function are anticipated to outweigh risks to the patient."[75]

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[69] Anfeng Xiang et al., *The Immediate Analgesic Effect of Acupuncture for Pain: A Systematic Review and Meta-Analysis*, 2017 EVIDENCE-BASED COMPLEMENTARY & ALTERNATIVE MED. 1, 4 (2017).
[70] Hugh MacPherson & Emily A. Vertosick, *The persistence of the effects of acupuncture after a course of treatment: a meta-analysis of patients with chronic pain*, 158 PAIN 1, 11 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5393924/.
[71] Aziz Asghar et al., *Acupuncture needling sensation: the neural correlates of deqi using fMRI*, 1315 BRAIN RESEARCH 111, 111 (2010).
[72] *Id*. at 111.
[73] Dowell et al., *supra* note 15, at 11.
[74] *Centers for Disease Control and Prevention*, GUIDELINES FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN, https://www.cdc.gov/drugoverdose/pdf/guidelines_factsheet-providers-a.pdf (last visited Nov. 21, 2019).
[75] *Id*. at 1.

The CDC explicitly notes that different evidence-based alternative treatments improve functionality, and the benefits last from 2 weeks to 6 months.[76] Due to controversy surrounding physician practices attributed to the guidelines that were inconsistent with its recommendations, the CDC released commentary highlighting that the guidelines are not a one-size-fits-all approach and, thus, not appropriate for patients with conditions where opioids are medically necessary, such as active cancer, sickle cell disease, and post-surgical pain.[77] The commentary also warned prescribers about the dangers of tapering patients off opioids too abruptly and applying the dosage guidelines improperly.[78] The guidelines recommend integrating non-pharmacological evidence-based alternatives,[79] but do not require such treatment for any particular length of time.

2. The Pain Management Best Practices Inter-Agency Task Force Report and its findings on gaps and recommendations

As a result of 2016 federal legislation enacted in response to the opioid crisis, representatives from the Departments of Health and Human Services, Veterans Affairs, and the Department of Defense joined forces to create the Pain Management Best Practices Inter-Agency Task Force ("Pain Management Task Force").[80] The Pain Management Task Force released a report with recommendations and guidelines for treatment of chronic pain on May 9, 2019.[81] The report emphasizes the critical role of alternative treatment methodologies for chronic pain and

[76] Dowell et al., *supra* note 15, at 7.
[77] *Id*. at 29.
[78] *Id*. at 13.
[79] *Id.* at 11.
[80] Comprehensive Addiction and Recovery Act of 2016, Pub. L. No. §114-198, 130 Stat. 695.
[81] *See generally* PAIN MANAGEMENT BEST PRACTICES INTER-AGENCY TASK FORCE, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, PAIN MANAGEMENT BEST PRACTICES INTER-AGENCY TASK FORCE REPORT: UPDATES, GAPS, INCONSISTENCIES, AND RECOMMENDATIONS (2019) [hereinafter TASK FORCE REPORT].

recommended physical therapy and occupational therapy, among others.[82] The Task Force also identified barriers to access to care, lack of understanding of these alternative therapies for pain by both patients and clinicians, and recommended investments in research to help providers incorporate these therapies into multidisciplinary treatment plans.[83] The report further focused on reimbursement, recommending that Medicare, Medicaid, and private payers "develop appropriate reimbursement policies; . . . minimize insurance coverage delays; restore reimbursement to nonhospital sites of service to improve access; and, lower the cost of interventional procedures."[84]

Agencies and Congress started to look at the Task Force's report and recommendations.[85] As the next section of this paper describes the funding that will help create change, it is important to remember that one element—a mandatory component implementing evidence-based treatment methods for chronic pain—is still missing.

3. National Institutes of Health funding initiatives as a step toward change

On September 26, 2019, the National Institutes of Health ("NIH") awarded $945 million in funding across 41 states to support efforts to treat chronic pain through non-addictive methods,

[82] *Id*. at 21.
[83] *Id*. at 62.
[84] *Id*. at 37.
[85] For example, under Section 6032 of the Substance Use Disorder Prevention the Promotes Opioid Recovery and Treatment for patients and Communities Act ("SUPPORT Act"), HHS's Secretary works with the Pain Management Task Force to develop an Action Plan to prevent opioid addiction and enhance access to medication-assisted treatment. As part of CMS efforts to implement Section 6032, they sent the American Pharmacists Association ("APhA") a request for information to help with the development of a Center for Medicare & Medicaid Services ("CMS") action plan to prevent opioid addiction and enhance access to medication-assisted treatment. APhA, in their response and effort to improve accessibility to patient care and public health, suggested that they "welcome the opportunity to work with HHS, CMS and Congress to develop alternative legislative solutions that utilize pharmacists to meet patients' care needs, including those who need pain management and substance use disorder services." It is critical that agencies stay focused on this initiative and forge forward toward a solution together. (*See* Letter from Thomas E. Menighan, Executive Vice President and CEO of the American Pharmacists Association to the Center for Medicare & Medicaid Services 1 (Oct. 11, 2019) (on file with the author)).

prevent opioid misuse and overdose, and improve recovery from opioid addiction, among other components.[86] As the HHS Secretary pointed out, "This historic investment by NIH was made possible by funding secured from Congress by President Trump and will support [the future ability to] 'manage pain in an effective, personalized way.'"[87] This initiative is called the Helping to End Addiction Long-Term Initiative ("NIH HEAL Initiative").[88] As part of the program, people suffering from chronic back pain will participate in a study on the effects of acupuncture on chronic back pain, and Medicare will cover the treatments for participants.[89]

Francis S. Collins, M.D., Ph.D., the NIH director who created the initiative stated,

> It's clear that a multi-pronged scientific approach is needed . . . and [t]his unprecedented investment in the NIH HEAL Initiative demonstrates the commitment to [reduce the risks of opioids, accelerate development of effective non-opioid therapies for pain and provide more flexible and effective options for treating addiction to opioids,] reversing this devastating crisis. [90]

"By the end of 2019, HHS will have awarded more than $9 billion in grants to states and local communities to help increase access to treatment and prevention services since the start of the

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[86] Kaiser Health Network, *NIH Awards $945M For Research On Treating Chronic Pain, Opioid Addiction*, KAISER HEALTH NEWS (Sept. 27, 2019), https://khn.org/morning-breakout/nih-awards-945m-for-research-on-treating-chronic-pain-opioid-addiction/.

[86] Press Release, U.S. Department of Health & Human Services, Trump Administration Announces $1.8 Billion in Funding to States to Continue Combating Opioid Crisis (Sept. 4, 2019), https://www.hhs.gov/about/news/2019/09/04/trump-administration-announces-1-8-billion-funding-states-combating-opioid.html [hereinafter FUNDING TO STATES].

[88] Press Release, NIH Office of the Director, NIH funds $945 million in research to tackle the national opioid crisis through NIH HEAL Initiative (Sept. 26, 2019), https://www.nih.gov/news-events/news-releases/nih-funds-945-million-research-tackle-national-opioid-crisis-through-nih-heal-initiative [hereinafter NIH HEAL FUNDING].

[89] *Id*. at 1.

[90] NIH HEAL FUNDING, *supra* note 87, at 1. *See also*, Acute to Chronic Pain Signatures Program, https://heal.nih.gov/research/clinical-research/pain-signatures (last visited Nov. 21, 2019) (awarding $40 million previously to researchers to study 3,600 patients over two and a half years to find pain biomarkers and determine the biological, psychological and social factors that predict who is prone to developing chronic pain, with the goal of determining preventative treatment strategies).

Trump administration."[91] This is a significant improvement in funding for chronic pain.[92] Efforts are underway to improve the treatment of chronic pain.

C. The necessity of individualized, patient-centered multidisciplinary treatment plans

Evidence-based therapies work well alone or as part of a multimodal treatment plan for chronic pain.[93] These non-opioid therapies are safe and effective ways to reduce the need for opioids.[94] Evidence-based alternative treatment methods are low risk, low cost, and accepted by patients, as discussed below.[95] Many alternative treatments have been used successfully for thousands of years.[96] Importantly, one modality may work for one pain condition but not others.[97]

There is significant support for the notion that evidence-based alternative are lower risk than opioid therapies.[98] The side effects are not potential drug dependency as with opioids, but instead have a reverse effect, helping to eliminate the need for opioids and reduce the dosage prescribed.[99] Lower opioid use decreases both pharmacological side effects and the potential for addiction and abuse.[100] For example, the NIH, as an agency deeply invested in human health

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[91] FUNDING TO STATES, *supra* note 86, at 1.
[92] For comparison, in 2014, the NIH received $30 billion in taxpayer funds to improve health across the country and spent 95% less on chronic pain than it did on heart disease, cancer and diabetes. Chronic pain funding at that time totaled approximately $402 million dollars. *See* Chronic Pain Research Alliance *Federal Investment in Pain Research*, http://www.chronicpainresearch.org/Research (last visited Nov. 26, 2019).
[93] Heather Tick et al., *Evidence-Based Nonpharmacologic Strategies for Comprehensive Pain Care: The Consortium Pain Task Force White Paper*, 14 EXPLORE 177, 187 (2018).
[94] *Id*. at 187.
[95] Syed A. Tabish, *Complementary and Alternative Healthcare: Is it Evidence-based?* 2 INT'L J. HEALTH SCI. 1, 1 (2008).
[96] *Id*. at 1.
[97] TASK FORCE REPORT, *supra* note 80, at 32.
[98] *See* The Joint Commission Division of Healthcare Improvement, *Non-pharmacologic and non-opioid solutions for pain management*, 44 QUICK SAFETY 1, 1 (2018), https://www.jointcommission.org/assets/1/23/QS_Nonopioid_pain_mgmt_8_15_18_FINAL.pdf.
[99] Sun et al., *supra* note 59, at 6.
[100] *Id*. at 1.

outcomes, released the "NIH Consensus Statement on Acupuncture . . . in 1998[, stating,] 'the incidence of adverse effects [from acupuncture] is substantially lower than that of many drugs or other accepted procedures for the same conditions.'"[101]

In terms of cost-effectiveness, several economic analyses compared the costs and health effects between two or more pain therapies and showed more benefit for the economic investment in non-pharmacological evidence-based alternatives than opioids.[102] For example, a review of cost-effectiveness of non-pharmacological alternatives for treating low back pain demonstrated that acupuncture was a cost-effective option; the paper reasoned that although individual acupuncture sessions costed more per session, the pain management benefits lasted for a longer duration than the three-month study, which overall led to a decrease in spending on treatment.[103]

Although a study on the barriers to increased uptake of non-pharmacological treatment modalities pointed out a belief among patients that nonpharmacologic therapies are an additional expense[104], an analysis of the scope of economic benefits changes this perception.[105] Costs savings from use of evidence-based alternatives include outcomes such as "the avoidance of high tech conventional care, lower future healthcare utilization, and reduction of productive loss for employers."[106] The State of Washington performed a study that reported that insurance

[101] Tick et al., *supra* note 92, at 25 (citing NIH Consensus Conference, *Acupuncture*, 280 THE J. OF THE AM. MED. ASS'N 1518 (1998)).
[102] Patricia M. Herman, *Evaluating the economics of complementary and integrative medicine*, 2 GLOB. ADVANCES IN HEALTH AND MED. 56, 59 (2013).
[103] Lazaros Andronis et al., *Cost-effectiveness of noninvasive and non-pharmacological interventions for low back pain: a systematic literature review*, 15 APPLIED HEALTH ECON. & HEALTH POLICY 173, 173 (2017).
[104] William C. Becker et al., *Barriers and facilitators to use of non-pharmacological treatments in chronic pain*, 18 BMC Family Practice 41 (2017).
[105] Herman, *supra* note 101, at 56.
[106] *Id*. at 56.

expenditures only modestly increased even when a significant number of insureds received non-pharmacological therapies.[107] This finding led to a follow-up study of state-insured patients with back pain, fibromyalgia and menopause symptoms, which showed lower overall insurance costs for people who used evidence-based alternatives versus those who did not.[108]

A different study that looked at costs in an interdisciplinary pediatric pain clinic using acupuncture, biofeedback, psychotherapy and massage with medication showed decreased inpatient and emergency department visits.[109] This resulted in an outstanding cost savings of $36,228 per patient per year in hospital costs and $11,482 per patient per year in insurance costs.[110] These cost analyses support the integration of an individualized interdisciplinary pain plan. It also shows how accessibility to and participation in a pain clinic over one year can significantly reduce economic costs by more than the cost of the intervention itself.[111]

Patients accept non-pharmacological alternatives. A review that looked at education on and accessibility to non-pharmacological alternatives showed that seventy-five percent (75%) of patients who previously did not use evidence-based alternatives would utilize these treatments after gaining awareness of and accessibility to such therapies.[112] This statistic came from a study of 103 Veterans in a Midwestern VA Medical Center that assessed whether Veterans would report

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[107] William E. Lafferty et al., *Insurance coverage and subsequent utilization of complementary and alternative medicine providers*, 12 AM. J. OF MANAGED CARE 1,6 (2006).
[108] Bonnie K. Lind et al., *Comparison of health care expenditures among insured users and nonusers of complementary and alternative medicine in Washington State: a cost minimization analysis*, 16 J. ALT. & COMPLEMENTARY MED. 411, 414 (2010).
[109] Nicole E. Mahrer et al., *A Cost-Analysis of an Interdisciplinary Pediatric Chronic Pain Clinic*, 19 J. PAIN 158, 163 (2018).
[110] *Id*. at 163.
[111] *Id*. at 164.
[112] David Cosio & Erica Lin, *Effects of a Pain Education Program in Complementary & Alternative Medicine Treatment Utilization at a VA Medical Center*, 23 COMPLEMENTARY THERAPIES IN MED., 413, 414 (2015).

an increase in evidence-based alternative utilization after completing a formal pain education program.[113] The educational course took place 1-day-per-week for 12-weeks and introduced the Veterans and their families to twenty-three (23) different nonpharmacologic therapies for pain.[114] The results of the study demonstrated a significant increase in the overall utilization of evidence-based alternatives by the Veterans after the education program.[115]

Patients have better outcomes when they play an active role in their improvement.[116] A study supported the literature suggesting that "when patients are partners in their own care, they have better outcomes and medication costs decrease."[117] When people reap the benefits of non-pharmacological alternatives, they feel better, and they actively choose to practice them on their own.[118] Resultantly, patients experience pain relief benefits that result in lower utilization of pharmacological medication.[119] Importantly, and as suggested by the CDC's 2016 prescribing guidelines commentary, clinicians need to weigh both the pros and cons of non-pharmacological alternatives based on the individual patient's pain and gear the treatment plan toward the patient's needs and goals.[120] Although chronic pain patients organized over the last few years, claiming that opioids are the best treatment modality for chronic pain and that they should not be tapered

[113] *Id*. at 1.
[114] *Id.* at 1.
[115] *Id*. at 1.
[116] Mack A. Thomas, *Pain Management – The Challenge*, 5 PAIN MGMT. 15, 19 (2003).
[117] Cecilia Kaechele, Improving Patient Comfort with Nonpharmacologic Therapies, (Apr. 20, 2018) (unpublished thesis, East Carolina University) (on file with East Carolina ScholarShip Digital Archive), http://thescholarship.ecu.edu/bitstream/handle/10342/6667/Kaechele_Final.docx?sequence=1&isAllowed=y.
[118] *Id*. at 13.
[119] Kaechele, *supra* note 116, at 47 (citing Anna Jarrett et al., *Nurses' knowledge and attitudes about pain in hospitalized patients*, 27 CLINICAL NURSE SPECIALIST, 81 (2017) and Lori P. Montross-Thomas et al., *Hospitalized patients' preferences, beliefs, and stated willingness to pay for complementary and alternative medicine treatments*, 23 J. ALT. & COMPLEMENTARY MED. 259 (2017).
[120] Mahrer et al., *A Cost-Analysis of an Interdisciplinary Pediatric Chronic Pain Clinic*, 19 J. PAIN, 158, 158 (2018).

off of prescription opioids, arguably, they vocalized their views because health care practitioners ignored their needs. Practitioners did not utilize the CDC guidelines properly, and patients did not have ready access to non-opioid treatment methods.[121] Resultantly, these patients sought relief.[122]

A multidisciplinary approach is critical. A study on the efficacy of a multidisciplinary approach for treating chronic pain assessed the effects of a 15-week multidisciplinary treatment program for pain rehabilitation, specifically focusing on pain and the ability to function and perform activities.[123] The program consisted of CBT and exercise, along with individual and group sessions that incorporated other treatment modalities.[124] The program rated participants' pain and assessed the patients' pain over time.[125] This 165 patient study showed statistically significant improvements for the subjects between admission and discharge.[126] The study reinforces the theory that non-pharmacological alternatives work for chronic pain, and a multimodal approach is effective.[127] A multidisciplinary, individualized approach to pain management is essential.

D. Disparities due to non-existent overarching pain management framework and lack of insurance coverage

1. Problems with a non-universal framework and gaps in coverage

Current law lacks an overarching framework for insurance coverage of pain management techniques. With the exception of a few individual states that pushed for the implementation of

[121] Jayne O'Donnell & Josephine Chu, *Chronic pain patients, overlooked in opioid crisis, getting new attention from top at FDA*, USA TODAY (Jul. 2, 2018), https://www.usatoday.com/story/news/politics/2018/07/02/chronic-pain-patients-needs-ignored-opioid-epidemic/727015002/.
[122] *Id*. at 1.
[123] Robin Koele et al., *Multidisciplinary rehabilitation for chronic widespread musculoskeletal pain: results from daily practice*, 12 MUSCULOSKELETAL CARE 210, 210 (2014).
[124] *Id*. at 210.
[125] *Id*. at 210.
[126] *Id*. at 210.
[127] *Id*. at 210.

specific evidence-based alternatives through now enacted or pending bills (Georgia, Massachusetts, New York, and Rhode Island cover or may in the future cover chiropractic care, for example), steps taken did not resolve the larger problems with the approach to coverage for pain management.[128] The current administration and federal agencies started dedicating significant funding toward pain management through its initiative to stop the opioid crisis, but now states through their medical boards which are responsible for regulating the practice of medicine, need to take control and handle pain management.[129]

Hospitals, including VA medical centers, pushed for transparency in opioid administration.[130] While these transparency measures certainly are steps in the right direction, it does not mean that the law should become so draconian and anti-opioid that people who need opioids are ultimately denied opioid treatment.[131] Without a national framework, unintended disparities in access to evidence-based alternatives will inherently exist and persist.

2. The status of insurance coverage: failure to cover and restrictions limiting accessibility

In reflecting on the American College of Physicians ("ACP") 2017 guidelines, scientists assessed the state of insurance coverage for non-pharmacological evidence-based alternatives.[132] The ACP guidelines recommended non-pharmacological alternatives for chronic low back pain.[133]

[128] *See e.g.*, W. Va. Code § 16-54-8 (2018) (showing a state bill that passed and includes coverage for chiropractic care as treatment for pain).
[129] Drew Carlson & James M. Thompson, *The Role of State Medical Boards*, AMA J. OF ETHICS, https://journalofethics.ama-assn.org/article/role-state-medical-boards/2005-04 (last visited: Nov. 29, 2019).
[130] Roe, *supra* note 10, at 3.
[131] O'Donnell, *supra* note 120, at 2.
[132] Robert Bonakdar et al., *Analysis of State Insurance Coverage for Nonpharmacologic Treatment of Low Back Pain as Recommended by the American College of Physicians Guidelines*, 8 GLOB. ADVANCES IN HEALTH & MED. 1, 2 (2019).
[133] *Id*. at 2.

The study looked at minimum required coverage and limitations and exclusions.[134] In nearly all state-based coverage policies, chronic pain management and multidisciplinary rehabilitation were not addressed.[135] Coverage was the highest for chiropractic care, in a total of 46 states.[136] Less than ten states covered acupuncture, massage, and biofeedback.[137] Insurance did not cover tai chi or yoga.[138] Insurance accepted CBT often as mental health therapy, but excluded it for treating pain.[139] The study shows that health care practitioners and facilities did not optimize the coordination of non-pharmacological care across disciplines, despite recommendations suggesting incorporation of non-pharmacologic alternatives.[140] Insurance impeded efforts to utilize such treatment methods due to its restrictions and exclusions, despite the evidence base for these treatment methods.[141]

E. Findings from brain imaging related to chronic pain and healing

Brain imaging demonstrates that pain causes neural pathways to rewire in the brain and, as patients recover from pain, these pathway changes uncouple.[142] A study on brain activity in chronic pain patient groups (chronic back pain, osteoarthritis, chronic pelvic pain, chronic post-herpetic neuralgia, chronic complex regional pain syndrome)—with either (i) spontaneous pain, (ii) pain due to a stimulus that does not normally provoke pain, or (iii) acute thermal mechanical stimuli—

[134] *Id*. at 2.
[135] *Id*. at 5.
[136] *Id*. at 3.
[137] *Id*. at 5.
[138] *Id*. at 5.
[139] *Id*. at 6.
[140] *Id*. at 8.
[141] *Id*. at 3.
[142] David Borsook, Address at the Mass General Hospital Center for Law, Brain & Behavior Public Symposium: The Pain Brain in Evidence and Policy—Visible Solutions: How Neuroimaging Helps Law Re-Envision Pain (June 30, 2015), 31:00-31:06.

found that each chronic pain condition evoked a brain activity pattern unique to the condition.[143] The study showed the presence of ongoing pain in different brain regions than acute pain, specifically regions more related to emotions and self-evaluation.[144]

Tools to show the physical correlates of pain include EEG, MRI, and X-ray, for example.[145] As for pain diagnosis, there is no way to map *how much* pain a person is experiencing; there is no test to measure pain intensity, and no instrument can locate pain precisely.[146] Chronic pain can cause a reduction in the brain's gray-matter volume, presumably due to the effects of chronic stress.[147] Neuroimaging studies demonstrated the reversal of such anatomical changes in the brain when effective CBT was part of the treatment regimen for chronic pain.[148]

A forthcoming study focused on "overcoming chronic pain" involves a researcher's use of a brain imaging study to determine the efficacy of a new mindbody approach for the treatment of chronic back pain.[149] The study—performed at the University of Colorado Boulder between July and September 2019—involved 90 chronic back pain patients: "30 patients [were] treated with a mindbody approach, 30 patients . . . receive[d] a placebo injection, and another 30 patients . . . receive[d] no treatment at all."[150] All 90 patients underwent fMRI brain scans both before and after

[143] Marwan N. Baliki & A. Vania Apkarian, *Nociception, pain, negative moods and behavior selection*, 87 NEURON 474, 485 (2015).
[144] *Id*. at 487.
[145] Debbie L Morton et al., *Brain imaging of pain: state of the art*, J. OF PAIN RESEARCH 613, 614 (2016) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5019436/pdf/jpr-9-613.pdf.
[146] OWEN D. JONES ET AL., LAW AND NEUROSCIENCE 591 (2014).
[147] Muhammad Hassan Majeed & Donna M. Sudak, *Cognitive Behavioral Therapy for Chronic Pain-One Therapeutic Approach for the Opioid Epidemic*, 23 J. PSYCHIATRIC PRACTICE 409, 412 (2017).
[148] *Id*. at 412.
[149] Howard Schubiner, *Breakthrough Study: Overcoming Chronic Pain*, https://www.indiegogo.com/projects/breakthrough-study-overcoming-chronic-pain#/ (last visited Nov. 24, 2019).
[150] *Id*. at 1.

treatment to objectively assess the changes in pain for members of each group.[151] The results have not been published yet. This study shows that society is, contrary to the *Carradine* case mentioned earlier, recognizing that some forms of chronic pain are not caused by physical problems in the body, but rather through modified neural pathways in the brain.[152] Just as the body learns pain and the brain forms new synaptic profiles, when pain relief and renormalization of cognitive abilities occur, gray matter can increase and the disease can reverse.[153]

III. SOLUTION—LEGAL REFORM: BRIDGING THE GAP THROUGH A MANDATORY EVIDENCE-BASED TREATMENT PLAN IN PLACE OF OPIOIDS (OR IN CONJUNCTION WITH OPIOIDS WHERE MEDICALLY NECESSARY)

A. Provision of chronic pain-related HHS funding to state medical boards contingent upon implementation of evidence-based alternative treatment plans

There are gaps in the protocol for treating chronic pain, and the law needs to make access to alternatives a priority. The proposed course of action is implementation of a mandatory evidence-based treatment plan in place of opioid therapy or, where medically necessary, in conjunction with prescription opioids. HHS should mandate alternative treatment as a component of chronic pain management. In order to avoid Tenth Amendment issues and running afoul of the Constitutional delegation of the right to regulate the practice of medicine to the states, HHS should condition future chronic pain funding to the states in connection with the initiative to stop the

[151] *Id*. at 1.
[152] *Id*. at 1.
[153] *Id*. at 1. *See also* A. Vania Apkarian, *The Brain in Chronic Pain: Clinical Implications*, 1 PAIN MANAGEMENT 577 (2011), in JONES ET AL., *supra* note 1, at 348.

opioid crisis, on each state's compliance with an mandatory evidence-based treatment plan program.[154] Under the U.S. Constitution,

> [A]lthough the states have ceded the power to regulate interstate commerce to the federal government, they retained, via their police powers, the right to regulate any activity that poses a threat to the public health or safety of their citizens. Thus, state laws that seek to ban the import of milk from outside the state to protect local dairies are an unconstitutional attempt to control trade. In contrast, state laws that focus on consumer protection, such as requiring the sanitary inspection of imported milk and banning the import of contaminated milk, are constitutional, provided they also apply to milk produced within the state. This distinction between laws affecting commerce and laws affecting health and safety is important to medical care practitioners because the regulation of the practice of medicine is considered a health and safety issue and thus reserved to the states as a police power.[155]

HHS contingent funding and resources should make an impact immediately to effectuate the required multidisciplinary non-pharmacological treatment plan for patients with chronic pain discussed in this paper. As part of this initiative, the state medical boards should require doctors to develop compliant treatment plans, and when practitioners are compliant, the state medical board becomes eligible for the funding from HHS.

The protocol that practitioners need to implement for their states to be eligible for HHS funding must ensure that the patient treatment plan is individualized, specific to each patient's needs and goals, and integrates some combination of non-pharmacological, evidence-based treatment alternatives, such as cognitive behavioral therapy, acupuncture, or physical therapy. A patient's plan could incorporate telehealth and telemedicine if mobility is an impediment to

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[154] *See* U.S. CONST. amend. X (reserving "the powers not delegated to the United States by the Constitution, nor prohibited by it to the States, . . . to the States respectively, or to the people.").
[155] Edward Richards, *State versus Federal Powers- The Regulation of Commerce*, THE LSU MEDICAL AND PUBLIC HEALTH LAW SITE 1, 1 (2009) (referencing *Dean Milk Co. v. Madison*, 340 U.S. 349 (1951)).

attending treatment sessions. The protocol also should mandate a 15-week treatment plan for patients that incorporates the treatment methodologies the patient needs to realize positive changes in health outcomes. The patients who need opioids visit their health care providers regularly to discuss their status regardless, in order to receive new prescriptions. Those visits should include provider inquiries about patient attendance at their mandated treatment plan sessions where providers evaluate the individual's plan and make adjustments as necessary.

B. Required Insurance Coverage

Additionally, HHS should ramp up Medicare and Medicaid reimbursement for alternative pain therapies. Insurance companies need to cover these alternatives. Analogous to the withholding of funding in *South Dakota v. Dole*, it is up to the states to follow the protocol here.[156] If a state elects to participate in this program, that state will receive enhanced reimbursement for providing evidence-based alternatives, and as a condition of receiving the bolstered reimbursement funding, the state will need to comply with HHS's rules for the program. Since the Center for Medicare and Medicaid Services (CMS) falls under the operating divisions of HHS, HHS and CMS should work together on this effort.[157] HHS would then provide reimbursement.[158]

[156] *See generally* South Dakota v. Dole, 483 U.S. 203 (1987) (withholding a percentage of highway funding from states that failed to raise the drinking age to 21).
[157] Assistant Secretary for Public Affairs, *HHS Organizational Chart*, U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES (Nov.14, 2018), https://www.hhs.gov/about/agencies/orgchart/index.html.
[158] *NFIB v. Sebelius*, 567 U.S. 519 (2012) also sheds light on how to implement this program. The Supreme Court, in reviewing the Medicaid expansion provision of Patient Protection and Affordable Care Act of 2010 found that the conditions on federal funding in that case exceeded Congress's spending power because it was impermissibly coercive and otherwise intruded on the role of the states in the federalist system and the delegation of the power over medicine to the states. The court's reasoning included that Congress can tell states that accept funding how to comply but cannot penalize states that do not comply by taking away all Medicaid funding. This is distinguishable from this program, because this is a supplemental reimbursement program for states that provide access to alternatives, separate and distinct from the current Medicare and Medicaid framework.

HHS's Pain Management Best Practices Inter-Agency Task Force, in its Task Force Report, made some relevant recommendations related to this paper.[159] The Task Force recommended that CMS and private payers implement improved payment models that cover integrated, multidisciplinary pain management, including CBT.[160] This model indicated that CMS and private payers should specifically provide reimbursement for pain management consistent with the time and resources dedicated to educating and evaluating the patient (including risk for misuse), re-evaluating the patient after initiating treatment, and integrating evidence-based non-pharmacological alternatives to opioid therapy.[161] CMS and private payers should also align their reimbursement guidelines for chronic multidisciplinary pain management with current clinical practice guidelines.[162] Additionally, payers need to provide reimbursement for non-opioid pharmacologic therapies that are more expensive than opioids, such as long-acting local anesthetic injections and infusions and intravenous acetaminophen analgesia, because as discussed previously, there are longer-term economic benefits of providing this coverage.[163] With a contingent funding mechanism, CMS and private payers will cover evidence-based alternatives.

C. The Pain Management Team Model

Crucial to the success of this proposal, the individualized, multidisciplinary treatment plans for chronic pain management require organization through a team of specialists.[164] This is a best practice, yet the current reimbursement models are barriers to providing this type of treatment.[165]

[159] *See generally* TASK FORCE REPORT, *supra* note 80, at 1-116.
[160] *Id*. at 46.
[161] *Id*. at 51.
[162] *Id*. at 71.
[163] *Id*. at 71.
[164] *Id*. at 62.
[165] *Id*. at 40.

Payers should follow a chronic disease management model for reimbursement and should include reimbursement for multidisciplinary pain care similar to that used for cardiac rehabilitation and diabetes programs.[166] In addition, the reimbursement should cover the time teams spend coordinating patient care.[167] The Task Force also recommends development of a CPT code for pain care coordination and conferences.[168] There should be a telehealth option for reimbursing pain management to facilitate access in underserved locations that payers cover as well.[169]

The law should necessitate that insurance companies cover all of the evidence-based alternatives that the doctor recommends for the patient, as mentioned above. Additionally, as part of the program, patients with chronic pain could use an identification card that allows them to attend unlimited sessions of group evidence-based alternative treatment sessions to supplement the mandated plan that the patient follows. HHS should post the locations that offer group medical treatments for chronic pain and make the services free to participants, as long as they sign up in advance—by phone or through the website—so the health care provider location can have the appropriate medical staff on site to provide the service. HHS, through the states, should provide these service providers with a stipend for the cost of having the necessary medically trained personnel conduct the sessions. HHS, as part of its contingent funding program, can withhold this funding unless states make the evidence-based alternative treatment plans mandatory.

[166] *Id*. at 71.
[167] *Id*. at 71.
[168] *Id*. at 71.
[169] *Id*. at 71.

D. Reasoning for 15-Week Program Length

This paper derived the calculation of a 15-week mandated program based on the results of the studies discussed earlier in this paper. The 15-week program mentioned previously showed statistically significant changes in patient outcomes attributable to their multidisciplinary treatment plan.[170] A CBT study showed that after 11 weeks of CBT, patients with chronic pain had healthier gray-matter volumes in their brains.[171] The physical therapy study showed improvements over 5 to 8 sessions.[172] The acupuncture study showed changes in patients over 12 weeks.[173] Fifteen weeks seems like a prudent determination of a meaningful duration to start to create improved health outcomes for patients with chronic pain. The plan should allow for extension as needed, depending on the patient's results and need for more therapy.

This proposal, while unique insofar as it is mandatory, is not novel in its elements or approach. A Position Statement from the American Academy of Pain Medicine, which discussed Minimum Insurance Benefits for Patients with Chronic Pain, proposed a framework on March 7, 2014 with regard to insurance coverage.[174] The proposal targeted the treatment of pain that is not expected to resolve in the near future and that is not responsive to other treatments.[175] The coverage framework included (i) Medical management; (ii) Evidence- or consensus-based interventional/procedural therapies; (iii) Ongoing behavioral/psychological/psychiatric therapies; (iv) Interdisciplinary care; and (v) Evidence-based complementary and integrative medicine (*e.g.*,

[170] Koele, *supra* note 122, at 210.
[171] Seminowicz, *supra* note 49, at 10.
[172] Sun, *supra* note 59, at 5.
[173] MacPherson & Vertosick, *supra* note 69, at 5.
[174] Position Statement, American Academy of Pain Medicine, Use of Opioids for the Treatment of Chronic Pain (Mar. 7, 2013), https://painmed.org/about/position-statements/use-of-opioids-for-the-treatment-of-chronic-pain.
[175] *Id*. at 3.

yoga, massage therapy, acupuncture, manipulation).[176] The American Academy of Pain Medicine suggested comparable coverage to the level of treatment coverage for people with mental-health disorders, and, similar to this paper, argued that limited visits and other restrictions including limited reimbursement are not appropriate for patients with unremitting pain.[177] The proposed mandated program of a 15-week multidisciplinary treatment plan for chronic pain patients will benefit people suffering from the disease of chronic pain.

IV. ADDRESSING THE RESISTANCE TO CHANGE

Doctors and patients voiced concerns about the "cost" of chronic pain management, and this section addresses those concerns. The arguments include higher costs and impracticability of spending time on alternatives, as well as requiring insurance companies to cover unprecedented treatment options.[178] The media, some studies, and other publications echoed these concerns.[179]

In a study that interviewed primary care providers regarding treating co-morbid chronic pain and opioid use disorder, the doctors reported that barriers to implementing alternatives include lack of resources like staff, time, and access to alternatives.[180] Regarding the barrier of time, the PCPs explained that they do not have the time to spend working with patients on alternative treatment plans.[181] A separate study by Lauren S. Penney and her team on provider and patient perspectives regarding alternatives to opioids for managing chronic pain, quotes a primary care

[176] *Id*. at 1.
[177] Allyson Varley et al., *Assessing Barriers and Facilitators to the Uptake of Best Practices for threating Co-Occurring Chronic Pain and Opioid Use Disorder*, Poster at the 11th Annual Conference on the Science of Dissemination and Implementation in Health (December 3-5, 2018).
[178] *Id*. at 1.
[179] Lauren S. Penney et al., *Provider and patient perspectives on opioids and alternative treatments for managing chronic pain: a qualitative study*, 17 BMC FAMILY PRACTICE 164, 170 (2016).
[180] Varley, *supra* note 176, at 1.
[181] Penney et al., *supra* note 178, at 171.

physician, who sheds light on this perspective, "We get our little ten-minute[s] per patient, which is so grossly, woefully an inadequate amount of time to see a patient. Ten minutes, right, for all your problems. And so nobody wants to take the time to explore things other than drugs for people with chronic pain."[182] This is problematic and is an issue that HHS contingent funding can address, especially if it compensates health care providers for the time spent implementing non-pharmacological alternatives and coordinating care among various service providers.

The aforementioned study from 2007, which discussed efficacy of alternative pain treatments flagged some duplicative issues and some different concerns relevant to the difficulties for practitioners making decisions about using or incorporating alternatives, including the following:

> additional time and energy investments, the need for specially trained personnel to administer the modalities, known or potential side effects, safety in combining alternatives and other modalities, likely acceptance by clients and the public (and hence the issue of long-term adherence), and ease of incorporation into traditional pain management practices.[183]

Another argument against the implementation of the proposed multidisciplinary, individualized evidence-based alternative plans for chronic pain patients is the contention that insurance companies will need to expend (potentially substantial) money on alternative treatments that they have failed to previously cover.[184]

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[182] *Id.* at 174.
[183] Tan et al., *supra* note 38, at 210.
[184] Tracey Walker, *Study Reveals Insurers Could Do More to Cover Opioid Alternatives*, MANAGED HEALTH CARE EXEC. (Oct. 14, 2018), https://www.managedhealthcareexecutive.com/pharma-forecast-report/study-reveals-insurers-could-do-more-cover-opioid-alternatives.

These critiques beg the question: How can we assess whether these concerns are legitimate if we have never truly attempted to incorporate these alternatives? This paper argues that quick fixes with opioids alone have failed to solve problems for people with chronic pain, and the need for integration of non-pharmacological, evidence-based alternatives is critical to helping these patients. Chronic pain costs our country because people are suffering and dying from misuse of opioids.[185] The cost of alternative treatments cannot truly be assessed without attempting to effectively implement a program to fill the known gaps in chronic pain treatment.

To put this in perspective, Professor Jennifer Oliva, who specializes in health law and is following the opioid crisis closely, pointed out that monetarily, "the cost of the opioid crisis exceeds $1 trillion dollars and is rising every day already."[186] These extravagant costs demand a new approach to try to fix this problem. Professor Oliva also pointed out that "by certain projections, the crisis will continue to get worse before it gets better, meaning that it is critical to implement evidence-based alternatives as soon as possible."[187]

Chronic pain costs the United States $560 to $635 billion annually, according to the National Academy of Medicine.[188] This cost is higher than the nation's annual expenditures for

[185] NATIONAL INSTITUTE ON DRUG ABUSE, *supra* note 12, at 1.
[186] Greg Allen, *Cost Of U.S. Opioid Epidemic Since 2001 Is $1 Trillion And Climbing*, NPR (Feb. 13, 2018 6:00 AM), https://www.npr.org/sections/health-shots/2018/02/13/585199746/cost-of-u-s-opioid-epidemic-since-2001-is-1-trillion-and-climbing.
[187] German Lopez, *How America's opioid epidemic could get even worse*, VOX (Aug. 29, 2019, 1:00 PM), https://www.vox.com/policy-and-politics/2019/8/29/20836719/opioid-epidemic-fentanyl-rand-report.
[188] Darrell J. Gaskin & Patrick Richard, *The economic costs of pain in the United States*, 13 J. PAIN 715, 723 (2012) (citing IOM REPORT).

heart disease, cancer, and diabetes combined.[189] "We can expect the chronic pain burden to escalate,"[190] especially as chronic illnesses increase over time.

This paper takes the position that "most of the nonpharmacologic strategies are underutilized due to lack of evidence dissemination, education, and reimbursement. It is time for civilian medicine to join the call to action of military medicine outlined by Schoomaker and Buckenmaier.[191] They urge the immediate incorporation of nonpharmacological evidence-based alternatives and active self-care, due to their safety, efficacy, and acceptance by patients.[192] Their call to action aims to increase awareness, access, and utilization of nonpharmacologic treatments through education of practitioners and patients; to disseminate and reimburse evidence-based treatment options; and to promote ongoing research focused on the therapeutic and economic impact, in the short and long term, of comprehensive care practices.[193] Importantly,

> [t]here is an additional benefit to many nonpharmacological pain care strategies; unlike drugs and surgery, the [evidence-based alternatives] involve patient participation and a commitment to self-care. Increased self-efficacy in managing pain correlates with improved mood and predicts improved outcomes in many chronic conditions, including pain. For example, the military has studied 'active self-care therapies' as a category of pain management that may be of value in an integrated, multimodal approach.[194]

Patients can perform many of these therapies on their own, reaping the ongoing benefits, cost free, as they apply the therapies and techniques in their everyday lives.[195] An individual can practice

[189] Gaskin & Richard, *supra* note 187, at 715.
[190] Tick et al., *supra* note 92, at 179.
[191] *Id.* at 197.
[192] Schoomaker & Buckenmaier, *supra* note 40 at 2.
[193] Tick et al., *supra* note 92, at 197.
[194] *Id.* at 187.
[195] Anne Kennedy et al., *Support for self care for patients with chronic disease*, 335 BRITISH MED. J. 1, 3 (2007), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2071971/.

the CBT coping skills on their own and perform exercises on their own, for example, causing accelerated healing rates because of the added benefits achieved between sessions.[196]

Medicine and policy decision-making professionals acknowledge the crisis in pain and pain care.[197] "If we could find a way of intervening, . . . then the . . . need [for] opioids or heavy doses of analgesics will diminish."[198] Through an effective legislative framework, a solution can be found. As mentioned earlier and worth repeating, "[i]nstead of symptom management, we would be managing the disease."[199]

CONCLUSION

People suffering from the disease of chronic pain need a mandatory program that incorporates evidence-based alternatives in place of, or if medically necessary, in conjunction with, the prescribing of opioids. Since states are responsible for regulating the practice of medicine, HHS should condition state funding for chronic pain, provided in connection with the funding for the opioid crisis, on each state's implementation of mandatory alternative treatment programs. HHS should similarly set up a program for supplemental insurance reimbursement for provision of these evidence-based alternatives. This contingent funding will boost integration of effective pain management techniques, help mitigate the deadly and costly opioid epidemic, and create longer sustaining benefits for chronic pain management.

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[196] *Cleveland Clinic*, CHRONIC PAIN MANAGEMENT AND TREATMENT, https://my.clevelandclinic.org/health/diseases/4798-chronic-pain/management-and-treatment (last visited Nov. 26, 2019).
[197] Bernstein, *supra* note 1, at 5.
[198] *Id*. at 5.
[199] *Id*. at 5.