

MEDICAL CANNABIS ACCESS FOR PAIN TREATMENT

2016

A Viable Strategy to Address the Opioid Crisis



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With over 100,000 active members in all 50 states, Americans for Safe Access (ASA) is the largest national member-based organization of patients, medical professionals, scientists and concerned citizens promoting safe and legal access to cannabis for therapeutic use and research. ASA works to overcome political and legal barriers by creating policies that improve access to medical cannabis for patients and researchers through legislation, education, litigation, grassroots actions, advocacy and services for patients and their caregivers, the medical cannabis industry, and governments.

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INTRODUCTION

Use of prescription opioids has greatly increased over the last few decades, despite a lack of data supporting their efficacy in long-term use, and immediate efforts are needed to mitigate the public health crisis created by the over-reliance on opioids to treat pain (Chou, 2015). Data from the Centers for Disease Control and Prevention (CDC) show that opioids—a class of drugs that includes prescription pain medications and heroin—were involved in 28,648 deaths in 2014 (Rudd, Aleshire, Zibbell, J. E., Gladden, 2015).

Thousands of patients are dying every year from opioid overdoses because they are in pain and do not have a safer alternative to relieve their pain. While the evidence that cannabis is medicinally useful in treating chronic pain continues to increase, without a single documented case of an overdose, federal legislators continue to fight against rescheduling cannabis to a schedule that would allow it to be used as medicine. Americans for Safe Access (ASA) has created this document to educate and inform legislators and regulators of the growing need for an alternate treatment for the millions of patients suffering from pain every day.

THE OPIOID CRISIS

Data from the CDC shows that the U.S. represents 5% of the world's population but consumes roughly 80% of the world's opioid supply. Nearly 50% of patients who use opioids for more than 30 days in the first year of use, continue to use them for 3 years or longer, and 50% of this population take short-acting opioids, putting them at a greater risk of addiction (Manchikanti & Singh et al., 2008). Opioid administration decreases respiration and the chance of accidental overdose and/ or death significantly increases when opioids are co-administered with muscle relaxants and other drugs, such as alcohol.

It is estimated that more than 100 million medications effectively treat acute pain and ducted.

7,000 Americans are treated in emergency rooms every day for adverse events related to prescription opioid use. More Americans die from drug overdoses than moter vehicle crashes.

help relieve chronic pain for some patients, their addiction risk presents a dilemma for people suffer from chronic pain in this coun- healthcare providers who seek to relieve suftry, (Johannes, 2012) with the largest ma- fering while preventing drug abuse and addicjority of patients experiencing chronic pain tion. Scientists debate the appropriateness of (approximately 38 million, excluding pain chronic opioid use for these conditions in light conditions related to cancer) or osteoarthritis of the fact that long-term studies demonstrat-(approximately 17 million). Although opioid ing benefits versus risks have not been conOn average, 46 people die each day (16,000 per year) from prescription opioid overdose. The death rate for prescription opioid overdose has quadrupled over the last 15 years.



FINDING A SOLUTION

In a briefing earlier this year, President Obama made it clear that addressing the opioid overdose epidemic is a priority for his Administration and proposed \$1.1B in new funding for a multi-pronged approach (White House, 2016).

The plan included provisions to expand access to treatment for prescription drug abuse as well as heroin use, expand state-level prescription drug overdose prevention strategies, increase the availability of medication-assisted treatment programs, improve access to the overdose-reversal drug naloxone, and support targeted enforcement activities.

These actions build on efforts that began in 2010 when the President released his first National Drug Control Strategy, which em-

phasized the need for action to address opioid use disorders and overdose while ensuring that individuals with pain receive safe, effective treatment.

In July, the Comprehensive Addiction and Recovery Act (CARA) was signed into law by the President

, but contained less than half of the funding the President requested. Rep. Frank Pallone Jr. (D-NJ) commented that the legislation "is only a small step at a time when the American people need us to run." Much of the provisions in CARA focus on post-addiction strategies for treating drug abuse, heroin use, and overdose prevention strategies. Provisions that focus upstream, including addiction prevention strategies and ways to reduce the amount of opioids prescribed while still ensuring patients receive effective treatment, are underrepresented. Yet, efforts to include cannabis as part of CARA never materialized.

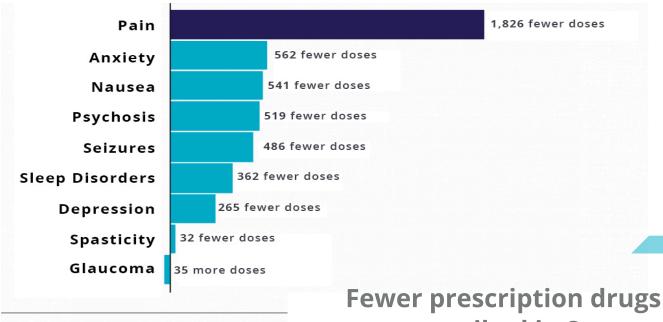
Nearly 80% of heroin users report using prescription opioids before initiating herion use and of those 45% become addicted to prescription opioids.

In a February 2016 letter to CDC Director Dr. Tom Frieden, Senator Elizabeth Warren (D-MA)



Fewer pills prescribed in medical cannabis states

Difference between annual drug doses prescribed per physician in medical cannabis states, and in states without medical cannabis law, by drug category



Source: Bradford and Bradford, Health Affairs, July 2016 Washington Post, WAPOST/WONKBLOG

urged action on a variety of fronts in response to the escalating epidemic of opioid abuse, including calling on Frieden and the CDC to collaborate with states and other federal agencies on the exploration of "alternative pain relief options" including medical cannabis. Additionally, she requested that the CDC evaluate the impact of medical and recreational cannabis on opioid overdose deaths in states where it is legal.

In the Guidelines for Using Opioids for Treating Chronic Pain, issued on March 18, 2016, the CDC advises clinicians against testing for cannabis, specifically tetrahydrocannabinol (THC) as criteria for eligible care. The guidelines state that a positive test for cannabis is not an effective indication for patient management outcomes and warns clinicians that dismissing a patient from care based solely on a urine drug test result could have adverse consequences for the patient's safety.

In a study published in Health Affairs, researchers examined data on all prescription

Fewer prescription drugs are prescribed in States with medical cannabis laws

drugs paid for under Medicare Part D from 2010 to 2013 in the 17 states with medical cannabis laws in place by 2013 (Lichtenberg & Sun, 2007). Results revealed that prescriptions for painkillers and other drugs were far fewer, and physicians have prescribed 1,826 fewer doses of painkillers per year than in states that did not have medical cannabis programs. Listed on the chart above are the conditions for which medical cannabis is predominantly approved in states with medical cannabis laws.

The researchers also ran a similar analysis on drug categories for which cannabis is not typically recommended, such as blood thinners, anti-viral drugs and antibiotics, and found no changes in the prescribing patterns of these drug categories after the passage of cannabis laws. Researchers concluded "this provides strong evidence that the observed shifts in prescribing patterns were in fact due to the passage of the medical cannabis laws (Bradford et al. 2016)."

CANNABIS: A SAFE AND EFFECTIVE TOOL FOR PAIN MANAGEMENT

Cannabis and cannabis-derived products have been found to be safe and effective for treating certain types of chronic pain conditions, with over 9,000 patient/years of data from modern clinical studies in existence (Russo & Hohmann, 2012). A lethal toxic overdose of cannabis has never been documented because, unlike opioids, cannabis derived compounds, such as THC, do not depress respiration due to sparse receptor density in medullary centers of the human brain (Glass, Dragunow, & Faull, 1997; Herkenham et al., 1990). Furthermore, lifetime use is not significantly associated with increased morbidity, brain damage, or cerebral atrophy (Karst et al., 2003, Weiland et al., 2015, Russo et al. 2002).

Researchers have found that THC works in concert with opioid-based painkillers, to increase their combined effectiveness, particularly in cases of neuropathic pain. In addition to enhancing the pain relieving effects of opioids, THC also serves to lower the dose of an opioid necessary for relief thus minimizing the inherent risks of opioid use (Abrams, et al., 2011; Abrams et al., 2007, Desroches & Beaulieu, 2010; Lucas 2012; Wallace et al., 2007; Welch & Eads, 1999). Research in animals has also demonstrated that the addition of cannabinoids to opioids enhances analgesic efficacy, helps diminish the likelihood of the development of opioid tolerance, and can prevent opioid withdrawal symptoms (Morel et al., 2009).

Data gathered from states that have medical cannabis programs has shown a 24.8% reduction in deaths attributed to opioid-related overdose compared to states without programs (Bachhuber, Saloner, Cunningham,

& Barry, 2014). Examination of the association between state medical cannabis laws and opioid analgesic overdose mortality in each year after implementation of the program showed that such laws were associated with a lower rate of overdose mortality that generally strengthened over time.

Surveys of medical cannabis patients have suggested that cannabis is often used to decrease the use of other drugs, most significantly opioid-based painkillers (Reiman, 2009). Sixty-six percent of patients surveyed reported using cannabis as a substitute for prescription drugs. The most common reasons given for substituting included less adverse side effects (65%), better symptom management (57%), and less withdrawal potential (34%) with cannabis.

As opioid-related overdose rates surge in communities across the country, lawmakers should look to states like Vermont, where medical cannabis is now being used as a tool in the fight against opioid addiction. In June 2016, Vermont Governor Pat Shumlin signed legislation that added chronic pain to the state's list of qualifying health conditions for medical cannabis treatment saying, "At a time when opioid addiction is ravaging our state and drug companies continue to urge our doctors to pass out painkillers like candy, we need to find a more practical solution to pain management." Of the 26 states with full medical cannabis programs, only about three quarters currently include chronic pain as a qualifying condition; however, several of these states (such as New Hampshire and Pennsylvania) require that the pain be nonresponsive to conventional therapy.

66% of Patients Surveyed Reported Using Cannabis as a Substitute for Prescription Drugs





OPIOID-DEPENDENT PATIENTS HAVE BENEFITED FROM MEDICAL CANNABIS

There are many cases demonstrating how cannabis therapies have successfully replaced or reduced a patient's dependence on opioids. The three narratives that follow exemplify the experiences of many, and shouldn't be viewed as atypical (Sulak, 2016).

Victim of Pedestrian Hit-and-Run

A 43 year-old man was the victim of a pedestrian hitand-run at age 25, resulting in multiple spinal disc hernias and weakness in one of his legs. He had tried cortisone injections, chiropractic manipulations, physical therapy, and had been prescribed several medications including muscle relaxants, anti-inflammatories, anti-nausea drugs, and the opioids tramadol and hydrocodone prescribed for chronic pain relief, without seeing any improvement in his condition. Surgery was recommended to improve his leg function, but due to his young age, he wanted to postpone surgery for as long as possible. Under a doctor's supervision he began a Cannabis therapy regimen, and after six months of treatment was able to discontinue use of the opioid medications,

one of the anti-inflammatory medications, and was able to reduce the frequency of muscle relaxant use from daily to once a month because his muscle spasms had all but disappeared. His leg function returned to normal, eliminating the need for surgery. In thanking his doctor for recommending his treatment he said, "Cannabis gave me my life back."

Patient suffering from debilitating back injury

A 34 year-old man had suffered a debilitating back injury at age 19, and took various forms of opioids and benzodiazepines for 15 years following the injury to manage the resulting chronic pain. Over time the dosage required to manage his pain had increased to the point where he was taking a high-dose opioid cocktail of two 80 mg Oxy-Contin® and a 15 mg Dilaudid® multiple times per day. Eventually, he realized he had become addicted and was desperate to change his situation. He tried and failed to

detox 27 times, went to rehab 3 times, and still could not escape the hold opioids had on him. A physician recommended cannabis to reduce his dependence on opioids, and only a short while after beginning treatment he was able to stop using all opioids for good, and noted that the cannabis reduced his withdrawal symptoms. The patient simply remarked, "I truly believe that cannabis saved my life."

Veteran with chronic pain due to combat injuries

A veteran of the U.S. Army was prescribed several medications to treat chronic pain resulting from injuries sustained in combat. He found the opioid medications were not sufficiently addressing his pain, and he didn't like the side effects he experienced. He started supplementing his opioids with cannabis, which allowed him to reduce the amount of opioids needed while getting sufficient pain relief without the undesirable side effects.

States with medical cannabis programs had 24.8% reduction in opioid-related deaths

RECOMMENDATIONS

It is clear that opioids are an inefficient way to treat the thousands of patients that deal with chronic pain. While more funding into treatment programs is important, it is also important to find new, less harmful, treatment options. As demonstrated by a recent review of Medicare part D spending, that showed a reduction in prescriptions and associated costs in states with medical cannabis programs, adding cannabis to a physician's arsenal for pain management would not only be cost neutral, it would likely save taxpayers thousands (Bradford et al., 2016, Richard et al. 2012). The following are ASA's recommendation for ensuring access to cannabis as a safe and effective treatment option for pain conditions.

1

Pass the CARERS Act

With the mounting evidence of cannabisbased medicines' effectiveness to enhance opioid pain treatment in a safe manner while preventing addiction, it is time to take action, and one of the first steps is to pass the Compassionate Access, Research Expansion, and Respect States (CARERS) Act (S.683).

The CARERS Act would protect medical cannabis patients, doctors, and the businesses that manufacture, test, and sell cannabis medicines. It would also lift research barriers that currently make clinical studies in the U.S. difficult, if not impossible.

Passage of CARERS would allow more doctors, including Veterans Administration physicians, the opportunity to include cannabis in their patients' pain management strategy, without fear or the stigma associated with recommending medical cannabis as a viable treatment option. Although physician resources on cannabis treatment currently exist, they could be more widely shared by federal agencies like the CDC to broaden the scope of treatment options for providers.

Senator Cory Booker (D-NJ), a CARERS Act lead sponsor, summed up the need for this legislative solution in his July 2016 testimony before the Senate Judiciary

Subcommittee on Crime and Terrorism:

"No person living with a debilitating disease in America should have to have a life of pain when possible treatment is available and they are barred from assessing [that treatment option]. We must embrace what is just common sense inquiry, scientific inquiry, broader understanding. We must embrace pathways towards research and we must do so with a greater sense of urgency in our country because so many are suffering. How many more people are going to have to suffer because of the federal bureaucracy, because of federal inaction, because of Congressional inaction. Too many people have had to suffer because of inaction such as this," (Researching the Potential, 2016).

"We must change these laws. It is time to fix our broken drug policy that lacks compassion for those in pain. It's time for Congress to support abundant research It is time to allow states, medical professionals, scientists to make these decisions that are rooted in facts and evidence. The CARERS Act would move our country forward, end senseless barriers to medical research, and help countless individuals gain access to the care they need. So I urge this committee and encourage this committee in the pathway you have taken to take up these issues and work to pass the CARERS Act," (Researching the Potential, 2016).



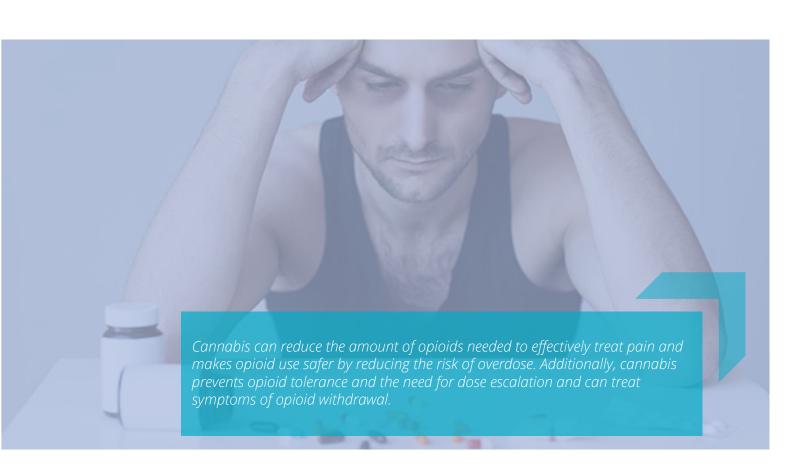
2

State Medical Cannabis Laws Should Include Chronic Pain as a Qualifying Conditions

Several states with medical cannabis laws have omitted chronic pain as a qualifying condition for fear that it could lead to abuse of cannabis. However, many patients feel that cannabis is a safer, less addictive alternative to opioid-based medicines. While opioids may be a great option to help treat pain for the short-term, because of its high addictive qualities it may not be the best option for long-term treatment. Vermont recently

expanded their state's medical cannabis program by allowing patients with chronic pain access to medical cannabis, thereby allowing patients to have a treatment option other than opioid-based prescription drugs for pain management. Other states, such as New York, New Jersey, Connecticut, Florida,, and Illinois, should follow Vermont's lead by including chronic pain in their condition lists.

Cannabis is an effective tool to enhance pain treating ability of opioids & prevent addiction





Medical Boards Should Promote Medical Cannabis Education

3

In April 2016, the Federation of State Medical Boards (FSMB) adopted "Model Guidelines for the Recommendation of Marijuana in Patient Care" as policy citing escalating public interest in cannabis for medicinal purposes behind the adoption of this policy. "This policy document is intended as a resource to state medical boards in regulating physicians and physician assistants (or other licensees regulated by the board) with a full and unrestricted license participating in marijuana programs and may also be valuable in educating licensees as to the board's expectations when recommending marijuana to a patient for a particular medical condition."

This was the first time that the dispensing or use of cannabis products were highlighted in a FSMB policy

recommendation (Federation of State Medical Boards, 2016).

The Answer Page, Inc. (TAP), which has provided quality medical educational content for over 19 years, along with ASA, created the Cannabis Care Certification (CCC) program to help doctors provide the best care for legal medical cannabis patients, and to help patients get the most from their medical cannabis use. CCC was created by recognized world experts and designed for individuals as well as companies and organizations that need to meet state requirements for patient medical cannabis education or CME requirements for physicians. TAP provides content that is designed to satisfy the new credentialing and licensure requirements for CME in Pain, Opioid Prescribing, Palliative Care, Medical Marijuana and Risk Management.

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ACTION. EDUCATION. POLICY. CONSUMERS SAFETY. RESEARCH.

The mission of Americans for Safe Access (ASA) is to ensure safe and legal access to cannabis (marijuana) for therapeutic use and research.

ASA was founded in 2002, by medical cannabis patient Steph Sherer, as a vehicle for patients to advocate for the acceptance of cannabis as medicine. With over 100,000 active members in all 50 states, ASA is the largest national member-based organization of patients, medical professionals, scientists and concerned citizens promoting safe and legal access to cannabis for therapeutic use and research. ASA works to overcome political, social and legal barriers by creating policies that improve access to medical cannabis for patients and researchers through legislation, education, litigation, research, grassroots empowerment, advocacy and services for patients, governments, medical professionals, and medical cannabis providers.

ASA and our members have moved public policy forward by light years by incorporating strategies across many disciplines. ASA has brought together policy experts, public health experts, attorneys, lobbyists, scientists, industry associations and medical professionals to create the campaigns, projects and programs that have broken down

political, social, academic, and legal barriers across the US.

Ensuring safe and legal access to cannabis means:

- International, federal and state laws and regulations recognized cannabis as a legal medicine.
- Medical professionals recommend medical cannabis options as a frontline treatment option or an adjunct therapy.
- Patients and their caregivers have the information they need to make educated choices about medical cannabis therapies.
- Patients and medical professionals can incorporate a diverse group of products and delivery methods to create required personalized treatment regimen.
- Patients can trust labels on products and that medicines are free of pesticides and contaminants.
- Medical cannabis treatments are covered by insurance.

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