

# Stetson Journal of Advocacy and the Law

The first online law review designed to be read online



7 Stetson J. Advoc. & L. 124 (2020)

## The Fifth Vital Sign: An Overview of the Opioid Crisis and Its Effects on Veterans

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# The Fifth Vital Sign: An Overview of the Opioid Crisis and Its Effects on Veterans

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## I. Introduction

124. There is a crisis that has been steadily rising in the United States and has claimed almost 218,000 American lives from 1999 to 2017.<sup>2</sup> As of 2017, according to the White House Opioid Commission Report, 175 Americans are dying from opioid addiction every day.<sup>3</sup> That is 3,675 American being lost every three weeks. To add perspective, the terrorist attacks on September 11, 2001, claimed 2,997 lives compared to the 3,675 lives lost every three weeks to opioid addiction. It is because of data like this, and the countless stories of how opioid addiction has destroyed lives and families, that on

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  - 2 Centers for Disease Control and Prevention, *Opioid Overdose*, PRESCRIPTION OPIOID DATA, [CDC.GOV](#).
  - 3 Chris Christie, et al., *The President's Commission on Combating Drug Addiction and the Opioid Crisis Report and Recommendation*, [WHITEHOUSE.GOV](#).

October 26, 2017, President Donald Trump declared the opioid crisis a national public health emergency.<sup>4</sup> While the opioid crisis poses a threat on a national scale, it has severely affected one group in particular — military veterans.

125. This paper is meant as a survey to discuss the opioid crisis and its affect on veterans. Specifically, this paper will briefly discuss how the opioid crisis was in part endorsed by the Veterans Administration (VA), how the VA pushed prescription opioids to veteran patients, and how policies failed to stem the tide in rising opioid dependence. We will first look at the history of the Fifth Vital Sign Movement and how this movement was incorporated into the VA treatment plan for veterans. Second, we will discuss the impact prescription opioids had on veterans who were receiving care from the VA. Finally, we will look at the VA's recent policies related to prescription opioids and discuss potential loopholes, gaps, and unintended consequences related to veteran healthcare.

## II. The Fifth Vital Sign Movement

126. The infamous story of the Fifth Vital Sign Movement may have had ideal beginnings, but created unintended consequences. In the field of medicine, doctors measure four functions of the body that allow the medical providers to diagnose and treat a patient. Those four functions are measured as body temperature, pulse rate, respiration rate, and blood pressure. Together, the four functions represent the four vital signs medical providers keep track of with any given patient. In fact, if you were to go to a hospital right now, you would see all four vital signs being tracked/measured on vital monitors. Vital signs are an important tool that medical providers use to provide diagnoses; see the effects of treatment on the body; and monitor the patient — but there is something that you won't see on these vital monitors — a measurement for pain. The reason for this is because pain is subjective and, even with the medical advances of today, we still have not discovered an objective way to monitor it. This is significant because orthodox medicine (versus alternative forms of medicine such as homeopathy) as we know it today focuses on a rationalism based philosophy.<sup>5</sup>

127. This has resulted in mainstream medicine taking a laboratory approach to medicine where doctors focus on treatments and diagnostic tools that can be objectively tested and verified. Since a patient's level of pain cannot be tested through any objective test, doctors have focused on treating the disease or ailment that is triggering the pain, rather than seeking to get rid of the pain itself. In other words, doctors do not see pain as a disease that needs its own form of treatment. Because of this, there was a sentiment that doctors were not concerned enough with a patient's level of pain. A doctor

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4 Greg Allen, et al., *Trump Administration Declares Opioid Crisis A Public Health Emergency*, [NPR](#).

5 John Warner, *The Therapeutic Perspective: Medical Practice, Knowledge, and Identity in America 1820–1885*, [HARVARD UNIVERSITY PRESS](#) (1986).

could be pursuing a variety of treatments that either exacerbate, or leave pain levels unchanged. There was a disconnect between doctors and patients. However, even with treatment, patients would either go through more pain receiving the treatment, such as with chemotherapy, or would still be left with some level of pain. The problem was that doctors had traditionally only prescribed pain medications for short-term treatment, usually after major surgeries, and treatment for chronic pain was not a focus. Doctors feared patients may become addicted. Patients, however, wanted to be completely pain free. It was this disconnect regarding pain between the doctors and patients that led to the Fifth Vital Sign Movement.

128. Regardless of patients' desires, doctors still needed some form of scientific evidence or approval from the medical community before prescribing prescription opioids, often referred to as being a part of the analgesic category drugs (analgesics meaning that the agent reduces pain sensations). In 1980, a one-hundred-word letter to the editor was published in the *New England Journal of Medicine*. The letter stated that of the 11,882 patients that had received a narcotic drug while at the Boston University Medical Center, there were only four cases of addiction where a patient had no prior history of addiction. From this data, the letter states, "[w]e conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction."<sup>6</sup> The significance of this letter is that it helped to alleviate medical providers' doubts about prescribing opioids, as an alternative therapy, for fear that patients may become addicted. After the letter mentioned above, more articles/studies were published attesting to the same general theme that analgesics could be used as an alternative form of therapy and to reduce patients' pain without a realistic fear of addiction.

129. For example, in 1986, a study published by the *Journal of Pain* stated that analgesics "can be safely and effectively prescribed to selected patients with relatively little risk of producing the maladaptive behaviors which define opioid abuse." The study went on to state that "[w]e conclude that opioid maintenance therapy can be a safe, salutary and more humane alternative to the options of surgery or no treatment in those patients with intractable non-malignant pain and no history of drug abuse."<sup>7</sup> To the authors' credit, they mention the need for long-term studies on the use of analgesics to treat chronic pain — something that has yet to be done. This article represented a growing shift in the medical community — that chronic pain is something that can be safely treated, should be thought of as a non-invasive alternative therapy, and should be something that doctors try to alleviate.

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6 Jane Porter, et al., *Letter to Editor: Addiction Rare in Patients Treated With Narcotics*, 302 *NEW ENG. J. MED.* 123 (1980).

7 R.K. Portenoy, et al., *Chronic use of opioid analgesics in non-malignant pain: report of 38 cases*, 25 *JOURNAL OF PAIN* 171–86 (1986).

130. This is where Dr. James Campbell stepped into the light to advocate for doctors to treat a patient's pain and see pain as a fifth vital sign. Dr. Campbell was the president of the American Pain Society and, back in 1996, Dr. Campbell gave a keynote speech advocating greater awareness about pain and trying to change medical providers' philosophy regarding pain treatment. Dr. Campbell stated in his 1996 speech, "If pain were assessed with the same zeal as other vital signs are, it would have a much better chance of being treated properly." While Dr. Campbell advocated for medical providers to be trained in treating pain generally, he also advocated for a shift in treating chronic pain with opioids. Around the same time as Dr. Campbell's speech, prescription opioids were just hitting the market for the treatment of pain. Dr. Campbell's speech not only highlighted a problem, but also shed light on the recent pharmaceutical developments that offered a solution. In fact, OxyContin, a powerful prescription opioid, had been released on the market in 1996 — the same year as Dr. Campbell's speech. An even further coincidence is that during Dr. Campbell's presidency of the American Pain Society, the organization received funding from Purdue Pharmaceutical — the manufacturer of OxyContin.<sup>8</sup> It should be noted that this is neither the first nor the last time a pharmaceutical company has funded movements, launched advertising campaigns, or created "educational" events for medical providers just to market their pharmaceuticals — but, the ethics of Big Pharma is a topic for another paper.

131. After Dr. Campbell's speech, the Fifth Vital Sign Movement was born. Dr. Campbell's speech illuminated an unnecessary epidemic of doctors' undertreatment of pain. It was 'unnecessary,' because medical providers now had prescription opioids. Government officials soon joined the fray advocating for medical providers to do more to treat patients' pain. Specifically, the Veterans Health Administration (VHA) stepped in to bridge the gap and to make pain the fifth vital sign. According to Vox, an online investigative journalism site, "In November 1998, the Veterans Health Administration sent a memo to its 1,200 clinics requiring clinicians to ask patients' about their pain level at each visit. The initiative was called 'Pain as the 5th Vital Sign.' A pain score above 4 was meant to trigger 'a comprehensive pain assessment and prompt intervention.'"<sup>9</sup> The memo has since been taken down from the VA's website. It is with this back drop that we take a closer look at the VA's implementation of pain assessment and management through the "Fifth Vital Sign." It's clear that the VHA wanted to bring a prompt response to the under treatment of pain, but the VHA's plan was premature and its execution led to unforeseen consequences for veterans at VA hospitals.

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8 Sarah Kliff, *The Opioid Crisis Changed How Doctors Think About Pain*, [VOX.COM](#) (2017).

9 Sarah Kliff, *The Opioid Crisis Changed How Doctors Think About Pain*, [VOX.COM](#) (2017).

### III. The VA and The Fifth Vital Sign

132. When the VA implemented assessment plans for medical providers to use to treat patients' pain its actions provided an example to the rest of the American healthcare community to follow. For the first time, the VA was receiving praise for being at the forefront of patient care. To say that the VA was not influential in promoting the Fifth Vital Sign philosophy is an understatement. Around the time that the VA was implementing the Fifth Vital Sign project, it was the largest trainer of healthcare professionals and treated around 3.5 million patients a year. At the beginning of March 1999, veterans began to be assessed for the pain they were experiencing. A Washington Post article at the time discussed the VA's Fifth Vital Sign Movement project in assessing patient pain stating, "VA officials said the change in routine is designed to call physicians' attention to what is widely considered one of the most unrecognized and untreated symptoms in American health care. In a study of 10,000 dying patients published in 1995 in the Journal of the American Medical Association, for instance, researchers found that almost half died in severe pain; other studies report that as many as three-quarters of advanced cancer patients are in pain." The article discusses many reasons why the VHA project was needed and how patients, up to that point, did not discuss pain with doctors for fear it was either a worsening of the condition or distracted the doctor from the "real issues."<sup>10</sup> Two things that were not mentioned in that article: 1) what methods would be used to treat pain; and 2) the possibility of addiction.

### IV. Implementation of the National Pain Management Strategy

133. To really understand how the VA's Fifth Vital Sign Movement project led to an opioid crisis amongst its patients and contributed to the crisis abroad, one must look at the policies put in place by the VA. As part of the Fifth Vital Sign Movement, the VHA created the National Pain Management Strategy. The goal of the strategy was to reduce pain and suffering for veterans in the VHA's healthcare system. As part of that goal, the VHA distributed the "Pain as the Fifth Vital Sign Toolkit" to VHA managers and staff to implement policies and procedures at VA medical facilities. While the goal of the strategy was to reduce pain and suffering, the toolkit itself was designed as a screening mechanism. Specifically, the toolkit states, "Screening for pain can be administered quickly for most patients on a routine basis. As with any other vital sign, a positive pain score should trigger further assessment of the pain, prompt intervention, and follow-up evaluation of the pain and the effectiveness of treatment." Essentially, the VHA wanted

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<sup>10</sup> Janice Lynch Schuster, *Veterans Health Administration's Addition of Pain as a Fifth Vital Sign May Have Far-Reaching Effects*, [WASH. POST](#) (1999).

medical providers to ask patients about their levels more often and, by doing so, help to instill in medical providers the need to treat pain. Overall, the National Pain Management Strategy was composed of essentially four tasks: 1) “Routine pain screening for the presence and intensity of pain for all patients using a 0–to–10 Numeric Rating Scale (NRS);” 2) “Documentation of present pain intensity (i.e., “pain score”) for all patients as part of the vital sign record;” 3) “Completion of a comprehensive pain assessment, as clinically indicated, for patients reporting a significant level of pain;” 4) “Documentation of the comprehensive pain assessment, the plan for improved pain management, and a timeframe for reassessment.”<sup>11</sup>

134. Once again, these directives reflect how the VHA used the Fifth Vital Sign Movement as only a screening measure. However, the problem was that the VHA’s strategy focused on screening and assessing for pain but failed to instruct or attempt to educate medical providers on how to treat patients with pain. Now it may seem obvious that the decision on how to treat a patient should lie with the doctor alone, given his or her medical expertise, but VHA’s lack of guidance may have contributed to medical providers prescribing prescription opioids more freely to meet the National Pain Management Strategy’s goals.

135. The “Pain as the Fifth Vital Sign Toolkit” clearly reflects a gap in how medical providers should meet the goals. The VHA essentially stated that medical providers need to screen patients more for pain, create policies and procedures to assess pain, and, inevitably, treat a patient’s pain. However, nowhere in the “Toolkit” does it ever go into any detail on how that should be done. In general, the “Toolkit” states that local facilities are to “create pain management system,” utilize experts in the pain management field, and educate medical providers on how to treat/manage pain — but provides nothing specific about what a patient’s treatment for pain would look like. To be fair, the VHA created sample questions and answers on how doctors could ask patients about their pain and how to inform patients about the VHA’s new pain management strategy. Also, in an effort to screen for pain, the VHA instituted the Numeric Rating Scale (NRS) which would be used by medical providers to assess a patient’s level of pain. While the NRS may sound like a sophisticated tool, the NRS was merely a zero to ten (0–10) scale that many patients see posted on a doctor’s office. A score between 1–4 represented mild pain, 5–6 moderate pain, and anything over 7 was severe pain. However, if VHA had created policies not only on screening for pain but also guidelines on how to treat pain, then perhaps VA medical providers would not have prescribed prescription opioids so easily.

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11 GERIATRICS AND EXTENDED CARE STRATEGIC HEALTHCARE GROUP, ET AL., [PAIN AS THE FIFTH VITAL SIGN TOOLKIT 7](#) (Dep’t. of Veterans Affairs, 2000).

## V. Veterans Affected by Opioid Addiction

136. With medical providers being influenced by academic articles purporting the safety of prescribing opiates; pressure from the VHA to reduce pain and suffering for patients; and prescription opiates hitting the market — a perfect storm was created. As mentioned earlier, OxyContin was approved by the FDA in 1996, as an analgesic, and was one of the first of its kind. By no coincidence, OxyContin's release on the market occurred at the same time the Fifth Vital Sign Movement began to grow. What made medical providers more willing to prescribe OxyContin to patients was not only academic journals professing the low likelihood of opioid addiction, but Purdue Pharmaceutical also marketed the drug as having a low risk of addiction.<sup>12</sup> While there are other prescription opioids that would hit the market, it is important to realize how pharmaceutical companies played a role in changing the minds of, not only medical providers, but an entire healthcare system into being more liberal in prescribing opioids to treat pain whether acute or chronic. The significance of this is that it explains why veterans in the VA system were often over-medicated, or given medication under a fallacy that addiction was unlikely. While pharmaceutical companies stood to make a profit, it was veterans in the VA healthcare system that ultimately suffered. As we go forward, keep in mind that the issues in the VA healthcare system are a microcosm of the American healthcare system at large.

137. To illustrate how the liberalization of prescribing opioids affected veterans and to understand the gravity of the VHA's overbroad policies, we look at one of the VA's most tragic examples — “Candy Land.” Candy Land is not a theme-park based on the popular board game. Instead, it is the nickname given to a VA hospital in Tomah, Wisconsin. Why was a VA hospital nicknamed Candy Land? Because of the number of prescription opioids received by veterans from that one facility. On top of that, the hospital's chief of staff, psychiatrist Dr. David Houlihan, was also dubbed “the Candy Man.” The title is a perfect fit because from 2004 to 2012, the prescribing of oxycodone (a main ingredient in OxyContin) skyrocketed from 50,000 to over 712,000 at this one VA facility, alone, even though the number of veterans receiving treatment at Tomah declined.<sup>13</sup> Many veterans at the facility either became addicted to the opioids or were veterans that already had an opioid addiction to begin with, and were seeking a facility that was willing to dole them out. The over-prescribing of opiates continued for years, even though complaints were made against Dr. Houlihan's prescribing habits.

138. Unfortunately, for Marine veteran Jason Simcakoski the warnings did not come soon enough. Mr. Simcakoski was taking a drug cocktail of over fourteen different drugs,

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12 Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 AM. J. PUB. HEALTH 221–227 (2009).

13 Aaron Glantz, *Veterans: VA hospital nicknamed “Candy Land” because painkillers given out freely*, CHI. TRIB. (2015).

including prescription opioids. In 2014, he passed away because of a mixed drug toxicity including opioids. Mr. Simcakoski is not the only victim of the VA's over-prescribing. In 2015, the Center for Investigative Reporting (CIR) released a report stating that since 9/11, the prescribing of opiates in VA facilities had increased by 270%. Not only has the over-prescribing of opiates led to addiction, but it has also led to many deaths as well. In 2011, a study using 2005 data revealed that of the 1,013 veterans who died because of the VA's services, a third of the deaths were caused by prescription opioids and twenty-two percent involved psychiatric drugs and sedatives.<sup>14</sup> Specifically at Tomah, thirty-three veterans' deaths have been linked to the liberal and negligent prescribing of opioids by the "Candy Man," Dr. Houlihan.<sup>15</sup>

139. Another interesting point worth noting is how the opioid epidemic relates to veterans suffering psychological illnesses. A study done by the Department of Veteran Affairs revealed that veterans suffering from mental health disorders such as PTSD were more likely to be prescribed prescription opioids than compared to other veterans.<sup>16</sup> This fact is significant because it is well-documented that veterans suffering from PTSD are likely to have a substance abuse disorder (such as alcoholism as a form of self-medication).<sup>17</sup> Some veterans were suffering from PTSD and already had substance abuse disorders, yet the VA still prescribed them opioids, essentially feeding their addictions. While an entire book could be written on the shortcomings of the VA in treating veterans with mental health disorders, the fact that veterans suffering from PTSD were being prescribed not only psychotropic drugs and sedatives but also opioids illustrates another way opioids affected veterans — it led to overdoses. The over-prescribing of opioids is merely a symptom of the larger problem, which is that the VA haphazardly prescribes multiple drug cocktails without knowing how they work in concert to one another.

140. A study done in 2011, by Amy Bohnert, a VA researcher at the University of Michigan, illustrates the VA's overdose problem. According to the study, Ms. Bohnert found that veterans were more likely to die from accidental overdoses than from suicides.<sup>18</sup> Many of the overdoses were accidental because the veteran either took the wrong dosage or did not understand how their other prescription medications interacted with one another. It may be easy to say that the VA could not foresee these kinds of deaths but in 2014, the Department of Veterans Affairs Inspector General released a report stating that VA clinicians were not following federal guidelines in prescribing

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14 Art Levine, *How the VA Fueled the National Opioid Crisis and Is Killing Thousands of Veterans*, [NEWSWEEK](#) (2017).

15 Aaron Glantz, *Congressional hearing reveals 4 more deaths at Tomah, Wisconsin, VA*, [REVEAL](#) (2015).

16 Karen H. Seal, et. al., *Association of Mental Health Disorders With Prescription Opioids and High-Risk Opioid Use in US Veterans of Iraq and Afghanistan*, [307 J. AM. MED. ASSOC'N 940-947](#) (2012).

17 Dep't of Veteran Aff., *PTSD and Substance Abuse in Veterans*, [PTSD.VA.GOV](#).

18 American-Statesman Investigative Team, *Prescription drug abuse, overdoses haunt veterans seeking relief from physical, mental pain*, [AUSTIN AMERICAN STATESMAN \(TEXAS\)](#) (2016).

take home opioids, because “one out of ten chronic pain opioid users also receiv[ed] benzodiazepines in the course of a year — and 92 percent got them at the same time,” a practice that should not be done because of its likelihood of overdoses.<sup>19</sup> Deaths by accidental overdoses are just some of the effects prescription opioids had on veterans.

141. While this paper has discussed the prevalence of addiction among veterans who were prescribed opioids, it is important to clarify how addiction itself negatively impacts a veteran. Many veterans in the VA system suffer from iatrogenic addiction, meaning that their addiction was the result of actual medical treatment, essentially the addiction was a byproduct of the treatment. This is not surprising because VA clinicians began prescribing opioids to treat chronic pain that was essentially non-malignant, meaning it was not the result of some acute injury or disease but rather persisted long after. Opioid addiction has led to the destruction of some veterans’ families, resulted in homelessness, overdoses, emergency hospitalizations, withdrawals, and death. On top of that, you have veterans who begin to develop a tolerance to the drugs they are prescribed, which leads to either higher doses, which can lead to death, or the veteran starting to use other delivery methods to get a stronger “high” — such as injecting the opioid intravenously. This kind of behavior should sound familiar. So in reality, the VA and the healthcare system at large had engaged in a practice of essentially prescribing heroin to patients — backed, at the time, by alleged medical evidence.

## VI. The Response to the Opioid Crisis

142. When evidence came to light that prescription opioids led to addiction, the Department of Veterans Affairs, the Department of Defense (DoD), and the VHA responded by creating in-depth policies on treating chronic pain with opioids, and creating initiatives to cut back on the prescribing of opioids. In May 2010, the Department of Veterans Affairs and the DoD implemented the “Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain.” The 2010 publication was an update to an earlier version published in 2003. In the 2010 version, the VA and DoD recognized the growing prevalence of prescription opioids stating:

Sales of long-acting opioids have increased by five (5) times over the last six years and prescriptions of long-acting opioids are expected to double every three to four years. Non-specialists now prescribe opioid therapy, and 95% of long acting opioids are prescribed for non-cancer pain. More than 50% of male VA patients in primary care report chronic pain.

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<sup>19</sup> Art Levine, *How the VA Fueled the National Opioid Crisis and Is Killing Thousands of Veterans*, [NEWSWEEK](#) (2017).

143. An even more interesting point is that the guideline goes on to say, “The review of the American Pain Society (APS) /American Academy of Pain Medicine (AAPM) also revealed the lack of solid evidence based research on the efficacy of long-term opioid therapy. Almost all the randomized trials of opioids for chronic noncancer pain were short-term efficacy studies.” Remember that back in 1998, the VHA created a National Pain Management Strategy to bring more awareness and treatment to patients’ pain based upon a slogan by the American Pain Society (Pain as the Fifth Vital Sign), yet by 2010, the VA and the DoD are citing the same organization, the APS, for the proposition that there is no real evidence supporting long-term therapy. Returning to the main point, the 2010 guidelines provided more in-depth policies/procedures for those VA clinicians who contemplated using opioid therapy because the VHA now had data regarding the seriousness of the opioid addiction crisis.

144. One example of the 2010 guidelines more thorough approach to opioid treatment is that it categorized low, medium, and high-risk characteristics associated with the likelihood to develop an opioid addiction and abuse. The VHA made recommendations on how to initiate opioid treatment — the need for consent on behalf of the patient, other alternative therapies, and starting patients on a low dose. The detail given in the 2010 guidelines was far greater in comparison to the “Pain as the Fifth Vital Sign Toolkit” discussed previously. The 2010 guidelines went as far as cautioning VA clinicians in prescribing opioids with other prescription drugs and recommending that patients log the time and dosage when taking opioid medication. As a general summary, the guidelines also created a four-page flowchart/algorithm outlining the steps a clinician should go through before using opioid therapy; initiating opioid therapy; and maintaining opioid therapy.<sup>20</sup> Another key component is that the guidelines also recommend that patients with symptoms of opioid addiction should be given a referral to an addiction specialist. Overall, the 2010 guidelines on chronic pain and opioid prescribing provide more narrow recommendations reflecting the VHA and DoD’s intent to curtail opioid abuse.

145. Although the VHA responded with more guidelines on opioid therapy, it did little to stem the tide. By 2013, the VHA responded by creating the Opioid Safety Initiative (OSI). This was done in response to an Annual Meeting of the American Academic of Pain Medicine that described how over one million veterans who were prescribed opioids, “continued to use them chronically or beyond 90 days... ”<sup>21</sup> While the OSI has had some success, it still has not reached its goal. Remember that the Tomah VA facility was still prescribing hundreds of thousands of opioids up until 2015, so the OSI initiative has been slow in its results. By 2016, the Center for Disease Control published its own guidelines on prescription opioid therapy. The “CDC Guideline for Prescribing Opioids for Chronic Pain” brought additional insight on agencies’, whether governmental or

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20 The Management of Opioid Therapy for Chronic Pain Working Group, *Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain*, [DEP’T OF VETERAN AFF, 7, 12–16, 20](#) (2010).

21 Brenda L. Mooney, *New VA Initiative Seeks to Reduce Opioid Use*, [U.S. MED.](#) (2014).

professional, attempts to curb addictions and abuse. The CDC guideline stated that most guidelines on the issue:

... share some common elements, including dosing thresholds, cautious titration, and risk mitigation strategies such as using risk assessment tools, treatment agreements, and urine drug testing. However, there is considerable variability in the specific recommendations (e.g., range of dosing thresholds of 90 MME/day to 200 MME/day), audience (e.g., primary care clinicians versus specialists), use of evidence (e.g., systematic review, grading of evidence and recommendations, and role of expert opinion), and rigor of methods for addressing conflict of interest [ ]. Most guidelines, especially those that are not based on evidence from scientific studies published in 2010 or later, also do not reflect the most recent scientific evidence about risks related to opioid dosage.<sup>22</sup>

146. The fact that many guidelines retained the same common elements over the years reflects that policy change alone is not enough. Policy is different than practice. Yet the VA, in general, continued to create further guidelines that essentially stated the exact same principles. By 2017, the VA released another guideline on prescription opioid treatment for chronic pain, incorporating aspects of the CDC guideline mentioned above. When the VHA and DoD released their 2017 update to the guidelines, it retained a clear majority of the same recommendations made in 2010 and 2014. There were still recommendations of alternative therapies, patient education, patient's consent to opioid therapy, and drug testing. However by 2017, the "VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain" recommended that clinicians avoid using long-term opioid therapy altogether and that if clinicians did use opioid therapy, they should only do so for a short period of time.<sup>23</sup> Over the years, the VHA's and DoD's guidelines have gotten larger in their page-length, relying more on scientific evidence as it comes out, yet the guidelines have continued to recommend the same types of treatment with no real results.

## VII. Critique of the Response to the Opioid Crisis

147. One of the main issues with the VHA's response to the opioid crisis is that the policy does not equate to practice. The VA healthcare system has thousands of patients using its systems. The VHA suffers from the same issue that the wider healthcare system suffers from, the fact that there are more patients than doctors. The news is replete of

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<sup>22</sup> Deborah Dowell, et al., *CDC Guideline for Prescribing Opioids for Chronic Pain — United States*, 65 [CENTERS FOR DISEASE CONTROL AND PREVENTION 1–49](#) (2016).

<sup>23</sup> The Opioid Therapy for Chronic Pain Work Group, *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain*, [DEPT OF VETERANS AFF. 7](#) (2017).

veterans who have died waiting for appointments at the VA, because, for one reason, there are not enough doctors. What this means is that VA clinicians must do their best to resolve a patient's issues within the limited visits they have. But the problem is that doctors and patients alike have been influenced by pharmaceutical companies who promote prescription medications as having this magical effect that once taken alleviates patients' symptoms. On top of that, patients are becoming more educated in advocating for certain treatments they want — if they don't get what they want from one doctor, they simply go shopping for one that will. It is one reason why many veterans did not protest Dr. Houlihan's prescribing practices at "Candy Land." Another reason why the VHA's policies do not equate to practice is because insurance providers do not cover for alternative therapies.

148. For example, acupuncture has been found to be effective in reducing pain sensation and can be an alternative to opioid therapy. In 2012, a study found that acupuncture relieved pain in 50% of patients who were given the treatment.<sup>24</sup> Yet, Tricare (health insurance for veterans and their family) does not cover acupuncture.<sup>25</sup> On top of that, many facilities do not offer a variety of alternative therapies. In 2014, one in ten VA hospitals offered at least one form of alternative therapy ranging from things like yoga and meditation to acupuncture.<sup>26</sup> There remains hope for change in this area, though. In June 2017, a bill was introduced into the House of Congress in response to many insurance companies not covering acupuncture treatment, called the "Acupuncture for Our Heroes Act," which would provide veterans with the options to receive acupuncture.<sup>27</sup> Why is the lack of alternative therapies a problem? The VHA has advocated for years for alternative therapies to be used to treat chronic pain, yet the VA facilities have not caught up and are not able to provide what the VHA is asking. More importantly, if insurance companies do not respond by covering alternative therapies, it makes no difference for the VHA to promote alternatives, because it is not possible for veterans to receive them.

149. Also, the VHA and the government in general are trying to combat the opioid issue from the clinician's perspective. The idea being that if they educate doctors more on the safe way to use opioid therapy, or avoid it altogether, they can reduce addiction and abuse. However, attacking the opioid crisis from one side is short-sighted and fails to reflect reality. As mentioned previously, doctors often deal with patients who ask for certain prescription drugs. This is because in the United States, it is legal for pharmaceutical companies to provide Direct to Consumer (DTC) advertising. Interestingly, only

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24 Andrew J. Vickers, *Acupuncture for Chronic Pain Individual Patient Data Meta-analysis*, 172 *ARCH. INTERN. MED.* 1444–1453 (2012).

25 Tricare Covered Services, *Acupuncture*, [TRICARE.MIL](https://www.tricare.mil).

26 Mitch Mirkin, *Complementary and Alternative Medicine: yoga, acupuncture and more*, [BLOGS.VA.GOV](https://www.va.gov) (2014).

27 [H.R. 2838, 115th Cong.](https://www.congress.gov/bills/115/2838) (2017).

two countries in the entire world allow DTC advertising for pharmaceuticals that promote a product's claim — the United States and New Zealand.<sup>28</sup> The reason why DTC for pharmaceuticals is not allowed in most other countries is because advertising works too well. Almost every pharmaceutical commercial or advertisement says the phrase, “ask your doctor,” and patients do ask their doctors. DTC advertising puts additional pressure on medical providers because they must worry about their patients demanding certain drugs or going to someone else if they do not give the patient what they want.

150. To be fair, there are some benefits to DTC pharmaceutical advertising. One benefit is that it educates patients about certain illnesses or diseases that they have but did not realize they have. For example, many commercials that advertise treatment for Chrons disease often start out by educating audiences about the symptoms of Chrons. Thus someone could see the commercial, see that they have the same symptoms, and go to a doctor to receive treatment. One critique on DTC for pharmaceutical advertising is that they can be misleading. For example, some critics argue that the advertisements give false expectations by showing actors who are allegedly suffering from the illness smiling and happy after taking the advertised drug. A more relevant example is Purdue Pharmaceutical's 1998 OxyContin promotional video. It features a doctor by the name of Alan Spanos stating that opioids are the best form of treatment for chronic pain. He cites the same article mentioned in the beginning of this paper, which discusses how addiction for pain patients is less than one percent and that opioid treatment is the most effective treatment for pain sufferers.<sup>29</sup> This is very similar to what big tobacco used to do when they had medical doctors state that smoking cigarettes was safe. We know now that opioids drugs are highly addictive, but for patients, including veterans, such statements from a medical doctor influence them into believing that opioid therapy is safe and encourages them to ask their doctor about opioid drug therapy, which was a factor contributing to the opioid crisis. There was a demand for opioids created by pharmaceutical advertising and doctors fulfilled the demand.

151. The federal government, specifically the FDA, should promote stricter regulation on pharmaceutical advertising by requiring that statements made by any medical professional in an advertisement be supported by scientific evidence that has not been funded by a pharmaceutical company. Also, advertisements should reflect more of the realities of illness and not present images of actors returning to “normal” after taking a medication. Additionally, advertisements should educate consumers and patients that medication alone may not be enough to treat their symptoms so as not to down-play the benefits of healthy nutrition and exercise. While the VHA is not directly responsible for the accountability of ethical pharmaceutical advertising, as one of the largest

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28 C. Lee Ventola, *Direct-to-Consumer Pharmaceutical Advertising: Therapeutic or Toxic?*, 36 *PHARMACY AND THERAPEUTICS* 669–684 (2011).

29 *Purdue Pharma OxyContin Commercial*, [YOUTUBE.COM](https://www.youtube.com/watch?v=K1v1v1v1v1).

providers in the healthcare system, it should use its influence, and coordinate with other governmental agencies, so they can promote more ethical regulation on pharmaceutical advertising. By stopping misleading information at the consumer/patient level, the VHA and healthcare system in general may see a downturn in patients asking doctors for opioid therapy.

## VIII. The Consequences

152. The government's response to the opioid crisis had a large effect on opioid therapy, but its lack of foresight has left many patients, including veterans, worse off. To understand why this is the case, some context of the government's actions is needed. One of the biggest actions the government has made to curtail the opioid crisis is to cut back on the production of opioids. For many years now, the Drug Enforcement Agency (DEA) has issued production quotas for prescription drugs. Essentially, the DEA has hoped that by reducing the supply of prescription opioids, we will see a decline in opioid addiction and opioid related deaths, at least for prescription opioids. The DEA has recently added a new proposal to the Federal Registrar on August 7, 2017, that reduces the production of opioids by twenty percent in 2018.<sup>30</sup> This is after the DEA already reduced opioid production by twenty-five percent in 2017.<sup>31</sup> Not only has the DEA reduced the supply of prescription opioids, but the VA has also reduced the prescribing of opioids.

153. Previously we discussed the VHA/DoD's new 2017 guidelines for treating chronic pain and while it remains to be seen what the effects will be, the current trend is that the VA has reduced its prescribing of opioids. According to the VA's own data, the number of veterans prescribed opioids fell by 25%, and the number of veterans receiving concomitant opioids and benzodiazepines fell by 47%.<sup>32</sup> These numbers seem promising, but it does not consider what percentage of those veterans suffered from opioid addiction and abuse or reflect the percentage of veterans who have resorted to heroin or prescription narcotics from off the street.

154. The government's reduction in the supply of opioids, along with the reduction in prescribing opioids, has left some veterans with no real treatment alternatives, has led to some veterans seeking the prescription drugs illegally on the street, and has left others purchasing heroin as a substitute.

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30 *Proposed Aggregate Production for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine Pseudoephedrine, and Phenylpropanolamine for 2018*, 82 *FED. REG.* 36830–36831 (2017).

31 Alicia Ault, *DEA Proposes Significant Cuts to Opioid Production in 2018*, *MEDSCAPE.COM* (2017).

32 Julianne Himstreet, et al., *TRANSFORMING THE TREATMENT OF CHRONIC PAIN MOVING BEYOND OPIOIDS, A CLINICIANS GUIDE*, *PBM.VA.GOV* (2017) (citing Walid F. Gellad, Chester B. Good & David J. Shulkin, *Addressing the Opioid Epidemic in the United States: Lessons from the Department of Veteran Affairs*, 177 *J. Am. Med. Assoc.* 611–612 (2017)).

155. First, let's start with the premise that the government's and VA's response has resulted in no real alternatives for veterans and patients who do suffer from chronic pain. Earlier, we discussed the how VHA's policies promoted opioid therapy alternatives and doctors starting opioid therapy. The problem with the VHA's policies is that many VA facilities do not carry more than one form of alternative therapy, and Tricare doesn't always cover alternative therapies like acupuncture. The government's continuous reduction in opioids has further hindered patients with real chronic pain from getting any treatment. To put it concisely, the government reacted with no foresight. The government cutback the supply of opioids, but has not put any real alternatives in place for patients or veterans to use. While this is really a restatement of what has already been discussed previously. Restating it here briefly adds to the logical steps that eventually led veterans and patients alike to pursue opioids illegally.

156. Without a ready alternative to opioid therapy, some veterans/patients have resorted to pursuing prescription opioids on the street illegally or using heroin. As prescription rates and the supply of prescription opioids have decreased, heroin overdoses have increased.<sup>33</sup> Another contributing factor was found in a study conducted in June of 2017, which concluded that OxyContin's "abuse-deterrent" ("abuse-deterrent" opioids will be discussed more in-depth later) reformulation led to consumers and patients substituting OxyContin with heroin.<sup>34</sup> This seems like a logical conclusion. The government cuts back on opioid production and prescribing and those who are either addicted or in actual need seek alternatives on the illegal market. To be fair, one study has concluded that veterans' heroin use is associated with the non-medical use of prescription opioids.<sup>35</sup> But to say that veterans do not resort to using heroin when denied prescription opioids, like the civilian population, would be inaccurate. Ryan Trunzo was an Army veteran who was given painkillers by the VA for his back injuries. However, because of a history of addiction while in the service, the VA did not prescribe anything stronger than Ibuprofen. Because of Mr. Trunzo's pain and lack of treatment by the VA, he started using illegal narcotics. Mr. Trunzo tragically passed away from heroin toxicity.<sup>36</sup> Unfortunately, Mr. Trunzo's story is most likely not the only one. For other veterans, the result of battling addiction is jail time.

157. One natural consequence of seeking prescription medication illegally or using cheaper narcotics like heroin is jail time. Some of these veterans have either built up a

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33 Jeffery A. Singer, *In the Opioid Crisis, Keep Your Eyes on Heroin and Fentanyl*, [NATIONREVIEW.COM](http://NATIONREVIEW.COM) (2017).

34 William N. Evans, et al., *How the Reformulation of OxyContin Ignited the Heroin Epidemic*, [12 J. ECON. LIT. 1](http://12J.ECON.LIT.1) (2017).

35 Edelman G. Banerjee, et. al., *Non-medical use of prescription opioids is associated with heroin initiation among US veterans: a prospective cohort study*, [111 ADDICTION 2021–2031](http://111.ADDICTION) (2016).

36 Mark Brunswick, *VA doctors freely handed out pain medications to veterans for years. Then they stopped. The results have sometimes turned tragic*, [STAR TRIB.](http://STARTRIB) (2015).

tolerance to what they have been prescribed, cannot afford what is prescribed, or are no longer getting prescribed any pain medication. But remember that not all veterans have a drug addiction and for these veterans, they are simply trying to self-medicate, because of either the costs involved or the lack of treatment from the VA. Back in 2013, in Muskogee, Oklahoma, the Jack C. Montgomery VA Medical Center prescribed 1.6 opiates per veteran, and it was said that it was reflected in the city's jail along with its courthouse.<sup>37</sup>

158. Luckily, many states like Oklahoma have Veteran Treatment Courts where veterans are given more tailored treatment versus simply going through the criminal justice system. Veteran Treatment Courts often provide a variety of resources that assist veterans in getting the treatment they need by connecting them with local VA facilities. One upswing to this is that Veteran Treatment Courts also provide resources for veterans suffering from addiction, such as prescription opioid addiction. The good news for veterans suffering from opioid addiction is that the Department of Justice, on September 22, 2017, awarded \$58.8 million dollars to combat the opioid epidemic. Some of the \$58.8 million dollars will go to jurisdictions to support the creation of diversion/alternative incarceration programs. Specifically, for veterans, \$22.2 million dollars will be used to support the implementation and enhancement of drug courts and Veteran Treatment Courts.<sup>38</sup>

159. Although the government's quick reduction in the supply and prescription of opioids has left some veterans worse off, there is at least hope that those suffering from opioid abuse will receive the help they need through Veteran Treatment Courts. In a way, the government is obligated to help veterans because the situation is at least partly the government's fault. As we have seen, the government encouraged the treatment of pain and supported the use of prescription opioids. Then, when the government discovered that opioid therapy was not supported by leading medical evidence, they tried to pull the rug out from under veterans by reducing the supply of opioids, and law enforcement's response to those who obtained opioids illegally was to throw them in jail. Arguably, many patients, specifically veterans, would not have developed an opioid addiction, but for the government's naïve endorsement of opioids. At the very least, the government is taking steps in the right direction by providing veterans with treatment courts to help fight opioid addiction.

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37 Aaron Glantz, Center for Investigative Reporting, *VA increases opiate prescriptions for veterans*, [THE OKLAHOMAN](#) (2013).

38 Dep't of Justice, Off. Pub. Aff., *Department of Justice Awards Nearly \$59 Million to Combat Opioid Epidemic, Fund Drug Courts*, [DEP'T. OF JUSTICE](#) (2017).

## IX. “Abuse-Deterrent” Opioids

160. Another response to the opioid crisis is that the FDA has encouraged the production of “abuse-deterrent” formulations for prescription opioids. Abuse-deterrent opioids receive their name because the new formulations make it difficult for the pills to be crushed, injected, or snorted. However, the abuse-deterrent is somewhat of a mislabel, as it does not prevent the most common form of abuse, which is simply swallowing the pill. However, in 2010, Purdue Pharmaceutical created an abuse-deterrent formulation for OxyContin. The FDA was intrigued by the prospect and subsequently ordered Purdue Pharmaceutical to conduct further research on abuse-deterrent medications — eventually a few manufacturers have started producing “abuse-deterrent” opioids at the FDA’s encouragement. It sounds like a promising alternative to an outright ban to prescription opioids and would help those veterans/patients who really do need some form of treatment for chronic pain. However, according to an article by “STAT,” there is little evidence that “abuse-deterrent” opioids actually deter abuse and reduce chances of opioid addiction.<sup>39</sup>

161. While it is not this paper’s direct goal to expose pharmaceutical companies, it is worth noting why pharmaceutical companies are interested in producing “abuse-deterrent” opioids. According to the same “STAT” article, a major incentive to produce abuse-deterrent opioids is because the companies can charge more money for them and the fact that their new formula alleges that it deters abuse means that it can 1) have a patent that protects its formulations for five years; and 2) they can compete directly with generic opioid medications that are far cheaper because society is currently trying to deter and reduce opioid abuse.<sup>40</sup> Pharmaceutical companies would stand to make a huge profit if the FDA, and the medical community, started pushing abuse-deterrent opioids as an alternative to current opioids on the market. The “STAT” article provided an eerie example:

A mandate to use abuse-deterrent opioids at an up to twentyfold increase in cost would be staggering to health care systems. For example, the Department of Veterans Affairs spent nearly \$100 million in fiscal year 2016 on opioids for 1.2 million patients with at least one opioid prescription. Only 1.9 percent of the opioids dispensed were for an abuse-deterrent product, but they accounted for 37 percent of overall opioid spending. Long-acting abuse deterrent opioids were approximately 10 times the cost of long-acting opioids without abuse-deterrent properties.

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39 C. Bernie Good, et al., *There’s little evidence abuse-deterrent opioids work. Why should we use them?*, [STATNEWS.COM](https://www.statnews.com/2017/05/02/abuse-deterrent-opioids/) (2017).

40 C. Bernie Good, et al., *There’s little evidence abuse-deterrent opioids work. Why should we use them?*, [STATNEWS.COM](https://www.statnews.com/2017/05/02/abuse-deterrent-opioids/) (2017).

Applying a conservative tenfold increase in price for abuse-deterrent opioids would increase the VA's expenditures for opioids to approximately \$1 billion a year, and could represent as much as 20 percent of the entire VA pharmacy budget. Such an increase would also compete against funding of other important opioid use disorder treatments, such as medication-assisted treatment and rehabilitation programs.<sup>41</sup>

162. The promotion of abuse-deterrent drugs has made veterans worse off because once again, veterans and doctors are being misled to believe that somehow these drugs are less addictive and prone to abuse, when there is no credible evidence to substantiate the claims. What is worse about this development is it reveals pharmaceutical companies' profit motive that, at least in this instance, trumps the well-being of patients. As of June 2017, the FDA has started to take a closer look at the efficacy of abuse-deterrent opioids and one can only hope that the government, especially the VA, does not mandate or encourage the use of abuse-deterrent opioids when there is no evidence they do deter abuse.<sup>42</sup>

## X. Conclusion

163. The opioid crisis that is plaguing the United States today is rooted in the Fifth Vital Sign Movement. The mission was to bring more awareness to pain, but instead it opened the floodgates to long-term opioid therapy. At the same time as the Fifth Vital Sign Movement, the medical community touted the unlikelihood of prescription opioids and the efficacy of opioid therapy. The VHA jumped onboard and told its medical providers to do more to treat pain. The market provided a solution with prescription opioids, like OxyContin, that claimed low chances of addiction that proved to be false. Under the VHA's support, veterans became addicted to opioids. Once the government realized that opioid abuse and overdose was a problem, they quickly curtailed the production/prescribing of opioids. The government's quick reaction left many veterans with no alternatives because either their insurance did not cover it or the VA facilities did not offer it. Yet the VHA/DoD kept telling medical providers to use alternative therapies that essentially did not exist for both the doctor and patient. When veterans began to seek treatment illegally, they were thrown into jail. Luckily, Veteran Treatment Courts have provided an alternative to give veterans the help they need.

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41 C. Bernie Good, et al., *There's little evidence abuse-Deterrent opioids work. Why should we use them?*, [STATNEWS.COM](http://STATNEWS.COM) (2017).

42 Michael Mezher, *FDA to Take Closer Look at Abuse-Deterrent Opioids*, *Regulatory Affairs Professionals Society*, [RAPS.ORG](http://RAPS.ORG) (2017).