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AIR COMMAND AND STAFF COLLEGE

AIR UNIVERSITY

THE EVOLUTION OF VETERAN AFFAIRS HEALTHCARE –
IS IT HIGH TIME FOR CANNABIS TREATMENT?

by

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A Research Report Submitted to the Faculty

In Partial Fulfillment of the Graduation Requirements

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PREFACE

Inspiration for this research came from my cousin Mike, a disabled veteran who served in Operation IRAQI FREEDOM. Mike suffers from Post-Traumatic Stress Disorder (PTSD) and severe chronic pain. He is rated 100% disabled by the United States Department of Veteran Affairs (DVA), and is treated with heavy doses of schedule II pain medication to deal with his ailments. Mike was medically discharged from the Air Force 10 years ago, and to date his symptoms have not shown much improvement.

One afternoon Mike was telling me about the numerous medications he had to take each day. He said that he could not fully function in society with the amount of medication he was prescribed, and did not know what else to do. He said he had heard from other veterans that medicinal marijuana was being used as an alternate treatment for both PTSD and chronic pain, but was worried how it would affect his disability with the DVA.

During my initial research, I found that there was some legitimacy to what he has said about the use of medicinal marijuana as an alternate treatment for PTSD and chronic pain. Furthermore, I found that the DVA had also issued a directive to Veteran Affairs (VA) doctors regarding state approved medical marijuana programs, leading me to believe that there would be enough evidence to support his statement

ABSTRACT

This research addresses the question, “Should Consideration Be Given to Permitting VA Doctors to Recommend Medical Marijuana to Veterans?” The Veterans Affairs (VA) Office of Inspector General reported that more than 50 percent of all veterans enrolled and receiving DVA Healthcare are affected by chronic pain. Furthermore, the DVA estimates that approximately 35% of patients with chronic pain also have PTSD.¹ Medicinal marijuana has been used throughout history as a valid form of treatment since the 18th century. In the last decade, the research on medicinal marijuana has increased dramatically. There have been hundreds of reviews and studies by research centers, state-funded programs and independent physicians on the medical benefits of marijuana. More recent studies have shown significant evidence that marijuana is an effective treatment for chronic pain and PTSD.² To date, a total of 23 states, the District of Columbia and Guam allow for comprehensive public medical marijuana and cannabis programs. Evidence provided in this research supports the use of medicinal marijuana for PTSD and chronic pain and allowing for VA doctors to recommend, and complete state approved medicinal marijuana program forms.

INTRODUCTION

Research Question

Should Consideration Be Given to Permitting VA Doctors to Recommend Medical Marijuana to Veterans?

Studies have shown that marijuana is an effective treatment for a variety of medical conditions, including chronic pain and post-traumatic stress disorder (PTSD), most common ailment among veterans returning from Iraq and Afghanistan.³

Over 370,000 Operation ENDURING FREEDOM, IRAQI FREEDOM, and NEW DAWN veterans were seen for PTSD following their return from deployment.⁴ A study conducted in 2014 showed that people with PTSD had a greater than 75% reduction in severity of symptoms when prescribed marijuana to treat PTSD.⁵ Civilian doctors in states with legalized marijuana programs are prescribing it to treat PTSD, chronic pain, neuropathic (nerve) pain, muscle spasms, glaucoma, and seizures.⁶ Unfortunately, marijuana is not a Food and Drug Administration (FDA) approved drug and is currently illegal under federal law. The US Department of Justice continues to rely on state and local laws to govern their own legalized marijuana programs. In addition to the 2014 federal government approved study to look at marijuana as a treatment for veterans with PTSD, there are currently several bills (H.R. 607/1538,2029) introduced to Congress that would allow veterans to participate in state-approved medicinal marijuana programs.

Problem Background and Significance

The use of medical marijuana to treat veterans has grown immensely popular among the veteran community over the last decade. Recent studies by the Canadian Forces Health Services Centre, the Journal of Psychoactive Drugs and University of California have shown that the use of medical marijuana can effectively treat ailments commonly seen in veterans, such as PTSD and chronic pain. Over 370,000 Operations ENDURING FREEDOM, IRAQI FREEDOM, and NEW DAWN veterans have been seen for PTSD.⁷ However, under current federal law, marijuana is classified as a Schedule I drug and is not accepted for medical use, thus prohibiting Veteran Affairs healthcare providers from discussing, recommending and/or prescribing medical marijuana to veterans seeking treatment. Furthermore, it is the Veterans Health Administration (VHA) policy to prohibit VA providers from completing forms seeking recommendations or opinions regarding a Veteran's participation in a state marijuana program.⁸

The use of medical marijuana is legal in 23 states and the District of Columbia, in addition to 16 states that allow the regulated use of oils made from the plant.⁹ Veterans in Support of Medical Marijuana are lobbying for more states to legalize cannabis for medical use. However, their primary focus is the federal government and, in particular, the Department of Veterans Affairs (DVA). Recently, lobbyists have proposed new laws to Congress that would allow veterans to participate in state-approved medicinal marijuana programs. H.R.667, the Veterans Equal Access Act, would authorize the DVA health care providers to provide recommendations and opinions to veterans regarding participation in State marijuana programs.¹⁰ And amendment to H.R. 2029, the Military Construction and Veterans Affairs and Related Agencies Appropriations Act, prohibiting the use of funds to interfere with the ability of

veterans to participate in state-approved medicinal marijuana programs or deny services to such veterans.¹¹

Qualifying conditions in states with medical marijuana programs include seizures, glaucoma, muscle spasms, neuropathic pain, anxiety, chronic pain and PTSD.¹² PTSD affects 30% of Vietnam veterans, 12% of Gulf War veterans, and 20% of Iraq and Afghanistan War veterans.¹³ A report from the U.S. Department of Health and Human Services, National Institutes of Health, showed that 44 percent of returning combat veterans suffer from chronic pain, compared to 26 percent of the general public.¹⁴ There is no cure for PTSD or chronic pain, only treatment. Veterans are often treated with a variety of medications and told to “manage” their symptoms.¹⁵ Studies have shown that people had a greater than 75% reduction in severity of PTSD¹⁶ symptoms and 30% reduction in pain¹⁷ when prescribed marijuana for treatment.

In 2013, President Obama committed to providing "unprecedented support" to veterans, to include improving veterans' health care.¹⁸ There are approximately 21 million living veterans in the United States, 9 million of which are currently enrolled in the VA health care system.¹⁹ In the last decade, 16 states have approved the use of marijuana for medicinal purposes. Does the federal government's definition of “unprecedented support”²⁰ include the use of medicinal marijuana? Is it time for the VHA to legally participate in these state programs if it will ease the suffering and improve the overall wellbeing of veterans? This research will assess the uses of medical marijuana and benefits it may provide to veterans, the legal constraints and current efforts in favor of veterans being allowed to participate in state medicinal marijuana programs, and address the impact to the VA healthcare system if approved for use.

Methodology

This research will utilize the evaluation framework to assess if consideration should be given to permitting Veteran Affairs doctors to recommend medical marijuana to veterans. The primary objective of this research is to evaluate if veterans can benefit from the use of medical marijuana to treat significant ailments like PTSD and chronic pain.

It begins by providing a background on medicinal marijuana, state and federal laws, Veteran Affairs Healthcare treatment limitations, as well as the Obama Administration's promise to improve VA Healthcare and recent proposed legislation changes. Next it will utilize a combined quantitative and qualitative approach to evaluate common veteran medical statistics and refereed studies on medical marijuana treatment for PTSD and chronic pain. Additionally, it will assess alternative treatments for these types of ailments and the federal and state management programs for Schedule I-III drugs.

Based on the analysis of the evaluation research criteria, this research will offer a recommendation for the use of medical marijuana among veterans and potential federal program management options for prescribed Schedule I drugs.

BACKGROUND

Medicinal Marijuana

History of Medicinal Marijuana

The first recorded medicinal use of cannabis was during the reign of the Chinese Emperor Shen Nung around the 28th century B.C. Shen, determined to find an alternate means of relieving sickness, recommended cannabis for female weaknesses (menstruation), gout, rheumatism, malaria, constipation, and absentmindedness.²¹ Other Chinese herbalists used cannabis resin with wine as an analgesic to perform extremely complicated surgical procedures.²² From its first recorded use in China during the Nung Dyanasty, cannabis has been used around the world for medicinal purposes. In India, “the first marijuana-oriented culture,”²³ cannabis has been recommended to quicken the mind, lower fevers, induce sleep, cure dysentery, stimulate appetite, improve digestion, relieve headaches, and cure venereal disease.²⁴ It was used for dysentery, malaria, and fevers in parts of Africa. It is still used today by certain tribes to treat snakebites and a pain remedy before childbirth.²⁵ Between 1621 and 1794, hundreds of published works suggested cannabis as treatment for depression, inflammation, coughs, venereal disease, and urinary incontinence.²⁶ Although cannabis was not established as a medicine in the West until the mid-nineteenth century, it was much more common in the East. Later, all the conditions were summarized for which it was supposed to be medically useful.²⁷

From 1840 to 1900, Western physicians were recommending cannabis for various illnesses and discomforts. More than 100 papers were published in the Western medical literature on the medical uses of cannabis. Physicians during this time were captivated with explorations of its therapeutic potential. However, as the development of more stable and reliable synthetic

drugs like aspirin came about toward the 19th century, the interest and exploration in cannabis declined²⁸

By 1890, small percentages of Western patent medicines contained marijuana. However, it was small amounts compared to the number of medicines containing opium or cocaine. From 1850 until 1942, cannabis was listed in the United States Pharmacopeia and was prescribed for numerous conditions, including labor pains, nausea, and rheumatism.²⁹

By the 1930s, the increased demand for marijuana-based medications pushed pharmaceutical firms to produce more potent and reliable drugs from cannabis. Parke-Davis and Eli Lilly, two American based companies started selling cannabis for use as an analgesic, an antispasmodic and sedative. Others, like Grimault & Company sold marijuana as a remedy for asthma.³⁰

By 1937, Congress passed the Marihuana Tax Act. Sponsored by Harry Anslinger, Commissioner of the Federal Bureau of Narcotics, the act imposed registration and reporting requirements and a tax on the growers, sellers, and buyers of marijuana.³¹ Though it did not completely prohibit the use of marijuana, the complicated and stringent requirements had the same impact.³² By 1942, marijuana was removed from the US Pharmacopeia, where it had been listed for almost a century, ultimately losing its remaining therapeutic legitimacy.³³

In 1970 Congress passed the Controlled Substances Act (CSA), which classified controlled substances into five schedules. This framework was designed to provide a hierarchy of the substance potential for abuse, medical utility, and health consequences. The CSA classified marijuana along with heroin and LSD as a Schedule I drug, "...having the relatively high abuse potential and no accepted medical use."³⁴

In 1976, a federal court ruled in favor of a man [Robert Randall] with glaucoma (US v. Randall) defending himself against criminal charges of marijuana cultivation. The court ruled, “While blindness was shown by competent medical testimony to be the otherwise inevitable result of the defendant’s disease, no adverse effects from the smoking of marijuana have been demonstrated. Medical evidence suggests that the ‘MEDICAL PROHIBITION’ is not well-founded.”³⁵ It was constituted as a medical necessity and charges were dismissed. Following a petition filed by Randall, the FDA approved access to government medical marijuana, making Randal the first American to receive medicinal marijuana treatment for a medical condition.³⁶

In 1978, Lynn Pierson, a cancer patient stricken with nausea and vomiting caused by chemotherapy, encouraged New Mexico to become the first state to pass a law recognizing the medical value of marijuana [Controlled Substances Therapeutic Research Act 1978].³⁷ Thirty more states followed suite with similar legislation over the next few years.

In May 1985, Marinol was approved for nausea and vomiting associated with cancer patients in chemotherapy. “Marinol is the trade name for dronabinol, a synthetic form of delta-9 tetrahydrocannabinol (THC), one of the principal psychoactive components of botanical marijuana. In December 1992, it was approved by FDA for the treatment of anorexia associated with weight loss in patients with AIDS. Marketed as a capsule, Marinol was originally placed in Schedule II.”³⁸

By 1991, California had passed a medical marijuana initiative, Proposition P. that would restore hemp to the list of available medicines.³⁹ Later in 1996, California passed a state medical marijuana initiative called Proposition 215 (P215). P215 permitted patients and their primary caregivers, to possess and cultivate marijuana for the treatment of AIDS, cancer, muscular spasticity, migraines, and several other disorders. Additionally, P215 prohibited penalizing

physicians from prescribing cannabis for medical purposes.⁴⁰ From 1996 to 2010, 15 states legalize the use of medical marijuana.

On July 22, 2010, the US Department of Veterans Affairs released a VHA directive, stating that veterans who participate in legal state medical marijuana programs will no longer be disqualified from "...substance abuse programs, pain control programs, or other clinical programs."⁴¹ However, the directive also stated that VA doctors were not authorize to recommend or consult with patients regarding its use, and could alter pain treatment programs if patients were found to be participating in medicinal marijuana programs.

June 2015, the Obama Administration made medical marijuana research easier by removing a long-standing bureaucratic time-consuming obstacle on privately-funded medical marijuana research.⁴² To date, a total of 23 states, the District of Columbia and Guam allow for comprehensive public medical marijuana and cannabis programs. An additional 17 states allow the use of low THC, high cannabis oil products for medical reasons.⁴³

State-Approved Medicinal Marijuana Programs

Most states have very limited and restrictive medical marijuana laws. The laws vary state-by-state and can be broader than others, and include types of medical conditions that allow for treatment. Some states, not shown on Figure 1, have passed laws that only allow cannabis oils if individuals prove they suffer from required medical illnesses.

State Marijuana Laws

At least 17 states have "per se" drugged driving laws that make it illegal to have certain levels of THC in one's body while operating a vehicle. Others have "under the influence" policies, which consider whether a driver is affected by THC, or "incapacity" standards, which require a prosecutor to show a connection between drug ingestion and inability to drive safely. Hover over each state for more information.

Marijuana Legalization Status

- Adult Use Legal
- Decriminalized
- Illegal
- Medical Use Legal
- Medical Use Legal and Decriminalized

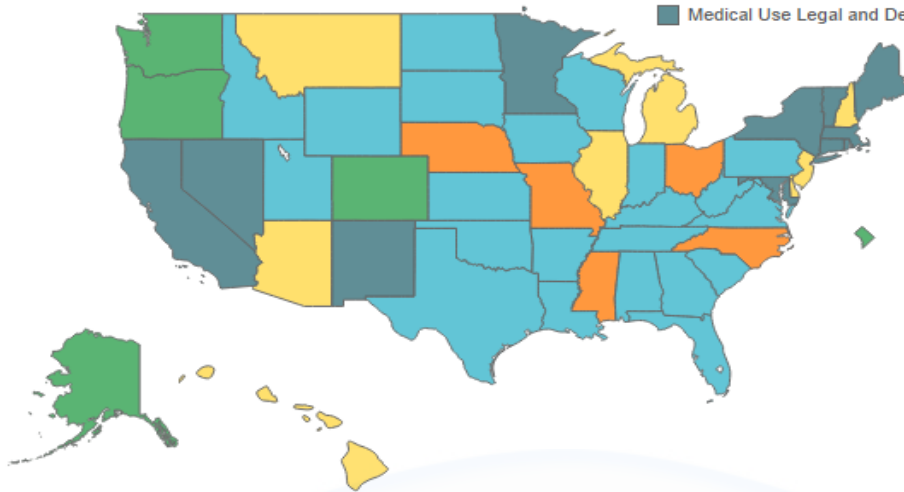


Figure 1 State Marijuana Laws⁴⁴ Reprint from Huffingtonpost, As Legal Marijuana Expands, States Struggle with Drugged Driving, Aug 21, 2015.

23 Legal Medical Marijuana States and DC

State	Year Passed	How Passed (Yes Vote)	Possession Limit
1. Alaska	1998	Ballot Measure 8 (58%)	1 oz usable; 6 plants (3 mature, 3 immature)
2. Arizona	2010	Proposition 203 (50.13%)	2.5 oz usable; 0-12 plants
3. California	1996	Proposition 215 (56%)	8 oz usable; 6 mature or 12 immature plants
4. Colorado	2000	Ballot Amendment 20 (54%)	2 oz usable; 6 plants (3 mature, 3 immature)
5. Connecticut	2012	House Bill 5389 (96-51 H, 21-13 S)	One-month supply (exact amount to be determined)
6. DC	2010	Amendment Act B18-622 (13-0 vote)	2 oz dried; limits on other forms to be determined
7. Delaware	2011	Senate Bill 17 (27-14 H, 17-4 S)	6 oz usable
8. Hawaii	2000	Senate Bill 862 (32-18 H; 13-12 S)	3 oz usable; 7 plants (3 mature, 4 immature)
9. Illinois	2013	House Bill 1 (61-57 H; 35-21 S)	2.5 ounces of usable cannabis during a period of 14 days
10. Maine	1999	Ballot Question 2 (61%)	2.5 oz usable; 6 plants

11. Maryland	2014	House Bill 881 (125-11 H; 44-2 S)	30-day supply, amount to be determined
12. Massachusetts	2012	Ballot Question 3 (63%)	60-day supply for personal medical use
13. Michigan	2008	Proposal 1 (63%)	2.5 oz usable; 12 plants
14. Minnesota	2014	Senate Bill 2470 (46-16 S; 89-40 H)	30-day supply of non-smokable marijuana
15. Montana	2004	Initiative 148 (62%)	1 oz usable; 4 plants (mature); 12 seedlings
16. Nevada	2000	Ballot Question 9 (65%)	1 oz usable; 7 plants (3 mature, 4 immature)
17. New Hampshire	2013	House Bill 573 (284-66 H; 18-6 S)	Two ounces of usable cannabis during a 10-day period
18. New Jersey	2010	Senate Bill 119 (48-14 H; 25-13 S)	2 oz usable
19. New Mexico	2007	Senate Bill 523 (36-31 H; 32-3 S)	6 oz usable; 16 plants (4 mature, 12 immature)
20. New York	2014	Assembly Bill 6357 (117-13 A; 49-10 S)	30-day supply non-smokable marijuana
21. Oregon	1998	Ballot Measure 67 (55%)	24 oz usable; 24 plants (6 mature, 18 immature)
22. Rhode Island	2006	Senate Bill 0710 (52-10 H; 33-1 S)	2.5 oz usable; 12 plants
23. Vermont	2004	Senate Bill 76 (22-7) HB 645 (82-59)	2 oz usable; 9 plants (2 mature, 7 immature)
24. Washington	1998	Initiative 692 (59%)	24 oz usable; 15 plants

Table 1 Legal Medical Marijuana State and DC, Reprint from National Conference of State Legislatures. State Medical Marijuana Laws, September 2015.⁴⁵

LIMITED ACCESS MARIJUANA PRODUCT LAWS (LOW THC/HIGH CBD- CANNABIDIOL)			
State	Program Name and Statutory Language (year)	Specifies Conditions	Definition of Products Allowed
Alabama	SB 174 "Carly's Law" (Act 2014-277) Allows University of Alabama Birmingham to conduct effectiveness research using low-THC products for treating seizure disorders for up to 5 years. Not operational as of April, 2015.	Yes, debilitating epileptic conditions or life-threatening seizures.	Extracts that are low THC= below 3% THC
Florida	Compassionate Medical Cannabis Act of 2014 CS for SB 1030 (2014) Patient treatment information and outcomes will be collected and used for intractable childhood epilepsy research	Yes, cancer, medical condition or seizure disorders that chronically produces symptoms that can be alleviated by low-THC products	Cannabis with low THC= below .8% THC and above 10% CBD by weight

LIMITED ACCESS MARIJUANA PRODUCT LAWS (LOW THC/HIGH CBD- CANNABIDIOL)

State	Program Name and Statutory Language (year)	Specifies Conditions	Definition of Products Allowed
Georgia	HB 1 (2015) (signed by governor 4/16/15)	Yes, end stage cancer, ALS, MS, seizure disorders, Crohn's, mitochondrial disease, Parkinson's, Sickle Cell disease	Cannabis oils with low THC= below 5% THC and at least an equal amount of CBD.
Iowa	SF 2360, Medical Cannabidiol Act of 2014 (Effective 7/1/14)	Yes, intractable epilepsy	"Cannabidiol- a non-psychoactive cannabinoid" that contains below 3% THC, no more than 32 oz, and essentially free from plant material.
Idaho	SB 1146 (VETOED by governor 4/16/15)	The possessor has, or is a parent or guardian of a person that has, cancer, amyotrophic lateral sclerosis, seizure disorders, multiple sclerosis, Crohn's disease, mitochondrial disease, fibromyalgia, Parkinson's disease or sickle cell disease;	Is composed of no more than three-tenths percent (0.3%) tetrahydrocannabinol by weight; is composed of at least fifteen (15) times more cannabidiol than tetrahydrocannabinol by weight; and contains no other psychoactive substance.
Kentucky	SB 124 (2014) Clara Madeline Gilliam Act Exempt cannabidiol from the definition of marijuana and allows it to be administered by a public university or school of medicine in Kentucky for clinical trial or expanded access program approved by the FDA.	Intractable seizure disorders	No, only "cannabidiol".
Louisiana	SB 143 The "Alison Neustrom Act"	Yes	"THC shall be reduced to the lowest acceptable therapeutic levels available through scientifically acceptable methods."
Mississippi	HB 1231 "Harper Grace's Law" 2014	Yes, debilitating epileptic condition or related illness	"CBD oil" - processed cannabis plant extract, oil or resin that contains more than 15% cannabidiol, or a dilution of the resin that contains at least 50 milligrams of cannabidiol (CBD) per milliliter, but not more than one-half of one percent (0.5%) of tetrahydrocannabinol (THC)
Missouri	HB 2238 (2014)	Yes, intractable epilepsy that has not responded to three or more other treatment options.	"Hemp extracts" equal or less than .3% THC and at least 5% CBD by weight.

LIMITED ACCESS MARIJUANA PRODUCT LAWS (LOW THC/HIGH CBD- CANNABIDIOL)

State	Program Name and Statutory Language (year)	Specifies Conditions	Definition of Products Allowed
North Carolina	HB 1220 (2014) Epilepsy Alternative Treatment Act- Pilot Study	Yes, intractable epilepsy	"Hemp extracts" with less than three-tenths of one percent (0.3%) tetrahydrocannabinol (THC) by weight. Is composed of at least ten percent (10%) cannabidiol by weight. Contains no other psychoactive substance.
Oklahoma	HB 2154 (2015)	People under 18 (minors) Minors with Lennox-Gastaut Syndrome, Dravet Syndrome, or other severe epilepsy that is not adequately treated by traditional medical therapies	A preparation of cannabis with no more than .3% THC in liquid form.
South Carolina	SB 1035 (2014) Medical Cannabis Therapeutic Treatment Act- Julian's Law	Lennox-Gastaut Syndrome, Dravet Syndrome, also known as severe myoclonic epilepsy of infancy, or any other form of refractory epilepsy that is not adequately treated by traditional medical therapies.	Cannabidiol or derivative of marijuana that contains 0.9% THC and over 15% CBD, or least 98 percent cannabidiol (CBD) and not more than 0.90% tetrahydrocannabinol (THC) by volume that has been extracted from marijuana or synthesized in a laboratory
Tennessee	SB 2531 (2014) Creates a four-year study of high CBD/low THC marijuana at TN Tech Univ. HB 197 (2015)	Yes, intractable seizure conditions. Yes, intractable seizure conditions.	"Cannabis oil" with less than .9% THC as part of a clinical research study Same as above.
Texas	SB 339 (2015) Texas Compassionate Use Act	Yes, intractable epilepsy.	"Low-THC Cannabis" with not more than 0.5 percent by weight of tetrahydrocannabinols; and not less than 10 percent by weight of cannabidiol
Utah	HB 105 (2014) Hemp Extract Registration Act	Yes, intractable epilepsy that hasn't responded to three or more treatment options suggested by neurologist	"Hemp extracts" with less than .3% THC by weight and at least 15% CBD by weight and contains no other psychoactive substances

LIMITED ACCESS MARIJUANA PRODUCT LAWS (LOW THC/HIGH CBD- CANNABIDIOL)			
State	Program Name and Statutory Language (year)	Specifies Conditions	Definition of Products Allowed
Virginia	HB 1445	Intractable epilepsy	Cannabis oils with at least 15% CBD or THC-A and no more than 5% THC.
Wisconsin	AB 726 (2013 Act 267)	Seizure disorders	Exception to the definition of prohibited THC by state law, allows for possession of "cannabidiol in a form without a psychoactive effect." THC or CBD levels are not defined.
Wyoming	HB 32 (2015) Supervised medical use of hemp extracts. Effective 7/1/2015	Intractable epilepsy or seizure disorders	"Hemp extracts" with less than 0.3% THC and at least 5% CBD by weight.

Table 2 States with Limited Access Marijuana Laws, Reprint from National Conference of State Legislatures. "State Medical Marijuana Laws," September 2015.⁴⁶

The U.S. Food and Drug Administration (FDA)

Although some states have passed medicinal marijuana laws and programs, the U.S. Food and Drug Administration (FDA) has not approved marijuana as a safe and effective drug for any indication. The FDA is a federal agency within the Department of Health and Human Services. It is tasked to regulate over-the-counter and prescription drugs, including generic drugs. Drug companies must get FDA approval before selling a new drug in the United States. To obtain approval, the FDA requires carefully conducted clinical trials. Though the FDA does not approve the marijuana plant as medicine, it has recognized chemicals in marijuana called cannabinoids as a legitimate form of medicine.⁴⁷

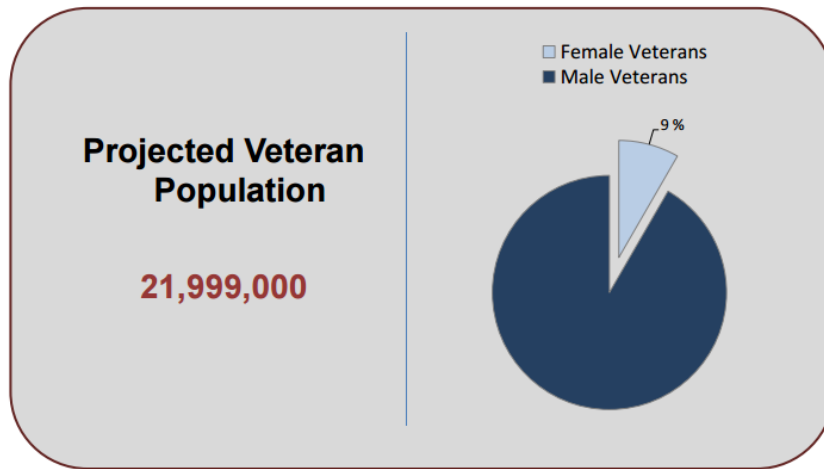
The two cannabinoids from the marijuana plant that have been approved for medical use are THC and CBD. THC is used to increase appetite, reduce nausea, decrease pain, inflammation,

and muscle spasms. CBD can be used to reduce pain, inflammation, controlling epileptic seizures and to treat mental illness an addition.⁴⁸

Veteran Statistics

A 2014 DVA report estimates that there are 22 million living veterans.⁴⁹ These veterans represent, World War II, Korean Conflict, Vietnam Era, Peacetime, Gulf War I (Pre 9/11) and Gulf War II (post 9/11). Roughly 9 million of these veterans are currently enrolled in the DVA Healthcare system and have utilized some form of medical benefits.⁵⁰ A report produced by the VA Office of Inspector General in 2014, as requested by United States Senate Committee on Veterans' Affairs, claimed that more than 50 percent of all veterans enrolled and receiving DVA Healthcare are affected by chronic pain.⁵¹ Furthermore, the report went on to note that most veterans who suffer from chronic pain also experience much higher rates of other co-morbidities, like PTSD, depression and traumatic brain injury (TBI).⁵² The DVA estimates that approximately 35% of patients with chronic pain also have PTSD.⁵³ For people with chronic pain, the pain may serve as a reminder of the traumatic event, which will tend to exacerbate the PTSD.⁵⁴

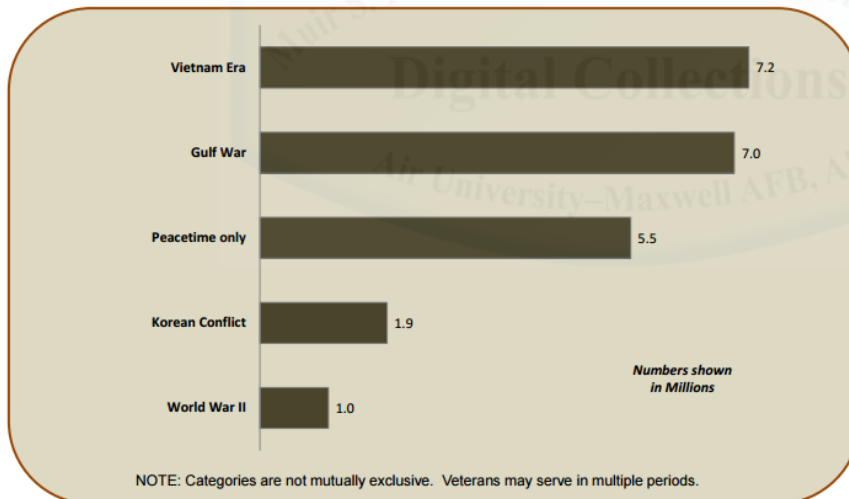
Department of Veterans Affairs: Veteran Population Statistics at a Glance
(as of 9/30/2014)



Source: Department of Veterans Affairs, Office of the Actuary, Veteran Population Projection Model (VetPop 2014). 4

Table 3 Veteran Population Statistics

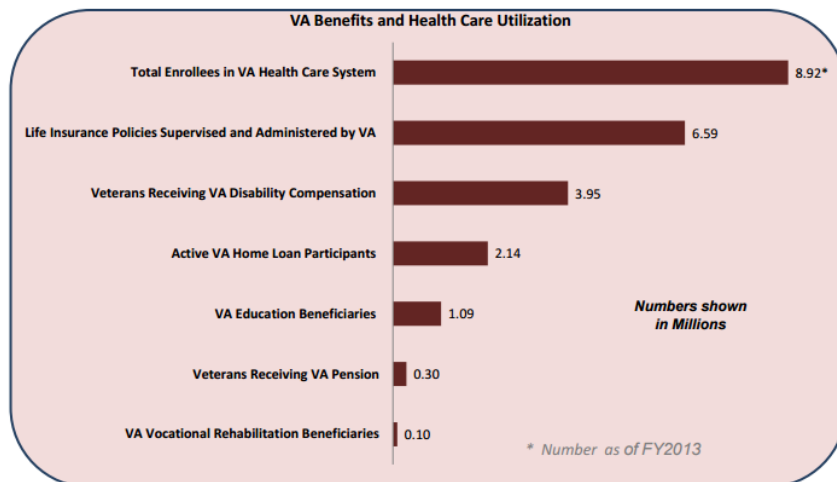
Department of Veterans Affairs: Veteran Period of Service Statistics at a Glance
(as of 9/30/2014)



Source: Department of Veterans Affairs, Office of the Actuary, Veteran Population Projection Model (VetPop2014). 5

Table 4 Veteran Period of Service Statistics

Department of Veterans Affairs: VA Benefits and Health Care Utilization Statistics at a Glance
(as of 9/30/2014)



Source: Department of Veterans Affairs, Veterans Benefits Administration and Veterans Health Administration.

Table 5 VA Benefits and Health Care Utilization Statistics

PTSD

Post-traumatic stress disorder (PTSD) is the body's continued reaction to fear or danger after an event. It can be caused by a traumatic event that involves physical harm or the threat of physical harm. However, physical injury is not always required to get PTSD. It can occur simply by witnessing someone harmed or threatened.⁵⁵ PTSD is most commonly associated with veterans that have seen or been in combat. Hundreds of thousands of living veterans have seen combat. The DVA estimates that PTSD afflicts 20% of veterans who served in OIF and OEF and 12% of Gulf War veterans annually.⁵⁶ Additionally, it was estimated that 30% of Vietnam veterans had PTSD at some point in their life, and 15% are currently diagnosed with PTSD.⁵⁷

Though PTSD was originally brought to public attention by returning war veterans, it can stem from a wide range of traumatic incidents, i.e. Child sexual or physical abuse, terrorist

attack, sexual or physical assault, car accidents, and natural disasters.⁵⁸ Its symptoms can start as soon after the traumatic event or possibly months or years later. The DVA National Center for PTSD has identified four major types of symptoms of PTSD.⁵⁹

- Reliving the event
- Avoiding situations that remind you of the event
- Negative changes in beliefs and feelings
- Feeling keyed-up⁶⁰

Chronic Pain

The DVAs refers to chronic pain as intractable pain that exists for three or more months and does not resolve in response to treatment.⁶¹ It varies in severity, and can be as severe as or more severe than acute pain. In contrast to acute pain, chronic pain persists beyond the amount of time that is normal for an injury to heal.⁶² Chronic pain can last for weeks, months, or even years. It often does not ease with regular pain medication. Chronic pain can have a distinct cause, such as a temporary injury or infection or a long-term disease. There is no obvious cause for chronic pain.⁶³ The DVA Pain Management list the following as factors of chronic pain.⁶⁴

Physiological/Biological Factors⁶⁵

- Site of injury or source of painful stimuli
- Intensity of stimulation/degree of tissue damage
- Type and density of receptors present
- Biologically-based individual differences in pain threshold and sensitivity
- Amount of competing sensory activity

Psychological Factors⁶⁶

- Emotional status of the individual
- Attentional effects
- Individual beliefs and expectations regarding the experience of pain
- The individual's belief regarding their ability to establish control over the pain
- The individual's history of pain experiences and pain sensations
- General physical health of the person with pain

According to a JAMA Internal Medicine report in 2014, 44 percent among members of the U.S. military after combat deployment, compared to 26 percent in the general public.⁶⁷

There are many different forms of chronic pain. Each type of condition can cause different experiences of pain and disability. Patients with severe chronic pain and limited mobility, in most cases, are unable to perform activities of daily living, such as walking, standing, sitting, lifting light objects, standing.⁶⁸ Most people that suffer from chronic pain cannot work because of their pain or physical limitations.⁶⁹

VA Healthcare Treatment Limitations

The VHA is the largest integrated health care system in the United States. It encompasses 150 hospitals and medical centers and roughly 1,400 community-based outpatient clinics, community living centers, Vet Centers, and domicilies. The VHA has more than 53,000 independent licensed health care practitioners that provide care to more than 9 million veterans each year.⁷⁰ The VHAs treatment for PTSD and chronic pain can range from an assortment Schedule II-III prescription medications, physical therapy, psychotherapy, to invasive surgical procedures. Unfortunately, there is no one cure for either PTSD or chronic pain, and many veterans still suffer from their ailments. The VHAs policy does not currently allow VA doctors

to proscribe or recommend marijuana as an alternate medical treatment option, and prohibits VA providers from completing forms seeking recommendations or opinions regarding a Veteran's participation in a State marijuana programs. This guidance was issued in VHA Directive 2011-004, published on January 31, 2011. It states that DVA providers must comply with all Federal laws, including the Controlled Substances Act. It goes on to note that, "Marijuana is classified as a Schedule I drug under the Controlled Substances Act... State laws authorizing the use of Schedule I drugs, such as marijuana, even when characterized as medicine, are contrary to Federal law. While patients participating in State marijuana programs must not be denied VHA services, the decisions to modify treatment plans in those situations need to be made by individual providers in partnership with their patients."⁷¹ Additionally, per a report provided by the VA Office of Inspector General in 2014, other limitations in VA health care services have been identified, including limited PTSD interventions in some VAMCs and limited specialized PTSD programs for women veterans.

Veteran Support for Medicinal Marijuana Use

The support among veterans for the use of medicinal marijuana has gained momentum over the last decade. Some veteran are demanding alternate treatments for PTSD and chronic pain because traditional treatment is limited or completely ineffective. Organizations like Veterans for Medical Cannabis Access (VMCA) and Grow for Vets, have successfully lobbied for veterans' rights to access medical cannabis for therapeutic purposes. The Military Construction, Veterans Affairs, and Related Agencies Appropriation Bill, H.R.2029, S. Rept. 114-57, currently in the House Subcommittee would provide veterans with recommendations and opinions regarding participation in their state's marijuana programs, and allow VA physicians to

complete forms reflecting such recommendations and opinions.⁷² Also, if passed the Veterans Equal Access Act, H.R.667, would prohibit the VA from interfering with or denying services to veterans participating in state-approved medicinal marijuana programs.⁷³ It is the intent of these types of organizations to continue to encourage both legislative bodies to endorse veterans' rights to use medical cannabis therapeutically and responsibly, and grant the ability to safely discuss medical cannabis use within the V.A. healthcare system without fear of punishment or retribution.

Administration's Promise to Improve Healthcare for Veterans

"Keeping faith with those who serve must always be a core American value and a cornerstone of American patriotism. Because America's commitment to its servicemen and women begins at enlistment, and it must never end."

-- Barack Obama, Speech in Kansas City, MO

August 21, 2007

The United States' commitment to its veterans "is more urgent than ever" as noted by, President Obama during the Veterans Day commensuration at a wreath-laying ceremony at Arlington National Cemetery.⁷⁴ As the veteran population grows, VA healthcare has become a widely and controversial topic on Capitol Hill. President Obama promised to provide "unprecedented support" to veterans, improving veterans' health care, reducing claims backlogs and providing them with access to education, "even as we make difficult fiscal choices as a nation."⁷⁵ He committed to ensuring the sacred trust to care for our nation's veterans was upheld.⁷⁶ As part of this commitment, he promised to create a 21st Century Department of

Veterans' Affairs that provides the care and benefits the nation's veterans deserve. This included the following:⁷⁷

- Strengthen VA Care: Make the VA a leader of national health care reform so that veterans get the best care possible.
- Fully Fund VA Medical Care: Fully fund the VA so it has all the resources it needs to serve the veterans who need it, when they need it.
- Improve Mental Health Treatment: Recruit more health professionals, improve screening, offer more support to families and make PTSD benefits claims fairer.
- Improve Care for Traumatic Brain Injury: Establish standards of care for Traumatic Brain Injury, the signature injury of the Iraq war.⁷⁸

In 2014, Congress enacted the Veterans Access, Choice, and Accountability Act. The Veterans Choice Act was established to help improve access to timely, high-quality health care for Veterans. Under Title II – Health Care Administrative Matters, Section 201 calls for an independent assessment of 12 areas of VA's health care delivery systems and management processes.

EVALUATION RESEARCH CRITERIA

Medicinal Marijuana Reviews and Studies

In the last decade the research on medicinal marijuana has increased dramatically. There have been hundreds of reviews and studies by research centers, state funded programs and independent physicians on the medical benefit of marijuana. Those studies include its use as an alternative means to treat PTSD and chronic pain. In 2000, the Center for Medicinal Cannabis Research (CMCR) was established at the University of California. It was charged with conducting clinical and pre-clinical studies of cannabinoids, including smoked marijuana, to support the claim of its therapeutic value. The CMCR worked with leading California institutions to conduct carefully designed studies and later published their results in scientific journals. The CMCR has completed 13 studies to date on the use of cannabis that include treatment for HIV related peripheral neuropathy, multiple sclerosis, and chronic pain related to spinal injury. As a result, the CMCR concluded that there is "...reasonable evidence that cannabis is a promising treatment in selected pain syndromes cause by injury or disease of the nervous system, and possibly for painful muscle spasticity due to multiple sclerosis." ⁷⁹

	Completed CMCR Studies	
1	Cannabis for Treatment of HIV-Related Peripheral Neuropathy	Donald Abrams, M.D.
2	Vaporization as a "Smokeless" Cannabis Delivery System	Donald Abrams, M.D.
3	Short-Term Effects of Cannabis Therapy on Spasticity in MS	Jody Corey-Bloom, M.D., Ph.D.
4	Sleep and Medicinal Cannabis	Sean Drummond, Ph.D.
5	Placebo-controlled, Double Blind Trial of Medicinal Cannabis in Painful HIV Neuropathy	Ronald Ellis, M.D., Ph.D.
6	Impact of Repeated Cannabis Treatments on Driving Abilities	Thomas Marcotte, Ph.D.
7	Mechanisms of Cannabinoid Analgesia	Ian Meng, Ph.D.
8	Effects of Cannabis Therapy on Endogenous Cannabinoids	Daniele Piomelli, Pharm.D., Ph.D.
9	Effects of Medicinal Cannabis on CD4 immunity in AIDS	Rachel Schrier, Ph.D.
10	Analgesic Efficacy of Smoked Cannabis	Mark Wallace, M.D.
11	Efficacy of Inhaled Cannabis in Diabetic Peripheral Neuropathy	Mark Wallace, M.D.
12	A Double Blind, Active Placebo Controlled Crossover Trial of the Antinociceptive Effects of Smoked Marijuana on Subjects with Neuropathic Pain; Correlation with Changes in Mood, Cognition, and Psychomotor Performance	Barth Wilsey, M.D.
13	<u>The Analgesic Effect of Vaporized Cannabis on Neuropathic Pain in Spinal Cord Injury</u>	Barth Wilsey, M.D.

Table 6 Completed CMCR Studies⁸⁰ Reprint from Center for Medicinal Cannabis Research, Research Studies, September 2015.

In 2008, Dr. R.J. Ellis, Dr. F. Vaida, and Dr. J.H. Atkinson, from the Departments of Neurosciences, Family and Preventive Medicine, Pharmacy and Psychiatry at the University of California, conducted a clinical trial for the CMCR to assess the impact of smoked cannabis on neuropathic pain in HIV. The study, Smoked Medicinal Cannabis for Neuropathic Pain in HIV, was later published with the National Center for Biotechnology Information and concluded that pain relief was greater with cannabis than the placebo. It concluded, “Despite management with opioids and other pain modifying therapies, neuropathic pain continues to reduce the quality of life and daily functioning in HIV infected individuals. Cannabinoid receptors in the central and peripheral nervous systems have been shown to modulate pain perception...”⁸¹ (see Appendix A)

In 2009, *The Use of a Synthetic Cannabinoid in the Management of Treatment-resistant Nightmares in Posttraumatic Stress Disorder (PTSD)*, published in the *CNS Neuroscience and Therapeutics*, reported that 72% of patients receiving cannabinoids had a significant reduction in nightmares resulting from PTSD.⁸² Dr. George Fraser, from the Operational Trauma and Stress Support Centre, Canadian Forces Health Services Centre, conducted a clinical trial to evaluate the effects of nabilone, a synthetic cannabinoid, on treatment-resistant nightmares in patients diagnosed with PTSD. In addition to improved reduction in nightmares, there was subjective improvement in sleep time, the quality of sleep, and the reduction of daytime flashbacks and nightsweats. Dr. Fraser concluded, "...The results of this study indicate the potential benefits of nabilone, a synthetic cannabinoid, in patients with PTSD experiencing poor control of nightmares with standard pharmacotherapy."⁸³ (see Appendix A)

In 2011, Dr. George R. Greer, a private practice physician, Dr. Charles S. Grob, from the Department of Psychiatry and Bio-behavioral Sciences at UCLA Medical Center, CA, and Dr. Adam L. Halberstadt, from the Department of Psychiatry, at the University of California, conducted a clinical trial to review the psychometric data on PTSD symptoms from patients applying to the New Mexico Medical Cannabis Program. The study, *PTSD Symptom Reports of Patients Evaluated for the New Mexico Medical Cannabis Program*, concluded that cannabis is associated with reduction in PTSD symptoms. A greater than 75% reduction in PTSD symptoms were reported by patients using cannabis to patients that were not.⁸⁴ The study concluded that, "Cannabis is associated with reductions in PTSD symptoms in some patients, and prospective, placebo-controlled study is needed to determine efficacy of cannabis and its constituents in treating PTSD."⁸⁵ (see Appendix A)

An article published in the Open Neurology Journal in May of 2012, Medical Marijuana: Clearing Away the Smoke, suggested that there has been enough evidence provided over the last 10 years to support cannabinoids as useful medicine.⁸⁶ Dr. Grant, from the University of California's Center for Medicinal Cannabis Research, Dr. Atkinson, Psychiatry Services, from the VA Sand Diego healthcare System, and Dr. Gouaux, from the University of California's Department of Physical Medicine and Rehabilitation, reviewed past and recent studies on medicinal cannabis, preservation of masking in clinical trials, risks and management of medicinal cannabinoids, and patient selection. They also concluded that, though cannabis may have some potential for abuse, it resembles more drugs listed in Schedule III than Schedule I.⁸⁷ Additionally, they developed an algorithm to guide physicians in the decision-making process in states with medicinal marijuana programs.⁸⁸

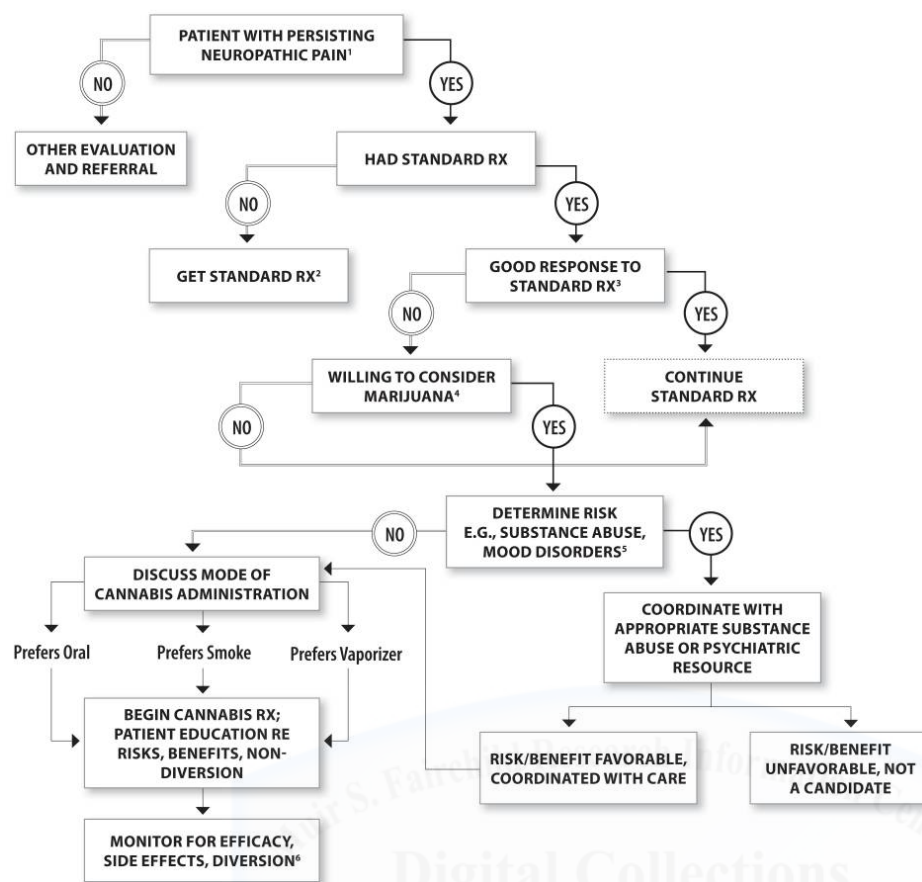


Figure 2 A decision tree approach for physicians who may be considering recommending medicinal cannabis to a patient⁸⁹
 Reprint from The Open Neurology Journal, "Medical Marijuana: Clearing Away the Smoke," Volume 6 (Summer 2012).

In August 2014, a study published with JAMA Internal Medicine assessed chronic pain prevalence and opioid use in a non-treatment-seeking, active duty infantry population following deployment. The study, Chronic Pain and Opioid Use in US Soldiers after Combat Deployment, conducted by Dr. Toblin, Center for Military Psychiatry and Neuroscience, Walter Reed Army Institute of Research, and Dr. Quartana, Commissioned Corps of the US Public Health Service, concluded that of the 2597 soldiers that took part in the survey, 44% experience chronic pain, of which 57% reported the use of opioids as result of the pain.⁹⁰ Its suggested findings revealed a "...large

unmet need for assessment, management, and treatment of chronic pain and related opioid use and misuse in military personnel after combat deployments.”⁹¹

“Notably, 44.1% of soldiers reporting opioid use reported no or mild past-month pain, including 5.6% with no pain. This might imply that opioids are working to mitigate pain, but it is also possible that soldiers are receiving or using these medications unnecessarily. This is cause for concern because opioids should be prescribed generally for moderate to severe pain^{1,3} and have high abuse and overdose potential.^{1- 3} Prescription practices should be examined to ensure that opioid use is consistent with standards of care and practice guidelines and non-opioid alternatives are considered whenever possible.^{1,3} The benefits of opioids for treating pain, particularly in those with combat-related injuries, must be balanced by careful assessment of risks, including the potential for misuse...”⁹² (see Appendix A)

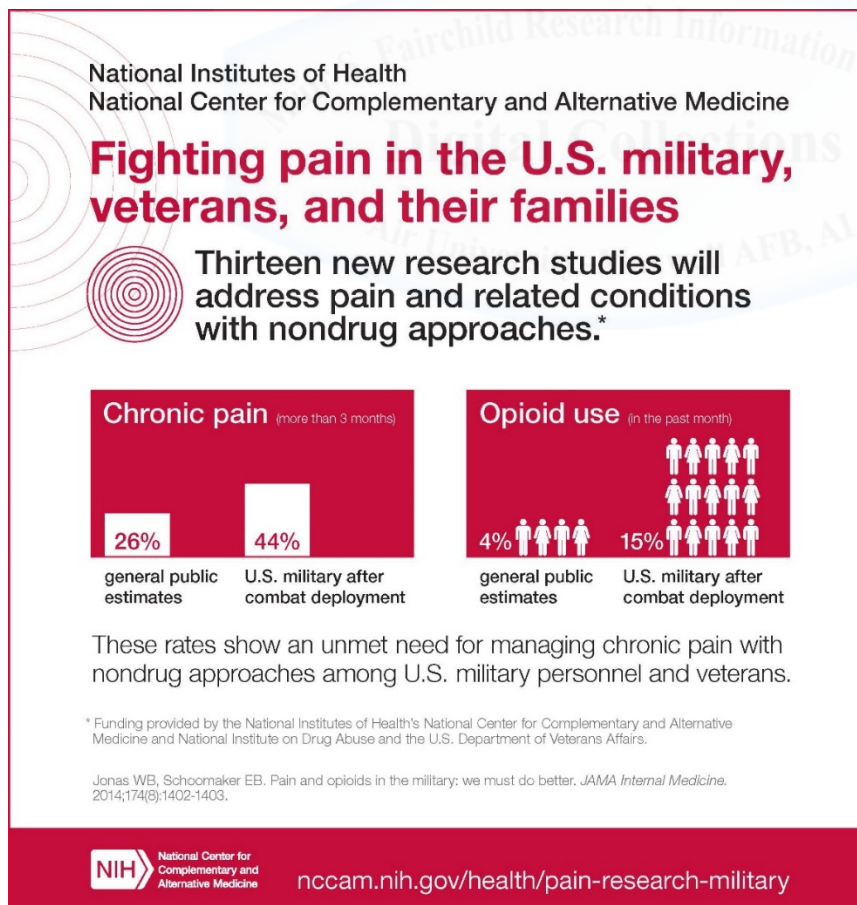


Figure 3 Managing Chronic Pain with Opioids ⁹³ Reprint from U.S. Department of Health and Human Services, National Center for Complementary and Integrative Health, *Fighting Pain in the U.S. Military, Veterans and Their Families*, September 2015.

Application and applicable dosages of medicinal marijuana are also questions that researchers are working to answer. The Journal of Pain and Palliative Care Pharmacotherapy published a study in 2014 that explored the pharmacokinetics, safety, tolerability, efficacy, and ease of use of a portable thermal-metered-dose inhaler for cannabis in eight patients suffering from chronic neuropathic pain. Dr. Elon Eiesner, Director, Pain Relief Unit, Rambam Medical Centre, and Associate Professor of Neurology, Rappaport Faculty of Medicine, The Technion-Israel Institute of Toxicology, Haifa, Israel and Dr. Shlomo Almog, PhD, Department of Physiology and Pharmacology, Sackler School of Medicine, Tel-Aviv University, and the Institute of Pharmacology and Toxicology, Chaim Sheba Medical Center, Tel-Hashomer, Israel, highlighted the need for evidence regarding the administration of medicinal cannabis and the accurate and precise dosing capabilities. During their research, a significant reduction in pain intensity was achieved after cannabis inhalation with a vaporizer.⁹⁴ The study concluded that the, "...Trial suggests the potential use of the Syqe Inhaler device as a pharmaceutical method for cannabis dosing, adding a much needed treatment in the limited armamentarium of effective therapies for the management of chronic pain."⁹⁵ (see Appendix A)

Alternative Treatments for PTSD and Chronic Pain

FDA Approved Medications (PTSD)

The U.S. Food and Drug Administration (FDA) approved two medications for treating adults with PTSD, Zoloft (Sertraline) and Paxil (Paroxetine). These medications are considered antidepressants, and are also used to treat depression, obsessive-compulsive disorder, panic attacks and social anxiety disorder.⁹⁶ They may help control PTSD symptoms such as sadness,

worry, anger, and feeling numb inside. Taking these medications may make it easier to go through psychotherapy.⁹⁷

These medications, like all medications, may cause mild or severe side effects. The most severe side effects of antidepressants like sertraline and paroxetine are seizures, fever, sweating, confusion, fast or irregular heartbeat, severe muscle stiffness, abnormal bleeding or bruising, and hallucinating.⁹⁸ Moreover, some studies suggested these medications can cause unintentional effects in some people. The FDA recognized the possibility of unintentional effects and conducted a review of all antidepressants clinical trials. The review revealed four percent of those taking antidepressants thought about or attempted suicide, compared to two percent of those receiving placebos.⁹⁹ Neither Zoloft or Paxil is an FDA controlled substance.

FDA Approved Medication (Chronic Pain)

The FDA has several approved medications that can be used to treat chronic pain. The most common medications can be broken down into five categories, nonsteroidal anti-inflammatory drugs and acetaminophen (NSAIDs), antidepressants, anticonvulsants or anti-seizure, muscle relaxants, and opioids. However, some patients with severe chronic pain choose more invasive treatments like surgery to help relieve the pain.

There are many different types of NSAIDs, the most common being ibuprofen and aspirin, that can be obtained over-the-counter to relieve pain, tenderness, swelling, and stiffness.¹⁰⁰ They can be used for acute muscular pain, bone pain, and certain types of chronic pain syndromes. Some of the more severe side effects include difficulty breathing or swallowing, fast heartbeat, cloudy, discolored, or bloody urine, back pain, difficult or

painful urination and vision problems.¹⁰¹ NSAIDs are not a controlled drug and, therefore are not identified as a FDA Scheduled Drug.

Anticonvulsants are used to treat nerve pain, such as burning or shooting pains. A few of the most common anticonvulsants are Lyrica, Trileptal, and Neurontin.¹⁰² These medications relieve pain from damaged nerves in the body by decreasing the number of pain signals that are sent out by the damaged nerves. Some of the more severe side effects include swelling of the eyes face, throat, mouth, lips, gums, tongue, head or neck, wheezing, and chest pain.¹⁰³ Anti-conulsants are typically Schedule V controlled substance.

Two of the most common muscle relaxants are Amrix and Flexeril. They are prescribed to relieve pain and discomfort of chronic pain, but most commonly used for short-term muscle spasms. The most severe side effects can be swelling of the face or tongue, difficulty breathing or swallowing, irregular heart rate, and seizures.¹⁰⁴ Amrix and Flexeril are not controlled drugs, therefore are not identified as a FDA Scheduled Drug

Lastly, opioids which include morphine, oxycodone, and methadone, are used to treat moderate to severe pain. All of which are listed on the Schedule II drugs, as a “high potential for abuse.”¹⁰⁵ Some of the most severe side effects include, fast or slow heartbeat, chest pain, and seizures.¹⁰⁶ Opioids, morphine, oxycodone and methadone are all Schedule II drugs.

Psychotherapy

Psychotherapy, considered “talk” therapy, involves talking with a mental health professional to treat a mental illness.¹⁰⁷ For PTSD, typically occurs one-on-one or in a group session and usually lasts 6 to 12 weeks, but can take more time given the severity of the symptoms.¹⁰⁸ Additionally, support from family and friends is also an important part of psychotherapy therapy.¹⁰⁹

There are many types of psychotherapy for PTSD and chronic pain. The type of psychotherapy is decided by the therapist, based on an assessment of the individual’s needs. Some focus on the symptoms directly, others focus on social, family, or job-related problems.¹¹⁰ One of the most common is Cognitive behavioral therapy (CBT), originally created to treat depression. CBT includes exposure therapy, cognitive restructuring, and stress inoculation training. Exposure therapy helps patients face and control their fear and exposes them to the trauma they experienced in a safe way.¹¹¹ While cognitive restructuring helps people make sense of the bad memories or helping remember an event differently than the way it may have seemed to happen.¹¹² Lastly, stress inoculation training tries to reduce symptoms by teaching a person how to reduce anxiety.¹¹³

In 2012, the National Institute of Mental Health sponsored Dr. Stefan Hofmann to conduct a review of CBT, *The Efficacy of Cognitive Behavioral Therapy: A Review of Meta-analyses*, to provide a comprehensive assessment of its efficiency. Though PTSD was not identified specifically in this review, symptoms of PTSD that were will be considered as such (anxiety disorder, general stress, personality disorders, anger and aggression, insomnia and depression). Dr. Hofman concluded that the evidence-base of CBT was “enormous.”¹¹⁴

Physical Therapy

Physical therapy (PT) can benefit veterans with both PTSD and chronic pain. Specifically, it can help veterans who are experiencing pain, impairment or disability and can significantly improve their wellbeing. In some cases, it helps improve their way of life with minimal or no prescribed medication. “Instead of being dependent on pills and other passive treatment ‘fixes’ that too often fall short, our program [VHA] and those like ours teach patients daily skills to take with them so that their pain does not feel so overwhelming.”¹¹⁵ PT can include low-impact aerobic training, strengthening exercises, pain relief exercises, and repetitive stretching. A study published by the National Institute of Health in 2010, *Physical Therapy in Palliative Care: From Symptom Control to Quality of Life: A Critical Review*, concluded that PT was shown to have “positive influence on quality of life...”¹¹⁶

FDA Schedule Drugs

The FDA Scheduled Drugs (Schedule I – V) can be divided into three specific categories: potential for abuse, medical use, and consequences of abuse. Each category has a schedule rating and definition. All drugs listed on the schedule are considered controlled.

	Schedule I	Schedule II	Schedule III	Schedule IV	Schedule V
Potential for abuse	The drug or other substance has a high potential for abuse	The drug or other substance has a high potential for abuse	The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II	The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule III	The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule IV
Medical use	The drug or other substance has no currently accepted medical use in treatment in the United States	The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions	The drug or other substance has a currently accepted medical use in treatment in the United States	The drug or other substance has a currently accepted medical use in treatment in the United States	The drug or other substance has a currently accepted medical use in treatment in the United States
Consequences of abuse	There is a lack of accepted safety for use of the drug or other substance under medical supervision	Abuse of the drug or other substance may lead to severe psychological or physical dependence	Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence	Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III	Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV

Table 7 Criteria for Scheduled Substances, Reprint from Huntington's Outreach Project for Education, at Stanford, Medical Marijuana Policy in the United States, May 15, 2012, September 2015.



ANALYSIS OF RESEARCH

The evidence-based of this research suggests that cannabis, approved FDA medications, psychotherapy, and physical fitness can all be effective treatments for PTSD and chronic pain. Additionally, the potential medical risks/side effects with FDA approved medications far exceeded the risks/side effects than medicinal marijuana (see Appendix B). The U.S National Library of Medicine lists 56 possible side effects/risks associated with FDA approved PTSD medication (Paxil), 30 of which are considered severe. It also list potential side effects with approved chronic pain medications; opioids (23), muscle relaxants (11), NSAIDs (32), anticonvulsants (34) and antidepressants (56). The National Institute of Drug Abuse (NIDA) lists nine possible side effects of marijuana. Because there has not been a FDA approved study on medicinal marijuana, it is assumed that the side effects of the recreational use of marijuana are the same as the medicinal application. Psychotherapy and physical fitness had no listed side effects. Lastly, two of the approved FDA medications for chronic pain (opioids and anticonvulsants) are listed as controlled substances. Both are defined as having the potential for abuse.

RECOMMENDATIONS

An immediate FDA approved clinical study should be conducted on the medical benefits of marijuana. Specifically, PTSD and chronic pain. Furthermore, VA doctors should be allowed to consult and complete forms for Veterans requesting to participate in state-approved programs until the review is complete. Only veterans living in states with approved medicinal marijuana programs should be allowed to participate. Additionally, serious consideration should be made to list marijuana as a Schedule II Drug. If marijuana is recognized by the FDA to have medical benefits, VA doctors should then be allowed to prescribe cannabis to veterans for approved ailments. Until then, program management should be left up to the individual state of residency.



CONCLUSION

“The scientific community, the medical community in particular, is divided on the real therapeutic effectiveness of marijuana. Some are quick to say that opening the door to medical marijuana would be a step toward outright legalization of the substance. But none of that should matter to physicians or scientists. It is not a question of defending general public policy on marijuana or even all illegal drugs. It is not a question of sending a symbolic message about “drugs”. It is not a question of being afraid that young people will use marijuana if it is approved as a medicine. The question, and the only question, for physicians as professionals is whether, to what extent and in what circumstances, marijuana serves a therapeutic purpose.” - Canadian Senate Special Committee On Illegal Drugs. Cannabis: Summary Report 2002.

Though the FDA does not approve the use of medicinal marijuana and lists it as a Scheduled I drug with no accepted medical use, there is significant evidence supporting its use as an effective treatment for veterans suffering from PTSD and chronic pain. Studies have shown that people had a greater than 75% reduction in severity of PTSD¹¹⁷ symptoms and 30% reduction in pain.¹¹⁸ An approved FDA clinical study on the medical benefits of marijuana will help further support this claim. Additionally, it will assist in the reassignment of marijuana as a Schedule II Drug. The need for an alternative treatments for veterans is imperative given the number suffering from these ailments. The Even more so given the number of suicides each year. If the use of cannabis can prevent one veteran suicide a year, then it should be considered as an acceptable medical alternative. The controversy of medicinal marijuana within the DVA will evolve and eventually prevail with continued veteran support and pending changes in legislation. The DVA support of medicinal marijuana for PTSD and chronic pain, and the approval for VA doctors to recommend and complete state-approved medicinal marijuana program forms, would be an evolutionary step forward.

APPENDIX A

1. Smoked Medicinal Cannabis for Neuropathic Pain in HIV:¹¹⁹

Background and Objectives: Despite management with opioids and other pain modifying therapies, neuropathic pain continues to reduce the quality of life and daily functioning in HIV infected individuals. Cannabinoid receptors in the central and peripheral nervous systems have been shown to modulate pain perception. We conducted a clinical trial to assess the impact of smoked cannabis on neuropathic pain in HIV.

Design and Methods: This was a phase II, double-blind, placebo-controlled, crossover trial of analgesia with smoked cannabis in HIV-associated distal, sensory predominant polyneuropathy (DSPN). Eligible subjects had neuropathic pain refractory to at least two prior analgesic classes; they continued on their pre-study analgesic regimens throughout the trial. Regulatory considerations dictated that subjects smoke under direct observation in a hospital setting. Treatments were placebo and active cannabis ranging in potency between 1 and 8% delta-9-tetrahydrocannabinol (THC), four times daily for five consecutive days during each of two treatment weeks, separated by a two-week washout. The primary outcome was change in pain intensity as measured by the Descriptor Differential Scale (DDS) from a pretreatment baseline to the end of each treatment week. Secondary measures included assessments of mood and daily functioning. Results: Of 127 volunteers screened, 34 eligible subjects enrolled and 28 completed both cannabis and placebo treatments. Among completers, pain relief was greater with cannabis than placebo (median difference in DDS pain intensity change, ELLIS 3 3.3 points, effect size=0.60; $p = 0.016$). The proportions of subjects achieving at least 30% pain relief with cannabis versus placebo were 0.46 [95%CI 0.28, 0.65] and 0.18 [0.03, 0.32]. Mood and daily functioning improved to a similar extent during both treatment periods. Although most side effects were mild and self-limited, two subjects experienced treatment-limiting toxicities.

Conclusions: Smoked cannabis was generally well-tolerated and effective when added to concomitant analgesic therapy in patients with medically refractory pain due to HIV DSPN.

2. The Use of a Synthetic Cannabinoid in the Management of Treatment-Resistant Nightmares in Posttraumatic Stress Disorder (PTSD)¹²⁰

Background: This is the report of an open label clinical trial to evaluate the effects of nabilone, an endocannabinoid receptor agonist, on treatment-resistant nightmares in patients diagnosed with posttraumatic stress disorder (PTSD).

Methods: Charts of 47 patients diagnosed with PTSD and having continuing nightmares in spite of conventional antidepressants and hypnotics were reviewed after adjunctive treatment with nabilone was initiated. These patients had been referred to a psychiatric specialist outpatient clinic between 2004 and 2006.

Conclusions: The majority of patients (72%) receiving nabilone experienced either cessation of nightmares or a significant reduction in nightmare intensity. Subjective improvement in sleep time, the quality of sleep, and the reduction of daytime flashbacks and nightsweats were also noted by some patients. The results of this study indicate the potential benefits of nabilone, a synthetic cannabinoid, in patients with PTSD experiencing poor control of nightmares with standard pharmacotherapy. This is the first report of the use of nabilone (Cesamet; Valeant Canada, Ltd., Montreal, Canada) for the management of treatment-resistant nightmares in PTSD.

3. PTSD Symptom Reports of Patients Evaluated for the New Mexico Medical Cannabis Program¹²¹

Background: New Mexico was the first state to list post-traumatic stress disorder (PTSD) as a condition for the use of medical cannabis. There are no published studies, other than case reports, of the effects of cannabis on PTSD symptoms. The purpose of the study was to report and statistically analyze psychometric data on PTSD symptoms collected during 80 psychiatric evaluations of patients applying to the New Mexico Medical Cannabis Program from 2009 to 2011.

Methods: The Clinician Administered Posttraumatic Scale for DSM-IV (CAPS) was administered retrospectively and symptom scores were then collected and compared in a retrospective chart review of the first 80 patients evaluated. Results: Greater than 75% reduction in CAPS symptom scores were reported when patients were using cannabis compared to when they were not.

Conclusions: Cannabis is associated with reductions in PTSD symptoms in some patients, and prospective, placebo-controlled study is needed to determine efficacy of cannabis and its constituents in treating PTSD

Chronic Pain and Opioid Use in US Soldiers After Combat Deployment¹²²

Methods - Institutional review board approval for the study was given by Walter Reed Army Institute of Research. Confidential surveys were collected in 2011 from 1 infantry brigade 3 months after return from Afghanistan under a protocol approved by the Walter Reed Army Institute of Research. Group recruitment briefings were attended by 80.3% of soldiers (3076 of 3832); 93.5% consented to participate (2876 of 3076). The final sample included 2597 soldiers who had been deployed to Afghanistan or Iraq. Participants provided written informed consent. Chronic pain was defined by soldiers reporting pain duration of at least 3 months Past-month pain frequency and severity (range, 0-10; none [0], mild [1-4], moderate [5-6], and severe [7-10])6 were also assessed (Table 1). Opioids and other pain medications were assessed by past-

month frequency of use (never, few or several days, more than half the days, nearly every day) (Table 1). Standardized scales assessed injuries during combat, combat intensity, posttraumatic stress disorder (PTSD), major depressive disorder (MDD) and alcohol misuse.⁴ Multiple logistic regressions examined correlates of chronic pain and opioid use.

Results - The 2597 participants were predominantly male (93.1%), 18 to 24 years old (41.3%), high school educated (48.2%), married (54.9%), and junior enlisted rank (56.1%). Nearly half (45.4%) reported injuries during combat. The prevalences of PTSD, MDD, and alcohol misuse screening were 9.1%, 5.8%, and 16.4%, respectively. Past-month opioid use was reported by 15.1% of soldiers (Table 1); among these, 5.6% reported no past-month pain, and 38.5%, 37.7%, and 18.2% reported mild, moderate, and severe pain, respectively. Most using opioids (62.6%) reported few or several days' use. Chronic pain was reported by 44.0%. Of these, 48.3% reported duration 1 year or longer, 55.6% reported nearly daily or constant frequency, and 51.2% reported severity of moderate to severe; 23.2% reported past-month opioid use, and 57.9% of those reported few or several days use (Table 1). Chronic pain was significantly associated with age 30 years or older, being married or having been married previously, injury during combat, combat intensity, PTSD, and MDD (Table 2). Opioid use was associated with sex, age 25 years or older, being married, rank, injury during combat, chronic pain, and pain severity (Table 2).

Discussion - The prevalence of chronic pain (44.0%) and opioid use (15.1%) in this non-treatment-seeking infantry sample were higher than estimates in the general civilian population of 26.0% and 4.0%, respectively.² These results are notable because this is an operational unit of young soldiers surveyed at their workplace and are likely, in part, related to deployment effects (including injuries, combat exposure, and mental health conditions). These findings suggest a large unmet need for assessment, management, and treatment of chronic pain and related opioid use and misuse in military personnel after combat deployments. Notably, 44.1% of soldiers reporting opioid use reported no or mild past-month pain, including 5.6% with no pain. This might imply that opioids are working to mitigate pain, but it is also possible that soldiers are receiving or using these medications unnecessarily. This is cause for concern because opioids should be prescribed generally for moderate to severe pain^{1,3} and have high abuse and overdose potential.¹⁻³ Prescription practices should be examined to ensure that opioid use is consistent with standards of care and practice guidelines and nonopioid alternatives are considered whenever possible.^{1,3} The benefits of opioids for treating pain, particularly in those with combat-related injuries, must be balanced by careful assessment of risks, including the potential for misuse.

4. The Pharmacokinetics, Efficacy, Safety, and Ease of Use of a Novel Portable Metered-Dose Cannabis Inhaler in Patients With Chronic Neuropathic Pain: A Phase 1a Study¹²³

Abstract: Chronic neuropathic pain is often refractory to standard pharmacological treatments. Although growing evidence supports the use of inhaled cannabis for neuropathic pain, the lack of standard inhaled dosing plays a major obstacle in cannabis becoming a “main stream”

pharmacological treatment for neuropathic pain. The objective of this study was to explore the pharmacokinetics, safety, tolerability, efficacy, and ease of use of a novel portable thermal-metered-dose inhaler (tMDI) for cannabis in a cohort of eight patients suffering from chronic neuropathic pain and on a stable analgesic regimen including medicinal cannabis. In a single-dose, open-label study, patients inhaled a single 15.1 ± 0.1 mg dose of cannabis using the Syqe Inhaler device. Blood samples for 9-tetrahydrocannabinol (THC) and 11-hydroxy-9-THC were taken at baseline and up to 120 minutes. Pain intensity (0–10 VAS), adverse events, and satisfaction score were monitored following the inhalation. A uniform pharmacokinetic profile was exhibited across all participants (9-THC plasma $C_{max} \pm SD$ was 38 ± 10 ng/mL, $T_{max} \pm SD$ was 3 ± 1 minutes, $AUC_{0 \rightarrow \infty} \pm SD$ was 607 ± 200 ng·min/mL). Higher plasma C_{max} increase per mg 9-THC administered (12.3 ng/mL/mg THC) and lower interindividual variability of C_{max} (25.3%), compared with reported alternative modes of THC delivery, were measured. A significant 45% reduction in pain intensity was noted 20 minutes post inhalation ($P = .001$), turning back to baseline within 90 minutes. Tolerable, light-headedness, lasting 15–30 minutes and requiring no intervention, was the only reported adverse event. This trial suggests the potential use of the Syqe Inhaler device as a smokeless delivery system of medicinal cannabis, producing a 9-THC pharmacokinetic profile with low interindividual variation of C_{max} , achieving pharmaceutical standards for inhaled drugs.



APPENDIX B

1. List of Potential PTSD Medication Side Effects

Cannabis	Zoloft	Paxil	
altered senses	Nausea,	headache	tenderness or swelling of joints
altered sense of time	diarrhea,	dizziness	muscle weakness or tightness
changes in mood	constipation,	weakness	flushing
impaired body movement	vomiting	difficulty concentrating	sore teeth and gums
difficulty with thinking and problem-solving	dry mouth	nervousness	unusual dreams
impaired memory	gas or bloating	forgetfulness	painful or irregular menstruation
breathing problems	loss of appetite	confusion	seeing things or hearing voices that do not exist (hallucinating)
Increased heart rate	weight changes	sleepiness or feeling "drugged"	fainting
hallucinations and paranoia	drowsiness	nausea	rapid, pounding, or irregular heartbeat
	dizziness	vomiting	chest pain
	excessive tiredness	diarrhea	difficulty breathing
	headache	constipation	seizures
	pain, burning, or tingling in the hands or feet	gas	fever, sweating, confusion, fast or irregular heartbeat, and severe muscle stiffness or twitching
	nervousness	stomach pain	abnormal bleeding or bruising
	uncontrollable shaking of a part of the body	heartburn	tiny red spots directly under the skin
	sore throat	changes in ability to taste food	peeling or blistering of skin
	changes in sex drive or ability	decreased appetite	sore throat, fever, chills, cough, and other signs of infection
	excessive sweating	weight loss or gain	uncontrollable shaking of a part of the body
	seizures	changes in sex drive or ability	unsteady walking that may cause falling
	fever	dry mouth	sudden muscle twitching or jerking that you cannot control
	abnormal bleeding or bruising	sweating	numbness or tingling in your hands, feet, arms, or legs
	sweating	yawning	difficult, frequent, or painful urination
	confusion	sensitivity to light	swelling, itching, burning, or infection in the vagina
	fast or irregular heartbeat	lump or tightness in throat	painful erection that lasts for hours
	severe muscle stiffness	pain anywhere in the body	sudden nausea, vomiting, weakness, cramping, bloating, swelling, tightness in hands and feet, dizziness, headache and/or confusion
		hoarseness	hives
		black and tarry stools	skin rash
		red blood in stools	itching
		bloody vomit	swelling of the face, throat, tongue, lips, eyes, hands, feet, ankles, or lower legs
		vomit that looks like coffee grounds	tenderness, swelling, or bruising of one part of your body
		bone pain	

Table 8 List of potential Side Effects of Cannabis\Zoloft\Paxil, Data collected from U.S. National Library of Medicine and NIH, National Institute on Drug Abuse.

2. List of Potential Chronic Pain Medication Side Effects

Opioids	Muscle Relaxants	NSAIDs	Anticonvulsants	Antidepressants
nausea	drowsiness	constipation	tiredness	See Table # (Paxil & Zoloft)
vomiting	dry mouth	diarrhea	dizziness	
loss of appetite	dizziness	gas or bloating	headache	
dry mouth	upset stomach	dizziness	dry mouth	
dizziness	severe skin rash	nervousness	nausea	
stomach pain	swelling of the face or tongue	ringing in the ears	vomiting	
drowsiness	difficulty breathing or swallowing	unexplained weight gain	constipation	
flushing	irregular heart rate	fever	gas	
sweating	chest pain	blisters	bloating	
weakness	fever	rash	"high" or elevated mood	
headache	seizures	itching	speech problems	
mood changes		hives	difficulty concentrating or paying attention	
fast or slow heartbeat		swelling of the eyes, face, throat, arms, hands, feet, ankles, or lower legs	confusion	
chest pain		difficulty breathing or swallowing	difficulty remembering or forgetfulness	
hives		hoarseness	anxiety	
itching		excessive tiredness	lack of coordination	
rash		pain in the upper right part of the stomach	loss of balance or unsteadiness	
swelling of the face, throat, tongue, lips, eyes, hands, feet, ankles, or lower legs		nausea	uncontrollable shaking or jerking of a part of the body	
hoarseness		loss of appetite	muscle twitching	
difficulty breathing or swallowing		yellowing of the skin or eyes	weakness	
seizures		flu-like symptoms	increased appetite	
extreme drowsiness		pale skin	weight gain	
lightheadedness when changing positions		fast heartbeat	swelling of the arms, hands, feet, ankles, or lower legs	
		cloudy, discolored, or bloody urine	back pain	
		back pain	blurred vision, double vision, or other changes in eyesight	
		difficult or painful urination	hives	
		blurred vision, changes in color vision, or other vision problems	rash	
		red or painful eyes	itching	
		stiff neck	blisters	
		headache	swelling of the eyes face, throat, mouth, lips, gums, tongue, head or neck	
		confusion	shortness of breath	
		aggression	wheezing	
			muscle pain, tenderness, soreness, or weakness, especially if it comes along with fever	
			chest pain	

Table 9 List of potential chronic pain medication side effects, Data collected from U.S. National Library of Medicine and NIH, National Institute on Drug Abuse.

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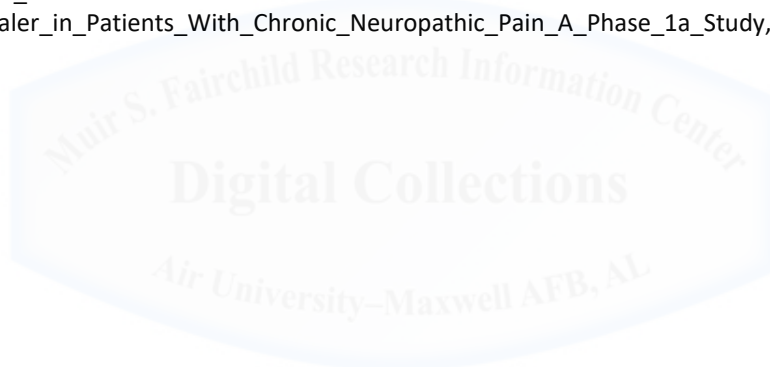
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