

# MEDICAL CANNABIS IN AMERICA

## THE MEDICAL CANNABIS BRIEFING BOOK

**116<sup>TH</sup> CONGRESS**



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THE MEDICAL  
CANNABIS  
BRIEFING BOOK

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**INTRODUCTION.....4**  
MEDICAL CANNABIS BY THE NUMBERS ..... 6

**CHAPTER 1: CANNABIS THERAPEUTICS: THE BASICS.....8**  
KEY POINTS..... 9  
TALKING POINTS..... 10  
THE CANNABIS PLANT .....11  
THE ENDOCANNABINOID SYSTEM ..... 12  
CLINICAL OVERVIEW.....13  
MEDICINAL PREPARATIONS.....15  
THE MEDICAL USE OF CANNABIS ..... 16

**CHAPTER 2: LABORATORIES OF DEMOCRACY: OVERVIEW OF STATE MEDICAL CANNABIS PROGRAMS.. ....18**  
KEY POINTS..... 19  
TALKING POINTS..... 20  
OVERVIEW OF CURRENT MEDICAL CANNABIS PROGRAMS..... 21  
PARTICIPATING PATIENTS AND MEDICAL PROFESSIONALS..... 22  
PRODUCT SAFETY AND THE MEDICAL CANNABIS SUPPLY CHAIN..... 24  
PUBLIC HEALTH IMPACTS OF MEDICAL CANNABIS PROGRAMS 25  
THE ECONOMICS OF MEDICAL CANNABIS PROGRAMS..... 26  
STATE MEDICAL CANNABIS PROGRAM REGULATIONS AND OVERSIGHT ..... 28

**CHAPTER 3: IMPACT OF THE STATE-FEDERAL CONFLICT: WHAT’S AT STAKE..... 30**  
KEY POINTS..... 31  
TALKING POINTS..... 32  
HISTORICAL PERSPECTIVES ..... 33  
THE COST OF WAR..... 36  
THE “CEASEFIRE”: JOYCE-BLUMENAUER AMENDMENT AND ATTORNEY GENERAL COMMITMENTS .....37  
MEDICAL CANNABIS TIMELINE..... 38



**CHAPTER 4: PATIENT TESTIMONIALS... 40**  
KEY POINTS..... 41  
TALKING POINTS..... 42  
TESTIMONIALS..... 43

**CHAPTER 5: ENDING THE FEDERAL CONFLICT THROUGH CURRENT CONGRESSIONAL PROPOSALS ..... 48**  
KEY POINTS..... 49  
TALKING POINTS..... 50  
ROLE OF CONGRESS: LEGISLATIVE NEEDS ..... 51  
LEGISLATIVE EFFORTS 115<sup>TH</sup>, 116<sup>TH</sup> CONGRESSES ..... 52  
APPROPRIATIONS OPPORTUNITIES ..... 55  
REGULATORY IMPACT OF COMPREHENSIVE LEGISLATION ..... 56  
AGENCY ROLES POST-COMPREHENSIVE LEGISLATION..... 58

**CHAPTER 6: ENDING THE FEDERAL CONFLICT: DIRECT ACTION FROM THE PRESIDENT & EXECUTIVE BRANCH ..... 60**  
KEY POINTS..... 61  
POTUS..... 62  
DIVERSE SUPPORT FOR FEDERAL ACTION..... 64  
THE GATEWAY THEORY DISPROVED .....67

**CHAPTER 7: ENDING THE FEDERAL CONFLICT: CHANGING THE PARADIGM ON MEDICAL CANNABIS .. 68**  
KEY POINTS..... 69  
CHANGING THE PARADIGM ON MEDICAL CANNABIS .....70  
AN ACT .....72



# AMERICANS FOR SAFE ACCESS

THE MISSION OF AMERICANS FOR SAFE ACCESS (ASA) IS TO ENSURE SAFE AND LEGAL ACCESS TO CANNABIS (MARIJUANA) FOR THERAPEUTIC USES AND RESEARCH. ASA WORKS WITH OUR GRASSROOTS BASE OF OVER 100,000 MEMBERS AND OUR PROFESSIONAL ADVISORY GROUPS TO EFFECT CHANGE THROUGH PUBLIC EDUCATION, SUPPORT SERVICES, PROFESSIONAL DEVELOPMENT, RESEARCH, LITIGATION, AND DIRECT ADVOCACY AT THE LOCAL, STATE, AND FEDERAL LEVEL.



## INTRODUCTION

Since 1996, 47 states, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, the Commonwealth of the Northern Mariana Islands, and Guam have passed laws that grant their residents the right to possess, cultivate, and/or obtain cannabis (marijuana) or cannabis-based products under the care of their physician. These laws have been passed to address healthcare needs of residents who may benefit from cannabis-based treatments, often where conventional medications have failed. These patient populations include people living with or treating cancer, HIV/AIDS, multiple sclerosis, Crohn's disease, amyotrophic lateral sclerosis (ALS), epilepsy, severe childhood epilepsy disorders such as Dravet syndrome, post-traumatic stress disorder, chronic pain, and a myriad of other conditions.

Today, more than 310 million Americans live under these laws – about 95% of the U.S. population. Americans for Safe Access (ASA) has estimated that these medical cannabis programs serve at least 2.4 million patients under physician supervision. Physicians may now recommend cannabis-based treatments for over 95 medical conditions and symptoms approved through these programs.

After more than 20 years of experimentation, medical cannabis programs now include robust regulations that address public health and safety issues such as diversion for non-medical use and product safety protocols. Studies on these programs have shown little to no negative impact and some positive effects on public health outcomes.

In 2014, an article from the Journal of the American Medical Association found that, “States with medical cannabis laws had a 24.8% lower mean annual opioid overdose mortality rate compared with states without medical cannabis laws.”<sup>1</sup> Several additional studies support this determination. In 2015, the National Bureau of Economic Research reported “Our findings suggest that providing broader access to medical marijuana may have the potential benefit of reducing abuse of highly addictive painkillers.”<sup>2</sup> A study from 2017 demonstrated that states with comprehensive medical cannabis programs saw a 23% reduction in hospitalizations related to opioid dependence or

1 Bachhuber, M.A., Saloner, B., Cunningham, C., et al. Medical Cannabis Laws and Opioid Analgesic Overdose Mortality in the United States 1999-2010. October 2014; Journal of the American Medical Association. 174(10):1668-1673. doi:10.1001/jamainternmed.2014.4005.

2 Powell, D., Pacula, R.L., Jacobson, M. Do Medical Marijuana Laws Reduce Addiction and Deaths Related to Pain Killers? July 2015; NBER Working Paper No. 21345. doi: 10.3386/w21345.

**MEDICAL CANNABIS PROGRAMS SERVE APPROXIMATELY 2.4 MILLION PATIENTS UNDER PHYSICIAN SUPERVISION. THE PURPOSE OF THIS BRIEFING BOOK IS TO PROVIDE MEMBERS OF CONGRESS AND POTUS THE NECESSARY INFORMATION TO MAKE WELL-INFORMED DECISIONS.**

abuse.<sup>3</sup> More recently, a study published in the Journal of General Internal Medicine concluded that “In states where marijuana is available through medical channels, a modestly lower rate of opioid and high-risk opioid prescribing was observed. Policy makers could consider medical marijuana legalization as a tool that may modestly reduce chronic and high-risk opioid use.”<sup>4</sup> Furthermore, states with medical cannabis programs have not experienced increased rates of teen use of cannabis.

Surveys of medical cannabis patients have suggested that cannabis is often used to decrease the use of other drugs. A 2016 study on 2013 Medicare Part D spending from the University of Georgia found that Medicare expenditures were \$165.2 million lower than they otherwise would have been that year thanks to decreases in money spent on prescription drugs across the 17 states and the District of Columbia with medical cannabis laws; reported savings in 2013 would have reached \$468 million if all states had medical cannabis programs.<sup>5</sup> More recent data show that state spending on pain-related health care is 11% lower in states with access to medical or adult-use cannabis.<sup>6</sup>

**However, all of these patients and programs are in violation of federal law.**

For the past six years, state-sponsored medical cannabis programs have operated under the guidance of federal agency memos and Congressionally imposed spending restrictions, which have limited federal interference and created a “ceasefire” for states implementing medical cannabis programs. The relative détente between state programs and federal enforcement has spurred an increase in the number of states with medical cannabis laws, allowing these states to move forward with more robust licensing requirements and product safety protocols.

We contend that a paradigm shift is long overdue. To that end, we have drafted and included within this briefing book legislation to exempt cannabis from the Controlled Substances Act (CSA) and create a new federal agency with centralized regulatory authority.

The U.S. government has recognized the medical value of cannabis, putting current federal law at odds with science. The National Institute on Drug Abuse (NIDA) acknowledges that “THC itself has proven medical benefits in particular formulations.”<sup>7</sup> Two NIDA-funded studies demonstrated a reduction in opioid overdose deaths in states with medical cannabis dispensaries.<sup>8</sup>

The World Health Organization (WHO) has recognized that cannabis has medical benefits and has recommended that the United Nations Commission on Narcotic Drugs vote to remove cannabis and cannabis resin from Schedule IV of the 1961 Single Convention on Narcotic Drugs. The WHO further recommended that cannabis preparations that predominantly contain cannabidiol (CBD) and not more than 0.2% THC be free from international control.<sup>9</sup> Globally, more than 30 countries have developed their own national medical cannabis laws. The United States, which once prided itself on being a bold leader on the international stage, must adapt or continue to lag behind other nations in this regard.

As with the tension between federal law and science, the tension between state and federal laws is untenable. Millions of suffering Americans are being criminalized because the federal government refuses to bring outdated laws in line with reality. The federal government must resolve the conflict with state laws in a manner that protects patient access to medical cannabis, and it must do so now.

3 Shi, Y. Medical Marijuana Policies and Hospitalizations Related to Marijuana and Opioid Pain Reliever. April 2017; Drug and Alcohol Dependence. 173:144-150. doi: 10.1016/j.drugalcdep.2017.01.006.

4 Shah, A., Hayes, C.J., Lakkad, M. et al. Journal of General Internal Medicine. 2019. <https://doi.org/10.1007/s11606-018-4782-2>

5 Bradford, A. and Bradford, W. Medical Marijuana Laws Reduce Prescription Medication Use in Medicare Part D. July 2016; Health Affairs 35(7). <https://doi.org/10.1377/hlthaff.2015.1661>

6 New Frontier Data. Understanding Cannabis. Jan. 2019.

7 National Institute on Drug Abuse. Is Marijuana Safe and Effective as Medicine? Updated June 2018. Available from <https://www.drugabuse.gov/publications/research-reports/marijuana/marijuana-safe-effective-medicine>

8 *Id.*

9 World Health Organization, Letter to Secretary General, *Cannabis and Cannabis Related Substances*, (Jan 24, 2019).

## MEDICAL CANNABIS BY THE NUMBERS

47

States with Medical  
Cannabis Laws



0

Deaths Caused by Cannabis



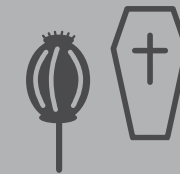
30,000+

Studies Published on the  
Endocannabinoid System



↓ 25%

Average Drop in Opiate Related  
Deaths in States with Medical  
Cannabis Laws



2.4 MIL.+

Medical Cannabis Patients  
in the US



\$500+ MIL.

Federal Tax Dollars Spent on Federal  
Interference in Medical Cannabis  
States before Rohrabacher-Farr  
CJS Amendment. (Now the Joyce-  
Blumenauer Language in the Base CJS  
Appropriations Bill)



\$165 MIL.

Federal Prescription Drug  
Cost Savings in Medical Cannabis  
States in 2013



93%

Americans Supporting  
Medical Cannabis



9,000+

Clinical Trial Data Using Cannabis  
for Pain in Patient Years



113+

Known Cannabinoids



70,237

Deaths Caused by Prescription  
Drugs in 2017



126 MIL.+

Number of Americans Suffering  
from Pain in the Past Three Months



95+

Qualifying Medical Conditions in  
Medical Cannabis Programs



# 1

## CANNABIS THERAPEUTICS: THE BASICS

KEY POINTS  
TALKING POINTS

1. THE CANNABIS PLANT
2. THE ENDOCANNABINOID SYSTEM
3. CLINICAL OVERVIEW: CANNABINOIDS, TERPENES, AND THE ECS
4. MEDICINAL PREPARATIONS



### KEY POINTS

- CANNABIS WAS AVAILABLE IN PHARMACIES AND A PART OF THE U.S. PHARMACOPOEIA UNTIL 1942, WHEN IT WAS REMOVED ALONG WITH OVER 200 OTHER NATURAL COMPOUNDS LIKE ST. JOHN'S WORT AND ECHINACEA. THESE HERBAL MEDICINES DID NOT RETURN TO THE U.S. PHARMACOPOEIA UNTIL 2004.
- CANNABIS HAS BEEN USED MEDICINALLY FOR THOUSANDS OF YEARS, BUT IT WAS NOT UNTIL THE DISCOVERY OF THE CB1 RECEPTOR IN 1988 THAT SCIENTISTS COULD EXPLAIN THE VAST INTERACTIONS IN THE HUMAN BODY.
- IN THE SAME WAY THAT OPIATES MIMIC ENDORPHINS THAT INTERACT WITH OPIATE RECEPTORS, COMPOUNDS CONTAINED IN CANNABIS (CANNABINOIDS) MIMIC ENDOCANNABINOIDS THAT INTERACT WITH ENDOCANNABINOID SYSTEM (ECS) RECEPTORS.
- THE ECS IS A SOPHISTICATED GROUP OF LIGANDS, THEIR RECEPTORS, AND SIGNALING PATHWAYS THAT ARE INVOLVED IN REGULATING A VARIETY OF PHYSIOLOGICAL PROCESSES INCLUDING MOVEMENT, MOOD, MEMORY, APPETITE, AND PAIN.
- A LETHAL TOXIC OVERDOSE OF CANNABIS HAS NEVER BEEN DOCUMENTED, BECAUSE UNLIKE OPIATES, CANNABIS COMPOUNDS DO NOT DEPRESS RESPIRATION OR HEART FUNCTION.
- PATIENTS' PREFERENCE FOR WHOLE PLANT CANNABIS VS SYNTHETIC CANNABINOID-BASED DRUGS IS SUPPORTED BY SCIENTIFIC CONSENSUS REGARDING THE THERAPEUTIC "ENTOURAGE EFFECT" CREATED BY INTERACTIONS AMONG VARIOUS CANNABINOIDS AND TERPENES.
- THE THERAPEUTIC USE OF CANNABIS IS SUPPORTED BY OVER 30,000 PUBLISHED STUDIES ON THE ECS AND OVER 9,000 PATIENT YEARS OF CLINICAL TRIAL DATA DOCUMENTING SUCCESSFUL USE OF CANNABIS FOR TREATING PAIN.
- THE NEUROPROTECTIVE QUALITIES OF CANNABIS PRESENT ENORMOUS POTENTIAL IN PROTECTING THE BRAIN AND CENTRAL NERVOUS SYSTEM FROM THE DAMAGE OF DISEASE OR INJURY.
- PATIENTS USE A VARIETY OF DELIVERY METHODS (E.G., EDIBLES, OILS, SPRAY) TO ACHIEVE DESIRED THERAPEUTIC EFFECTS FROM CANNABIS.





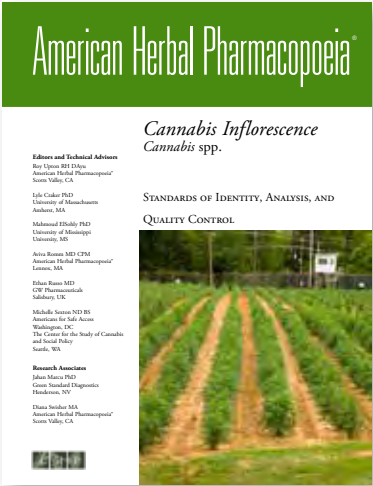
TALKING POINTS

- ◆ CANNABIS HAS BEEN USED MEDICINALLY FOR THOUSANDS OF YEARS, BUT IT WAS NOT UNTIL THE DISCOVERY OF THE BODY’S NATURAL ENDOCANNABINOID SYSTEM (ECS) IN 1988 THAT SCIENTISTS UNDERSTOOD HOW CANNABIS AFFECTS PHYSIOLOGICAL PROCESSES, INCLUDING MOVEMENT, MOOD, MEMORY, APPETITE, AND PAIN.
- ◆ THE THERAPEUTIC USE OF CANNABIS IS SUPPORTED BY OVER 30,000 PUBLISHED STUDIES ON THE ECS AND OVER 9,000 PATIENT YEARS OF CLINICAL TRIAL DATA DOCUMENTING SUCCESSFUL USE OF CANNABIS FOR TREATING PAIN.
- ◆ A DIVERSE GROUP OF MEDICAL ASSOCIATIONS AND PATIENT ADVOCACY ORGANIZATIONS SUPPORT THE USE OF MEDICAL CANNABIS.
- ◆ MEDICAL CANNABIS IS AN ESSENTIAL TOOL TO REDUCE OPIOID DEATHS IN AMERICA.

MYTH: SMOKING CANNABIS CAUSES SEVERE LUNG DAMAGE.

**FACT: THERE HAVE BEEN VERY LARGE, CONTROLLED STUDIES THAT HAVE FAILED TO FIND ANY LONG-TERM PULMONARY EFFECTS IN PEOPLE WHO ARE SMOKING CANNABIS. THERE MAY BE A FEW CHANGES IN LUNG FUNCTION, BUT THERE AREN'T ANY OF THE CHANGES THAT YOU SEE WITH CHRONIC CIGARETTE SMOKING.**

Citation: Ware, M. Cannabis and the Lung, No More Smoking Gun?. *Annals of the American Thoracic Society*. June 2013; Vol. 10, No. 3.



1. THE CANNABIS PLANT

Cannabis is a flowering plant that has fibrous stalks used for paper, clothing, rope, and building materials. The leaves, flowers, and roots have been documented for medicinal purposes for millennia. Cannabis leaves and flowers are consumed in several forms: dried flower buds or various types of concentrated, loose, or pressed resin that is extracted through a variety of methods.



Once mature, the plant’s leaves and flowers become covered with trichomes, tiny glands of resinous oil containing cannabinoids and terpenes, medicinal compounds found in the cannabis plant. There are at least 113 cannabinoids and a minimum of 554 known compounds in the cannabis plant. Cannabis varieties produce different types of terpenes and cannabinoid profiles.

Cannabis was available in pharmacies and was part of the U.S. Pharmacopoeia until 1942, when it was removed along with over 200 other natural compounds like St. John’s wort and Echinacea. Medicinal herbal products such as St. John’s Wort and Echinacea did not return to the U.S. Pharmacopoeia until 2004. In 2013, the American Herbal Pharmacopoeia published the first cannabis monograph, Cannabis Inflorescence: Standards of Identity, Analysis, and Quality Control, to provide scientifically valid methods for cannabis and its preparations.

## 2. THE ENDOCANNABINOID SYSTEM

Humans have used drugs derived from plants such as the opium poppy for thousands of years to lessen pain and produce euphoria. In 1973, scientists discovered the brain receptors that interact with these opiates, which include opium, morphine, and heroin. In 1975, the first of the brain's natural chemicals that stimulate these receptors was identified. The similarity of this chemical, enkephalin, to morphine suggested opiate drugs work primarily by mimicking natural opiate-like molecules. The discovery of this endorphin (a term meaning endogenous morphine) system helped explain the effects of opiate drugs and opened the door to the development of powerful new therapeutic drugs that revolutionized pain management.

Similarly, humans have used the cannabis plant for thousands of years to reduce pain, control nausea, stimulate appetite, control anxiety, and produce feelings of euphoria. The first cannabinoid was isolated in 1899, but it wasn't until 1964 that THC was isolated. Since the discovery of THC, researchers have made new discoveries that help us better understand not just why and how cannabis works so well for so many people, but its full therapeutic potential.

In 1988, the first cannabinoid receptor in the human body, CB1, was discovered. Four years later, a second receptor, CB2, was discovered. Scientists found that the body produces its own cannabinoids, such as the endocannabinoid anandamide. These endocannabinoids work by stimulating cannabinoid receptors. This system of sophisticated compounds, their receptors, and signaling pathways is now known as the Endocannabinoid System (ECS). The ECS is probably the most ubiquitous system in the human body, with the cannabinoid receptors CB1 and CB2 abundantly located throughout the brain and the periphery of the body.<sup>1</sup> This system is involved in regulating a variety of physiological processes, including movement, mood, memory, appetite, and pain.

The ECS is the body's own mechanism for preserving homeostasis, keeping all body functions running smoothly. Unlike opiate receptors, cannabinoid receptors do not lower respiratory rate or heart function. A lethal toxic overdose of cannabis has never been documented because cannabinoid receptors are not found in the areas of the brain that control breathing. However, CB1 receptors are found elsewhere in the central nervous system and in other organs and tissues, such as the eyes, lungs, kidneys, liver, and digestive tract. CB2 receptors are primarily located in tissues associated with immune function, such as the spleen, thymus, tonsils, bone marrow, and white blood cells.



THE SHINY RESIN ON CANNABIS FLOWER BUDS IS WHERE THE MAJORITY OF MEDICINAL CANNABINOIDS ARE LOCATED.

MYTH: "MARIJUANA IS A GATEWAY DRUG." - CHRIS CHRISTIE (FORMER GOVERNOR, NJ)

**FACT: THE GATEWAY THEORY HAS BEEN DISPROVED. IN THE DENIAL OF A PETITION TO RESCHEDULE CANNABIS, THE DRUG ENFORCEMENT ADMINISTRATION (DEA) CITED THE FDA'S FINDING THAT "OVERALL, RESEARCH DOES NOT SUPPORT A DIRECT CAUSAL RELATIONSHIP BETWEEN REGULAR CANNABIS USE AND OTHER ILLICIT DRUG USE."**

Citation: Drug Enforcement Administration. Denial of Petition To Initiate Proceedings To Reschedule Marijuana. *Federal Register*. August 2016; 53687-53766. 81 FR 53687.

## 3. CLINICAL OVERVIEW

The therapeutic benefits of cannabis are derived from the interactions of cannabinoids, terpenes, and the ECS. Of the 113+ cannabinoids found in the cannabis plant, scientists have identified a handful of those that are most active. Researchers have also found that the therapeutic effects are the result of cannabinoids and terpenes working synergistically to enhance their impact: the "entourage effect."

- Cannabidiol (CBD) is a non-intoxicating cannabis compound that counteracts the psychoactivity of THC. Research points to CBD's potential in the treatment of inflammation, pain, anxiety, seizures, and spasms. Like all cannabinoids, CBD is a potent antioxidant and neuroprotectant.
- Tetrahydrocannabinol (THC) is found in certain varieties of the cannabis plant. THC has psychoactive effects. Scientific and clinical research has pointed to its potential in the treatment of many conditions, including chronic pain, PTSD, nausea and vomiting, asthma, glaucoma, and insomnia.
- Tetrahydrocannabinolic acid (THCA) is a non-psychoactive cannabinoid found in raw and live cannabis. As cannabis dries, THCA slowly converts to THC. Heat converts THCA to THC via decarboxylation, which describes what happens when one smokes or vaporizes cannabis. THCA interacts with many targets and has anti-inflammatory, immunomodulatory, neuroprotective, and anticancer properties.
- Cannabigerol (CBG) can affect serotonin reuptake, relieve pain in skin conditions, and inhibit the growth of cancer cells. CBG has a lot of therapeutic potential as an antidepressant and in the treatment of psoriasis and other skin conditions.
- Cannabichromene (CBC) relieves pain, has anti-inflammatory effects, and is reported to have strong antimicrobial properties while lacking toxicity.
- Cannabinol (CBN) is the non-intoxicating degradation product of THC and other cannabinoids. It has sedating, anti-microbial, analgesic, and anti-inflammatory properties, and it may stimulate bone growth.
- Terpenes are constituents of the essential oil of cannabis and are synthesized in trichomes. Terpenes are not unique to cannabis, but are found on other plants such as lavender, hops, mangoes, citrus fruit, pine trees, pepper, and green tea. Terpenes, not cannabinoids, are responsible for the smell of cannabis. All terpenes found on cannabis are FDA-approved as generally regarded as safe (GRAS). Terpenes produce therapeutic effects when inhaled, even at ambient air levels, that can enhance the effects of cannabinoids. Terpenes can modulate the effects of cannabinoids through pain relieving, muscle relaxing, sedative, anxiolytic (anti-anxiety), and antidepressant effects.

<sup>1</sup> Grotenhermen, F. The therapeutic potential of cannabis and cannabinoids. July 2012; Dtsch Arztebl Int. 109 (PMC3442177):495–501.doi:10.3238/arztebl.2012.0495.



To date, more than 30,000 modern peer-reviewed scientific articles on the chemistry and pharmacology of cannabis and cannabinoids have been published. The research has demonstrated that cannabinoids can act as potent anti-inflammatory, antioxidant, neuroprotective, and neuroregenerative agents. In the treatment of neurodegenerative diseases, cannabinoids have demonstrated efficacy in treating the symptoms of both multiple sclerosis and Parkinson's disease (e.g., pain, spasticity, sleep, urinary dysfunction, motoric symptoms). Cannabis also has a therapeutic potential for treating the symptoms of amyotrophic lateral sclerosis and Huntington's disease. In addition to slowing the progression of these diseases, cannabis has been shown to positively influence both quality of life indicators and the depression inherent to progressive and chronic disorders.

Clinical trials also support the effectiveness of herbal, whole-plant cannabis – either alone, or as adjuvant to opioids – to treat chronic or neuropathic pain, such as pain resulting from spasticity or injuries. Basic medical science has extensively evaluated the pain-relieving effects of the cannabinoids, as well as the mechanism through which they are mediated. Summarily, the cannabinoids are described as producing a significant decrease in perceived pain when administered through nearly any route, with no definable risk of either death or overdose. Similarly, cannabinoids have been shown to attenuate pain induced by various traumas. Myriad clinical studies have been completed in the United States and have shown significant and measurable benefits in subjects receiving cannabis products for pain.

In addition to cannabis' proven efficacy for cancer palliative care, it may confer a direct benefit in cancer treatment as there exists evidence of an additive synergy amongst the chemotherapeutic effects of the cannabinoids with conventional radiation or chemotherapy. Whereas anecdotal reports of chemotherapy-related nausea and antiemetic efficacy of the cannabinoids go back to 1972, more than three dozen clinical studies since 1975 have provided solid, compelling empirical evidence of palliative and antineoplastic value.

The neuroprotective qualities of cannabis mean it has enormous potential in protecting the brain and central nervous system from the damage of disease or injury. Researchers have found that cannabinoids fight the effects of strokes, brain trauma, spinal cord injury, multiple sclerosis, and neurodegenerative diseases.



TINCTURES ALLOW PATIENTS TO CONTROL THEIR DOSAGE THROUGH THE USE OF A DROPPER.

4. MEDICINAL PREPARATIONS

The therapeutic threshold for cannabis is unique to each patient, so unlike most prescription medications, cannabis therapeutics do not come with a specific dose. Patients and their medical professionals choose preparations based on potency and delivery methods (routes of administration) and determine optimal treatment protocols through a process of guided experimentation and self-titration.

Cannabis can be inhaled, ingested, and administered topically, sublingually, or buccally. The method used can depend on personal choice, the medical condition being treated, the age of the patient, the patient's tolerance for the methods, etc. There are several types of products available for each of the delivery methods.


Inhalation is absorption via the internal surface of the lungs. Cannabis can be efficiently and safely inhaled through vaporization. Absorption through the lungs completely bypasses potential drug-drug interactions in the liver. The time to onset is quick and effects last for over an hour.

Ingestion is absorption via the internal surfaces of the stomach and intestines. Cannabis products can be swallowed and absorbed through the gut, similar to other vitamins and herbal supplements. This requires first-pass metabolism in the liver before becoming active. The time to onset varies greatly (hours) and the duration of effects is longer.


Topical applications are absorbed via the external surface of the skin. Cannabis can be used topically without reaching the bloodstream if specially formulated to do so. Topical applications of cannabis have a rapid onset (potentially less than a minute) and can provide hours of relief.

Oral administration is the absorption of a drug by the internal surfaces of the mouth. Cannabis sprays, such as those made with ethanol, can be absorbed through the cheeks (buccally) or under the tongue (sublingually). Onset occurs within minutes to an hour and first-pass liver metabolism is avoided.

SAMPLE MEDICAL CANNABIS LABEL



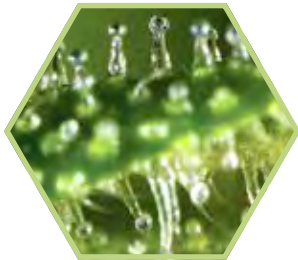
ndc333333



Do not drive a motor vehicle or operate heavy machinery while using this product.  
This product is for medical use and not for resale or transfer to another person.

Qty	90.25 (g)	<b>Date tested</b> 10/17/2018
Batch/Lot#:	ndc3333333	
Date Pkgd:	10/22/2018	
Use by:	04/22/2019	
Ingredients:	Cannabis	
THCA	< 1%	<b>Microbiology:</b> Pass
CBD	.12%	<b>Mycotoxin:</b> Pass
CBDA	.11%	<b>Pesticide:</b> Pass
		<b>Solvent Residue:</b> Pass

THE MEDICAL USE OF CANNABIS



**TRICHOMES**  
Resin-filled glands that contain the majority of the THC in a cannabis plant. They are typically a cloudy white color when ready for harvest.

DELIVERY METHODS

PATIENTS USE MANY METHODS TO TAKE CANNABIS. THE METHOD USED CAN DEPEND ON PERSONAL CHOICE, THE MEDICAL CONDITION BEING TREATED, THE AGE OF THE PATIENT, THE PATIENT'S TOLERANCE FOR THE METHODS, ETC.

INHALATION

**Types of products:** whole plant, oils, waxes, and concentrates  
**Expected onset:** 0-10 minutes  
**Duration:** 1-4 hours



INGESTION

**Product types:** edible products, beverages, teas, capsules  
**Expected onset:** 30 to 90 minutes  
**Duration:** Up to 8 hours



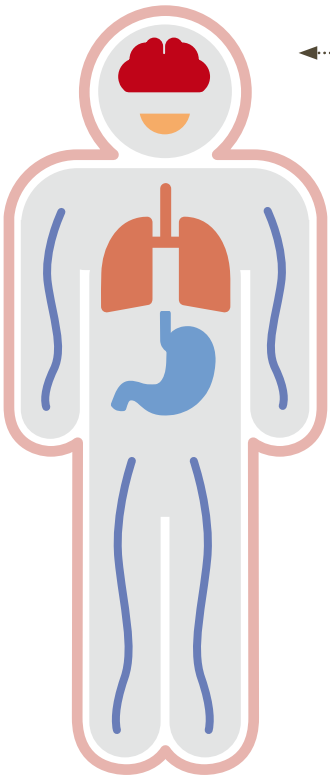
TOPICAL

**Product types:** lotions, salves, oils  
**Expected onset:** a few minutes  
**Duration:** 1-4 hours



ORAL

**Product types:** alcohol-based tinctures, lozenges  
**Expected onset:** 0-60 minutes  
**Duration:** 1-8 hours



AmericansForSafeAccess.org

ECS: EAT, SLEEP, RELAX, FORGET, AND PROTECT

The endocannabinoid system is the body's mechanism for preserving homeostasis (keeping all body functions running smoothly). This system is composed of a sophisticated group of neuromodulators, their receptors, and signaling pathways involved in regulating a variety of physiological processes including movement, mood, memory, appetite, and pain.

The endocannabinoid system is probably the most ubiquitous system in the human body, with the cannabinoid receptors **CB<sub>1</sub>** and **CB<sub>2</sub>** located throughout the brain and the periphery of the body.

Inflorescence Cannabis (flower)

**BENEFIT**  
Anti-inflammatory, immunomodulatory, neuroprotective, anti-cancer

THCA-A

**BENEFIT**  
Effective against MRSA, sedative, topical analgesic for burns, may stimulate bone growth

CBN

CBD

**BENEFIT**  
Non-intoxicating, antiepileptic, anti-inflammatory, anti-convulsant, anti-emetic, anxiolytic, analgesic, muscle relaxant

THC

**BENEFIT**  
Psychotropic, analgesic, anti-inflammatory, anti-microbial, muscle relaxant

CBC

**BENEFIT**  
Anti-inflammatory, analgesic, anti-anxiety, antidepressant

CBG

**BENEFIT**  
Muscle relaxant, anti-eurythmic, analgesic, digestive aid

CANNABINOIDS & TERPENOIDS



LEMON

LIMONENE

Potent immunostimulant via inhalation, anxiolytic, apoptosis of breast cancer cells and acne bacteria  
SYNERGISTIC CANNABINOIDS: **CBD, CBG, THC**



PINE

α-PINENE

Anti-inflammatory, bronchodilatory, acetylcholinesterase inhibitor (aiding memory)  
SYNERGISTIC CANNABINOIDS: **CBD, THC**



HOPS

β-MYRCENE

Blocks inflammation, analgesic, sedative, muscle relaxant, hypnotic, blocks hepatic carcinogenesis by aflatoxin  
SYNERGISTIC CANNABINOIDS: **CBD, CBG, THC**



LAVENDER

LINALOOL

Anti-anxiety, local anesthetic, analgesic, anticonvulsant/anti-glutamate  
SYNERGISTIC CANNABINOIDS: **CBD, THC, THCV, CBDV**



PEPPER

β-CARYOPHYLLENE

Gastric cytoprotective, anti-malarial, selective CB<sub>2</sub> agonist, anti-inflammatory  
SYNERGISTIC CANNABINOIDS: **THC**



ORANGE

NEROLIDOL

Sedative  
SYNERGISTIC CANNABINOIDS: **THC, CBN**



GREEN TEA

PHYTOL

GABA via SSADH inhibition  
SYNERGISTIC CANNABINOIDS: **CBG**



POTENTIAL SIDE EFFECTS

Sedation, dizziness, nausea, vomiting, constipation, physical dependence, tolerance, respiratory depression, death



POTENTIAL SIDE EFFECTS

Liver failure, loss of language, cognitive decline, respiratory depression, rage, suicide, paranoia, death



POTENTIAL SIDE EFFECTS

Dry mouth, dizziness, increased appetite, dry eyes, sedation, euphoria, disorientation/short-term memory impairment



YEARLY DEATHS 2017



OPIOIDS

47,600

Nearly 36% from prescribed opioids



PRESCRIPTION DRUGS

70,200 +

(Source CDC 2018)



CANNABIS

0

# 2

## LABORATORIES OF DEMOCRACY: OVERVIEW OF STATE MEDICAL CANNABIS PROGRAMS

### KEY POINTS TALKING POINTS

1. OVERVIEW OF CURRENT MEDICAL CANNABIS PROGRAMS
2. PARTICIPATING PATIENTS AND MEDICAL PROFESSIONALS
3. PRODUCT SAFETY AND THE MEDICAL CANNABIS SUPPLY CHAIN
4. PUBLIC HEALTH IMPACTS OF MEDICAL CANNABIS PROGRAMS
5. THE ECONOMICS OF MEDICAL CANNABIS PROGRAMS



### KEY POINTS

- 47 STATES HAVE MEDICAL CANNABIS LAWS: 33 STATES (PLUS THE DISTRICT OF COLUMBIA, PUERTO RICO, THE U.S. VIRGIN ISLANDS, THE COMMONWEALTH OF THE NORTHERN MARIANA ISLANDS, AND GUAM) HAVE PASSED COMPREHENSIVE LEGISLATION AND 14 ADDITIONAL STATES HAVE MORE RESTRICTIVE CBD/CANNABIS LAWS.
- IT IS ESTIMATED THAT THE CURRENT NUMBER OF LEGAL CANNABIS PATIENTS IN THE U.S. IS 2.4 MILLION AND GROWING.
- ACCORDING TO MEDSCAPE, 67% OF U.S. PHYSICIANS BELIEVE MEDICAL CANNABIS SHOULD BE AN OPTION FOR PATIENTS. PHYSICIANS CAN ACT IN ACCORDANCE WITH THE FEDERATION OF STATE MEDICAL BOARD'S "MODEL GUIDELINES FOR THE RECOMMENDATION OF MARIJUANA IN PATIENT CARE."
- STATE MEDICAL CANNABIS PROGRAMS HAVE EVOLVED INTO HIGHLY REGULATED PROGRAMS THAT INCLUDE AN ARDUOUS APPLICATION PROCESS, PRODUCT SAFETY PROTOCOLS WITH EXTENSIVE LABORATORY TESTING, RULES FOR DOCTORS AND PATIENTS, AND STATE COMPLIANCE INSPECTIONS.
- ORGANIZATIONS LIKE THE AMERICAN HERBAL PRODUCTS ASSOCIATION (AHPA), THE AMERICAN SOCIETY FOR TESTING AND MATERIALS (ASTM), AND THE AMERICAN HERBAL PHARMACOPOEIA (AHP) ARE WORKING WITH THE CANNABIS INDUSTRY AND GOVERNMENTS TO ENSURE PRODUCT SAFETY.
- STATES WITH MEDICAL CANNABIS PROGRAMS HAVE NOT EXPERIENCED INCREASED RATES OF TEEN USE OF CANNABIS OR HIGHWAY FATALITIES. THEY HAVE, HOWEVER, EXPERIENCED A 24.8% LOWER MEAN ANNUAL OPIOID OVERDOSE MORTALITY RATE COMPARED WITH STATES WITHOUT MEDICAL CANNABIS LAWS.
- MEDICAL CANNABIS PROGRAMS SAVED THE MEDICARE PART D DRUG PROGRAM MORE THAN \$165 MILLION IN 2013 DUE TO A DECREASE IN PRESCRIPTION MEDICATIONS. MEDICAID SAVINGS COULD HAVE REACHED \$1.01 BILLION IF MEDICAL CANNABIS WAS LEGAL ACROSS THE NATION.
- WORKPLACE ABSENCES DUE TO ILLNESS DROPPED 8-15% PERCENT AMONG VARIOUS SUBGROUPS IN STATES WITH MEDICAL CANNABIS LAWS.





TALKING POINTS

- ◆ 47 STATES HAVE MEDICAL CANNABIS LAWS: 33 STATES (PLUS THE DISTRICT OF COLUMBIA, AND FOUR OUT OF THE FIVE U.S. TERRITORIES) HAVE PASSED COMPREHENSIVE LEGISLATION AND 14 ADDITIONAL STATES HAVE MORE RESTRICTIVE CBD/CANNABIS LAWS.
- ◆ STATE MEDICAL CANNABIS PROGRAMS ARE HIGHLY REGULATED AND INCLUDE PRODUCT SAFETY PROTOCOLS WITH EXTENSIVE LABORATORY TESTING, RULES FOR DOCTORS AND PATIENTS, AND STATE COMPLIANCE INSPECTIONS.
- ◆ STATES WITH MEDICAL CANNABIS PROGRAMS HAVE NOT EXPERIENCED INCREASED RATES OF TEEN USE OF CANNABIS OR HIGHWAY FATALITIES. THEY HAVE, HOWEVER, EXPERIENCED A 24.8% LOWER MEAN ANNUAL OPIOID OVERDOSE MORTALITY RATE COMPARED WITH STATES WITHOUT MEDICAL CANNABIS LAWS.
- ◆ 67% OF U.S. PHYSICIANS ARE SUPPORTIVE OF THE USE OF MEDICAL CANNABIS.
- ◆ MEDICAL CANNABIS PROGRAMS SAVED THE MEDICARE PART D DRUG PROGRAM MORE THAN \$165 MILLION IN 2013 DUE TO A DECREASE IN PRESCRIPTION MEDICATIONS. MEDICAID SAVINGS COULD HAVE REACHED \$1.01 BILLION IF MEDICAL CANNABIS WAS LEGAL ACROSS THE NATION.
- ◆ THE RAPID GROWTH OF THE CANNABIS INDUSTRY IS OFTEN REPORTED TO BE LIKE THE WILD WEST, BUT THE INCREASINGLY ROBUST REGULATIONS FOR MEDICAL CANNABIS ADHERE TO STRICT SCIENTIFIC STANDARDS.
- ◆ GONE ARE THE STEREOTYPES. TODAY OUR INDUSTRY’S SELF-REGULATION HAS THE SCIENTIFIC BACKING OF THE AMERICAN MEDICAL ASSOCIATION, THE AMERICAN HERBAL PRODUCTS ASSOCIATION, THE AMERICAN SOCIETY FOR TESTING AND MATERIALS (ASTM), AND DOCTORS AT HARVARD MEDICAL SCHOOL.



PHYSICIANS ARE BETTER QUALIFIED TO DETERMINE IF MEDICAL CANNABIS IS APPROPRIATE FOR THEIR PATIENTS THAN POLITICIANS.

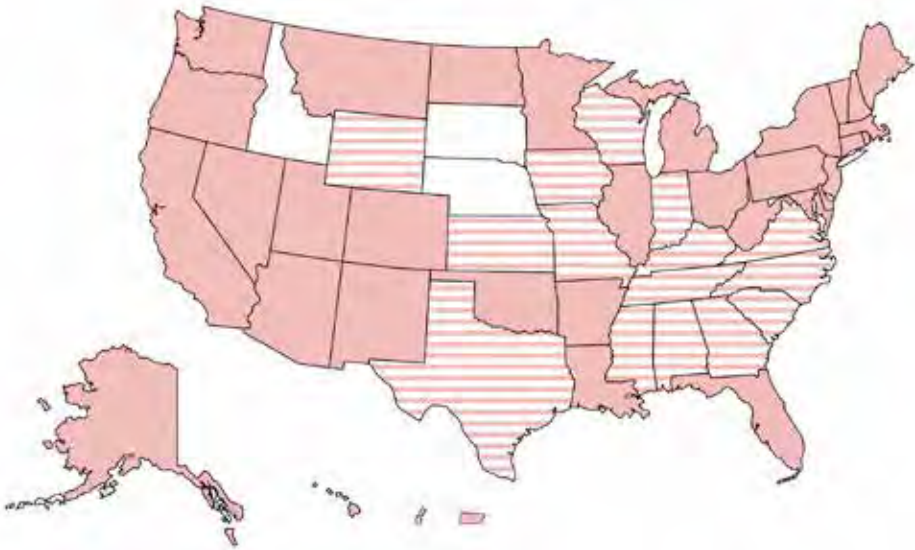
1. OVERVIEW OF CURRENT MEDICAL CANNABIS PROGRAMS

Thirty-three states, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, the Commonwealth of Northern Mariana Islands, and Guam have all passed comprehensive medical cannabis laws. These states cover over 95 qualifying conditions, with some states leaving it to the discretion of physicians to decide when medical cannabis would be an appropriate therapy. Another 14 states have more restrictive laws that only allow for the medical use of cannabidiol (CBD) oil. These programs are overseen by local, state, and federal regulations. After a law is enacted, state agencies create a series of regulations that govern everyone participating in the program and all products produced.

Current medical cannabis laws are a byproduct of a movement of doctors, scientists, patients, their families, and policymakers advocating to allow patients safe access. Over the last 30 years, medical cannabis laws have evolved from “criminal exemption laws” into highly regulated programs that include an arduous application process, product safety protocols with extensive monitoring and laboratory testing, rules for doctors and patients, and state compliance inspections.

The first medical cannabis states such as California, Oregon, and Washington passed laws to protect qualified patients from arrest and prosecution and allowed them to cultivate limited amounts of cannabis. These laws anticipated that patients would need to obtain their medicine from a legal market but provided no framework to make that happen. By the late 2000s, production and distribution programs were included in every new law.

In 2011, the American Herbal Products Association (AHPA), the principal U.S. trade association and voice of the herbal products industry, created industry-wide product safety protocols for commercial cultivation, manufacturing, distribution, and laboratory testing of medical cannabis products. In 2013, the American Herbal Pharmacopoeia (AHP) issued the Cannabis Inflorescence Monograph, a comprehensive description of the plant’s botany, constituent



components, analysis, and quality control. This monograph, authored by the world's leading experts on the plant, provides scientifically valid methods of testing the identity, purity, potency, and quality of cannabis products. Both the AHPA and AHP standards are rapidly being adopted by state regulators to ensure consumer safety.

The number of states with medical cannabis more than doubled under the Obama Administration. All of these programs are in adherence with the Department of Justice (DOJ) guidelines in the 2013 “Cole Memo.” Although this memo was rescinded in 2018 by then Attorney General Jeff Sessions, medical cannabis programs have been approved or become operational in ten states during the first two years of the Trump Administration.

2. PARTICIPATING PATIENTS AND MEDICAL PROFESSIONALS

Patients:

It is estimated that the current number of legal cannabis patients in the U.S. is at 2.4 million and growing (an average of 1 % of the populations in each state). There are over 95 medical qualifying conditions covered by the various state medical cannabis programs. In addition to adults, all states now allow pediatric patients to utilize their medical cannabis programs although the qualifying conditions and specifications for approval differ, and some states require two physician recommendations as opposed to one for adults.

Conditions Commonly Using Cannabis Treatment	# of estimated cases in US
Annual New Cases of Cancer	1,633,390
Inflammatory Bowel Diseases	3,000,000
Multiple Sclerosis	947,000
Post-Traumatic Stress Disorder	24,400,000
Chronic Pain	116,000,000

Source: Center for Disease Control, National MS Society, and PTSD United

A 2014 study of 2012 data from the California Behavioral Risk Factor Surveillance system of 7,525 people found that 2-9% of Californians depending on age group reported using medical cannabis for a serious medical condition including chronic pain, arthritis, migraine, and cancer. Interestingly, there was not one demographic, age, or sex that stood out as more likely to use medical cannabis. According to the study's authors, “Our study's results lend support to the idea that medical marijuana is used equally by many groups of people and is not exclusively used by any one specific group.” There were similar usage rates among both men and women. Adults of all ages reported medical cannabis use, although young adults were the most likely to use it.<sup>1</sup>

MYTH: “MARIJUANA DOES KILL PEOPLE IN THE FORM OF CAR CRASHES.” - KEVIN SABET (CO-FOUNDER, SMART APPROACHES TO MARIJUANA)

FACT: WHILE MORE DRIVERS ARE TESTING POSITIVE, THIS IS MOST LIKELY DUE TO INCREASED TESTING, AS OVERALL NUMBER HIGHWAY FATALITIES HAVE NOT SIMILARLY INCREASED. "IN FACT, A 2013 UNIVERSITY OF CHICAGO STUDY FOUND A 9-11% REDUCTION IN TRAFFIC FATALITIES IN STATES WITH MEDICAL CANNABIS LAWS"

Citation: Anderson, M.D., Hansen, B., Rees, D.I. Medical marijuana laws, traffic fatalities, and alcohol consumption. 2013; The Journal of Law and Economics. 56:2, 333-369.



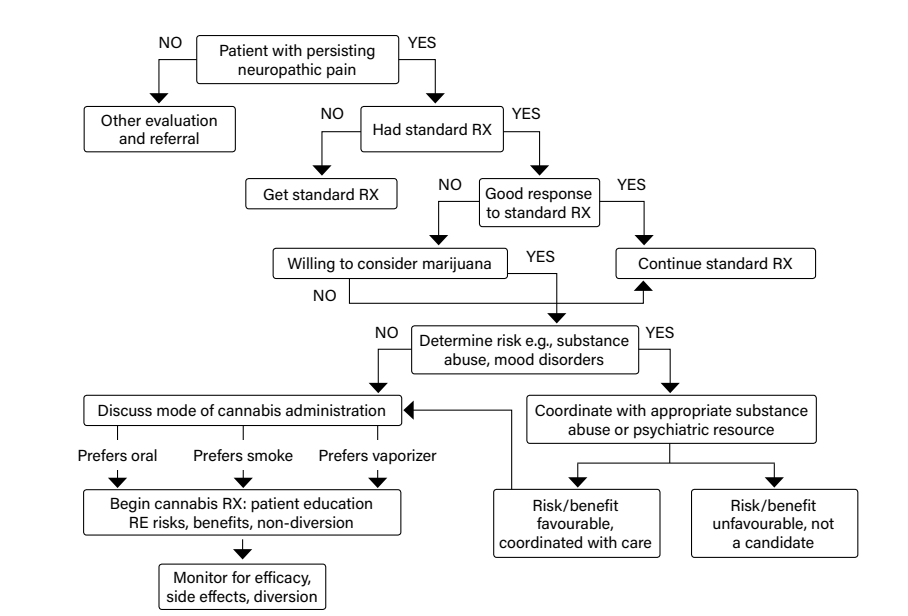
In addition to the AHPA Recommendations for Regulators, states are also incorporating the laboratory testing standards set forth in the American Herbal Pharmacopoeia Cannabis Inflorescence Monograph.

In addition, the California study found that 92% of medical cannabis patients reported that cannabis was an effective treatment for their conditions.<sup>2</sup> Similar results of a patient survey conducted by the Minnesota Department of Health found that 88% of patients and 69% of health care practitioners reported some benefit or greater.<sup>3</sup>

Medical Professionals

For every current medical cannabis patient in America, there is a doctor who has recommended its use. In a 2013 New England Journal of Medicine poll, 76% of physicians were supportive of the use of medical cannabis in certain circumstances.<sup>4</sup> Some medical schools are teaching required coursework which includes the endocannabinoid system and the therapeutic applications of cannabis, however the majority of medical schools curriculums do not contain sufficient education hours about medical cannabis or the endocannabinoid system.<sup>5</sup> The Accreditation Council for Continuing Medical Education (ACCME), which sets and enforces standards in physician continuing medical education (CME) within the United States, has accredited some CME courses in medical cannabis. For example, TheAnswerPage.org is an ACCME-accredited provider of 23 CME courses on the subject of medical cannabis.

State medical boards in medical cannabis states across the country have worked with regulatory agencies and legislators to provide guidance for doctors. In April 2016, the Federation of State Medical Boards (FSMB) adopted “Model Guidelines for the Recommendation of Marijuana in Patient Care.” Protocols, like the one illustrated in the following example for neuropathic pain, are being established to help guide doctors in recommending cannabis for their patients.



<sup>2</sup> *Id.*  
<sup>3</sup> Scott Smith, *Most Patients Report Benefits from Medical Cannabis*, Minn. Dep't Health, Press Release (June 6, 2016).  
<sup>4</sup> Adler, J. M.D., and Colbert, J. M.D. Medicinal Use of Marijuana — Polling Results. May 2013; New England Journal of Medicine. 368:e30 DOI: 10.1056/NEJMcld130515  
<sup>5</sup> Anastasia Evanoff, *Physicians-in-Training are not Prepared to Prescribe Medical Marijuana*, Drug and Alcohol Dep. 180(1), (Nov. 2017), 151-55

<sup>1</sup> Ryan Ibarra, *Prevalence of Medical Marijuana Use in California, 2012*, Drug. Alcohol Rev., (March 2015), 34(2):114-6

However, many physicians are still reluctant to recommend or even discuss medical cannabis with their patients due to its Schedule I status. Additionally, hospitals, community health centers, nursing homes and health plans that participate with Medicare or Medicaid are required to comply strictly with all federal laws. Many of those medical facilities prohibit their physicians from recommending medical cannabis to their patients for fear of losing federal funding.

### 3. PRODUCT SAFETY AND THE MEDICAL CANNABIS SUPPLY CHAIN

(see STATE MEDICAL CANNABIS PROGRAM REGULATIONS AND OVERSIGHT Graphic on pages 28 and 29)

State agencies or groups of several agencies (such as the Departments of Health, Agriculture, Consumer Affairs, etc.) are tasked with creating and monitoring regulations through all phases of production, issuing licenses for businesses, and coordinating patient enrollment. These agencies also conduct inspections or work with third-party accreditors to ensure compliance, monitor adverse event reporting, and implement product recalls if necessary.

Regulations begin at the application stage – where criteria are set for who can own, operate, and work in medical cannabis businesses – and end with purchasing criteria at the retail point. From seed to consumption, regulations include track and trace functions, security requirements, product safety protocols, staff training, and adverse event reporting and recall procedures.

States are now adopting the rigorous best practice regulations and standards set forth in the AHPA Recommendations for Regulators and incorporating laboratory testing based on standards set forth in the AHP Cannabis Inflorescence monograph.

State-licensed and -mandated laboratory testing means that patients in state medical cannabis programs are able to obtain safe, reliable, consistent products to treat their medical needs. When state governments are free from issues related to conflicts with federal laws, it becomes easier for states to implement sophisticated product safety regulations.



**A 2016 study examining the impact of medical cannabis laws on crime found, “There is no evidence of negative spillover effects from medical marijuana laws (MMLs) on violent or property crime. Instead, we find significant drops in rates of violent crime associated with state medical marijuana laws.”**

Citation: Shepard, E.M. and Blackley, P.R. Medical Marijuana and Crime: Further Evidence from the Western States. April 2016; Journal of Drug Issues. 46(2): 22-134



**There has never been a death directly associated with cannabis use.**

### 4. PUBLIC HEALTH IMPACTS OF MEDICAL CANNABIS PROGRAMS

Public health data collected over the past 23 years have shown that fears expressed by opponents of medical cannabis are non-evidence-based concerns. In fact, quite to the contrary, health data provides compelling evidence of a variety of notable benefits to public health:

- There has never been a death directly associated with cannabis use.
- A 2014 study published in the Journal of the American Medical Association found that states that implemented medical cannabis laws appeared to have a 25% lower annual opioid overdose death rate (both from prescription painkillers and illicit drugs such as heroin) compared to states without medical cannabis programs.<sup>6</sup> Data from 2018 support this conclusion showing that when given access to cannabis, individuals currently using opioids for chronic pain decrease their use of opioids by 40–60% and report that they prefer cannabis to opioids.<sup>7</sup>
- A 2016 study found no associations between in utero exposure to cannabis and the following health outcomes: maternal diabetes, rupture of membranes, premature onset of labor, use of prenatal care, duration of labor, placental abruption, secondary arrest of labor, elevated blood pressure, hyperemesis gravidarum, maternal bleeding after 20 weeks, antepartum or postpartum hemorrhage, maternal weight gain, maternal postnatal issues, duration of maternal hospital stay, or hormone concentrations.<sup>8</sup>
- A 2016 study examining the impact of medical cannabis laws on crime found, “There is no evidence of negative spillover effects from medical marijuana laws (MMLs) on violent or property crime. Instead, we find significant drops in rates of violent crime associated with state medical marijuana laws.”<sup>9</sup>
- A 2005 Journal of Acquired Immune Deficiency Syndromes study found that, “patients who use cannabis therapeutically are 3.3 times more likely to adhere to antiretroviral therapy regimens than non-cannabis users.”<sup>10</sup>

6 Bachhuber, M.A. MD, et al. Medical cannabis laws and opioid analgesic overdose mortality in the united states 1999-2010. October 2014; J. American Medical Association.

7 Wiese, B., & Wilson-Poe, A. R. (2018). Emerging Evidence for Cannabis' Role in Opioid Use Disorder. *Cannabis and cannabinoid research*, 3(1), 179-189. doi:10.1089/can.2018.0022

8 Gunn, J. K., Rosales, C. B., Center, K. E., Nuñez, A., Gibson, S. J., Christ, C., & Ehiri, J. E. (2016). Prenatal exposure to cannabis and maternal and child health outcomes: a systematic review and meta-analysis. *BMJ open*, 6(4), e009986. doi:10.1136/bmjopen-2015-009986

9 Shepard, E. M., Blackley, P. R., Medical marijuana and crime further evidence from the western states. April 2016; Journal of Drug Issues. vol. 46 no. 2 122-134.

10 De Jong, B.C. MD et al. Marijuana use and its association with adherence to antiretroviral therapy among HIV-infected persons with moderate to severe nausea. 2005. Journal of Acquired Immune Deficiency Syndromes 38: 43-46.



## 5. THE ECONOMICS OF MEDICAL CANNABIS PROGRAMS

According to a study by the University of Georgia, medical cannabis saved the Medicare Part D drug program more than \$165 million in 2013 due to a decrease in prescription medication.<sup>11</sup> According to the researcher's estimates, if medical cannabis had been legal across the nation, Medicaid savings would have been approximately \$1.01 billion.<sup>12</sup> The fact is, fewer pills are prescribed in states with medical cannabis laws. It is estimated that cannabis and related products can replace prescriptions overall for savings of approximately 17% to 19% by 2019.<sup>13</sup>

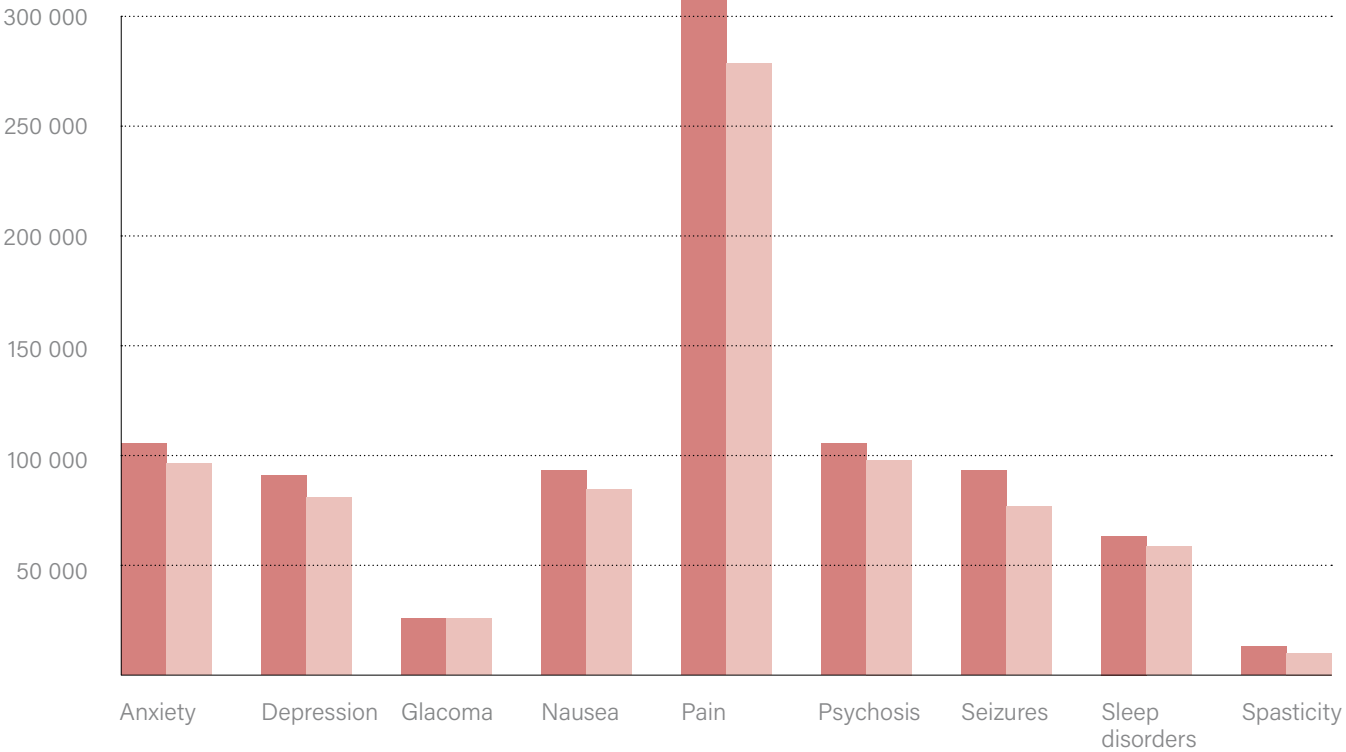
The cost saving of medical cannabis may also be realized by employers as recent research is showing that states that have legalized medical cannabis access have seen statistically significant declines in employee sick days. A July 2016 study found that workplace absences due to illness dropped between 8 and 15 percent among various subgroups in states with medical cannabis laws.<sup>14</sup>



11 Bradford, A., & Bradford, W., Medical marijuana laws may be associated with a decline in the number of prescriptions for medicaid enrollees, Health Affairs, (May 2017), <https://doi.org/10.1377/hlthaff.2016.1135>  
12 *Id.*  
13 *Supra* n. 6  
14 Darren Ullman, *The Effect of Medical Marijuana on Sickness Absence*, Health Economics, 26 (2017), 1322-27



Annual # of Daily Doses of Pharmaceuticals Prescribed by Physicians in States





# 3

## IMPACT OF THE STATE-FEDERAL CONFLICT: WHAT'S AT STAKE

KEY POINTS  
TALKING POINTS

1. HISTORICAL PERSPECTIVES
2. THE COST OF WAR
3. THE "CEASEFIRE" JOYCE-BLUMENAUER AMENDMENT AND ATTORNEY GENERAL COMMITMENTS



### KEY POINTS

- PATIENT ADVOCATES TURNED TO PASSING LOCAL AND STATE MEDICAL CANNABIS LAWS AFTER THE FEDERAL GOVERNMENT CLOSED DOWN ITS COMPASSIONATE INVESTIGATIONAL NEW DRUG PROGRAM IN THE EARLY 90'S (A PROGRAM THAT THEN-CONGRESSMAN NEWT GINGRICH TRIED TO EXPAND IN 1981).
- SINCE THE FIRST STATE MEDICAL CANNABIS LAWS WERE ENACTED IN 1996, THE FEDERAL GOVERNMENT HAS APPLIED DIVERSE TACTICS OF INTERFERENCE AND INTIMIDATION WITH A PRICE TAG OF OVER \$600 MILLION – APPROXIMATELY \$250 MILLION DURING THE BUSH ADMINISTRATION AND \$350 MILLION DURING THE OBAMA ADMINISTRATION.
- THANKS TO THE CJS AMENDMENT, THE TRUMP ADMINISTRATION HAS BEEN LARGELY BARRED FROM CONDUCTING RAIDS, BUT THE DOMESTIC CANNABIS ERADICATION PROGRAM CONTINUES TO COST \$17 MILLION A YEAR.
- FEDERAL INTERVENTION HAS INCLUDED OVER 500 YEARS OF JAIL TIME FOR INDIVIDUALS FOLLOWING STATE LAW, THREATENING STATE OFFICIALS IN OVER A DOZEN STATES, ASSET FORFEITURE THREATS, ACTIONS TO HUNDREDS OF LANDLORDS SERVING LEGAL CANNABIS BUSINESSES, AND OVER 500 DRUG ENFORCEMENT AGENCY (DEA) PARAMILITARY STYLE RAIDS.
- ON MANY OCCASIONS, PATIENTS HAVE BEEN IN THE CROSSHAIRS OF FEDERAL AGENTS USING "DYNAMIC ENTRY" (SWAT-STYLE) TACTICS DURING RAIDS. IN THE AFTERMATH OF EVERY RAID, THOUSANDS OF PATIENTS WERE LEFT DEALING WITH A DISRUPTION IN THEIR SUPPLY OF MEDICINE, WHICH AT THE VERY LEAST DIMINISHED THEIR QUALITY OF LIFE AND OFTEN CAUSED THEIR CONDITIONS TO WORSEN.
- SINCE 2013, STATE MEDICAL CANNABIS PROGRAMS HAVE OPERATED UNDER A "CEASEFIRE" THANKS TO CONGRESSIONALLY IMPOSED SPENDING RESTRICTIONS (JOYCE-BLUMENAUER AMENDMENT).
- STATE MEDICAL CANNABIS CHANGES IN THESE POLICIES WOULD MEAN OVER 2 MILLION PATIENTS LEFT WITH ONLY THE ILLICIT MARKET TO FIND THEIR MEDICINE, INCREASES IN MEDICAID COSTS, INCREASES IN OPIATE-RELATED DEATHS, AND LOSS IN WORKPLACE PRODUCTIVITY.





TALKING POINTS

- SINCE THE FIRST STATE MEDICAL CANNABIS LAWS WERE ENACTED IN 1996, THE FEDERAL GOVERNMENT HAS APPLIED DIVERSE TACTICS OF INTERFERENCE AND INTIMIDATION WITH A PRICE TAG OF OVER \$600 MILLION.
- FEDERAL INTERVENTION HAS INCLUDED OVER 500 YEARS OF JAIL TIME FOR INDIVIDUALS FOLLOWING STATE LAW.
- PATIENTS HAVE BEEN IN THE CROSSHAIRS OF FEDERAL AGENTS USING PARAMILITARY STYLE “DYNAMIC ENTRY” TACTICS DURING MORE THAN 500 DEA RAIDS.
- IF CONGRESS CONTINUES TO FAIL TO PASS PERMANENT LEGISLATIVE SOLUTIONS, IT REMAINS CRITICAL TO INCLUDE THE JOYCE-BLUMENAUER AMENDMENT IN ANNUAL CJS APPROPRIATIONS TO PROTECT PATIENTS.

PARAMILITARY-STYLE  
RAIDS ON LICENSED  
MEDICAL DISPENSARIES  
CAN PLACE PATIENTS IN  
CROSS HAIRS OF DEA.

1. HISTORICAL PERSPECTIVES

In 1970, cannabis was placed in Schedule I under the Controlled Substance Act (CSA) as a placeholder, pending evaluation by a government-appointed commission that was later ignored. Today, cannabis remains a Schedule I drug under the CSA, which defines cannabis as having no accepted medical use. Various efforts to reschedule cannabis in the U.S. – based on peer-reviewed medical and scientific information – have been stymied by the Drug Enforcement Administration (DEA). Most recently, the DEA’s “Denial of Petition to Initiate Proceedings to Reschedule Marijuana” focused on the fact that cannabis does not fit with current federal regulations for an FDA-approved drug. In other words, the medical value assigned to cannabis simply does not meet the DEA’s definition of “medicine,” not that cannabis has no medical value.

In 1975, DC resident Robert Randall was arrested for cultivating cannabis in his home. Citing clinical evidence, Mr. Randall successfully used the Common Law Doctrine of Necessity to fight the charges. Mr. Randall then petitioned the federal government to provide him with access to medical cannabis in accordance with his medical necessity and shortly thereafter became the first American to receive a government-supplied source of cannabis. As a result, the FDA established the Investigational New Drug (IND) Compassionate Access Program to supply individuals who suffered from severe or chronic illness with a monthly supply of cannabis, up to nine pounds annually (a program that Newt Gingrich tried to expand in 1981 through legislation).

In 1992, in response to an overwhelming number of applications from people suffering the effects of AIDS, President H. W. Bush closed the program to all new applicants, citing concerns that the program undermined the “war on drugs.” Today, a handful of surviving IND-participants continue to receive medical cannabis from the U.S. government, paid for by federal tax dollars.

These federal roadblocks led frustrated patient advocates to turn to their local and state governments for protection. In 1996, patient advocates successfully brought their case to the voters in California and Arizona, passing medical cannabis laws in defiance of federal law.



The criminal cases brought by the government were consistently lopsided, as federal trial rules prevented (and still prevent) defendants from telling a jury that their cannabis use was for medical treatment in accordance with state law. Patients were essentially left with no defense, effectively ensuring convictions and giving federal prosecutors extraordinary leverage for obtaining plea deals. Raids continued for the next 13 years, and between 2005 and the end of George W. Bush's Administration, the DOJ conducted another 212 raids and

**FACT: AN EXHAUSTIVE COLUMBIA UNIVERSITY MEDICAL CENTER STUDY USING OVER 24 YEARS OF DATA FROM OVER A MILLION TEENAGERS IN 48 STATES FOUND NO SIGNIFICANT DIFFERENCE IN ADOLESCENT MARIJUANA USE IN THE 21 STATES WITH MEDICAL MARIJUANA LAWS. IN ADDITION, A 2016 SURVEY IN COLORADO FOUND THAT CANNABIS USE HAS NOT INCREASED SINCE LEGALIZATION.**

On August 29, 2013 the DOJ issued a guidance memo to prosecutors concerning cannabis enforcement under the CSA making it clear that prosecuting state legal medical cannabis cases is not a priority. The memo included eight guidelines for prosecutors to use to determine federal enforcement priorities. Many medical cannabis programs require the same guidelines laid out by the Cole Memo, ensuring that any business with a license is also meeting these requirements.





In 2018, this memo was rescinded by then-Attorney General Jeff Sessions, meaning that the DOJ had discretion as to how they would prosecute drug cases. This move left many patients and businesses uncertain about their medicine. In early 2019, Attorney General William Barr told the Senate Judiciary Committee that he does “not intend to go after parties who have complied with state law in reliance on the Cole Memorandum.” This commitment is reassuring but still leaves many unanswered questions surrounding research licenses, banking issues, and veteran access to medical cannabis.

## 2. THE COST OF WAR

**Price Tag:**

In an escalating war on medical cannabis patients that has spanned the terms of four Presidents, the DOJ has spent an estimated \$600 million to date in arrests, investigations, enforcement raids, pretrial services, incarcerations, and probations. The Obama Administration spent more than \$289 million – outspending the Bush Administration by \$100 million. In 2012 alone, the DEA used 4% of its budget on medical cannabis cases.

**Human Cost:**

The conflict between state and federal law has not only cost millions of dollars, but it has had a devastating cost to many patients and their families. Patients are often the innocent victims of the continuing war on medical cannabis. Federal intervention has included over 500 years of jail time for individuals following state law. The costs of this war are not just borne by taxpayers. For every raid the DEA carried out, thousands of patients were left searching for alternatives for safe and dignified access. It meant patients going to the illicit market, or even worse, going without medication and suffering needlessly. In many cases, patients were left dealing with a disruption in their supply of medicine, which, at the very least, diminished their quality of life and often caused their condition to worsen.



”

**The agents would make the staff and patients lay on the ground while they took all the medicine and cash – often without making an arrest. These have come to be known as “smash and grab” raids, in part because the cash seized is kept by the local DEA offices for their own use.**

## 3. THE “CEASEFIRE”: JOYCE-BLUMENAUER AMENDMENT AND ATTORNEY GENERAL COMMITMENTS

In 2014 and 2015, Congress passed the landmark Rohrabacher-Farr amendment to the Commerce, Justice, Science and Related Agencies (CJS) Appropriations Act, which prevents the DOJ from using any funds to interfere in state medical cannabis programs and bars ongoing federal cases. After this “ceasefire,” state medical cannabis programs have almost doubled, and due to the Cole Memo, all medical cannabis states include centralized state licensing. In August 2016, a federal appeals court upheld the Rohrabacher-Farr amendment in United States v. McIntosh and ruled in favor of the 10 cases that had been grouped together upholding the prohibition of the DOJ to use funds on enforcing cannabis prohibition under the Controlled Substances Act in states with medical cannabis reform laws.

The Rohrabacher-Farr amendment, now referred to as the Joyce-Blumenauer Amendment, is the best protection that medical cannabis patients and providers have ever enjoyed, but it must be renewed annually. Momentum is on the side of medical cannabis patients, but an annual appropriations amendment is always subject to shifting political will in Congress. The Joyce-Blumenauer amendment is also subject to review by federal courts, which over time may lead to varying interpretations from different federal jurisdictions regarding its scope and applicability.

Although Attorney General William Barr has made comments on the record that he will not prosecute cannabis businesses and patients complying with state law, patients desperately need the certainty of a federal legislative solution that protects their access to medicine.

A permanent solution to the federal and state conflict is desperately needed for both economic and humanitarian reasons. If state rights are not protected, over 2 million patients could be left with only the illicit market to find their medicine. In addition, based on research thus far, there would undoubtedly be an increase in Medicaid costs and opioid deaths and loss in workplace productivity.



# MEDICAL CANNABIS TIMELINE

## TOTAL STATES 8

California, Alaska, Oregon, Washington, Maine, Hawaii, Colorado, and Nevada

## TOTAL STATES 13

Montana, Vermont, Rhode Island, New Mexico, and Michigan

California adds distribution guidelines to state program, Vermont, Rhode Island and New Mexico follow.

## TOTAL STATES 20 PLUS DC

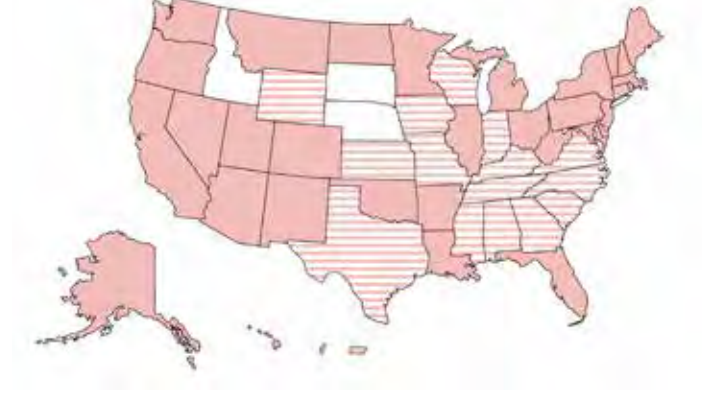
New Jersey, Arizona, Delaware, the District of Columbia, Connecticut, Massachusetts, New Hampshire, and Illinois

Colorado passed first commercial licensing medical marijuana program.

Medical cannabis program laws and regulations include product safety protocols.

## TOTAL STATES 47 PLUS DC, AND FOUR OF FIVE U.S. TERRITORIES

States without any cannabis or CBD law: Idaho, Nebraska, South Dakota



**1996-2002**  
PATIENTS  
50,000

**2002-2008**  
PATIENTS  
471,438

**2009-2013**  
PATIENTS  
1,073,596

**2014-2018**  
PATIENTS  
2,400,000+

## FEDERAL RAIDS 14

DOJ threatens licenses of any doctor recommending cannabis following passage of first medical cannabis law.

DOJ and DEA carry out paramilitary raids.

Congress blocks DC law.

**1998** - The Institute of Medicine (IOM) issues, "Marijuana & Medicine: Accessing the Science Base" calling on the federal government to do formal studies on cannabis.

## FEDERAL RAIDS 241

Federal Court rules in *Conant v. Walters* that government cannot revoke physicians' licenses for recommending medical cannabis.

DEA administrative law judge recommends allowing new source of cannabis for research.

## FEDERAL RAIDS 262

2009: US Attorney General Announces That DOJ Will Not Prioritize Prosecution of Legal Medical Marijuana Patients.

2011: DOJ threatens elected officials in 11 states implementing cultivation and distribution programs.

2013: DOJ issues a guidance memo to prosecutors concerning marijuana enforcement under the Controlled Substance Act (CSA).

**2012** - AHP issues Cannabis Monograph and AHPFA issues Recommendations for Regulators.

## FEDERAL RAIDS 2

2014-2018: Department of Justice prohibited from spending money to prevent states from implementing medical marijuana programs.

2015: The CARERS Act - first medical cannabis bill in US Senate history introduced.

2016: Courts uphold *Rohrabacher-Farr* protections in *U.S. vs Marin Alliance for Medical Marijuana* and *U.S. vs McIntosh*.

2016: DEA announces it will not move cannabis out of its Schedule I status.

# 4

## PATIENT TESTIMONIALS

### KEY POINTS TALKING POINTS

1. PARENTS WHO CHOOSE MEDICAL CANNABIS TO KEEP THEIR CHILDREN ALIVE AND HEALTHY STILL RUN THE RISK OF LOSING CUSTODY
2. MEDICAL CANNABIS PATIENTS ARE FREQUENTLY DISCRIMINATED AGAINST WHEN IT COMES TO RECEIVING ORGAN TRANSPLANTS DESPITE THERE BEING NO EVIDENCE OF ADVERSE EFFECTS
3. THERE ARE STILL MEDICAL CANNABIS PATIENTS IN PRISONS AROUND THE COUNTRY



### KEY POINTS

- VETERANS WHO RELY ON THE V.A. FOR THEIR HEALTH CARE CANNOT PARTAKE IN MEDICAL CANNABIS PROGRAMS UNLESS THE VETERANS HEALTH ADMINISTRATION CHANGES ITS POLICY TO ALLOW PHYSICIANS TO WRITE MEDICAL CANNABIS RECOMMENDATIONS IN STATES WITH MEDICAL CANNABIS LAWS.
- THE UNITED STATES OF AMERICA HAS BEEN AT WAR SINCE 2003. VETERANS WITH CHRONIC PAIN, PTSD, TRAUMATIC BRAIN INJURIES, OR OTHER INJURIES AND DISORDERS THAT LIMIT QUALITY OF LIFE DESERVE SAFE AND LEGAL ACCESS TO MEDICAL CANNABIS.
- PARENTS WHO CHOOSE MEDICAL CANNABIS TO KEEP THEIR CHILDREN ALIVE AND HEALTHY STILL RUN THE RISK OF LOSING CUSTODY.
- MEDICAL CANNABIS PATIENTS ARE FREQUENTLY DISCRIMINATED AGAINST WHEN IT COMES TO RECEIVING ORGAN TRANSPLANTS DESPITE THERE BEING NO EVIDENCE OF ADVERSE EFFECTS.
- THERE ARE STILL MEDICAL CANNABIS PATIENTS IN PRISONS AROUND THE COUNTRY.



TALKING POINTS

- MANY AMERICANS WHO STAND TO BENEFIT FROM MEDICAL CANNABIS STILL LACK SAFE AND LEGAL ACCESS TO IT.
- THE LACK OF INSURANCE COVERAGE FOR MEDICAL CANNABIS MEANS THAT EVEN PATIENTS WHO CAN ACCESS IT MAY NOT BE ABLE TO AFFORD IT.
- DENYING PATIENTS ACCESS TO MEDICAL CANNABIS, OR PUNISHING THEM FOR USING IT, CAN HAVE LIFE-ENDING CONSEQUENCES
- THE CRIMINALIZATION OF MEDICAL CANNABIS AND MEDICAL CANNABIS PATIENTS PLACES AN UNDUE BURDEN ON VULNERABLE PEOPLE WHO ARE ALREADY SUFFERING.



Veterans deserve the right, like everyone else, to access medical cannabis as an alternative to the pills that are currently being given to them.



JOSE BELEN



THE ZARTLERS

**Jose Belen** is a decorated United States Army combat veteran. Jose enlisted in the Army at age 19 and deployed to Iraq in 2003 during the initial Operation Iraqi Freedom invasion and spent 14 consecutive months in combat. After his honorable discharge in 2005, Jose began silently battling post-traumatic stress disorder. The VA began to treat him with antidepressants, mood stabilizers, sleeping pills, SSRI's, and other prescription drugs. The side effects of every medication that he took had adversely accelerated his symptoms and nearly drove him to suicide a number of times.

The war within his own mind almost robbed him of everything: His career, his family, nearly his own life. Ultimately, however, Jose was able to overcome his personal demons with the help of cannabis. Medical cannabis gave him the ability to function and find peace without the constant thoughts of the horrors of war and all of its baggage. Although he does not consider it a "cure" for PTSD, he finds cannabis to be vital in his recovery. He believes he would not be here and would have fallen victim to other medications had he not been introduced to medical cannabis.

Veterans deserve the right, like everyone else, to access medical cannabis as an alternative to the pills that are currently being given to them. PTSD does not have to be a death sentence.

For ten years, **Christy and Mark Zartler** struggled to control their daughter Kara's severe autism with conventional medications, but all the benzodiazepines and antipsychotic medications the doctors had tried had failed to stop her self-injuring behaviors. Kara was rendered near catatonic by the medications but still hit herself in the face as many as 3,000 times each day, at times breaking bones and inflicting injuries on anyone who tried to restrain her.

Christy and Mark knew there was an alternative that did work for Kara, but it was illegal in their state of Texas. So they decided it was time to try to change the law in Texas. Trips to Austin to talk to lawmakers took time and money, but the Zartlers were determined to make a difference for their family and others like them.

In February 2017, with a promising medical cannabis bill pending in the state Senate, Mark went public with his use of cannabis with Kara with a video of Kara's self-hitting fits and his intervention of a cannabis vapor-filled bag administered through a medical mask. Almost immediately Kara stopped hurting herself and visibly relaxed. After seeing the video, a representative from south Texas immediately introduced in the state House a companion medical cannabis bill to one pending in the Senate.

However, a few days later, Child Protective Services (CPS) came knocking at their door. Under Texas law, giving an illegal drug to a minor is classified as child abuse, and CPS had reason to believe Mark was abusing his daughter by giving her cannabis. Ultimately, the investigation was resolved.



The Zartlers recognize the power of public advocacy and are courageously sharing their family’s story with the world, despite the lack of legal protections in Texas. In May, the Zartlers traveled to Washington, D.C. for ASA’s National Unity Conference and Lobby Day meetings they had scheduled with their Congressional representatives, including Representative Pete Sessions.

Now that Kara is using cannabis consistently, she has weaned off most pharmaceutical medications and has had profound cognitive improvements. She no longer needs diapers and has begun to assert herself. Christy and Mark are more determined than ever to continue to spread the word about the therapeutic benefits of medical cannabis.

**Ellen Lenox Smith** was a competitive swimmer and dedicated teacher and coach when, at age 42, it became clear something was wrong. She had pain that could not be identified or treated but worsened over the next dozen years until she was finally diagnosed with Ehlers-Danlo Syndrome, a rare genetic disorder that attacks the body’s connective tissue. In the 25 years since her medical journey with this condition began, surgery after surgery has been required to deal with its effects, now totaling 24.

In 2007, Ellen decided she couldn’t take the pain anymore. She was preparing to leave for another surgery with a specialist in Wisconsin when she asked her primary care physician for a referral to pain clinic. At the clinic, her doctor confided that cannabis might help. She had never considered cannabis as an option for pain, and her minimal experience with it in college suggested the effects would be unpleasant. But now she was desperate for relief.

Rhode Island had just enacted a medical cannabis law the year before, but it did not then allow for anything other than home cultivation, so Ellen’s doctor suggested she find some cannabis on the illicit market and try it to see if it worked. For the first time in years, she’d slept through the night. With the help of her pain specialist, she enrolled in the Rhode Island medical cannabis program. Ellen was able to do things and smile again.

Together with her husband, Ellen has become a compelling voice for pain patients and medical cannabis access, serving on the board of the U.S. Pain Foundation and as co-director of the foundation’s cannabis advocacy, as well as working with the Rhode Island Patient Advocacy Coalition (RIPAC).

Recently, Ellen did genetic testing that revealed treating the pain for her condition has two options: ketamine, an anesthetic for which new applications are being explored, and cannabis, confirming what she discovered 13 years ago.

**Jerry Duval**, a registered Michigan medical cannabis patient, and his son Jeremy, a registered caregiver, were raided by the DEA in 2011, despite strictly adhering to Michigan law. The father and son were tried together in federal court and convicted of conspiracy to manufacture cannabis, intent to distribute, and maintaining a drug premises. Jeremy Duval served a five-year prison



JERRY DUVAL WITH HIS WIFE



ELLEN SMITH

sentence in a federal prison in West Virginia. Jerry, is currently serving a 10-year sentence in a prison at the Federal Medical Center in Devens, MA due to his specialized medical needs. It is estimated his incarceration will cost 1.2 million dollars over the course of his sentence. Jerry’s mother suffers from anxiety and PTSD after law enforcement armed with automatic weapons used a tank to raid her son’s house next door and stormed her home. Jerry’s wife, Tracey, was forced to leave the family home find a new job while waiting for her husband’s release.

**Norman Smith** was a 64-year-old living with inoperable liver cancer and was recommended cannabis by his oncologist at the world-renowned Cedars-Sinai Medical Center in Los Angeles. In 2010, Norman became eligible for a liver transplant, but after testing positive for cannabis in February 2012, he was removed from the transplant list. The medical center’s requirement that Norman undergo six months of random toxicology tests and weekly substance abuse counseling prevented him from ever getting back on the list, since he died six months later, in July 2012.

Discrimination is a serious issue faced by thousands of medical cannabis patients on a daily basis across the nation. One of the more egregious and heartbreaking forms of discrimination is health care centers that deny organ transplants to otherwise qualified candidates simply because the patient uses medical cannabis on the advice of their physician. A number of transplant clinics across the country, which are not governed by a single policy, routinely refuse to list medical cannabis patients for organ transplants based, in part, on the federal government’s outdated policy.

**Scott Day** of Montana, was a legal medical cannabis patient indicted on federal drug trafficking charges in 2007 for growing 96 plants at his home, which he used to treat his rare, terminal illness. In order to help him deal with the extreme pressure of the raid and subsequent prosecution, Scott’s doctor prescribed an anti-anxiety medication. Unfortunately, he had a fatal reaction to the drug and died of asphyxiation. Scott’s last months were filled with terror at the thought of perishing in prison.

**Jason Washington**, formerly a starting quarterback at the University of Montana, is known for his generous spirit and kind-hearted nature. He often participated in charity fundraisers and worked with terminally ill children. Jason’s company, Big Sky Health, was among the dozens of licensed Montana cannabis businesses raided by federal agents in March 2011. Jason and six of his employees were indicted, including one of his accountants. Several of the prosecution’s star witnesses included former associates who received immunity in exchange for their testimony. Jason was convicted of two drug trafficking charges and acquitted of a third. On May 1, 2013, he became the last of Montana’s medical cannabis defendants to be sentenced, receiving two years in prison.

**The Price of a Medical Cannabis Patient**

Because of the federal conflict, cannabis patients and their families, in addition to the burdens of an ongoing illness, must worry about:

- Traveling with their medicine
- Losing their Federal employment
- Losing their Veterans benefits
- Having CPS turn up at their door
- Having conversations about their use with their doctors
- Being able to use their medicine if hospitalized
- Getting turned away from their pain treatment centers

Another burden medical cannabis patients must face is cost. Because of its Schedule I status, insurance companies do not cover medical cannabis treatments. With the cost varying greatly state to state, this can cause an undue burden on patients, many of whom are already faced with large medical costs.





# 5

## ENDING THE FEDERAL CONFLICT THROUGH CURRENT CONGRESSIONAL PROPOSALS

### KEY POINTS TALKING POINTS

1. ROLE OF CONGRESS: LEGISLATIVE NEEDS
2. LEGISLATIVE EFFORTS 115<sup>TH</sup>, 116<sup>TH</sup> CONGRESSES
3. APPROPRIATIONS OPPORTUNITIES
4. REGULATORY IMPACT OF COMPREHENSIVE LEGISLATION



### KEY POINTS

- A NUMBER OF CURRENT CONGRESSIONAL PROPOSALS TAKE THE FIRST STEPS OF HARMONIZING STATE AND FEDERAL LAW, BUT MANY DO NOT GO FAR ENOUGH
- A DIVERSE GROUP OF MEDICAL ASSOCIATIONS AND PATIENT ADVOCACY ORGANIZATIONS SUPPORT THE USE OF MEDICAL CANNABIS AND CHANGES IN FEDERAL LAW.
- MANY MYTHOLOGICAL BELIEFS – LIKE “CANNABIS CAUSES CANCER” OR THE “GATEWAY THEORY” – THOUGH DISPROVED, HAVE PREVENTED FEDERAL REPRESENTATIVES FROM PASSING MEANINGFUL LEGISLATION.
- WITHOUT A NEW SCHEDULING DETERMINATION OR UNIFIED FEDERAL OVERSIGHT, ANY PIECE OF PENDING LEGISLATION MUST EXEMPT STATE-LEGAL MEDICAL CANNABIS ACTIVITY FROM THE CSA.
- REMOVING CANNABIS FROM SCHEDULE I INTO A NEW SCHEDULE WOULD SHOW THAT THE U.S. GOVERNMENT FINALLY HAS ACCEPTED MEDICAL USES FOR CANNABIS.
- EVEN LEGISLATION THAT DOES NOT MAKE A SCHEDULING DETERMINATION MAY STILL LAY A FOUNDATION FOR FURTHER POLICY DEVELOPMENTS. LEGISLATION LIKE THE CARERS ACT CAN GARNER BIPARTISAN SUPPORT IN BOTH HOUSES AND WIDE-SPREAD SUPPORT NATIONALLY FROM PATIENT ORGANIZATIONS.
- MEDICAL CANNABIS PATIENTS ARE STRIPPED OF THEIR 2ND AMENDMENT RIGHTS UNTIL THERE IS A CHANGE IN FEDERAL LAW OR A FORMAL POLICY CHANGE FROM THE ATF.
- A NEW SCHEDULING DETERMINATION, A CENTRALIZED AGENCY FOR CANNABIS OVERSIGHT AND COMMON-SENSE LEGISLATION WOULD ALLOW FEDERAL AGENCIES – LIKE THE DEA, FDA, AND HHS – TO MEANINGFULLY PARTICIPATE IN AND ENGAGE WITH MEDICAL CANNABIS PROGRAMS.





TALKING POINTS

- ◆ IF CONGRESS STEPS UP TO REGULATE MEDICAL CANNABIS, IT WILL GAIN MORE CONTROL OVER THIS SUBSTANCE, NOT LESS.
- ◆ A DIVERSE GROUP OF MEDICAL ASSOCIATIONS AND PATIENT ADVOCACY ORGANIZATIONS SUPPORT THE USE OF MEDICAL CANNABIS AND CHANGES IN FEDERAL LAW.
- ◆ MANY OF THE MYTHS SUCH AS THE “GATEWAY THEORY” OR THAT CANNABIS CAUSES CANCER HAVE BEEN DISPROVED BUT HAVE STILL PREVENTED FEDERAL REPRESENTATIVES FROM PASSING LEGISLATION.
- ◆ WITHOUT A NEW SCHEDULING DETERMINATION OR UNIFIED FEDERAL OVERSIGHT, ANY PIECE OF PENDING LEGISLATION MUST EXEMPT STATE-LEGAL MEDICAL CANNABIS ACTIVITY FROM THE CSA. THE MOST IMPORTANT COMPONENT OF ANY VIABLE FEDERAL LEGISLATIVE OPTION IS EXEMPTING THE 47 STATES WITH MEDICAL CANNABIS PROGRAMS (AS OF FEB. 2018) FROM THE CSA.
- ◆ EVEN LEGISLATION THAT DOES NOT COMPLETELY HARMONIZE STATE AND FEDERAL LAW CAN GAIN BIPARTISAN SUPPORT IN BOTH HOUSES OF CONGRESS AND ENJOY WIDE-SPREAD SUPPORT NATIONALLY FROM PATIENT ORGANIZATIONS.
- ◆ VETERANS CANNOT PARTAKE IN MEDICAL CANNABIS PROGRAMS WITHOUT THE EXPRESSED AUTHORITY THAT VETERANS HEALTH ADMINISTRATION PHYSICIANS ARE ABLE TO WRITE MEDICAL CANNABIS RECOMMENDATIONS IN STATES WITH MEDICAL CANNABIS LAWS.
- ◆ THERE IS SIGNIFICANT CONSENSUS CONCERNING THE VALUE OF MEDICAL CANNABIS OUTSIDE OF CONGRESS, INCLUDING PATIENT ADVOCACY GROUPS, LAWS IN 47 STATES, AND THE MAJORITY OF THE AMERICAN PUBLIC.



If Congress steps up to regulate medical cannabis, it will gain more control over this substance, not less.

1. ROLE OF CONGRESS: LEGISLATIVE NEEDS

It is necessary for Congress to take action in order to fully harmonize state and federal medical cannabis laws. While no current legislative proposal is completely ideal, there are a number of pieces of legislation that Congress could have hearings on and ultimately vote on without reinventing the wheel. There are several pending legislative proposals in Congress that could lay important groundwork for further medical cannabis reform throughout the country. Only an act of Congress can bring state medical cannabis programs into compliance with federal law.

Americans for Safe Access recognizes that a proposal that changes the scheduling of cannabis and creates a new oversight agency, the Office of Medical Cannabis and Cannabinoid Control (described in Chapter 7), is a process that takes both resources and time. However, in the interim, medical cannabis patients are depending on the members of Congress to pass legislation that ends the federal criminalization of the medicine on which they rely.



While waiting on the implementation of new federal oversight, Americans for Safe Access has five Congressional legislative goals to harmonize state and federal medical cannabis laws and promote the advancement of medical cannabis research:

1. Continue the “ceasefire” under the CJS Amendment that has stopped federal raids, intimidation, and interference with state law.
2. Establish federal legal protections for individuals acting in compliance with their state and local medical cannabis laws, as proposed by current Congressional legislation.

- 3. Allow federal agencies the ability to work with state agencies and individuals (such as patients, doctors, and producers) following medical cannabis programs.
- 4. Promote and facilitate research exploring the medical benefits of cannabis.
- 5. Develop a new scheduling framework and federal oversight for cannabis.

The passage of the Joyce-Blumenauer amendment has accomplished the first goal on this list, but it must be reauthorized every year. The best way to achieve the remaining goals is through the passage of comprehensive medical cannabis legislation such as the CARERS Act. The “ceasefire” and protection for state programs are the top priorities because patients who are finding relief from their debilitating conditions through medical cannabis should not have to worry that this relief will be taken away from them. Expanding the scientific knowledge of medical cannabis is an important objective; however, the benefits of research initiated today will not benefit patients for several years or decades to come.

## 2. LEGISLATIVE EFFORTS 115<sup>TH</sup>, 116<sup>TH</sup> CONGRESSES

The 115th Congress saw the introduction of more proposals to resolve the state-federal cannabis conflict than all previous Congresses combined, and the 116th Congress is sure to have the introduction of many pieces of legislation as well. The current and only protection for medical cannabis patients is the language contained in the annual CJS appropriations package.

In 2018, the language to protect state legal medical marijuana activities was included in both the House and Senate base appropriations bills. This marked the first time since the amendment’s introduction that it did not have to be voted on on the floor. The 116th Congress must continue to pass the Joyce-Blumenauer CJS amendment.

### Legislative Proposals in the 116th Congress

There are a number of legislative efforts that should be recognized as good initial steps to resolving the state-federal conflict. While some of these bills go beyond the scope of ASA’s mission, the reflect some of the important issues that must be considered.<sup>1</sup>

- Marijuana Data Collection Act (H.R. 6495 in 115th) Directs National Academy of Sciences to conduct and update biennially a study on the effects of state legalized cannabis programs.

MYTH: “THERE REALLY IS NO SUCH THING AS MEDICAL MARIJUANA, AND NOT ENOUGH EVIDENCE TO SUPPORT MARIJUANA’S MEDICAL PROPERTIES.” - DR. STUART GITLOW (PSYCHIATRIST, AMERICAN SOCIETY OF ADDICTION MEDICINE)

FACT: MORE THAN 100 ARTICLES HAVE BEEN PUBLISHED ON HOW CANNABINOIDS ACT AS NEUROPROTECTIVE AGENTS THAT SLOW THE PROGRESSION OF HUNTINGTON’S, ALZHEIMER’S, AND PARTICULARLY PARKINSON’S, A CONDITION THAT AFFECTS MORE THAN 52% OF PEOPLE OVER THE AGE OF 85.

Citation: Giacoppo, S., Mandolino, G., et.al. Cannabinoids: New Promising Agents in the Treatment of Neurological Diseases. 2014; Molecules. 19, 18781-18816; doi:10.3390/molecules191118781.



WHEN FORMER DEA ADMINISTRATOR CHUCK ROSENBERG CALLED MEDICAL CANNABIS “A JOKE,” PATIENTS RESPONDED BY PRESENTING THE DEA WITH 100,000 SIGNATURES SEEKING HIS REMOVAL.

- Marijuana Justice Act (H.R.1456/S.597) Removes marijuana from the list of controlled substances; incentivizes states through federal funds to change their cannabis laws if those laws were shown to have a disproportionate effect on low-income individuals and/or people of color; automatically expunges federal cannabis use and possession crimes; allows an individual currently serving time in federal prison for cannabis use or possession crimes to petition a court for a resentencing; and creates a community reinvestment fund to reinvest in communities most impacted by the federal drug prohibition policies.
- Medical Cannabis Research Act (H.R. 601) Increases number of manufacturers registered under the CSA to produce cannabis for research purposes and authorizes the VA to provide recommendations to veterans regarding participation in clinical trials.
- Marijuana Revenue and Regulation Act (H.R. 1120/S. 420) Amends the Internal Revenue Code of 1986 to provide for the taxation and regulation of marijuana products, and for other purposes.
- Regulate Marijuana Like Alcohol Act (H.R. 420) Removes marijuana from the CSA Schedule, creates a federal regulatory framework for cannabis. This bill approaches resolving the federal state conflict in a way similar to what is described in Chapter 7 of this book but falls short of truly providing for the needs of patients.
- VA Medicinal Cannabis Research Act (H.R. 712/S. 179) Requires the VA to conduct medical research into the safety and efficacy of medical cannabis by veterans with diagnoses such as PTSD and chronic pain.
- Veterans Medical Marijuana Safe Harbor Act (S. 445/ H.R. 1151) Creates a safe harbor for veterans who use, possess, or transport medical cannabis in accordance with the state laws and for VA physicians to provide recommendations and opinions regarding the participation of a veteran in a state medical cannabis program, including completing necessary forms, and requires the VA to conducts studies on the effects of medical cannabis on veterans in pain and on the use by veterans of state medical cannabis programs.
- Veterans Equal Access Act (H.R. 1820 in 115th) Autorizes VA health care providers to provide recommendations and opinions to veterans regarding participation in state cannabis programs

<sup>1</sup> The inclusion of these bills in this book does not necessarily indicate an endorsement by Americans for Safe Access, but provide a selection of the current proposals pending in Congress.



THE CARERS ACT

If Congress is going to pass an interim solution before making a scheduling change decision and new oversight as described in Chapter 7, the Compassionate Access, Research Expansion, and Respect States (CARERS) Act, H.R. 127 (H.R. 2920 and S. 1764 in the 115th Congress), is probably the best legislative proposal for patients. The CARERS Act was first introduced in 2015. The CARERS Act is a comprehensive piece of medical cannabis legislation. The intent of this bill is “to extend the principle of federalism to state drug policy, provide access to medical cannabis, and enable research into the medicinal properties of cannabis.”

Section 2 (which protects the states against federal interference) is the cornerstone of the CARERS Act and any future Congressional bill that attempts to harmonize state and federal medical cannabis laws must include a substantively similar paragraph.

The passage of the CARERS Act would also trigger a host of state-federal agency cooperation that would likely include state and federal health departments, food and agricultural agencies, the Food and Drug Administration, and law enforcement taskforces. Anticipating this cooperation, Americans for Safe Access has developed the framework for the creation of a new federal agency that would have centralized authority over medical cannabis. More on this new agency can be found in Chapter 7 of this briefing book.

Diverse Support for CARERS

In the 115th Congress, the CARERS Act had strong bipartisan support in both houses. The previous House version of the bill had 30 cosponsors (14R/16D) and the Senate version had 13 cosponsors (9D/3R/1I).

The CARERS Act also has overwhelming support among the 2.4 million legal cannabis patients and the condition-based organizations that represent them. In July 2016, Americans for Safe Access joined twelve other patient organizations to deliver a letter to Senator Chuck Grassley and Representative Joe Pitts asking them to give the CARERS Act a vote. These organizations included National Multiple Sclerosis Society, The Michael J. Fox Foundation, National Women’s Health Network, Epilepsy Foundation, Realm of Caring, Tuberous Sclerosis Alliance, Citizens United for Research in Epilepsy (CURE), Danny Did Foundation, Finding a Cure for Epilepsy and Seizures (FACES), Hope4Harper, Hope for Hypothalamic Hamartomas, and Lennox-Gastaut Syndrome (LGS) Foundation.



“  
The “ceasefire” and protection for state programs are the top priorities because patients who are finding relief from their debilitating conditions through medical cannabis should not have to worry that this relief will be taken away from them.

MYTH: MEDICAL MARIJUANA DISPENSARIES ARE MAGNETS FOR CRIME.

FACT: DUE TO THE PRESENCE OF SECURITY CAMERAS, SECURITY GUARDS, AND INCREASED FOOT TRAFFIC, DISPENSARIES HAVE ACTUALLY BEEN SHOWN TO HAVE A NEUTRAL-TO-SLIGHT DAMPENING EFFECT ON CRIME IN THE AREA IMMEDIATELY SURROUNDING THE DISPENSARY. A MULTI-STATE, PEER-REVIEWED STUDY FROM 2014 FOUND THAT “...ROBBERY AND BURGLARY RATES WERE UNAFFECTED BY MEDICINAL MARIJUANA LEGISLATION, WHICH RUNS COUNTER TO THE CLAIM THAT DISPENSARIES AND GROW HOUSES LEAD TO AN INCREASE IN VICTIMIZATION DUE TO THE OPPORTUNITY STRUCTURES LINKED TO THE AMOUNT OF DRUGS AND CASH THAT ARE PRESENT.”

Citation: Morris RG, TenEyck M, Barnes JC, Kovandzic TV (2014) The Effect of Medical Marijuana Laws on Crime: Evidence from State Panel Data, 1990-2006. PLoS ONE 9(3): e92816. doi:10.1371/journal.pone.0092816.

3. APPROPRIATIONS OPPORTUNITIES

In recent years, the most effective way to move policy legislation through Congress has been through the annual appropriations process. Policy provisions passed during the annual appropriations process are only temporary and must be renewed each cycle, so patients can be left in limbo if an appropriations provision is not renewed or the government shuts down, something that has happened with increasing frequency in recent years.

Patients have received a victory each year the CJS amendment is renewed (the current version is set to expire September 30, 2019), however there are opportunities for appropriators to include expanded protections for medical cannabis patients through amendments that have successfully passed through a House or Senate committee.

CJS Appropriations (Joyce-Blumenauer Amendment)

The aforementioned Joyce-Blumenauer amendment is the most vital current protection for state medical cannabis programs and the patients who rely on them. Without this amendment, DOJ could resume prosecuting individuals who are in compliance with the state medical cannabis law. This could trigger a host of adverse events, as it would increase the demand for illicit cannabis from patients who would still need it to treat their condition, or it would force patients to go without the treatment option that works best for them. If patients are forced to obtain their medical cannabis through illicit means, it would empower criminal drug cartels and harm the environment by causing an unintended increase in the amount of cannabis grown on public lands.

Banking Amendment (Merkley, Perlmutter)

The Banking amendment would prohibit the federal government from penalizing financial institutions (such as banks) who do business with state-legal cannabis businesses. The federal government currently prevents banks from doing business with dispensaries, cultivators, processors, etc. This amendment would allow these types of business to have access to all typical banking services such as credit cards, payroll, and loans. Like all appropriations amendments, the protection would last one year and would have to be renewed the end of each fiscal year. Without banking, medical cannabis business people are forced to deal with cash only, putting them at great risk of becoming victims of robbery.

Health and Human Services Amendment (Murray Amendment)

The Murray amendment to the Labor-HHS appropriations bill would prevent the agency from punishing doctors who receive HHS funding when they issue medical cannabis recommendations in accordance with state law. This means that doctors in medical cannabis states who work at community health clinics and other HHS-funded health centers would be able to recommend medical cannabis without fear of punishment. Like all appropriations amendments, the protection would last one year and would have to be renewed the end of each fiscal year.



**Veterans Equal Access Amendment (Daines-Merkley)**

The Veterans Equal Access amendment would lift the “gag order” that currently prevents V.A. doctors from discussing the benefits of medical cannabis therapy with their veteran patients. It would prevent the V.A. from punishing its doctors who write medical cannabis recommendations in accordance with state law. By prohibiting the punishment of V.A. doctors, the amendment would allow veterans living in medical cannabis states to obtain medical cannabis recommendations from their doctors.

**Department of Education Amendment**

This amendment would prevent the Department of Education from withholding Pell Grants or other federal aid grants from universities and schools that conduct medical cannabis research or allow medical cannabis patients to medicate on campus. While this amendment has not been introduced in previous appropriations cycles, it would create an opportunity for schools to set their own medical cannabis policies without risk of losing federal benefits.

**4. REGULATORY IMPACT OF COMPREHENSIVE LEGISLATION**

ASA recognizes the time and effort it would take to implement a structure for a new medical cannabis oversight authority described in Chapter 7. Understanding those delays, ASA proposes changes that executive agencies could make immediately to improve medical cannabis policies. Without the fear of federal interference, medical cannabis states are more likely to adopt more civil protections for patients, follow robust product safety protocols, and empower physicians to have a greater say as to which medical conditions can be treated with medical cannabis in these programs.

The following regulatory changes would allow federal agencies to immediately engage with state medical cannabis programs while a new federal oversight agency is being developed through the rulemaking process.

**Department of Justice**

- In absence of the Cole Memo, issue new guidelines to U.S. Attorneys about cannabis enforcement.
- Create a taskforce with Attorneys General to determine protocols for tackling “interstate commerce” issues as they relate to diversion.

**Drug Enforcement Administration**

- Create new protocols for activity in states with medical cannabis laws.
- Create new goals for the Domestic Cannabis Eradication/Suppression Program, including reprioritizing spending levels.
- Act on the 26 pending research licenses and approve at least 5 more licenses under Section 303 of the CSA (21 U.S.C. 823) to manufacture (cultivate) cannabis and cannabis-derivatives for research approved by the Food and Drug Administration.



**Without the fear of federal interference, medical cannabis states are likely to adopt more civil protections for patients, follow robust product safety protocols, and empower physicians to have a greater say as to which medical conditions can be treated with medical cannabis in these programs.**

- Allow DEA-licensed laboratory facilities the ability to test cannabis and cannabis-derived products.

**Food and Drug Administration**

- Work directly with state-based medical cannabis programs which would likely include issuing labeling requirements, Good Manufacturing Practices (GMP), and Good Agricultural Practices (GAP).
- Allow the United States Pharmacopoeia to issue an official cannabis monograph establishing internationally recognized protocols for the standardization of cannabis as an herbal medicine.
- With the passage of the 2018 Farm Bill, provide comprehensive regulations for CBD products. CBD-rich products become subject to the regulations of the Dietary Supplement Health and Education Act (DSHEA). The result of regulating CBD through DSHEA would likely mean that CBD would be treated as a nutraceutical and include product safety protocols as well as key labeling requirements including disease claims.

**Internal Revenue Service**

- The exemption of all state-legal medical cannabis conduct from the CSA would change the application of 280E of the tax code in regards to medical cannabis businesses.

**26 U.S. Code § 280E Expenditures in connection with the illegal sale of drugs:**

“No deduction or credit shall be allowed for any amount paid or incurred during the taxable year in carrying on any trade or business if such trade or business (or the activities which comprise such trade or business) consists of trafficking in controlled substances (within the meaning of Schedule I and II of the Controlled Substances Act) which is prohibited by Federal law or the law of any State in which such trade or business is conducted.”

**United States Department of Agriculture**

- Expand organic standards to cannabis and CBD grown for human consumption. Hold public input hearings on the implementation of hemp regulations.

**Environmental Protection Agency**

- Begin pesticide tolerance testing to establish standards for use on the cultivation of medical cannabis and hemp grown for human consumption and remove cannabis from the list of nonconforming uses.

**Department of the Treasury**

- Remove medical cannabis from the “suspicious activity” category of the Banking Secrecy Act, giving banks the clear and unequivocal legal protection they need in order to offer robust banking services to medical cannabis businesses.

**Housing and Urban Development**

- Remove the threat to medical cannabis patients who possess medicine in their federal subsidized (i.e., “Section 8”) housing unit from being evicted.

# AGENCY ROLES POST-COMPREHENSIVE LEGISLATION



## DRUG ENFORCEMENT ADMINISTRATION

DEA would develop new protocols for interacting with state programs, research and lab licensing. The DEA would oversee licensing for cannabis cultivation for research. With funds saved from ending investigations, raids, and arrests for conduct that is legal under state medical cannabis laws, the DEA could include environmental clean-up to federal land cannabis eradication programs.



## BUREAU OF ALCOHOL, TOBACCO, FIREARMS, AND EXPLOSIVES

ATF would restore medical patients' 2nd Amendment rights by removing the following warning from Form 4473, "The use or possession of marijuana remains unlawful under Federal law regardless of whether it has been legalized or decriminalized for medicinal or recreational purposes in the state where you reside."



## FOOD AND DRUG ADMINISTRATION

The FDA would monitor adverse event reporting and provide input on Good Manufacturing Practices, Good Agricultural Practices and Good Laboratory Practices. Additionally, FDA could provide standardization of product safety protocols, labeling requirements and product recalls. Opportunity would arise to redefine standards of acceptance for botanical medicine.



## DEPARTMENT OF JUSTICE

DOJ would continue to monitor activity outside of state laws. Would no longer be prosecuting and incarcerating people for state-legal medical cannabis conduct, would have more resources for crime-fighting efforts.



## INTERNAL REVENUE SERVICE

Agency would issue guidance for new businesses while continuing to collect taxes from licensed medical cannabis businesses across the country. Medical cannabis businesses acting in accordance with state law could take deductions they are currently being denied by Section 280E of the Internal Revenue Code, which should result in lower out-of-pocket expenses for patients.



## UNITED STATES DEPARTMENT OF AGRICULTURE

Agency could work directly with state medical cannabis programs to provide guidance on the production of crops for human consumption.



## ENVIRONMENTAL PROTECTION AGENCY

The EPA would conduct tolerance studies for the use of pesticides on cannabis, which could increase the levels of safety and production of state programs, ultimately driving down costs to patients.



## DEPARTMENT OF THE TREASURY

As state-licensed medical cannabis business activity would also be legal under federal law, banks would no longer have to file Suspicious Activities Reports under 31 CFR 1020.320 and the Bank Secrecy Act. Treasury would issue new guidance for dual-licensed medical/adult-use business. Banks would be free to do business with state-licensed medical cannabis businesses and the finances of medical cannabis businesses become easier to monitor and regulate than the current cash-only situations many businesses are forced to work under.



## DEPARTMENT OF VETERAN AFFAIRS

The VA would implement a policy that allows for physicians to complete state medical cannabis recommendation forms and could provide training on medical cannabis and the endocannabinoid system to V.A. physicians.



## HOUSING AND URBAN DEVELOPMENT

This agency would update protocols regarding the use of medical cannabis by patients in Section 8 housing.

# 6

## ENDING THE FEDERAL CONFLICT: DIRECT ACTION FROM THE PRESIDENT & EXECUTIVE BRANCH

- KEY POINTS
- 1. POTUS
  - 2. DIVERSE SUPPORT FOR FEDERAL ACTION
  - 3. THE GATEWAY THEORY DISPROVED



### KEY POINTS

- POTUS SHOULD CALL ON CONGRESS TO PASS MEDICAL CANNABIS LEGISLATION THAT ALLOWS FOR A NEW SCHEDULING DETERMINATION AND A NEW FEDERAL OVERSIGHT AGENCY FOR CANNABIS.
- PRESIDENT TRUMP SHOULD DIRECT DOJ TO REINSTATE AUGUST 2013 DOJ GUIDANCE MEMO (AKA “THE COLE MEMO”) FOR PRIORITIZING THE PROSECUTION OF STATE-COMPLIANT MEDICAL CANNABIS BUSINESSES, BUT SHOULD ALSO ADD REPORTING METRICS TO ENSURE THE GUIDANCE IS FOLLOWED.
- POTUS AND DEPARTMENT LEADERS CAN SET AN ARRAY OF POLICIES IN VARIOUS AGENCIES WITHOUT AN ACT OF CONGRESS.



1. POTUS

While the President may need substantial assistance from Congress to reconcile state and federal law, there are things that the President can do independently of Congress to improve patient access to medical cannabis. Harmonizing state and federal law may also require a new definition of medicines or the creation of a new pathway for herbal medicines to earn FDA approval. In fact, a May 2015 HHS internal memo from Acting Director of Food and Drugs Stephen M. Ostroff pointed out that the existing federal laws and regulations are preventing researchers from examining the therapeutic uses of cannabis and its compounds. The memo continues by suggesting an overhaul of the existing legal and regulatory framework may be in order. Other FDA officials and current Surgeon General Jerome Adams have echoed these sentiments by saying that the Schedule I status of cannabis blocks research.<sup>1</sup> A new framework to address these issues is proposed in Chapter 7.

Additionally, the President ought to look at commuting sentences of those currently in federal prison for state-legal medical cannabis activity. There are still individuals serving time in federal prison for charges based on now legal medical cannabis conduct, including Chris Williams, Lance Gloor, and Luke Scarmazzo, among others. As the President commutes these sentences, he should examine whether those with gun convictions were in fact of a violent nature, or if the gun was more incidental. The mere presence of a self-defense or even a hunting weapon has triggered certain mandatory minimum sentences in a number of medical cannabis prosecutions in states with high gun-ownership rates.

Change starts at the top, and perhaps the most import thing the president could do is make full use of the bully pulpit to push for an end to the state and federal conflict on medical cannabis, a new scheduling determination, and a new oversight agency for medical cannabis. President Trump has taken the initial steps on this by supporting medical cannabis on the campaign trail and publicly supporting Senator Cory Gardner’s STATES Act (S.3032 115th), however the issue of cannabis has been surrounded by confusion with Administration moves like the nomination of cannabis opponent Jeff Sessions for Attorney General and rumors of a Marijuana Policy Coordination Committee that sought to undermine the public’s opinion.

However, with medical cannabis having huge bipartisan support at over 90% of the population, there is plenty of room for a sitting president to take bolder action in support of medical cannabis reform. Prior to appointing someone to lead a new Office of Medical Cannabis and Cannabinoid Control, President Trump can immediately improve outcomes for patients by nominating officials to positions who are willing to guide their respective agency towards harmonizing state and federal medical cannabis policy.

”  
Change starts at the top, and perhaps the most import thing the president could do is make full use of the bully pulpit to push for an end to the state and federal conflict on medical cannabis, a new scheduling determination, and a new oversight agency for medical cannabis.

<sup>1</sup> Andrew Blake, Surgeon general says marijuana’s controlled substance status is hindering research, Wash. Times, (Dec 17, 2018), <https://www.washingtontimes.com/news/2018/dec/7/surgeon-general-suggests-reconsidering-marijuanas>

The following are policy recommendations that could be taken by President Trump unilaterally:

Department of Justice

- Direct the DOJ to reinstate the August 2013 Cole Memo for prioritizing the prosecution of state-compliant medical cannabis business.
- Outline clear reporting metrics for cases being investigated and making their way towards prosecution.

Drug Enforcement Administration

- Direct the DEA to begin issuance of additional research licenses.

Health and Human Services

- Call on HHS to create a taskforce to identify and eliminate obstructive regulations.
- Amend policies to clarify that hospitals, community health clinics and their medical professionals who wish to utilize their state’s medical cannabis program will not be in jeopardy of losing HHS funding and accreditation for research.

National Institutes of Health

- In annual budget request, place a greater emphasis on cannabis-based research.
- Work with state programs to facilitate research.

Internal Revenue Service

- Issue Prosecution Recommendation guidance to its special agents on deprioritizing the prosecution of Internal Revenue Code 280E cases if the businesses are in compliance with state law.

Environmental Protection Agency

- Authorize the EPA to conduct pesticide tolerance testing to establish standards for use on the cultivation of medical cannabis and hemp grown for human consumption.

Veterans Administration

- Direct VA to issue a new policy directive that allows its physicians to use their medical judgement in determining whether or not to give a patient a recommendation for medical cannabis.

Centers for Disease Control and Prevention

- Direct the CDC to collect and publish data on medical cannabis use. Findings from this data could be published in the CDC’s Morbidity and Mortality Weekly Report, which is influential in shaping the public policy of state health departments.

State Department

- Clearly state that the position of the United States is to support the World Health Organization’s recommendation about the international rescheduling of cannabis.
- Invite world leaders from the nearly 40 other nations with medical cannabis laws to a policy summit at the White House.

## 2. DIVERSE SUPPORT FOR FEDERAL ACTION

Support for medical cannabis is strong across many different demographics and continues to rise. A 2014 CNN/ORC national poll showed that 88% of Americans supported medical cannabis.<sup>2</sup> A 2016 poll by Quinnipiac University surveying 1,561 registered voters nationwide pegged support for medical cannabis at 89%.<sup>3</sup>

Subsequent polling Quinnipiac University conducted in 2018 revealed that the percentage of voters who support medical cannabis had grown to 93%.<sup>4</sup> The same poll showed that 70% of voters oppose the enforcement of federal laws against cannabis in states that have passed medical or adult-use cannabis laws and that 74% of voters would support a bill protecting states that have legalized medical or adult-use cannabis from federal prosecution.<sup>5</sup>

Support for medical cannabis cuts across party lines. Eighty-nine percent of Republicans, 97% of Democrats, and 95% of Independents are in favor of allowing safe and legal access to medical cannabis.<sup>6</sup> Similarly, medical cannabis enjoys support across all age groups: 96% of those aged 18-34, 93% of those aged 35-49, 95% of those aged 50-64, and 91% of those over the age of 65 are in favor of it.<sup>7</sup>

The American Medical Association, the American College of Physicians, the Texas Medical Association, the National Multiple Sclerosis Society, the Epilepsy Foundation, the U.S. Pain Foundation, The Leadership Conference on Civil & Human Rights, the American Legion, Iraq and Afghanistan Veterans of America, the American Civil Liberties Association, and the American Cancer Society are among the organizations that have released statements supporting further research into or the use of medical cannabis.

<sup>2</sup> CNN and ORC International. Poll. January 8, 2014.  
<sup>3</sup> Quinnipiac University. Allow Marijuana for Vets With PTSD, U.S. Voters Say 10-1, Quinnipiac University National Poll Finds; Slim Majority Says Legalize Marijuana in General. June 6, 2016.  
<sup>4</sup> Quinnipiac University. U.S. Voters Believe Comey More Than Trump, Quinnipiac University National Poll Finds; Support for Marijuana Hits New High. April 26, 2018.  
<sup>5</sup> *Id.*  
<sup>6</sup> *Id.*  
<sup>7</sup> *Id.*

### Statements from Qualified Experts and Medical Organizations

*National Multiple Sclerosis Society:* “The Society supports the rights of people with MS to work with their MS health care providers to access marijuana for medical purposes in accordance with legal regulations in those states where such use has been approved. In addition, the Society supports advancing research to better understand the benefits and potential risks of marijuana and its derivatives as a treatment for MS.”<sup>8</sup>

*Epilepsy Foundation:* “The Epilepsy Foundation supports the rights of patients and families living with seizures and epilepsy to access physician directed care, including medical marijuana. Nothing should stand in the way of patients gaining access to potentially life-saving treatment. If a patient and their healthcare professionals feel that the potential benefits of medical marijuana for uncontrolled epilepsy outweigh the risks, then families need to have that legal option now — not in five years or ten years. For people living with severe uncontrolled epilepsy, time is not on their side. This is a very important, difficult, and personal decision that should be made by a patient and family working with their healthcare team.”<sup>9</sup>

*U.S. Pain Foundation:* “U.S. Pain Foundation believes that people living with chronic illness and pain should have access to timely and appropriate treatments, which includes medical marijuana. Cannabinoids have well-documented analgesic properties that make medical marijuana an effective medicine to treat many cases of chronic pain where many traditional chronic pain medications do not.”<sup>10</sup>

*The Leadership Conference on Civil & Human Rights:* The Leadership Conference on Civil & Human Rights urges Congress to “Pass legislation de-scheduling marijuana with racial equity and justice reform components. End federal prohibition in a way that acknowledges decades of harm faced by communities of color and low-income communities.”<sup>11</sup>

*American Medical Association:* “Our AMA urges that marijuana’s status as a federal Schedule I substance be reviewed with the goal of facilitating the conduct of clinical research and development of cannabinoid-based medicines...”<sup>12</sup>

*American College of Physicians:* “ACP urges an evidence-based review of marijuana’s status as a Schedule I controlled substance to determine whether it should be reclassified to a different schedule.”<sup>13</sup>

<sup>8</sup> National Multiple Sclerosis Society. Medical Marijuana (Cannabis). ND. Available from <https://www.nationalmssociety.org/Treating-MS/Complementary-Alternative-Medicines/Marijuana>.  
<sup>9</sup> Epilepsy Foundation. Epilepsy Foundation Calls for Increased Medical Marijuana Access and Research. February 20, 2014.  
<sup>10</sup> U.S. Pain Foundation. U.S. Pain Foundation Position Statement – Medical Marijuana. April 2016.  
<sup>11</sup> The Leadership Conference on Civil & Human Rights. Leadership Conference Priorities for the 116th Congress. December 12, 2018.  
<sup>12</sup> American Medical Association. Report 5 of the Council on Science and Public Health (I-17): Clinical Implications and Policy Considerations of Cannabis Use. 2017.  
<sup>13</sup> American College of Physicians. Supporting Research into the Therapeutic Role of Marijuana. 2008.





*Texas Medical Association:* “The Texas Medical Association supports... further adequate and well-controlled studies of marijuana and related cannabinoids for potential medical uses, particularly in patients with serious conditions for which preclinical, anecdotal, or controlled evidence suggests possible efficacy and for the application of such results to the understanding and treatment of disease,” and affirms “the physician’s right to discuss with his or her patients any and all possible treatment options related to the patients’ health and clinical care, including the use of marijuana, without the threat to physician or patient of regulatory, disciplinary, or criminal sanctions.”<sup>14</sup>

*The American Legion:* “The American Legion urge Congress to amend legislation to remove Marijuana from Schedule I and classify it in a category that, at a minimum, will recognize cannabis as a drug with potential medical value.”<sup>15</sup>

*Iraq and Afghanistan Veterans of America:* “Veterans have fought for our nation and often sustained injuries as a result of their service. Our government allowed our men and women to handle weapons, warships and the most incredible technology in the world, but it prohibits them from having access to cannabis to treat their wounds. It’s backward and harmful that regressive federal policies still ridiculously prohibit our veterans from having access to something that can lessen their pain, treat their symptoms, and improve their lives. IAVA members nationwide have spoken loudly and clearly. We need change now. This is a non-partisan issue that requires clear and immediate support from everyone in America, from the average citizen citizen to our Commander-in-Chief. We encourage all Americans to stand with our veterans community to demand change.”<sup>16</sup>

*American Cancer Society:* “The American Cancer Society supports the need for more scientific research on cannabinoids for cancer patients, and recognizes the need for better and more effective therapies that can overcome the often debilitating side effects of cancer and its treatment. The Society also believes that the classification of marijuana as a Schedule I controlled substance by the U.S. Drug Enforcement Administration imposes numerous conditions on researchers and deters scientific study of cannabinoids. Federal officials should examine options consistent with federal law for enabling more scientific study on marijuana.”<sup>17</sup>

*American Civil Liberties Union:* “The War on Marijuana, like the War on Drugs, has failed by almost every measure – with the exception of successfully destroying communities of color. Marijuana criminalization negatively impacts public housing and student financial aid eligibility, employment opportunities, child custody decisions, and immigration status.”<sup>18</sup>

14 Texas Medical Association. Official TMA Policy 95.010 Marijuana. October 7, 2016.  
15 American Legion. Resolution No. 11: Medical Marijuana Research. Ninety-eighth National Convention of the American Legion. Cincinnati, OH. August 2016.  
16 Iraq and Afghanistan Veterans of America. #CannabisForVets Launches with Groundbreaking Ads in Washington Post, USA Today. October 4, 2018.  
17 American Cancer Society. Marijuana and Cancer. ND. Available from <https://www.cancer.org/treatment/treatments-and-side-effects/complementary-and-alternative-medicine/marijuana-and-cancer.html>.  
18 American Civil Liberties Union. ACLU Statement on DOJ Decision to Shift Federal Government’s Role in State Marijuana Laws. January 4, 2018.

MYTH: IF STATES LEGALIZE MEDICAL CANNABIS, THERE WOULD BE NO FEDERAL OVERSIGHT OF ANY SORT OVER STATE MEDICAL CANNABIS PROGRAMS. THERE WOULD BE PROBLEMS SUCH AS “QUALITY” DUE TO THERE BEING “50 DIFFERENT LAWS IN 50 DIFFERENT STATES.”

Quoted concerns of Senator Chuck Grassley at a Feb. 16, 2016 town hall meeting, as reported in the Tama News-Herald, Feb. 23, 2016.

FACT: THE PASSAGE OF COMPREHENSIVE LEGISLATION WOULD ALSO TRIGGER A HOST OF STATE-FEDERAL AGENCY COOPERATION THAT WOULD LIKELY INCLUDE STATE AND FEDERAL HEALTH DEPARTMENTS, FOOD AND AGRICULTURAL AGENCIES, THE FOOD AND DRUG ADMINISTRATION, AND LAW ENFORCEMENT TASKFORCES. SUCH COOPERATION COULD RESULT IN THE FEDERAL LICENSING FOR STATE-SANCTIONED CANNABIS OPERATIONS, SUCH AS DEA LICENSING OF CULTIVATION AND CANNABIS PESTICIDE RESEARCH AND GUIDANCE FROM THE ENVIRONMENTAL PROTECTION AGENCY.



THE BIPARTISAN INTRODUCTION OF THE CARERS ACT TO THE SENATE IN MARCH 2015 DEMONSTRATED HOW MAINSTREAM THE ISSUE OF MEDICAL CANNABIS HAS BECOME IN THE PAST TWO DECADES.

”  
**Researchers at Columbia University conducted a longitudinal study of 708 adolescents and concluded that early onset cannabis use did not lead to problematic drug use.**

*World Health Organization:* Has recommended to the United Nations that Cannabis and Cannabis Resin be removed from Schedule IV of the Single Convention on Narcotic Drugs, recognizing the therapeutic potential of cannabis.<sup>19</sup>

Broad support for changes to federal law that reflect the latest science and patient experiences with medical cannabis should embolden legislators to act quickly and decisively to rectify the injustice engendered by decades of cannabis prohibition. Millions of suffering Americans deserve nothing less.

### 3. THE GATEWAY THEORY DISPROVED

The “gateway drug” theory, which holds that an individual’s use of a psychoactive substance increases the probability that said individual will go on to use other psychoactive substances, is often used as an argument against medical cannabis efforts. It should be noted that more than four decades’ worth of epidemiological research has disproved the validity of this theory. In fact, in its denial of a petition to reschedule cannabis, the DEA included documentation from the FDA stating that “Overall, research does not support a direct causal relationship between regular cannabis use and other illicit drug use. [...] Although many individuals with a drug abuse disorder may have used cannabis as one of their first illicit drugs, this fact does not correctly lead to the reverse inference that most individuals who used cannabis will inherently go on to try or become regular users of other illicit drugs.”<sup>20</sup> The FDA cited several studies to support this conclusion, including a longitudinal study of 708 adolescents conducted by researchers at Columbia University that concluded that early onset cannabis use did not lead to problematic drug use.<sup>21</sup>

19 *Supra* n.9  
20 Drug Enforcement Administration. Denial of Petition to Initiate Proceedings to Reschedule Marijuana. Federal Register. August 2016; 53687-53766. 81 FR 53687.  
21 Kandel, D. and Chen, K. Types of Marijuana Users by Longitudinal Course. Journal of Studies on Alcohol. June 2000; 61(3):367-78. DOI: 10.15288/jsa.2000.61.367.



## 7

# ENDING THE FEDERAL CONFLICT: CHANGING THE PARADIGM ON MEDICAL CANNABIS

## KEY POINTS

1. CHANGING THE PARADIGM ON MEDICAL CANNABIS
2. MEDICAL CANNABIS CONTROL ACT OF 2019



## KEY POINTS

- A NEW FEDERAL FRAMEWORK IS NEEDED FOR CANNABIS REGULATION.
- OVERSIGHT OF CANNABIS NEEDS TO BE TRANSFERRED FROM DOJ, HHS, AND FDA.

# CHANGING THE PARADIGM ON MEDICAL CANNABIS

## Creating Federal Oversight and Creating a New Classification

Since the passage of the Controlled Substances Act (“CSA”), the conversation surrounding cannabis has always been tethered to cannabis’ Schedule I status. Though its original placement in Schedule I was intended to be temporary, medical cannabis patients have suffered from nearly 50 years of the side effects of prohibition. Schedule I status means that a drug has a high potential for abuse and no accepted medical value.<sup>1</sup> Efforts to end prohibition have focused on a dichotomy of rescheduling or descheduling, but the question of what happens after a rescheduling, descheduling or creation of a new scheduling category has been left undiscussed.

The overwhelming majority of substances listed in the Controlled Substances Act are synthetic compounds, not natural products. Cannabis (and perhaps a few other natural substances) does not organically fit into the schedules described by the CSA. The U.S. government has not recognized the medical value of cannabis, putting current law at odds with science. However, the National Institute on Drug Abuse (NIDA) acknowledges that “THC itself has proven medical benefits in particular formulations.”<sup>2</sup> Additionally, two NIDA-funded studies demonstrated a reduction in opioid overdose deaths in states with medical cannabis dispensaries.<sup>3</sup>

## Step 1. Amend CSA exemptions to include cannabis (“marihuana” under the CSA) or develop a new Scheduling Category for Cannabis

21 U.S.C § 802(6) currently defines a controlled substance as “a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V of part B of this subchapter. The term does not include distilled spirits, wine, malt beverages, or tobacco, as those terms are defined or used in subtitle E of the Internal Revenue Code of 1986.”<sup>4</sup>

ASA proposes to add cannabis (listed as “marihuana” in the CSA) as an exemption to this list, remove references to it elsewhere under the CSA, and create a new Internal Revenue Code Provision defining, and establishing the regulatory framework for, cannabis. As described below, this would delegate jurisdictional authority to a new federal agency, much like alcohol and tobacco have been delegated to the Bureau of Alcohol, Tobacco, Firearms and Explosives.

Alternatively, recognizing that one of the main factors the Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) consider in determining abuse potential is recreational use of a substance, ASA proposes a new scheduling parameter that maintains moderate controls but allows the greatest number of patients to access cannabis as a medicine.

”  
With international rescheduling of cannabis on the horizon, it is time the United States follow the lead of other countries, and in particular, those nations where the regulation and control of cannabis is placed in a centralized agency.

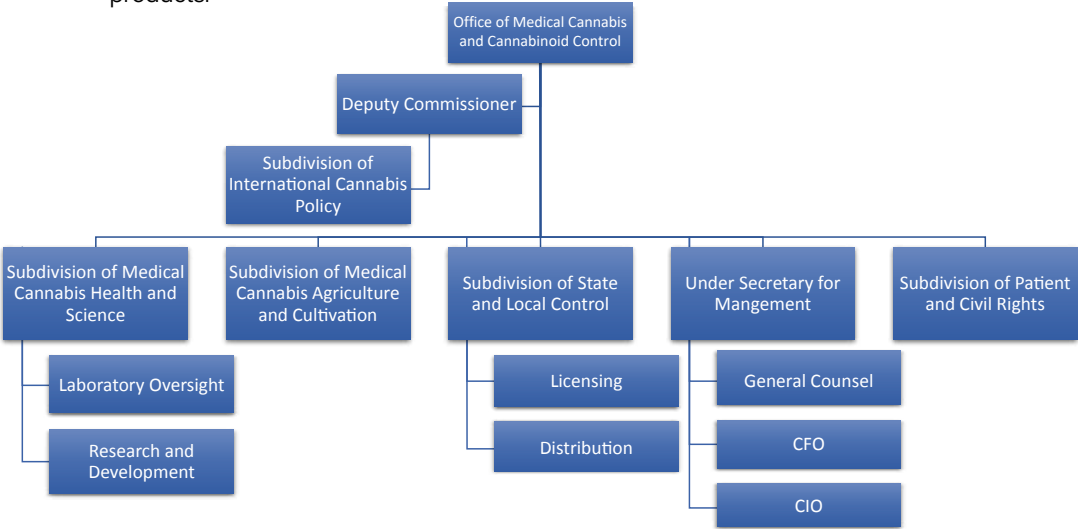
Based on its recognized medical potential and varying potential for abuse, cannabis should be placed in a new schedule, Schedule V(A), meaning that a prescription would be required for cannabis, but it would be widely accessible for patients and could be recommended by physicians as a first-line medication.

## Step 2. Create new federal Agency with centralized regulatory authority

Effective regulation of cannabis is strained by nearly a dozen agencies wanting to play a role in the decision making process. The Department of Justice, FDA, HHS, DEA, ONDCP, and other smaller agencies all clamor to provide input into federal scheduling decisions. With international rescheduling of cannabis on the horizon, it is time the United States follow the lead of other countries, and in particular, those nations where the regulation and control of cannabis is placed in a centralized agency. Without consistent oversight, cannabis cannot be produced and distributed as a medicine. For example, as long as HHS and the DEA have joint jurisdiction, movement cannot happen. This is because the primary goal of HHS is to enhance the health and well-being of Americans, while the primary function of the DEA is to act as a law enforcement agency that uses criminal and civil penalties to complete its mission.

The Administrative Procedures Act stipulates that there are two methods by which a new federal agency may be created.<sup>5</sup> The President can create a new agency through an executive order, or Congress can create it by way of an enabling statute that outlines the scope of the agency’s power. Executive agencies can be created by the President with broad authority, like the Department of State, Department of Justice, or the Department of Transportation. Congress can also create agencies through statute. For example, the FDA was created via the enabling legislation of the Federal Food, Drug, and Cosmetic Act.

The Office of Medical Cannabis and Cannabinoid Control, as laid out by the legislation and figure below, would create a central authority within the U.S. Government to regulate cannabis once it has been exempted from the Controlled Substances Act or rescheduled. Particularly important would be the Office of Cannabis Health and Science, which would assume responsibility for the roles currently filled by NIDA, HHS, and the FDA. The Office of Cannabis Health and Science would conduct research and provide guidance for new medical applications of the cannabis plant and cannabis products.



1 21 U.S.C. §812(b)(1)  
2 Nat’l Ins. on Drug Abuse, *Is Marijuana Safe and Effective as Medicine?*, (last updated June 2018), <https://www.drugabuse.gov/publications/research-reports/marijuana/marijuana-safe-effective-medicine>  
3 *Id.*  
4 21 U.S.C. §802(6)

5 5 U.S.C. ch. 5, subch. I § 500 et seq.

# AN ACT

To establish the Office of Medical Cannabis and Cannabinoid Control, and for other purposes

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

**TABLE OF CONTENTS- The table of contents for this Act is as follows:**

- Sec. 1- Short title;
- Sec. 2- Sense of Congress
- Sec. 3- Definitions.
- Sec. 4- Construction; Severability allowed
- Sec. 5- Effective Date

TITLE I- OFFICE OF MEDICAL CANNABIS AND CANNABINOID CONTROL

- Sec. 101- Legislative Agency; Mission
- Sec. 102- Commissioner, duties
- Sec. 103- Other Officers

TITLE II- SUBDIVISION OF MEDICAL CANNABIS SCIENCE AND HEALTH

- Sec. 201- Establishment of Subdivision, Under Secretary
- Sec. 202- Mission of Subdivision, Duties
- Sec. 203- Transfer of Functions
- Sec. 204- Federally funded research and development centers
- Sec. 205- Conduct of Research, Development, Demonstration Testing and Evaluation
- Sec. 206- Miscellaneous provisions

TITLE III- SUBDIVISION OF CANNABIS AGRICULTURE AND CULTIVATION

- Sec. 301- Establishment of Subdivision, Under Secretary
- Sec. 302- Mission of Subdivision, Duties
- Sec. 303- Transfer of Functions
- Sec. 304- Federally Funded Subsidies, Crop Insurance
- Sec. 305- Cannabis production; state and tribal plans
- Sec. 306- Miscellaneous provisions

TITLE IV- MANAGEMENT

- Sec. 401- Under Secretary for Management
- Sec. 402- Chief Financial Officer
- Sec. 403- Chief Information Officer
- Sec. 404- Establishment of Officer for Patient and Civil Rights

TITLE V- COORDINATION WITH NON-FEDERAL ENTITIES

- Subtitle A- Coordination with Non-Federal Entities
  - Sec. 501- Subdivision for State and Local Government Coordination
- Subtitle B– Miscellaneous Provisions
  - Sec. 502- Advisory Committees
  - Sec. 503- Military Activities
  - Sec. 504- Office of International Cannabis Policies

TITLE VI– TRANSITION

- Sec. 601- Definitions
- Sec. 602- Reorganization Plan

TITLE VII- IMPLEMENTATION

- Sec 701- Licensing; General Provisions
- Sec 702- Speciality Licensing
- Sec 703- Distribution, Guidelines
- Sec 704- Prescription Protocols
- Sec 705- Advisory Committee
- Sec 706- Transfer Of Functions

**SEC. 1 SHORT TITLE-** This Act may be cited as the Medical Cannabis Control Act of 2019

**SEC. 2 SENSE OF CONGRESS**

*Expressing the sense of Congress that a new federal agency, the Office of Medical Cannabis and Cannabinoid Control, would be beneficial to public and individual health.*

Whereas there are over two million medical cannabis patients and over 20,000 cannabis businesses in the United States.

Whereas thirty-three states, the District of Columbia, and four of five U.S. territories have comprehensive medical cannabis legislation.

Whereas oversight authority of medical cannabis has been handled on the state and local level, rather than through the federal government, putting the United States at odds with the 1961 Single Convention on Narcotic Drugs, as amended by the 1972 Protocol,<sup>6</sup> which requires a singular medical cannabis oversight body under Article 28.

Whereas on January 24, 2019 the World Health Organization (WHO) presented a letter to the Secretary-General of the United Nations calling for a change in scheduling under international law by removing cannabis and cannabis resin from Schedule IV of the Single Convention on Narcotic Drugs, and by removing cannabidiol completely from international control, acknowledging the medical value of cannabis.

Whereas over thirty countries in Europe, North America, South America, Africa, Asia, and Oceania have passed medical cannabis laws consistent with international treaty parameters.

Whereas the United States and its territories have created a patchwork of licensing, regulation, and enforcement laws that lack uniformity.

Whereas current federal oversight from the Drug Enforcement Administration (DEA) and the National Institute on Drug Abuse focuses on punitive measures and the harms of cannabis, rather than the expansion of therapeutic outcomes, which is inconsistent with the WHO’s recommendations.

Whereas due to resource constraints and political ideations, the DEA has failed to act on over two dozen legitimate requests for research licenses.

Whereas Schedule I researchers who do obtain the proper license may be forced to import cannabis from other countries or obtain cannabis that does not mirror what is otherwise available in state markets to patients.

Whereas administrators of the Food and Drug Administration and other agencies have called on Congress to resolve the conflict between state and federal laws.

Whereas the Investigational New Drug program, which previously had oversight over cannabis, has not enrolled a new patient since 1992, making the program functionally nonexistent.

<sup>6</sup> United Nations, *Treaty Series*, vol. 976, No 14152



Whereas research in the Journal of the American Medical Association has shown cannabis can play a critical role in reducing opioid overdose deaths, up to 25%, when compared to states without medical cannabis programs, and cannabis is widely used for alleviating the symptoms of numerous other medical conditions.

Now, therefore, be it

Resolved by the United States Congress that it is the sense of Congress that a new federal oversight agency for medical cannabis would be beneficial to public and individual health.

SEC 3 DEFINITIONS

In this Act, the following definitions shall apply:

- (1) The term “appropriate congressional committee” means any committee of the House of Representatives or the Senate having legislative or oversight jurisdiction under the Rules of the House of Representatives or the Senate, respectively, over the matter concerned.
- (2) The term “ASTM Guidelines” means guidelines developed by the American Society for Testing and Materials, including but not limited to guidelines developed for cannabis under their D37 committee.
- (3) The term “assets” includes contracts, facilities, property, records, unobligated or unexpended balances of appropriations, and other funds or resources (other than personnel).
- (4) The term “cannabis” means marihuana as defined in title 21, United States Code, §802 (16).
- (5) The term “Cannabis Headquarters Laboratory” means a federal laboratory created in consultation with the National Academies of Sciences, appropriate federal agencies and other experts that serves as the national model for cannabis laboratory testing. The laboratory may provide functions of testing and development of cannabis and cannabis products.
- (6) The term “cannabis products” means products derived from the cannabis plant, including but not limited to products made from the extraction of one or more cannabinoids.
- (7) The term “Commissioner” means the head of the Office of Medical Cannabis and Cannabinoid Control as defined in (13).
- (8) The term “Departments” means other executive and legislative agencies as defined under title 5, United States Code.
- (9) The term “executive agency” means an executive agency and a military department, as defined, respectively, in sections 105 and 102 of title 5, United States Code.
- (10) The term “functions” includes authorities, powers, rights, privileges, immunities, programs, projects, activities, duties, and responsibilities.
- (11) The term “key resources” means publicly or privately controlled resources essential to the minimal operations of the economy and government.
- (12) The term “local government” means—
  - (a) a county, municipality, city, town, township, local public authority, school district, special district, intrastate district, council of governments (regardless of whether the council of governments is incorporated as a nonprofit corporation under State law), regional or interstate government entity, or agency or instrumentality of a local government;
  - (a) an Indian tribe or authorized tribal organization, or in Alaska a Native village or Alaska Regional Native Corporation; and
  - (a) a rural community, unincorporated town or village, or other public entity.
- (13) The term “Office of Medical Cannabis and Cannabinoid Control” means a centralized federal oversight agency for cannabis as described in this chapter.
- (14) The term “personnel” means officers and employees.
- (15) The term “private sector” means businesses, associations, nonprofits or other entities organized under Federal, State, or Local laws for a non-governmental purpose.
- (16) The term “Non-Federal Agencies” means state and local departments of health, state and local cannabis oversight authorities, and other entities not organized under Federal law
- (17) The term “State” means any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, and any possession of the United States.

- (18) The term “Subdivision of Medical Cannabis Agriculture and Cultivation” means a sub-office of the Office of Medical Cannabis and Cannabinoid Control that oversees standards for cannabis cultivation and production.
- (19) The term “Subdivision of Medical Cannabis Science and Health” means a sub-office of the Office of Medical Cannabis and Cannabinoid Control that oversees medical cannabis science, development and research.
- (20) The term “United States,” when used in a geographic sense, means any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, any possession of the United States, and any waters within the jurisdiction of the United States.

SEC. 4 CONSTRUCTION; SEVERABILITY

Any provision of this Act held to be invalid or unenforceable by its terms, as applied to any person or circumstance, shall be construed as to give it maximum effect permitted by law, unless such holding shall be one of utter invalidity or un-enforceability, in which event such provision shall be deemed severable from this Act and shall not affect the remainder thereof, or the application of such provision to other persons not similarly situated or to other, dissimilar circumstances.

SEC. 5. EFFECTIVE DATE

This Act shall take effect sixty (60) days after the date of enactment.

TITLE I- OFFICE OF CANNABIS CONTROL

SEC. 101 LEGISLATIVE AGENCY; MISSION

- (a) There is established an Office of Medical Cannabis and Cannabinoid Control, as a legislative agency of the United States within the meaning of title 5, United States Code
- (b) Mission-
  - (i) IN GENERAL- the primary mission of the Office is to–
    - (A) ensure that there is a safe, legal and consistent way for Americans to access cannabis for research and cannabis therapies. The office ensures the consumer safety of cannabis and cannabis products, conducts research, issues licenses to manufacturers and cultivators, distributes to speciality pharmacies, and removes enforcement authority from the Department of Justice. The office seeks to advance science and knowledge related to cannabis to improve individual and public health;
    - (B) provide oversight for the licensure, production, manufacture, distribution, sale, and use of medical cannabis;
    - (C) provide minimum standards for labeling, packaging, product safety for cannabis and cannabis products, and pesticide and agricultural guidelines for cannabis cultivation and cannabis products;
    - (D) approve new applications and formulations of cannabis and cannabis products;
    - (E) provide oversight for research and development of new applications of cannabis and cannabis products;
    - (F) provide licensing processes for existing and new medical cannabis facilities;
    - (G) retain primary oversight of marijuana as defined in 21 U.S.C. §802 (16); and
    - (H) carry out the functions of all entities transferred to the office and serve as focal point for government functions related to medical cannabis.
  - (ii) RESPONSIBILITY FOR CANNABIS ENFORCEMENT ACTIONS– except as specifically provided by law with respect to entities transferred to this Office under this Act, primary responsibility for enforcement actions shall not be vested in the Office, but rather in State and local enforcement bodies with jurisdiction over the acts in question.

SEC. 102. COMMISSIONER, DUTIES

- (a) COMMISSIONER–
  - (i) IN GENERAL– There is a Commissioner of Medical Cannabis Control appointed by the President with the Advice and Consent of the Senate
  - (ii) HEAD OF OFFICE– The Commissioner is the head of the Office and shall have direction, authority, and control over it.
  - (iii) FUNCTIONS VESTED IN COMMISSIONER- All functions of all officers, employees, and organizational units of the Office are vested in the Commissioner

- (b) **FUNCTIONS-** The Commissioner–
  - (i) Except as otherwise provided by this Act, may delegate any of the Commissioner’s functions to any officer, employee or organizational unit of the office;
  - (ii) Shall have the authority to make contracts, grants, and cooperative agreements, and enter into agreements with other agencies, as may be necessary and proper to carry out the Commissioner’s duties under this act or otherwise provided by laws; and
  - (iii) Shall take reasonable steps to ensure that information and databases maintained by the Office are compatible with each other and with appropriate databases of other Departments.
- (c) **COORDINATION WITH NON-FEDERAL AGENCIES–** With respect to cannabis, the Commissioner shall coordinate through the Office of State and Local Coordination (established under section 401) with state and local departments of health, cannabis oversight bodies, the private sector, and other relevant authorities by –
  - (i) Coordinating with state and local cannabis boards, licensing authorities, and with the private sector to ensure adequate controls, equipment, and training activities;
  - (ii) Coordinating, and as appropriate, consolidating the Federal Government’s communications and systems of communications relating to cannabis with state and local government personnel, the private sector, other entities and the public; and
  - (iii) Distributing or, as appropriate coordinating, the distribution of warnings and recall notices of cannabis or cannabis products to state and local government personnel, the private sector, other entities and to the public.
- (d) **ISSUANCE OF REGULATIONS–** The issuance of regulations by the Commissioner shall be governed by the provisions of chapter 5 of title 5, United States Code, except as specifically provided in this Act, in laws granting regulatory authorities that are transferred by this Act, and in laws enacted after the date of enactment of this Act.

**SEC. 103 OTHER OFFICERS**

- (a) **DEPUTY COMMISSIONER; UNDER SECRETARIES.** – There are the following officers, appointed by the President, by and with the advice and consent of the Senate:
  - (i) Deputy Commissioner of Medical Cannabis Control, who shall be the Officer’s first assistant for purposes of subchapter III of chapter 33 of title 5, United States Code,
  - (ii) An Under Secretary for Medical Cannabis Science & Health;
  - (iii) An Under Secretary for Cannabis Agriculture & Cultivation;
  - (iv) An Under Secretary for Management; and
  - (v) A General Counsel, who shall be the chief legal officer of the Office.
- (b) **OTHER OFFICERS** – To assist the Commissioner in the Performance of the Commissioner’s functions, there are the following officers appointed by the president:
  - (i) Chief Financial Officer;
  - (ii) Chief Information Officer;
  - (iii) Officer for Civil and Patient Rights;
  - (iv) Director of Office of International Cannabis Policy; and
  - (v) Director of Office of State and Local Control
- (c) **PERFORMANCE SPECIFIC FUNCTIONS.** – Subject to the provisions of this Act, every officer of the Office shall perform the functions specified by law for the official’s office or prescribed by the Commissioner.

**TITLE II- SUBDIVISION OF CANNABIS SCIENCE AND HEALTH**

**SEC. 201- ESTABLISHMENT OF SUBDIVISION, UNDER SECRETARY**

- (a) **ESTABLISHMENT**
  - (i) **IN GENERAL–** There is hereby established with the cooperation of the Department of Health and Human Services, the National Institute on Drug Abuse, and the Food and Drug Administration, a subdivision of Cannabis Science & Health (hereinafter referred to as the “Subdivision”).
  - (ii) **AUTHORITY-** The subdivision shall be under the general authority of the assistant secretary of Health and Human Services and the Office of Medical Cannabis but shall maintain independent discretion when making decisions about medical cannabis.

- (iii) **UNDER SECRETARY–** The subdivision shall be headed by an under secretary who shall be an individual appointed based on approval of the Office of Personnel Management of the executive qualifications of the individual.

**SEC. 202- MISSION OF SUBDIVISION; DUTIES**

- (a) **MISSION–** The mission of the subdivision shall be–
  - (i) To serve as the national focal point for medical cannabis, removing authority from the National Institute on Drug Abuse, Drug Enforcement Administration, and Department of Health and Human Services;
  - (ii) To oversee medical cannabis research;
  - (iii) To carry out educational programs for medical cannabis practitioners;
  - (iv) To carry out programs that improve access to medical cannabis; and
  - (v) To develop new applications of cannabis and cannabis products for medical purposes.
- (b) **DUTIES-** In carrying out its mission, the subdivision shall have the following duties,
  - (i) Provide recommendation and advice about cannabis and cannabis medicines to the Commissioner of the Food and Drug Administration, as needed;
  - (ii) To establish and maintain advisory groups to assess the scientific needs of Federal, State and Local cannabis research facilities;
  - (iii) To establish minimum laboratory research standards in accordance with ISO 17025 and ASTM guidelines and test and evaluate research processes that may be used by federal, state, local and private researchers and laboratories;
  - (iv) To establish a program that certifies, validates, or otherwise approves research study designs that explore potential of cannabis as a medicine;
  - (v) To coordinate with other federal agencies and Executive Office of the President to establish a coordinated Federal approach to researching medical cannabis;
  - (vi) To carry out research, development, testing, evaluation and cost benefit analyses in fields that improve the safety and effectiveness of cannabis medicines, including but not limited to:
    - (1) Cannabis as a replacement for opioid therapies;
    - (2) Cannabis as a treatment for PTSD;
    - (3) Potency of medicine treating a variety of conditions;
    - (4) Development of an accurate biological or observational test to assess impairment; and
    - (5) Cannabis as a treatment option for veterans;
  - (vii) To develop and disseminate to State and Local departments of health training materials for regulators, law enforcement, and prosecutors; and
  - (viii) To support research fellowships in support of its mission.
- (c ) **COMPETITION REQUIRED–** Except as otherwise expressly provided by law, all research and development carried out by or through the Subdivision shall be carried out on a competitive basis.
- (d) **TRANSFER OF FUNDS–** The Subdivision may transfer funds to other federal agencies or provide funding to non-Federal entities through grants, cooperative agreements, or contracts to carry out its duties under this section.

**SEC. 203- TRANSFER OF FUNCTIONS**

- (a) **AUTHORITY TO TRANSFER FUNCTIONS–** The Attorney General, and other Secretaries as appropriate, shall transfer to the Subdivision any program or activity of another government agency that is consistent with the mission of the Office.
- (b) **TRANSFER OF PERSONNEL AND ASSETS-** With respect to any function, power, duty or any program or activity that is established in the Office, those employees and assets of another government agency may be transferred to the Office.

**SEC. 204- FEDERALLY FUNDED RESEARCH AND DEVELOPMENT CENTERS**

The Commissioner, acting through the Under Secretary of Medical Cannabis Science and Health, shall have the authority to establish or contract with one (1) or more federally funded research and development centers to

provide independent analysis of cannabis issues, the use of medical cannabis, production of medical cannabis and cannabis medicines, or to carry out other responsibilities under this Act.

**SEC. 205- CONDUCT OF RESEARCH, DEVELOPMENT, DEMONSTRATION, TESTING AND EVALUATION**

- (a) IN GENERAL- The Commissioner, acting through the Under Secretary for Cannabis Science and Health, shall carry out the responsibilities described in Section 202(b) through both extramural and intramural programs.
- (b) EXTRAMURAL PROGRAMS
  - (i) IN GENERAL- The Commissioner, acting through the Under Secretary for Cannabis Science and Health, shall operate extramural research, development, demonstration testing and evaluation programs so as to:
    - (1) Ensure that colleges, universities, private research institutes, and companies from as many areas of the United States with different grow climates for cannabis as practicable participate;
    - (2) Ensure that research funded is of high quality; and
    - (3) Distribute funds through grants, cooperative agreements and contracts.
  - (ii) UNIVERSITY-BASED CENTERS FOR CANNABIS RESEARCH
    - (1) ESTABLISHMENT- The Commissioner, acting through the Under Secretary of Cannabis Science and Health, shall establish within (one) 1 year of the date of enactment a university-based center or centers for cannabis research. The purpose of this center or centers is to enhance public health understanding of cannabis medicines.
    - (2) CRITERIA FOR SELECTION- In selecting colleges or universities as centers for cannabis research, the Commissioner shall consider the following criteria:
      - a) Demonstrated expertise in agriculture and cultivation practices, particularly with cannabis;
      - b) Demonstrated expertise in developing controlled trials;
      - c) Demonstrated expertise in providing medical services;
      - d) Strong affiliations with animal and plant diagnostic laboratories;
      - e) Demonstrated expertise in food safety;
      - f) Demonstrated expertise in water and waste-water operations;
      - g) Affiliation with Department of Agriculture Laboratories or training centers; and
      - h) Demonstrated expertise in interdisciplinary public policy research and communication outreach regarding science and public policy.
    - (3) AUTHORIZATION OF APPROPRIATIONS- There are authorized to be appropriated such sums as may be necessary to carry out this section.
  - (iii) INTRAMURAL PROGRAMS
    - (1) CONSULTATION- In carrying out the duties under section 202, the Commissioner, acting through the Under Secretary of Medical Cannabis Science and Health, may draw upon the expertise of any laboratory of the federal government or private entity.
    - (2) LABORATORIES- The Commissioner acting through the Under Secretary of Medical Cannabis Science and Health, may establish a headquarters laboratory for the Office at any site and may establish additional laboratory units at other laboratories or sites.
    - (3) CRITERIA FOR CANNABIS HEADQUARTERS LABORATORY- If the Commissioner chooses to establish a headquarters laboratory pursuant to paragraph (2), then the Commissioner shall do the following:
      - a) Establish criteria for the selection of the cannabis headquarters laboratory in consultation with the National Academy of Sciences, appropriate federal agencies, and other experts;
      - b) Publish criteria in the Federal Register;
      - c) Evaluate all appropriate laboratories or sites against the criteria;
      - d) Select a laboratory or site on the basis of the criteria; and
      - e) Report to appropriate Congressional committees on which laboratory was selected, how the selected laboratory meets the established criteria, and what duties the cannabis headquarters laboratory should perform.

**SEC. 206- MISCELLANEOUS PROVISIONS**

- (a) CLASSIFICATION- Notwithstanding privacy protections under the Health Insurance Portability and Accountability Act (Pub. L. 104-191) and other privacy statutes, to the greatest extent practicable research conducted by the office shall be available to the public.
- (b) REGULATIONS- The Commissioner, acting through the Under Secretary of Medical Cannabis Science and Health, may issue necessary regulations with respect to research, development, testing, medical products, and evaluation activities of the Subdivision, including the conducting, funding and reviewing of such activities.

**TITLE III- SUBDIVISION OF CANNABIS AGRICULTURE AND CULTIVATION**

**SEC. 301- ESTABLISHMENT OF SUBDIVISION, UNDER SECRETARY**

- (a) ESTABLISHMENT
  - (i) IN GENERAL– There is hereby established with the cooperation of the United States Department of Agriculture, the United States Environmental Protection Agency, and the National Institute on Drug Abuse an Office of Cannabis Agriculture & Cultivation (hereinafter referred to as the “Subdivision”).
  - (ii) AUTHORITY- The Subdivision shall be under the general authority of the assistant secretary of the Department of Agriculture and Office of Medical Cannabis but shall maintain independent discretion when making decisions about medical cannabis cultivation and production.
- (b) UNDER SECRETARY– The Subdivision shall be headed by an Under Secretary, who shall be an individual appointed based on approval of the Office of Personnel Management of the executive qualifications of the individual.

**SEC. 302- MISSION OF SUBDIVISION; DUTIES**

- (a) MISSION– The mission of the Subdivision shall be:
  - (i) To serve as the national focal point for the agricultural production of medical cannabis, removing authority from the National Institute on Drug Abuse;
  - (ii) To oversee the cultivation and production of cannabis in the United States;
  - (iii) To carry out educational programs for cannabis cultivators, including distribution of best practices; and
  - (iv) To provide guidance on sustainable farming and cultivation processes for cannabis.
- (a) DUTIES- In carrying out its mission, the Subdivision shall have the following duties:
  - (i) Provide recommendation and advice about cannabis and cannabis cultivation to the Secretary of the United States Department of Agriculture;
  - (ii) Establish and maintain advisory groups to assess the needs of Federal, State and Local cannabis cultivators and producers;
  - (iii) Establish minimum standards for approved and banned pesticides and good manufacturing practices that shall be used by federal, state, local and private cultivators and cultivation facilities;
  - (iv) Establish a program that certifies, validates, or otherwise approves cultivators or cultivation facilities as organic;
  - (v) Coordinate with other federal agencies and executive office of the president to establish a coordinated Federal approach to provide farming subsidies to those who cultivate cannabis to be used for medical purposes; and
  - (vi) Support research fellowships in support of its mission
- (c) TRANSFER OF FUNDS- The Subdivision may transfer funds to other federal agencies or provide funding to non-Federal entities through grants, cooperative agreements, or contracts to carry out its duties under this section.

**SEC. 303- TRANSFER OF FUNCTIONS**

- (a) AUTHORITY TO TRANSFER FUNCTIONS – The Attorney General, and other Secretaries as appropriate, shall transfer to the Subdivision any program or activity of another government agency that is consistent with the mission of the Subdivision.
- (b) TRANSFER OF PERSONNEL AND ASSETS- With respect to any function, power, duty or any program or activity that is established in the office, those employees and assets of another government agency may be transferred to the Subdivision.



**SEC. 304- FEDERALLY FUNDED SUBSIDIES; CROP INSURANCE**

- (a) SUBSIDISATION PLANS- The Commissioner, acting through the Under Secretary of Cannabis Agriculture and Cultivation, shall have the authority to develop subsidization programs for cannabis cultivators who submit a production plan pursuant to Section 305.
- (b) CROP INSURANCE- Cannabis Cultivators who present the Under Secretary with an approved plan are eligible to receive crop insurance as defined in Pub. L. 115-334, tit. XI and 7 U.S.C. § 508 et. seq.

**SEC. 305- CANNABIS PRODUCTION; STATE AND TRIBAL PLANS**

- (a) SUBMISSION OF PLANS–
  - (i) IN GENERAL– A State, Indian Tribe, or locality desiring to have primary regulatory authority over the cultivation and production of cannabis shall submit to the Under Secretary, through consultation with a state department of agriculture or tribal government, a plan under which the State or Indian tribe monitors and regulates that production as described in paragraph (ii)
  - (ii) CONTENTS- A State, Indian Tribe or Locality plan referred to in paragraph (i)
    - (1) Shall only be required to include:
      - a) A practice to maintain relevant information regarding land on which cannabis is produced in the State or territory, including a legal description of the land;
      - b) A procedure for testing, using post decarboxylation or other reliable methods, levels of delta-9 tetrahydrocannabinol, cannabidiol and other cannabinoids to determine concentration levels of cannabis produced in the State or territory;
      - c) A procedure to test cannabis for pesticides, heavy metals, bacteria and other contaminants that are harmful to individual or public health;
      - d) A procedure for conducting annual inspections of, at minimum, a random sample of cannabis producers to ensure that cannabis is produced according to at least the minimum standards provided by this subchapter;
      - e) A certification that the State, Indian Tribe or locality has the resources and personnel to carry out procedures described in clauses (a) to (d); and
      - f) May include any other practice or procedure established by State or Indian tribe, as applicable to the extent this practice or procedure is consistent with this subtitle.
  - (iii)RELATION TO STATE AND TRIBAL LAW
    - (1) NO PREEMPTION – Nothing in this subsection preempts or limits any law of a State or Indian Tribe that –
      - a) Regulates the cultivation and production of cannabis; and
      - b) Is more stringent than this subtitle.
    - (2) REFERENCES IN PLANS – A State, Tribal, or Local plan may refer to a state or local law or regulation regarding the production of cannabis provided that it is consistent with this subtitle.
- (b) APPROVAL
  - (i) IN GENERAL- Not later than 60 days after receipt of the plan, the Under Secretary shall
    - (1) Approve of the plan; or
    - (2) Send the plan back with suggestions as to how to improve the cultivation plan with best practices
  - (ii) AMENDED PLANS- If the Under Secretary returns a plan with suggestions for improvement, the State, tribe or locality shall submit an amended plan incorporating the suggestions of the Under Secretary within 60 days of receipt of notice from Under Secretary.
- (c) AUDIT OF COMPLIANCE–
  - (i) IN GENERAL- The Under Secretary may conduct an audit of a State, Locality, or Tribe to ensure that the jurisdiction is providing a sufficient supply of cannabis to the patient population and the cannabis being produced is free of substances that would endanger individual or public health.
  - (ii) NONCOMPLIANCE- If the Under Secretary determines through an audit conducted under paragraph (i) that a jurisdiction is not materially in compliance with a state or tribal plan approved under (b)(i)-(ii)
    - (1) The Under Secretary shall collaborate with the jurisdiction to develop a corrective action plan in the first instance of noncompliance; and

- (2) The Under Secretary may revoke approval of a state, Tribal or local plan in case of the second or further event of noncompliance.
- (iii) PENALTIES- The Under Secretary shall set penalties for noncompliance and production of cannabis that is deemed harmful to individual or public health.

**SEC. 306- MISCELLANEOUS PROVISIONS**

- (a) REGULATIONS- The Commissioner, acting through the Under Secretary for Cannabis Agriculture and Cultivation, may issue necessary regulations with respect to research, development, testing, and evaluation activities of the Office, including the conducting, funding and reviewing of such activities.
- (b) PERSONAL CULTIVATION- Nothing in this section shall prohibit an individual from cultivating cannabis for personal use, if legal in the State, and individual cultivators may take advantage of the provisions of this Act.
- (c) EFFECT ON INDUSTRIAL HEMP- Nothing in this chapter supersedes or preempts Pub. L. No. 115-334 (“The 2018 Farm Bill”) except for the transfer of authority from the Food and Drug Administration as described elsewhere in this chapter.

**TITLE IV- MANAGEMENT**

**SEC. 401- UNDER SECRETARY FOR MANAGEMENT**

- (a) IN GENERAL– The Commissioner, acting through the Under Secretary for Management, shall be responsible for management and administration of the office, including the following:
  - (i) The budget, appropriations, expenditures of funds, accounting and finance;
  - (ii) Procurement;
  - (iii) Human resources and personnel;
  - (iv) Information Technology and communications systems;
  - (v) Facilities, property, equipment and other material resources; and
  - (vi) Any other duties the Commissioner may designate.
- (b) TRANSFER OF FUNCTIONS– There shall be transferred to the Under Secretary for Management all functions performed immediately before such transfer occurs with respect to the following programs:
  - (i) The Investigational New Drug Program
  - (ii) The Cannabis Farm at the University of Mississippi
  - (iii) The Cannabis Eradication Program
  - (iv) All adjudications performed by the Drug Enforcement Administration

**Sec. 402- CHIEF FINANCIAL OFFICER**

The Chief Financial Officer shall report to the Commissioner or to another official of the office as the commissioner may designate.

**Sec. 403- CHIEF INFORMATION OFFICER**

The Chief Information Officer shall report to the Commissioner or to another official of the office as the commissioner may designate.

**SEC. 404- ESTABLISHMENT OF OFFICER FOR PATIENT AND CIVIL RIGHTS**

- (a) IN GENERAL– Recognizing that medical cannabis users have long been discriminated against, and the vestiges of this discrimination still exist, the Commissioner shall appoint in the Office an Officer for Patient and Civil Rights who shall:
  - (i) Review and assess information alleging abuses of patient rights, civil liberties, and policies that previously had a disparate racial impact, including but not limited to federal housing evictions for medical cannabis use, denial of firearm sales to medical cannabis patients, and disparities in arrest rates. The Officer shall also coordinate with the Office of State and Local Coordination to determine if state-based discrimination occurred in situations including employment, medical care, and custody determinations; and
  - (ii) Make public through the internet, radio, television or other media the responsibilities, functions and contact information of the Officer.

- (b) REPORT- The Commissioner shall submit to the President of the Senate, the Speaker of the House of Representatives, and the appropriate committees and subcommittees of Congress on an annual basis a report on the implementation of this section, including the use of funds appropriated to carry out this section, and detailing any allegations of abuses described under subsection (a)(1) and any actions taken by the Office in response to such allegations.

TITLE V- COORDINATION WITH NON-FEDERAL ENTITIES; GENERAL PROVISIONS

Subtitle A- Coordination with Non-Federal Entities

SEC. 501 SUBDIVISION FOR STATE AND LOCAL GOVERNMENT COORDINATION

- (a) ESTABLISHMENT- Recognizing that State and Local governments have already put substantial thought into policies regarding the regulation of medical cannabis, there is established within the Office of the Commissioner the Subdivision for State and Local Government Coordination to oversee and coordinate departmental programs for, and relationships with, State and Local governments, including determining the awarding of licenses for cultivation and manufacturing businesses as well as the licensing of specialty pharmacies.
- (b) RESPONSIBILITIES- The Subdivision established under this subsection shall:
  - (i) Set minimum standards for states regarding the regulation of cannabis cultivation and production and cannabis distribution and access. States may establish more stringent policies, but may not allow policies below the federal threshold;
  - (ii) Coordinate the activities of the Subdivision related to State and Local government;
  - (iii) Assess, and advocate for, the resources needed by State and Local governments to implement a national strategy for improving access to medical cannabis;
  - (iv) Provide State and Local governments with regular information, research, and support to assist efforts in ensuring safe and legal access to medical cannabis; and
  - (v) Develop a process for receiving meaningful input from State and Local governments to assist in the development of the national strategy for improving access to medical cannabis.

SUBTITLE B- MISCELLANEOUS PROVISIONS

SEC. 502- ADVISORY COMMITTEES

- (a) IN GENERAL- The Commissioner may establish, appoint members to, and use the services of advisory committees as the Commissioner may deem necessary. The Commissioner may appoint members of Federal or State governments or individuals from the public or nonprofit sector.
- (b) TERMINATION- Any advisory committee established by the Commissioner shall terminate two (2) years after the date of its establishment, unless the Commissioner makes a written determination to extend the advisory committee to a specified date, which shall not be more than two (2) years after the date on which a determination is made.

SEC. 503- MILITARY ACTIVITIES

Nothing in this authority should be deemed to affect the ability of the Department of Defense or the Department of Veterans affairs to conduct medical cannabis research.

SEC. 504 SUBDIVISION OF INTERNATIONAL CANNABIS POLICY

- (a) ESTABLISHMENT- There is established within the Office of the Commissioner a Subdivision of International Cannabis Policy. The Subdivision shall be headed by a Director who shall be a senior official appointed by the Commissioner.
- (b) DUTIES OF THE DIRECTOR– The Director shall have the following duties:
  - (i) Liaise with the World Health Organization for international decisions related to medical use of cannabis;
  - (ii) Promote information and education exchanges with nations that have developed medical cannabis programs, including the sharing of best practices;

- (iii) Identify areas for information and training exchanges where the United States has demonstrated weaknesses with medical cannabis policy; and
- (iv) Plan and undertake international conferences, exchange programs, and training activities.

TITLE VI- TRANSITION; REORGANIZATION PLAN

SEC 601- DEFINITIONS

For the purposes of this title:

- (1) The term “agency” includes any entity, organizational unit, program, or function.
- (2) The term “transition period” means the 12-month period beginning on the effective date of this Act.

SEC 602- REORGANIZATION PLAN

- (a) SUBMISSION OF PLAN– Not later than sixty (60) days after the enactment of this Act, the President shall transmit to the appropriate Congressional committees a reorganization plan regarding the following:
  - (i) The transfer of functions, personnel, assets, and obligations from agencies including, but not limited to, the DEA, NIDA, DOJ, HHS, and ONDCP to the Office pursuant to this Act; and
  - (ii) Any consolidation, reorganization, or streamlining of agencies transferred to the Office pursuant to this Act.
- (b) PLAN ELEMENTS- The plan transmitted under subsection (a) shall contain, consistent with this Act, such elements as the President deems appropriate, including any of the following:
  - (i) Identification of any cannabis-related agency functions transferred to the Office;
  - (i) Specification of which steps should be taken by the Commissioner to organize the Office, including delegation or assignment of functions transferred to the Office among officers of the Office in order to permit the Office to carry out the functions transferred under the plan;
  - (iii) Specification of funds available to each agency that will be transferred to the Office as a result of transfers under the plan; and
  - (iv) Specifications of proposed allocations within the Office of unexpended funds transferred in connection with transfers under the plan.
- (c) MODIFICATION OF PLAN- The President may, on the basis of consultations with the appropriate Congressional committees, modify or revise any part of the plan until that plan becomes effective.

TITLE VII- IMPLEMENTATION

SEC 701- LICENSING; GENERAL PROVISIONS

- (a) IN GENERAL- The Office shall grant federal licenses for cultivation, manufacturing or distribution to all those businesses that obtained or will obtain state medical cannabis licenses for cultivation, manufacturing or distribution in states implementing, with respect to those businesses, at least the minimum standards for regulation, as established by the Office pursuant to SEC 501 (b) (i) of this Act. The Office shall also establish a mechanism for granting federal licenses to applicants applying directly to the Office. The Office should develop regulations for dealing with such applications.
- (b) LICENSING PROVISIONS- The Office shall record the areas in which, and the plot(s) of land on which, the cultivation of cannabis for the purpose of producing or manufacturing of cannabis for medical purposes is federally permitted.
- (c) ONLY LICENSED BUSINESSES PERMITTED- Only cultivators and manufacturers federally licensed by the Office on the basis of appropriate state licenses or through its own mechanism shall be permitted to participate in the inter-state trade and in international trade of medical cannabis products.
- (d) IMPORTS, EXPORTS- The Office, in the respect to cannabis produced for medical purposes, shall have the exclusive right to import, and export, This exclusive right is not extended to medical cannabis products.

SEC 702- SPECIALITY LICENSING

- (a) IN GENERAL- The Office will issue federal speciality pharmacy licenses for dispensaries with state medical cannabis licenses that are operating on the date of the effective date of this act or will be approved for operation by the state in the future, in states implementing at least the minimum standards for the regulation of such cannabis businesses, as established by the Office pursuant to § 501 (b) (i) of this Act.



- (b) EXISTING LICENSES; SPECIALTY PHARMACIES- If in the opinion of the Commissioner there are not enough licensed specialty pharmacies to adequately serve the patient population in the state, the Commissioner shall may either issue up to one additional federal medical cannabis specialty pharmacy license for every five (5) existing pharmacy licenses issued under state law or allow the importation by individuals of medical cannabis and medical cannabis products from other states.
- (c) ADMINISTRATIVE REVIEW- the denial of a license by the Office is deemed a final agency action and is subject to judicial review under the Administrative Procedures Act.

**SEC 703- DISTRIBUTION; GUIDELINES**

- (a) IN GENERAL- The Office will develop a system to grant licenses to distribute medical cannabis and will give existing distributors and distribution networks preference when it comes to the issuance of licenses.
- (b) PHARMACIES- The Office will develop a system to ensure that pharmacies can obtain cannabis and cannabis products from licensed cultivators and manufacturers on a patient population basis to ensure there is an uninterrupted supply of medical cannabis.

**SEC 704- PRESCRIPTION PROTOCOLS**

- (a) IN GENERAL- The Office shall consult with the Secretary of Health and Human Services, pharmacists, and healthcare practitioners in developing prescription protocols for the prescribing of medical cannabis and medical cannabis products.
- (b) GUIDELINES- In consultation with the Secretary of Health and Human Services, the Office shall develop guidelines that allow the prescription of medical cannabis pursuant to existing prescription protocols.

**SEC 70 5- ADVISORY COMMITTEE**

- (a) IN GENERAL- The Commissioner shall establish, appoint members of, and use the services of advisory committees as the Commissioner may deem necessary. For the licensing advisory committee, the Commissioner shall appoint directors of state-based medical cannabis offices, or their designees, to advise on the process of issuing licenses.
- (b) TERMINATION- Any advisory committee established by the Commissioner shall terminate two (2) years after the date of its establishment unless the Commissioner makes a written determination to extend the advisory committee to a specified date, which shall not be more than two (2) years after the date on which a determination is made.

**SEC 706- TRANSFER OF FUNCTIONS**

- (a) AUTHORITY TO TRANSFER FUNCTIONS- The Secretary of Health and Human Services, the Director of the National Institute on Drug Abuse, the Administrator of the Drug Enforcement Administration, and other Secretaries and officials as appropriate shall transfer to the Office any program or activity of another government agency that is consistent with the mission of the Office, including but not limited to the oversight of licensing of cannabis cultivation and manufacturing as permitted by the 1961 Single Convention on Narcotic Drugs and subsequent international treaties.
- (b) TRANSFER OF PERSONNEL AND ASSETS- With respect to any function, power, duty, or any program or activity that is established in the Office, those employees and assets of another government agency may be transferred to the Office.



UNTIL THERE IS SAFE  
ACCESS WE ARE  
AMERICANS FOR  
SAFE ACCESS

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 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 recognize 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.

Become a part of History! Join us today  
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