

MEDICAL CANNABIS IN AMERICA

THE MEDICAL CANNABIS BRIEFING BOOK

115TH CONGRESS



MEDICAL CANNABIS IN AMERICA

THE MEDICAL
CANNABIS
BRIEFING BOOK

115TH CONGRESS

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 "CEASE-FIRE": ROHRBACHER-FARR AMENDMENT AND COLE MEMO.....39

MEDICAL CANNABIS TIMELINE.....40

CHAPTER 4: HARMONIZING STATE AND FEDERAL LAW: A FUNCTIONAL PLAN.....42

KEY POINTS.....43

TALKING POINTS.....44

ROLE OF CONGRESS: LEGISLATIVE NEEDS.....45

LEGISLATIVE EFFORTS 114TH CONGRESS.....46

REGULATORY IMPACT OF COMPREHENSIVE LEGISLATION.....49

AGENCY ROLES POST-COMPREHENSIVE LEGISLATION.....52

CHAPTER 5: A CALL TO THE 115TH CONGRESS AND 45TH POTUS.....54

KEY POINTS: LAME DUCK CONGRESS, LAME DUCK POTUS, 115TH CONGRESS, 45TH POTUS.....55

2016 LAME DUCK.....57

115TH CONGRESS.....57

45TH POTUS.....60

DIVERSE SUPPORT FOR FEDERAL ACTION.....62

THE GATEWAY THEORY DISPROVEN.....64

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, forty-four states, the District of Columbia, Puerto Rico 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 300 million Americans live under these laws -- about 85% of the U.S. population. Americans for Safe Access (ASA) has estimated that these medical cannabis programs serve approximately two million patients under physician supervision. Physicians may now recommend cannabis-based treatments for over fifty medical conditions and symptoms approved through these programs.

MEDICAL CANNABIS PROGRAMS SERVE APPROXIMATELY TWO 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.

After 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 in some areas, 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."¹ Recently 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."² 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 recent study from the University of Georgia found Medicare experienced a savings of \$165.2 million on prescription drugs across 17 states and the District of Columbia with medical cannabis laws, and reported savings would have reached \$468 million if all states had medical cannabis programs.

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

For the past three 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. Medical cannabis programs more than doubled under the Obama administration, going from 13 states with medical cannabis laws to 29 states, (plus the District of Columbia, Puerto Rico, and Guam) and 15 additional states with more restrictive cannabidiol (CBD)/cannabis laws.

The purpose of this briefing book is to provide members of Congress and the President of the United States (POTUS) with the information they need to make well-informed decisions on legislation, regulations and policies regarding medical cannabis. With millions of Americans living in states where medical cannabis is legal under state laws, the need for the federal government to show leadership and resolve the conflict with state laws is more important than ever.

1 Bachhuber, M.A. MD, Saloner, B. PhD, Cunningham, C. MD, MS; 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 BY THE NUMBERS

44
States with Medical
Cannabis Laws



0

Deaths Caused by Cannabis



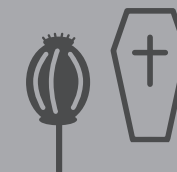
30,000

Studies Published on the
Endocannabinoid System



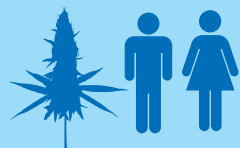
↓ 25%

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



2 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



\$165 MIL.

Federal Prescription Drug
Cost Savings in Medical Cannabis
States in 2013



89%

Americans Supporting
Medical Cannabis



9,000

Clinical Trial Data Using Cannabis
for Pain in Patient Years



66+

Known Cannabinoids



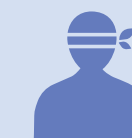
128,000

Annual Deaths Caused by
Prescription Drugs



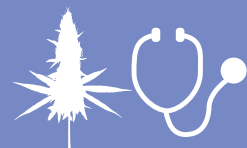
100 MIL.

Number of Americans Suffering
from Chronic Pain



50+

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 TO WHOLE PLANT CANNABIS VS SYNTHETIC CANNABINOID-BASED DRUGS IS SUPPORTED BY THE SCIENTIFIC CONSENSUS OF THE "ENTOURAGE EFFECTS" BETWEEN THE CANNABINOIDS WORKING TOGETHER TO CREATE VARIOUS THERAPEUTIC EFFECTS.
- 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 CREATED BY VARIOUS DISORDERS.
- PATIENTS USE A VARIETY OF DELIVERY METHODS (I.E., 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, AND IS NEEDED BY VETERANS ACROSS THE COUNTRY.

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.

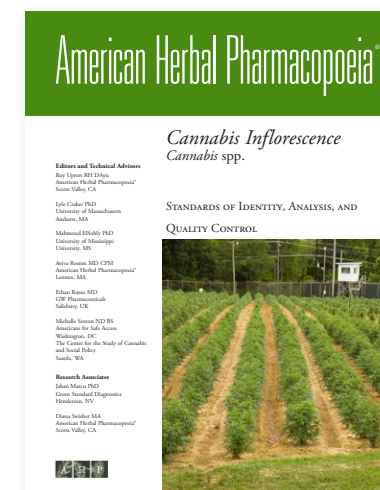
1. THE CANNABIS PLANT

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 100 cannabinoids and nearly 500 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 were 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 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.¹ 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 in the central nervous system, particularly in areas of the brain involved with mood, memory, appetite, and pain. CB1 receptors are found 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.



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.

3. CLINICAL OVERVIEW

The therapeutic benefits of cannabis are derived from the interactions of cannabinoids and the ECS. Of the 100 cannabinoids found in the cannabis plant, scientists have identified a handful of the most active cannabinoids. Researchers have also found that therapeutic effects are the result of “entourage effects”: cannabinoids and terpenes working together to enhance the effects of THC and CBD.

- 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 on the cannabis plant, CBD is a potent antioxidant and neuroprotectant.
- Tetrahydrocannabinol (THC): is found in small quantities 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-A) is a non-psychoactive cannabinoid found in raw and live cannabis. As cannabis dries, THCA-A slowly converts to THC. Heat converts THCA-A to THC via decarboxylation, which describes what happens when you smoke or vaporize cannabis flower. THCA-A 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): This compound is known to produce pain relief, have anti-inflammatory effects, and is reported to have strong antimicrobial properties while lacking toxicity.
- Cannabinol (CBN): This is the degradation product of THC and other cannabinoids. It lacks any psychoactivity, but can stimulate CB2 receptors and has mild anti-inflammatory properties.
- Terpenes: The essential oil of cannabis is a blend of active compounds called terpenes, synthesized in trichomes. These terpenes are not unique to cannabis, but are found on other plants such as lavender, hops, mangoes, citrus, pine, lemon, 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, anti-anxiety, and antidepressant effects.

¹ Grotenhermen, F. The therapeutic potential of cannabis and cannabinoids. Dtsch Arztebl Int. Jul 2012; 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, and more than 1,500 articles investigating the endocannabinoid system are published every year. In recent years, more placebo-controlled human trials have also been conducted demonstrating the potential of cannabinoids to treat neurodegenerative, pain disorders, and improving outcomes in cancer treatments.

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 (i.e., pain, spasticity, sleep, urinary dysfunction, motoric symptoms) and Parkinson's Disease. Cannabis also has a potential for treating 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 responsible for their mediation. 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 trauma. At least 33 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 (i.e., pain), there exists clear preclinical 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 40 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 that creates various disorders. Researchers have found that cannabinoids fight the effects of strokes, brain trauma, spinal cord injury, multiple sclerosis, neurodegenerative diseases and may have a direct benefit in the treatment of cancer.

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

FACT: THE GATEWAY THEORY HAS BEEN DISPROVEN. THE DRUG ENFORCEMENT ADMINISTRATION (DEA) IN ITS DENIAL OF PETITIONS TO RESCHEDULE STATED, "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.



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 administered through inhalation, ingestion, topically, or buccal. 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 delivered through inhalation, by using vaporization. Absorption through the lungs, completely by-passes potential drug-drug interactions in the liver. The time to onset is quick with the effects lasting 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.

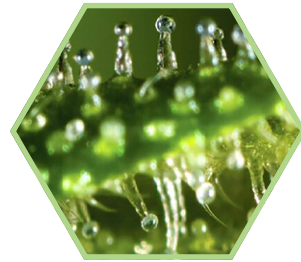
Topically: Is absorption via the external surface of the skin. Cannabis can be used topically, without reaching the bloodstream if specially formulated to do so. Topical applications of cannabis have a rapid onset, can be less than a minute, and can provide hours of relief.

Buccal: Is the absorption of drug by the internal surfaces of the mouth. Cannabis sprays, such as those in ethanol, can be administered through the mouth, cheeks, or under the tongue (sublingually). This can have a rapid onset, within minutes to an hour, and avoids first pass liver metabolism.

SAMPLE MEDICAL CANNABIS LABEL

		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) Batch/Lot#: ndc3333333 Date Pkgd: 10/17/2015 Use by: 10/31/2015 Ingredients: Cannabis THCA: < 1% CBD: .12% CBDA: .11%	Date tested: 10/22/2015 Microbiology: Pass Mycotoxin: Pass Pesticide: Pass Solvent Residue: 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.

Inflorescence Cannabis (flower)

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



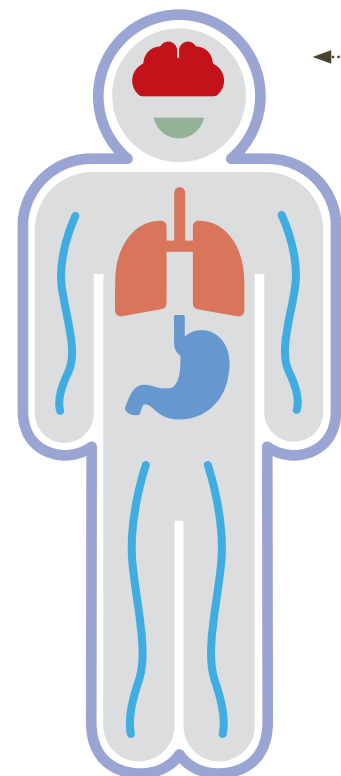
TOPICAL

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



BUCCAL

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



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 **CB₁** and **CB₂** located throughout the brain and the periphery of the body.

CANNABINOIDS & TERPENOIDS

CBD

BENEFIT
 Non-psychoactive, anti-depressant, anti-inflammatory, anti-convulsant, anti-nausea, anti-anxiety, analgesic, sedative, sleep aid and muscle relaxant

THC

BENEFIT
 Psychoactive, analgesic, anti-inflammatory, anti-microbial, muscle relaxant

CBC

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

CBG

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

CBN

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

THCA-A

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



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 CB₂ 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, and 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 2014



OPIOIDS

28 000 +

Over half from prescribed opioids



PRESCRIPTION DRUGS

128 000 +

(Source CDC 2014)



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

- 44 STATES HAVE MEDICAL CANNABIS LAWS: 29 STATES HAVE COMPREHENSIVE PROGRAMS, (PLUS THE DISTRICT OF COLUMBIA, PUERTO RICO, AND GUAM) AND 15 ADDITIONAL STATES HAVE MORE RESTRICTIVE CBD/CANNABIS LAWS.
- FOLLOWING THE COLE MEMO, EVERY MEDICAL CANNABIS STATE THAT DID NOT ALREADY HAVE A CENTRALIZED STATE-RUN LICENSING PROGRAM HAS PASSED LEGISLATION TO CREATE ONE INCLUDING CA, HI, WA, MI AND MT.
- IT IS ESTIMATED THAT THE CURRENT NUMBER OF LEGAL CANNABIS PATIENTS IN THE U.S. IS 2 MILLION AND GROWING.
- 76% OF U.S. PHYSICIANS ARE SUPPORTIVE OF THE USE OF MEDICAL CANNABIS AND 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) 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 DRUG PROGRAM MORE THAN \$165 MILLION IN 2013 DUE TO A DECREASE IN PRESCRIPTION MEDICATION. THAT SAVINGS COULD HAVE REACHED \$468 MILLION IF MEDICAL CANNABIS WAS LEGAL ACROSS THE NATION.
- WORKPLACE ABSENCES DUE TO ILLNESS DROPPED 815% PERCENT AMONG VARIOUS SUBGROUPS IN STATES WITH MEDICAL CANNABIS LAWS.



TALKING POINTS

- 44 STATES HAVE MEDICAL CANNABIS LAWS: 29 STATES HAVE COMPREHENSIVE PROGRAMS, (PLUS THE DISTRICT OF COLUMBIA, PUERTO RICO, AND GUAM) AND 15 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.
- 76% OF U.S. PHYSICIANS ARE SUPPORTIVE OF THE USE OF MEDICAL CANNABIS.
- MEDICAL CANNABIS PROGRAMS SAVED THE MEDICARE DRUG PROGRAM MORE THAN \$165 MILLION IN 2013 DUE TO A DECREASE IN PRESCRIPTION MEDICATION. THAT SAVINGS COULD HAVE REACHED \$468 MILLION 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 AND DOCTORS AT HARVARD MEDICAL SCHOOL.



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

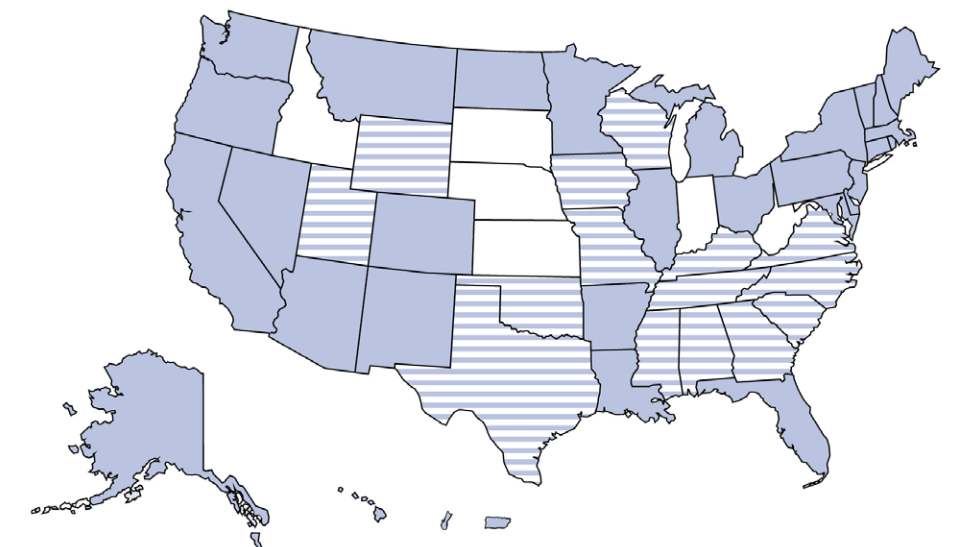
1. OVERVIEW OF CURRENT MEDICAL CANNABIS PROGRAMS

Twenty-nine states, the District of Columbia, Puerto Rico, and Guam have all passed comprehensive medical cannabis laws. These states cover over 50 qualifying conditions, with some states leaving it to the discretion of physicians to decide when medical cannabis would be an appropriate therapy. Another fifteen states have more restrictive cannabidiol (CBD) oil only laws. 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 20 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." In fact, every medical cannabis state that did not already have a centralized state-run licensing program has passed legislation to create one including CA, HI, WA, MI and MT.

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 million and growing (an average of 1% of the populations in each state). There are over 50 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
Cancer	1,685,210
Crohn's Disease	1,600,000
Multiple Sclerosis	4,000,000
Parkinson's Disease	1,000,000
Seizure Disorders	3,000,000
Post-Traumatic Stress Disorder	24,400,000
Chronic Pain	100,000,000

Source: Center for Disease Control

A 2014 study of 2012 data from the California Behavioral Risk Factor Surveillance system of 7,525 people, found that 5% of Californians 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!

1 Ryan-Ibarra S, Induni M, Ewing D. Prevalence of medical marijuana use in California. *Drug Alcohol Epub*. March 2014; 34(2):141-6. doi: 10.1111/dar.12207.

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, 2013 UNIVERSITY OF CHICAGO STUDY FOUND A 9-11% REDUCTION IN TRAFFIC FATALITIES IN STATES WITH MEDICAL CANNABIS LAWS. REGULAR CANNABIS USE AND OTHER ILLICIT DRUG USE!"

(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. 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.²

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.³ Medical schools are teaching required coursework which includes the endocannabinoid system and the therapeutic applications of cannabis. 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.

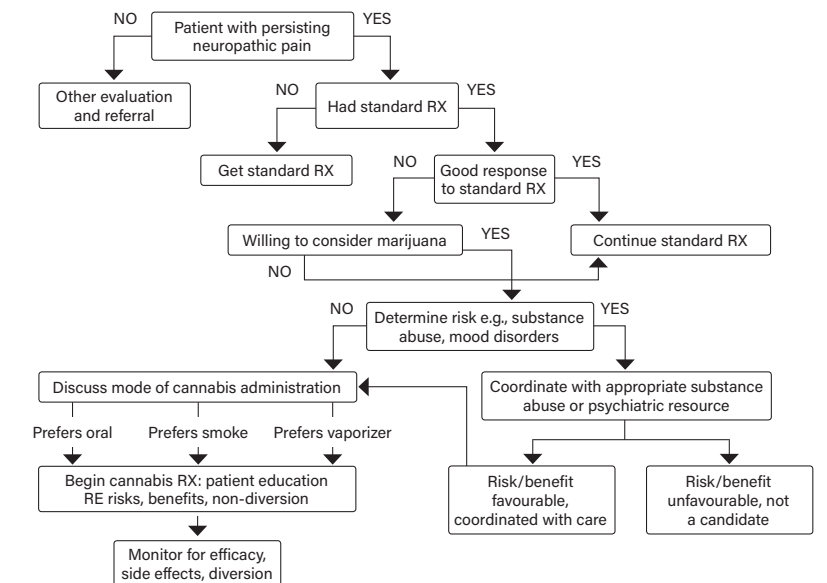


Figure courtesy of Center for Medical Cannabis Research

2 Minnesota Department of Health: Early Results of Office of Medical Cannabis Surveys. *Minnesota Department of Health Office of Medical Cannabis Report*. May 2016. <http://www.health.state.mn.us/topics/cannabis/about/surveyresults0516.pdf>

3 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/NEJMc1305159

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 with 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 and monitor adverse event reporting and implement product recalls if necessary.

Regulations begin at the application process 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 by the AHPA Recommendations for Regulators and incorporating laboratory testing based on standards set forth by the AHP Cannabis Inflorescence monograph.

State licensed 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 federal conflicts of laws, it becomes easier for states to implement sophisticated product safety regulations.³ Lab Testing

State government regulations are increasingly requiring laboratory testing to verify product safety and help patients understand the potency of the products' active compounds. As more state states adopt the AHPA guidelines, they will develop laboratory testing regulations that ensure that the analytical records of cannabis and derived products are made available at all levels of the supply chain (processing, packaging, and labeling).

State licensed laboratory testing means that patients in state medical cannabis programs are able to obtain safe, reliable, consistent product to treat their



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.

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, 2013 UNIVERSITY OF CHICAGO STUDY FOUND A 9-11% REDUCTION IN TRAFFIC FATALITIES IN STATES WITH MEDICAL CANNABIS LAWS. REGULAR CANNABIS USE AND OTHER ILLICIT DRUG USE.”

(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.)

medical needs. When state governments are free from dealing with issues of federal conflict of laws, it becomes easier for states to implement sophisticated product safety regulations.

4. PUBLIC HEALTH IMPACTS OF MEDICAL CANNABIS PROGRAMS

Public health data, collected over the past 20 years, have shown that fears expressed by opponents of medical cannabis – such as increased morbidity and mortality, birth defects, or heightened likelihood of traffic accidents – 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.⁴
- There has been no evidence of birth defects caused by woman using medical cannabis while pregnant. In fact, a 1992 study by researchers from the University of Massachusetts, compared neonatal assessments of babies of 24 Jamaican women who had used cannabis during pregnancy with babies of 20 women who had not. At three days, there was no difference between the two groups, and at one month, the children of the cannabis users actually had better scores.⁵
- 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.”⁶
- A 2013 University of Chicago study found that there is a drop in traffic fatalities in states with medical cannabis laws.⁷
- A 2005 study from the Journal of Acquired Immune Deficiency Syndromes found that, “patients who use cannabis therapeutically are 3.3 times more likely to adhere to their antiretroviral therapy regimens than non-cannabis users.”⁸

⁴ Bachhuber, M.A. MD, Saloner, B. PhD, Cunningham, C. MD, MS; 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.

⁵ Dreher, M.C. PhD, Nugent, K. PhD, Hudgins, R. MA. Prenatal marijuana exposure and neonatal outcomes in jamaica: an ethnographic study. Jun 1993; *American Academy of Pediatrics*. Volume 93, Number 2, pp. 254-260.

⁶ 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.

⁷ 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.

⁸ 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 drug program more than \$165 million in 2013 due to a decrease in prescription medication. According to the university's estimates, if medical cannabis had been legal across the nation, the savings would have been approximately \$468 million.⁹ The fact is, fewer pills are prescribed in states with medical cannabis laws.

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.¹⁰

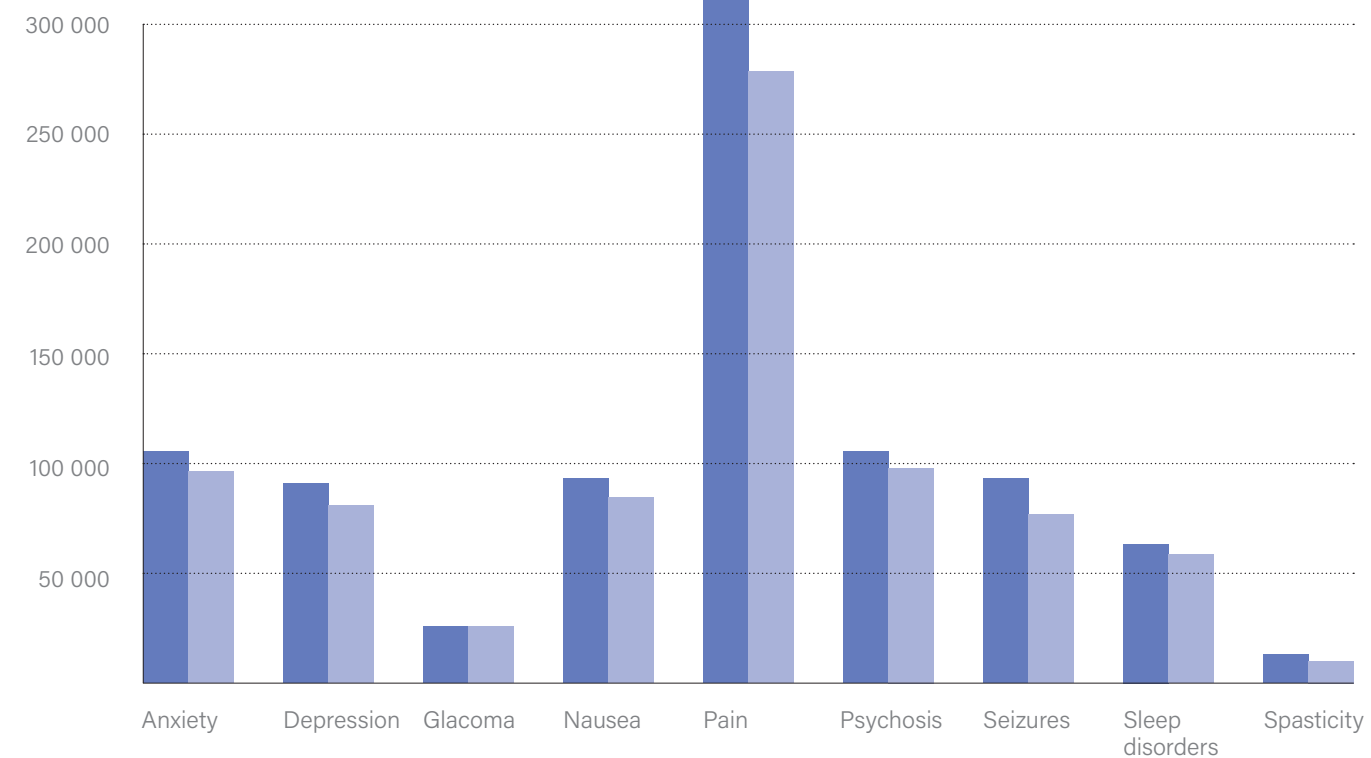


⁹ Bradford A.C, Bradford B.W. Medical marijuana laws reduce prescription medication use in medicare part d. July 2016. *Health Affairs* (Project Hope). 1;35(7):1230-6. doi: 10.1377/hlthaff.2015.1661.

¹⁰ Ullman, D.F. The effects of medical marijuana on sickness absence. July 2016. *Health Economics*. 1099-1050. Doi: 10.1002/hec.3390



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



STATE MEDICAL CANNABIS PROGRAM REGULATIONS AND OVERSIGHT

REGULATIONS

TODAY OVER 300 MILLION AMERICANS LIVE IN STATES WITH MEDICAL CANNABIS LAWS. 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.



MEDICAL MARIJUANA REGULATORY AGENCY

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



DEPARTMENT OF COMMERCE



DEPARTMENT OF HEALTH



DEPARTMENT OF AGRICULTURE

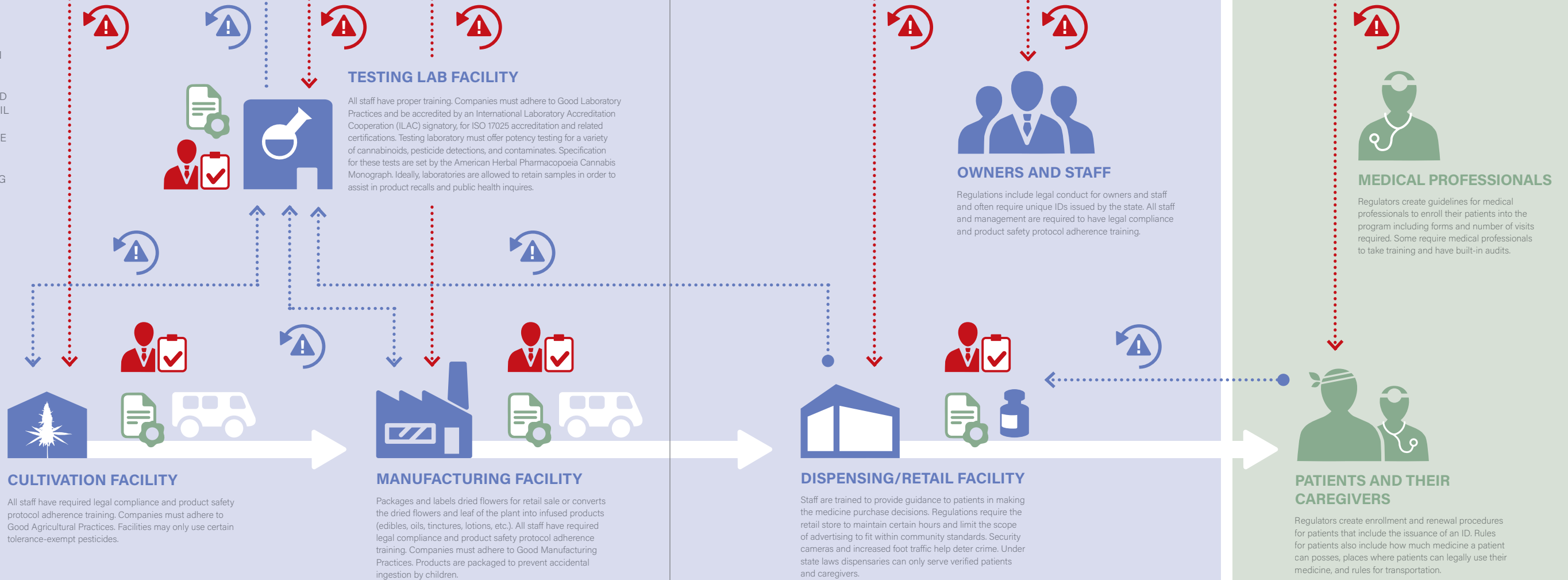


INSPECTIONS

Medical cannabis businesses must pass inspections to maintain licenses to operate. These inspections may be conducted by the state medical cannabis regulatory agency, third party accredited agencies, law enforcement, OSHA, municipal safety inspectors, etc.

SUPPLY CHAIN

REGULATIONS BEGIN AT THE APPLICATION PROCESS WHERE CRITERIA IS 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. MEDICAL CANNABIS BUSINESSES ARE SUBJECT TO INSPECTIONS. REGULATORS NOW HAVE RESOURCES SUCH AS THE AMERICAN HERBAL PHARMACOPOEIA CANNABIS MONOGRAPH AND THE AMERICAN HERBAL PRODUCTS ASSOCIATION RECOMMENDATIONS FOR REGULATORS IN CREATING ROBUST PRODUCT SAFETY PROTOCOLS. ALL COMPANIES MUST DEMONSTRATE ABILITY TO TRACK ADVERSE EVENTS AND INITIATE A RECALL.



AmericansForSafeAccess.org



PRODUCT SAFETY

Each batch of raw plant material and cannabis derived product must be quality assurance tested in order to ensure the integrity, purity, and proper labeling of medical cannabis products.



TRANSPORTATION

Regulations extend to transportation of cannabis products throughout the supply chain. Regulations require drivers to be registered with the state and require paperwork at pickup and drop off locations that include weighing product. Regulations also include special instructions for dealing with waste.



RECALL

When a product containing contaminants, molds, mildew, or an improperly labeled product enters the supply chain, regulatory agencies trigger a product recall to prevent patient consumption. This includes alerting the manufacturers, retail outlets, and the public. Recalled products are destroyed.



MEDICAL CANNABIS PRODUCTS

Products are labeled in accordance with state guidelines to display cannabinoid profile and other useful information, including expiration date if the item is perishable.

QUALIFICATION

REGULATORS DETERMINE REQUIREMENTS FOR PATIENTS TO PARTICIPATE IN THE MEDICAL CANNABIS PROGRAMS BASED ON AUTHORIZING STATUTE, INCLUDING GUIDELINES AND FORMS, MEDICAL PROFESSIONALS, AND RULES FOR TRANSPORTATION AND USE.

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: ROHRBACHER-FARR AMENDMENT AND COLE MEMO



KEY POINTS

- PATIENT ADVOCATES TURNED TO PASSING LOCAL AND STATE MEDICAL CANNABIS LAWS AFTER THE FEDERAL GOVERNMENT CLOSED DOWN ITS CANNABIS INVESTIGATION 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 DOLLARS; APPROXIMATELY \$250 MILLION DURING THE BUSH ADMINISTRATION AND \$350 MILLION DURING THE OBAMA ADMINISTRATION.
- 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 AND 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" FROM FEDERAL INTERFERENCE RESULTING FROM FEDERAL AGENCY GUIDANCE MEMOS (COLE MEMO) AND EXPANDED IN 2014 TO CONGRESSIONALLY IMPOSED SPENDING RESTRICTIONS (ROHRBACHER-FARR AMENDMENT).
- THE DEPARTMENT OF JUSTICE GUIDANCE MEMO (COLE MEMO) IS SUBJECT TO CHANGE UNDER A NEW ADMINISTRATION, AND THE 115TH CONGRESS WILL LIKELY BE RESPONSIBLE FOR INCLUDING THE ROHRBACHER-FARR AMENDMENT TO THE 2017 COMMERCE, JUSTICE, SCIENCE AND RELATED AGENCIES (CJS) APPROPRIATIONS BILL.
- STATE MEDICAL CANNABIS PROGRAMS ALMOST DOUBLED UNDER THE "CEASEFIRE," AND DUE TO THE REQUIREMENTS FOR COMPLIANCE UNDER THE COLE MEMO, ALL MEDICAL CANNABIS STATES INCLUDE CENTRALIZED STATE LICENSING.
- 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 DOLLARS.
- ◆ 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.
- ◆ FOR THE PAST THREE YEARS, STATE MEDICAL CANNABIS PROGRAMS HAVE OPERATED UNDER A "CEASEFIRE" FROM FEDERAL INTERFERENCE RESULTING FROM FEDERAL AGENCY GUIDANCE MEMOS (COLE MEMO) AND CONGRESSIONALLY IMPOSED SPENDING RESTRICTIONS (ROHRBACHER-FARR AMENDMENT).
- ◆ THE DEPARTMENT OF JUSTICE GUIDANCE MEMO (COLE MEMO) IS SUBJECT TO CHANGE UNDER A NEW ADMINISTRATION AND THE 115TH CONGRESS WILL LIKELY BE RESPONSIBLE FOR INCLUDING THE ROHRBACHER-FARR AMENDMENT TO THE 2017 CJS APPROPRIATIONS BILL.

PARA MILITARY-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.

From the start, the federal government met new medical cannabis laws with tactics of interference and intimidation. Following the passage of the first state medical cannabis laws, U.S. Attorney General Janet Reno announced that the DOJ would end the career of any doctors who recommended medical cannabis by revoking their license to prescribe medication. In response, a group of physicians led by AIDS specialist Dr. Marcus Conant challenged the policy in federal court as a Constitutional violation of their First Amendment rights to freedom of speech. In 2002, the U.S. 9th Circuit Court ruled in *Conant v. Walters* that physicians have a First Amendment right to make recommendations, but may not aid or abet patients in actually obtaining cannabis.

From 1997-1999 the Institute of Medicine (IOM) of the National Academy of Sciences, on directive from the Office of National Drug Control Policy (ONDCP), conducted a review of the scientific evidence on the potential health benefits and risks of cannabis. The report concluded that cannabis appears to be a beneficial treatment option for some debilitating conditions and called on the federal government to conduct more research on patients with specific conditions. Its recommendations were ignored.

”
The DOJ has spent an estimated \$600 million to date in arrests, investigations, enforcement raids, pretrial services, incarcerations, and probations.

MYTH: “IN COLORADO, SINCE THE LOOSENING OF STATE MARIJUANA LAWS, WE’VE SEEN INCREASES IN YOUTH MARIJUANA USE.” - SENATOR CHUCK GRASSLEY (R-IA)

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.

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

As the legal battle over physicians’ right to discuss treatment options with their patients was unfolding, the federal government began a campaign in 1997 to stop California from implementing its state law. That campaign included civil legal actions, armed raids on medical cannabis facilities, and prosecutions of medical cannabis patients and their providers. Between 1996 and 2002, there were 14 Federal raids on cannabis facilities.

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 prosecuted 55 individuals. These raids often included dozens of DEA agents in riot gear using “dynamic entry” tactics, such as kicking in the door without warning or using a battering ram to “surprise” patients and dispensary staff. The agents would then 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.

On October 19, 2009, the DOJ issued a memo authored by Deputy U.S. Attorney David Ogden to provide guidance to U.S. Attorneys for determining when to prosecute medical cannabis cases. The memo clearly stated that it was not the Administration’s policy to prosecute anyone “in clear and unambiguous compliance with existing state laws providing for the medical use of cannabis.”

Despite this, many of the U.S. attorneys in medical cannabis states ignored the memo and continued to authorize federal raids and prosecute medical cannabis patients and providers. In the spring of 2011, U.S. attorneys adopted a new tactic of threatening elected officials. Between February and May, federal prosecutors sent letters to elected state officials in Arizona, California, Colorado, Hawaii, Maine, Montana, New Hampshire, Rhode Island, Vermont, and Washington—either implicitly or explicitly threatening criminal prosecution of elected officials and state employees if they implemented laws regulating the distribution of medical cannabis. Some letters also threatened to seize the buildings housing state administrative offices that process license applications for medical cannabis providers.

The courts may have concluded that there is no direct conflict between federal and state laws, but the Justice Department seems intent on creating one. Prior to this, elected officials had never been threatened with prosecution for implementing state law. Letters were not the only attempts to pressure elected officials. Raids on 26 cannabis businesses in Montana in March 2011 were staged while state lawmakers were considering changing the law. The raids resulted in 31 plea deals and two trials that resulted



in convictions. Jurors did not have knowledge that the defendants were operating under the state's medical cannabis program because the fact was deemed as inadmissible evidence.

In July of 2011, the DOJ issued a new policy, drafted by Deputy Attorney General James Cole, claiming to "clarify" the policy set forth in the Ogden memo. In reality, the Cole memo rescinded the guidelines set forth in the Ogden memo. In September of that year, U.S. attorneys began sending letters to landlords who rented to medical cannabis facilities, threatening to seize their property. Over the next two years, U.S. attorneys would send more than 500 of these letters and begin asset forfeiture proceedings on approximately 30 properties.

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 current federal enforcement priorities. Fortunately, most medical cannabis programs require the same guidelines ensuring that any business with a license is also meeting these requirements.

2. THE COST OF WAR

Price Tag:

In an escalating war on medical cannabis patients that has spanned the terms of three Presidents, the DOJ has spent an estimated \$600 million to date in arrests, investigations, enforcement raids, pretrial services, incarcerations, and probations. The Obama Administration, in just his first term, 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 patients.

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. In California, this could mean driving four to five hours to another city. In other areas of the country, it can mean 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.



JERRY DUVAL WITH HIS WIFE

”
The agents would then 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.

Patient Stories:

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 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.

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 by 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 the federal government's outdated policy. One such victim of this kind of discrimination was 64-year-old **Norman Smith**. Norman had 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.

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 of 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.

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 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.



JASON WASHINGTON



3. THE "CEASEFIRE": ROHRBACHER-FARR AMENDMENT AND COLE MEMO

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 the Controlled Substances Act in states with medical cannabis reform laws.

The Rohrabacher-Farr amendment is the best protection that medical cannabis patients and providers have ever enjoyed, but it must be renewed annually. While many presume momentum is on the side of medical cannabis patients, shifting political will in Congress could result in this significant victory being reversed. The Rohrabacher-Farr 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.

The Cole Memo is subject to change under the new administration, and the 115th Congress will likely be responsible for including the Rohrabacher-Farr amendment to the 2017 CJS Appropriations bill.

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. Passing legislation such as the Compassionate Access, Research Expansion, and Respect States (CARERS) Act (S.683, H.R. 1583; 114th Congress) is the only way to ensure this does not occur.



Federal intervention has included over 500 years of jail time for individuals following state law.

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

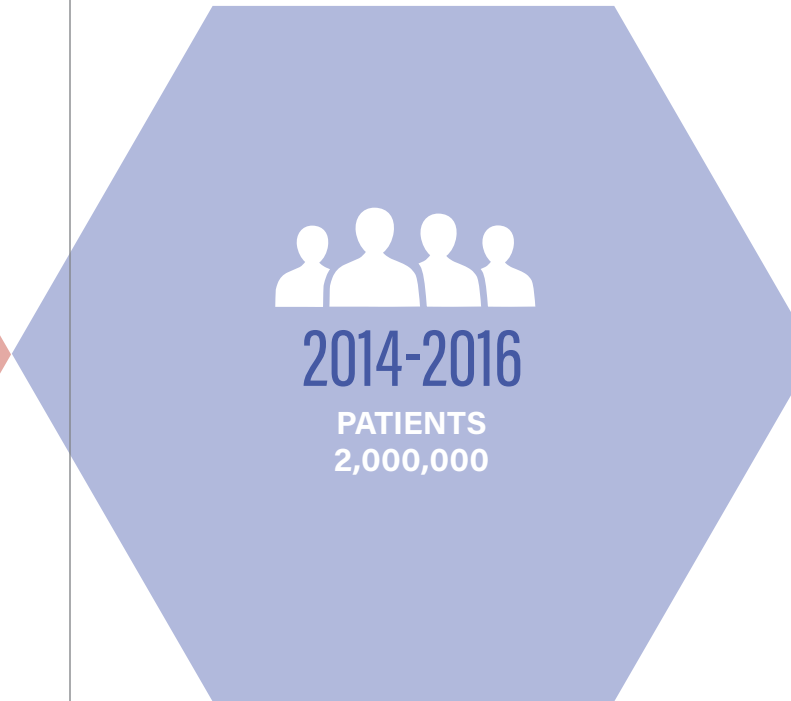
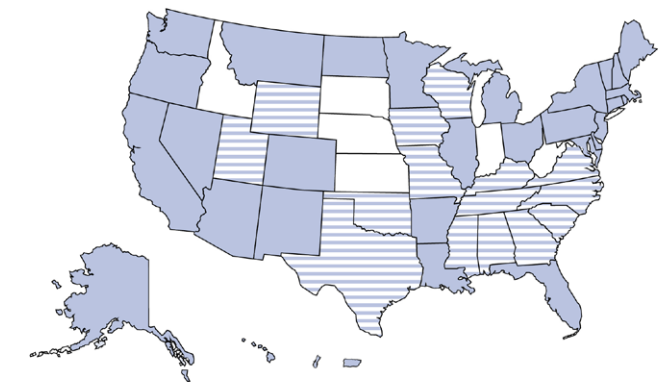
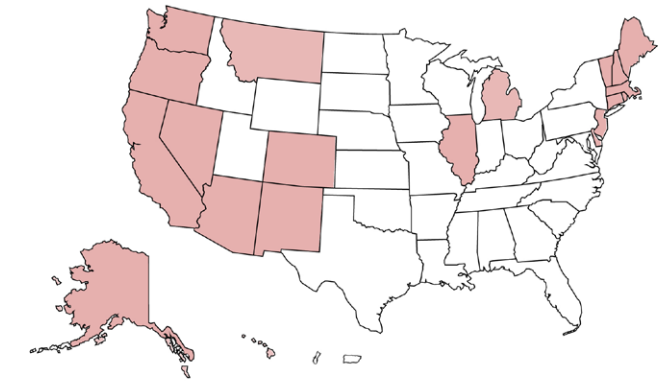
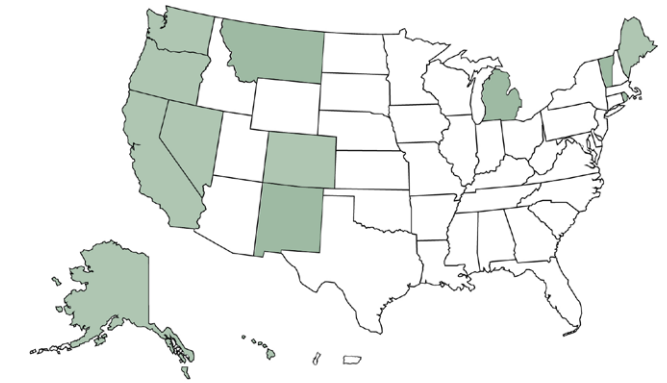
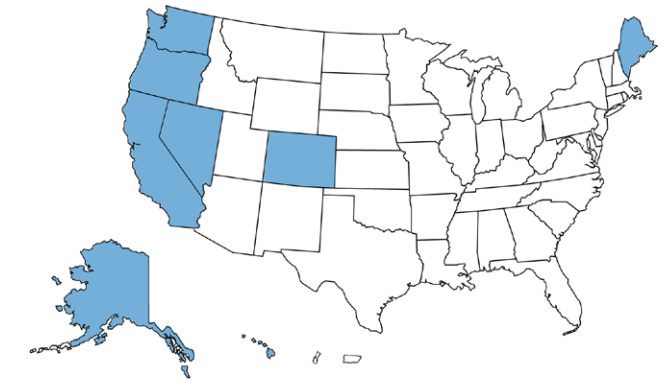
Colorado passed first commercial licensing medical marijuana program

Medical cannabis program laws and regulations include product safety protocols

TOTAL STATES 44 PLUS DC, PUERTO RICO AND GUAM

Maryland, Minnesota, New York, Pennsylvania, Louisiana, Ohio, Florida, Arkansas, North Dakota, Guam, and Puerto Rico

CBD only laws: 1. Alabama, Georgia, Iowa, Kentucky, Mississippi, Missouri, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Utah, Virginia, and Wisconsin



FEDERAL RAIDS 14

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

DOJ and DEA carry out parliamentary 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 AHPA issues recommendations for regulators

FEDERAL RAIDS 2

Rohrabacher-Farr CJS amendment passes and prohibits the Department of Justice from spending money to prevent states from implementing medical marijuana programs (2014 & 2015).

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

Courts uphold Rohrabacher-Farr protections *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 1 status

4

ENDING THE FEDERAL CONFLICT: A FUNCTIONAL PLAN

KEY POINTS
TALKING POINTS

1. **ROLE OF CONGRESS: LEGISLATIVE NEEDS**
2. **LEGISLATIVE ACTIVITY 114TH CONGRESS: CJS AMENDMENT AND THE CARERS ACT**
3. **REGULATORY IMPACT OF COMPREHENSIVE LEGISLATION**



KEY POINTS

- CONGRESS MUST PASS LEGISLATION TO HARMONIZE STATE AND FEDERAL LAW.
- 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 DISPROVEN, HAVE PREVENTED FEDERAL REPRESENTATIVES FROM PASSING MEANINGFUL LEGISLATION.
- THE MOST IMPORTANT COMPONENT OF ANY VIABLE FEDERAL LEGISLATIVE OPTION IS EXEMPTING THE 44 STATES WITH MEDICAL CANNABIS PROGRAMS (AS OF DEC. 2016) FROM THE CSA.
- THE CURRENT “CEASEFIRE” BETWEEN STATES AND FEDERAL GOVERNMENT IS THE RESULT OF AN AMENDMENT TO CJS APPROPRIATIONS BUDGET THAT MUST BE REAUTHORIZED EVERY YEAR.
- THE CARERS ACT GARNERED BIPARTISAN SUPPORT IN BOTH HOUSES AND WIDE-SPREAD SUPPORT NATIONALLY FROM PATIENT ORGANIZATIONS.
- MOVING CANNABIS TO SCHEDULE II, WOULD SHOW THAT THE U.S. GOVERNMENT HAS FINALLY ACCEPTED THE MEDICAL USES FOR CANNABIS.
- 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.
- 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.
- COMMON-SENSE LEGISLATION WOULD ALLOW FEDERAL AGENCIES – LIKE THE DEA, FDA, AND EPA – TO PARTICIPATE IN AND ENGAGE WITH MEDICAL CANNABIS PROGRAMS.



TALKING POINTS

- CONGRESS MUST PASS LEGISLATION TO ENSURE FEDERAL LAW RESPECTS STATE LAWS. 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 DISPROVEN BUT HAVE STILL PREVENTED FEDERAL REPRESENTATIVES FROM PASSING LEGISLATION.
- THE MOST IMPORTANT COMPONENT OF ANY VIABLE FEDERAL LEGISLATIVE OPTION IS EXEMPTING THE 44 STATES WITH MEDICAL CANNABIS PROGRAMS FROM THE CSA.
- THE CARERS ACT GARNERED BIPARTISAN SUPPORT IN BOTH HOUSES OF CONGRESS AND ENJOYED 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 44 STATES, AND THE MAJORITY OF THE AMERICAN PUBLIC.



The CARERS Act also has overwhelming support among the 2 million legal cannabis patients and the condition-based organizations that represent them.

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. The POTUS cannot change federal law through an executive order and therefore cannot unilaterally act to exempt state medical cannabis programs from the Controlled Substances Act. While the POTUS can take steps to ease research restrictions or to limit federal interference with state law, only an act of Congress can bring state medical cannabis programs into compliance with federal law. 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.

Americans for Safe Access has four Congressional legislative goals to harmonize state and federal medical cannabis laws and promote the advancement of medical cannabis research:

1. Continue the “ceasefire” 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.
- 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.

The passage of the Rohrabacher-Farr amendment has accomplished the first goal, 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 114TH CONGRESS

Rohrabacher-Farr Amendment to CJS Appropriations

The most effective legal provision to date in protecting state medical cannabis programs from federal interference is the Rohrabacher-Farr amendment to the Commerce, Justice, Science and Related Agencies (CJS) Appropriations Act. The provision was upheld several times in federal court in 2015 and 2016, most prominently in the 9th Circuit case of *U.S. vs. McIntosh*, holding that federal prosecutions can only take place after federal prosecutors establish that there was a violation of the state’s medical cannabis law.

The Rohrabacher-Farr amendment was first passed by Congress in December 2014 at the end of the 113th Congress to the FY2015 “CRomnibus” bill. That year, it was approved in the House by a floor vote of 211-189, improving to 242-186 in 2015 with even stronger bipartisan support with 67 Republicans voting to allow states to set their own policies. In the Senate Appropriations Committee, the amendment has been approved by votes of 21-9 and 21-8 in 2015 and 2016 respectively. Despite the strong passage the past two years on the House Floor, it is not expected that the House will vote directly on the Rohrabacher-Farr amendment during the 2016 lame duck session. Therefore, it could reappear within a CRomnibus type of bill, or could be temporarily reauthorized with the passage of a continuing resolution. In the event of a CR, the Rohrabacher-Farr amendment would remain in effect, which would mean the 115th Congress would have to reauthorize the amendment prior to the expiration of the continuing resolution.

The CARERS ACT

The **Compassionate Access, Research Expansion, and Respect States (CARERS) Act (S.683, H.R. 1583; 114th Congress)** was introduced into both chambers in 2015 and is the most comprehensive piece of federal medical cannabis legislation ever introduced. 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.”

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 Neurological Diseases. 2014; *Molecules*. 19, 18781-18816; doi:10.3390/molecules191118781)



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

The 114th Congress version of the CARERS Act would harmonize federal and state medical cannabis laws, with far-reaching impacts, including:

- Allowing state medical cannabis programs to continue without federal interference and intimidation.
- Moving cannabis out of the Schedule I list in the CSA – finally eliminating the “no accepted medical use” policy under federal law.
- Removing cannabidiol (CBD) from the CSA altogether.
- Creating access to banking services for legal cannabis businesses and organizations.
- Establishing a more robust federal supply of cannabis available for FDA-approved research by requiring the DEA to license additional cultivators for clinical research.
- Allowing Veterans Administration (VA) doctors to issue recommendations to veterans patients with qualifying conditions in states that have a medical cannabis program.

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. 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.

Diverse Support for CARERS

Both in the states and federally, medical cannabis has proven to be a bipartisan issue. Not only are the CARERS Act’s original sponsors - Senators Cory Booker (D-NJ), Rand Paul (R-KY), and Kirsten Gillibrand (D-NY) - from both sides of the political aisle, but Republicans and Democrats in both the House and the Senate have signed on as co-sponsors. As of November 2016, there were 42 cosponsors (28D, 14R) in the House and 19 (15D, 3R, 1I) in the Senate. This bipartisan support comes from Congressional leaders from across the U.S. and from those who do not normally agree on issues. John Hudak of the Brookings Institute highlighted this point in his article, *Why the CARERS Act is so significant for marijuana policy reform*, “To put it into perspective, two of the cosponsors Mick Mulvaney (R-S.C.) and Jerry Nadler (D-N.Y.) voted together only 20.3 percent of the time in the current Congress. Many of these members don’t agree on much, but they agree CARERS is a reform they can embrace.”¹

¹ Hudak, J. Why the CARERS Act is so significant for marijuana policy reform. April 2016; *The Brookings Press*. <https://www.brookings.edu/blog/fixgov/2016/04/13/why-the-carers-act-is-so-significant-for-marijuana-policy-reform/>

The CARERS Act also has overwhelming support among the 2 million legal cannabis patients and the condition-based organizations that represent them. Op-ed and other articles supporting the CARERS Act have appeared all over the country, including in conservative states like Utah, Iowa, and North Carolina.

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)

2. REGULATORY IMPACT OF COMPREHENSIVE LEGISLATION

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. Comprehensive legislation would not prevent the federal government from enforcing the CSA in other matters and would allow federal agencies to engage with the state medical cannabis programs.

The following is a summary of how some of the federal agencies will be affected by the passage of the CARERS Act or a successor bill that protects state legal medical cannabis activity from federal interference.

Department of Justice

- 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.
- Create new protocols for joint task forces across the country.
- Issue at least 3 more research 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.
- Clarify regulations on manufacturing equipment, such as capsule equipment.
- Allow DEA-licensed laboratory facilities the ability to test cannabis and cannabis-derived products.

Food and Drug Administration

- Work directly with 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.
- Upon the descheduling of CBD, CBD-rich products become subject to the regulations of the 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 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 grown for human consumption.

Environmental Protection Agency

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

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 within their federal subsidized (i.e., “Section 8”) housing unit from being automatically evicted.

Department of Veteran Affairs

- V.A. physicians would be able to write medical cannabis recommendations under state law.

Alcohol, Tobacco, Firearms and Explosives

- Restore medical patients 2nd Amendment rights, as medical cannabis patients are currently denied the right to legally purchase firearms.



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.



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 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 280(e) 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 drive 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.



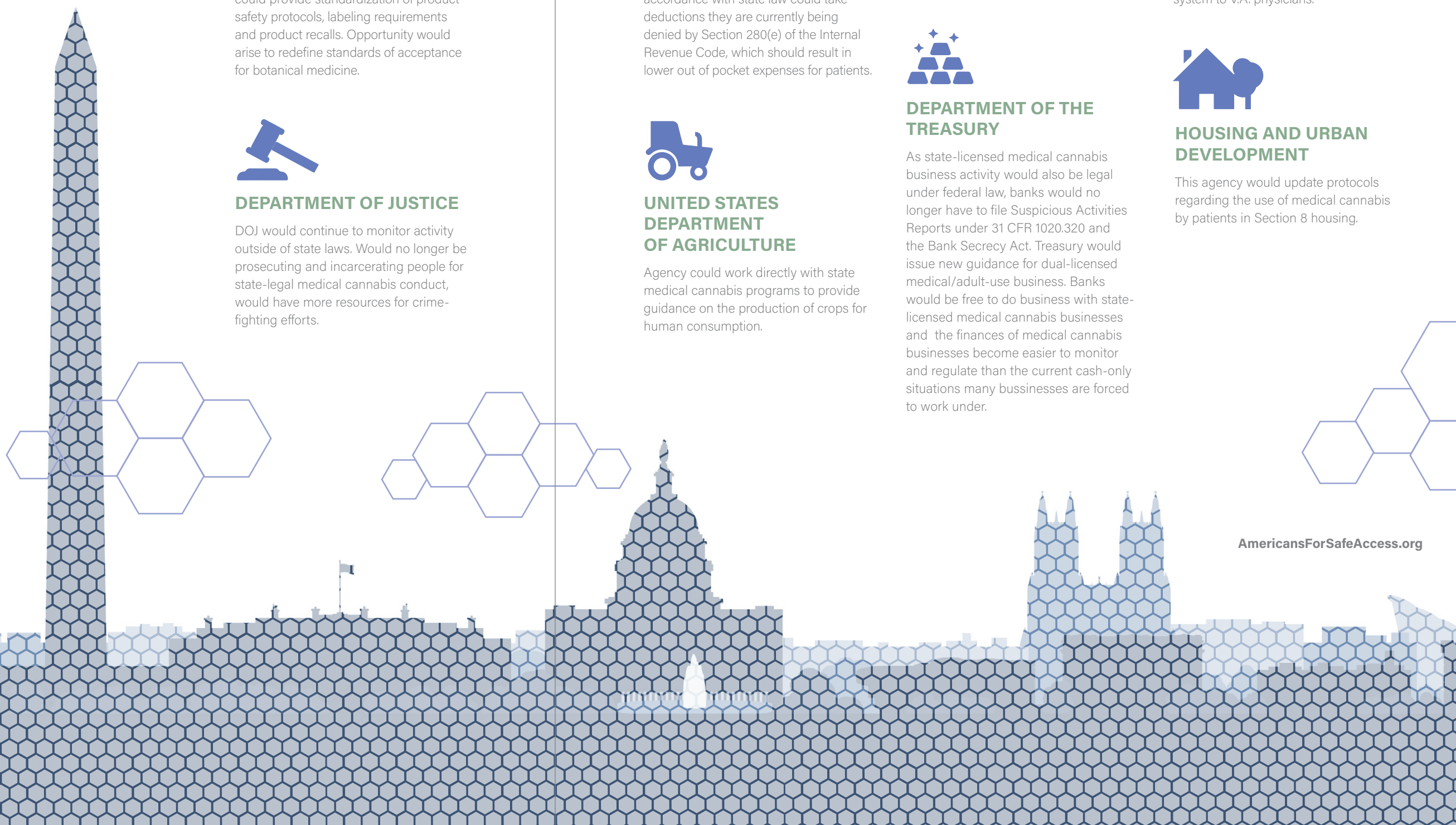
DEPARTMENT OF VETERAN AFFAIRS

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.



5

A CALL TO THE 115TH CONGRESS AND 45TH POTUS

KEY POINTS

1. 2016 LAME DUCK
2. 115TH CONGRESS
3. 45TH POTUS
4. DIVERSE SUPPORT FOR FEDERAL ACTION
5. THE GATEWAY THEORY DISPROVEN



KEY POINTS

LAME DUCK CONGRESS KEY POINTS

- PASS THE CARERS ACT.

LAME DUCK POTUS KEY POINTS

- RELEASE THE REMAINING MEDICAL CANNABIS POWS AND DROP THE HANDFUL OF REMAINING PROSECUTIONS.
- INSTRUCT DEA TO UPDATE THEIR WEBSITE AND PUBLICATIONS TO REFLECT THEIR MOST CURRENT THINKING.
- ORDER HHS AND DEA TO TAKE THE RECOMMENDATION FROM FDA ACTING COMMISSIONER STEPHEN OSTROFF TO EXAMINE AND POSSIBLY OVERHAUL THE REGULATIONS THAT ARE PREVENTING MEDICAL RESEARCH AND RESCHEDULING OF CANNABIS.
- ENGAGE WITH UN SECRETARY GENERAL ON THE SCHEDULING OF CANNABIS IN THE UN SINGLE CONVENTION OF DRUGS (WHICH IS BASED ON A REPORT FROM 1935).



KEY POINTS

115TH CONGRESS KEY POINTS

- PASS LEGISLATION THAT ESTABLISHES BINDING PROTECTION FOR STATE MEDICAL CANNABIS PROGRAMS AND THE PATIENTS WHO RELY ON THEM.
- CONTINUE TO PASS AMENDMENTS TO VARIOUS APPROPRIATIONS BILLS IN ORDER TO MAINTAIN AND INCREASE PROTECTIONS FOR THOSE ACTING IN ACCORDANCE WITH STATE LAW.
- USE THE CONFIRMATION HEARINGS TO ENSURE THAT POTUS APPOINTMENTS RESPECT STATE MEDICAL CANNABIS PROGRAMS.
- HOLD FEDERAL AGENCIES ACCOUNTABLE THROUGH CONGRESSIONAL OVERSIGHT HEARINGS IF THE AGENCIES ARE INTERFERING WITH STATE PROGRAMS, FAILING TO PROMOTE RESEARCH, OR ARE OTHERWISE HARMING PATIENTS THROUGH ACTION OR INACTION.
- ENSURE THAT THE ROHRBACHER-FARR AMENDMENT TO THE CJS APPROPRIATIONS ACT CONTINUES TO BE REAUTHORIZED

45TH POTUS KEY POINTS

- POTUS SHOULD CALL ON CONGRESS TO PASS MEDICAL CANNABIS LEGISLATION.
- DOJ SHOULD UPHOLD 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. 2016 LAME DUCK

Congress

During the "lame duck" session in December 2016, Congress should still move forward on the Compassionate Access, Research Expansion, and Respect States (CAREERS) Act (S.683, H.R. 1583; 114th Congress). While the CAREERS Act has not yet been given a markup in either the House or Senate, making passage in the lame duck a difficult endeavor.

POTUS

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.¹ The memo continues by suggesting an overhaul of the existing legal and regulatory framework may be in order.

Additionally, the DOJ and the President ought to look at commuting sentences of those currently in federal prison for state-legal medical cannabis activity. In doing so, they should seriously 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.

It is too late in the Obama Administration to reschedule cannabis out of Schedule I of the CSA. While Congressional action such as the CAREERS Act would enable swifter change from the Executive Branch agencies, there are several steps the current or future administration could take in order to reduce the conflict between state and federal medical cannabis policies.

2. 115TH CONGRESS

Legislation

In the next session of Congress, the focus should remain on (1) passing legislation that establishes binding protection for state medical cannabis programs and the patients who rely on them; and (2) maintaining and increasing ground through the appropriations channels. Reauthorizing and expanding aforementioned appropriations amendments is necessary for the second objective. The primary objective will be passing legislation that explicitly protects state medical cannabis, such as Section 2 of the CAREERS

¹ Acting Commissioner of Food and Drugs to Acting Assistant Sec. for Health, May 20, 2015, Recommendation to Maintain Marijuana in Schedule I of the Controlled Substances Act, Department of Health and Human Services, available at: https://www.scribd.com/document/325957054/FDA-Acting-Commission-On-Marijuana-Rescheduling#from_embed.

Act. While the CARERS Act contains many provisions, Section 2 protections are the core of the bill and must be carried over into any succeeding piece of legislation. Additionally, the CARERS act would enable the Office of National Drug Control Policy (ONDCP) to incorporate medical cannabis in its strategy to counteract the opioid epidemic. The ONDCP is prohibited by law from “any study or contract relating to the legalization (for a medical use or any other use) of a substance listed in Schedule I.”²

Congress will have the opportunity to adopt several medical cannabis amendments to the negotiated “CRomnibus” that will likely contain the majority of appropriations bills for FY2017. The most important, the Rohrabacher-Farr amendment, has been discussed previously in this report; however, there were several other amendments that the Senate Appropriations Committee approved in 2016.

CJS Appropriations (Rohrabacher-Farr amendment)

The aforementioned Rohrabacher-Farr amendment is the most vital current protection for state medical cannabis programs and the patients who rely on them. Without the Rohrabacher-Farr 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.

² 21 USC §1703(b)(12).



The most viable step that Congress could take to end the conflict between state and federal laws regarding medical cannabis is passing the Compassionate Access, Research Expansion, and Respect States (CARERS) Act (S.683, H.R. 1583; 114th Congress).

Banking Amendment (Merkley-Murray amendment)

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 become 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. While the amendment passed both the House and Senate, it was removed from the bill with no public explanation and will not be in effect in FY2017. It is unlikely that this amendment could have been included in the Dec. 2016 CRomnibus bill because the FY2017 Military Construction, Veterans Affairs, and Related Agencies Act were passed independently. However, Congress may be able to consider ways to add the provision.

Confirmations

- Ensure that all executive appointments are properly vetted to ensure that they will respect state medical cannabis laws, particularly for positions in the DOJ
- Make certain the appointments to positions in HHS, DOJ, and other agencies work to promote more robust medical cannabis research

Oversight

- Hold agency officials accountable if the agency has interfered with state medical cannabis programs
- Require DOJ and other agencies to report on enforcement actions against parties claiming to be in compliance with state medical cannabis laws

3. 45TH POTUS

Change starts at the top, and perhaps the most important 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. When both President Donald Trump and former Secretary of State Hillary Clinton made statements as presidential candidates in support of medical cannabis, it did not negatively affect their popularity. In fact, the statements barely seemed controversial. This shows that there is plenty of room for a sitting president to take bolder action in support of medical cannabis reform.

One way the 45th POTUS could do this is by appointing individuals to the cabinet and other positions who are willing to guide their respective agency towards harmonizing state and federal medical cannabis policy. While the biggest changes with agencies might need to be enabled through Congressional legislation, there are many steps that several agencies could take towards the goal of harmonization.

The following are policy recommendations for the 45th POTUS that can be taken even without passage of a bill such as the CARERS Act:

Department of Justice

- Uphold the August 2013 guidance 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

- Begin issuance of additional research cultivation licenses.
- Update the website and publications.

Health and Human Services

- Create 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

- Place a greater emphasis on cannabis-based research.
- Work with state programs to facilitate research.

Food and Drug Administration

- Coordinate with state departments of health on adverse event reporting.

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.

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 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. 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 THIS ISSUE OF MEDICAL CANNABIS HAS COME IN THE PAST TWO DECADES.

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

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

Bureau of Alcohol, Tobacco, Firearms and Explosives

- Clarify each of its gun application and ownership transfer forms to make clear that state-legal medical cannabis use is not consider "unlawful use."

Centers for Disease Control

- 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

- Request that the UN begin rescheduling process under the guidance of the UN Single Treaty.
- Coordinate with the other 19 countries with medical cannabis laws to participate in UNGASS 2019.

4. DIVERSE SUPPORT FOR FEDERAL ACTION

Support for medical cannabis is strong across many different demographics. A May 2016 poll by Quinnipiac University surveying 1,561 registered voters nationwide found support of medical cannabis at 89%. This poll closely mirrors the results of a 2014 CNN/ORC national poll, which showed the support level at 88%. The support was strong across all ages and party affiliations. While Republicans and older Americans have traditionally been the least likely to support legal access to medical cannabis therapy, their support levels were 81% and 89%, respectively. Again, these results nearly replicate the 2014 CNN/ORC poll, in which 84% of Republicans and 84% of voters over age 65 stated their support. Support is also strong among physicians, with 76% of physicians supportive of the use of medical cannabis in certain circumstances in a 2013 New England Journal of Medicine poll.

American Academy of Family Physicians, the American Medical Association, the American College of Physicians, the American Public Health Association, American Preventive Medical Association, Texas Medical Association, The Rhode Island Medical Society, New York County Medical Society, American Medical Student Association, National Nurses Society on Addictions, National Multiple Sclerosis Society, Epilepsy Foundation, Leukemia & Lymphoma Society and the American Cancer Society have all come forward with supportive statements regarding medical cannabis.

Statements from Qualified Experts and Medical Organizations

“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.”

National Multiple Sclerosis Society

“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.”

Epilepsy Foundation

“(T)he Leukemia & Lymphoma Society supports legislation to remove criminal and civil sanctions for the doctor-advised, medical use of marijuana by patients with serious physical medical conditions.”

Leukemia & Lymphoma Society



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

“Based on much evidence, from patients and doctors alike, on the superior effectiveness and safety of whole Cannabis (marijuana) compared to other medicines for many patients — suffering from the nausea associated with chemotherapy, the wasting syndrome of AIDS, and the symptoms of other illnesses ... we hereby petition the Executive Branch and the Congress to facilitate and expedite the research necessary to determine whether this substance should be licensed for medical use by seriously ill persons.”

American Academy of Family Physicians

The American Medical Association *“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.”*

The American College of Physicians *“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.”*

The American Public Health Association *“adopted a resolution [...] which urged federal and state drugs laws to exclude Marijuana as a narcotic drug,” and “conclude[d] that Cannabis was wrongfully placed in Schedule I of Controlled Substances, depriving patients of its therapeutic potential.”*

“Marijuana should be available for appropriate medicinal purposes, when such use is in accordance with state law, and that physicians who recommend and prescribe marijuana for medicinal purposes in states where such use is legal, should not be censured, harassed, prosecuted or otherwise penalized by the federal government.”

American Preventive Medical Association

“The Texas Medical Association supports (1) the physician’s right to discuss with his/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 the physician or patient of regulatory, disciplinary, or criminal sanctions; and (2) further well-controlled studies of the use of marijuana with seriously ill patients who may benefit from such alternative treatment.”

Texas Medical Association

The Rhode Island Medical Society has stated that *“There is sufficient evidence for us to support any physician-patient relationship that believes the use of marijuana will be beneficial to the patient.”*

“The definitive review of scientific studies ... found medical benefits related to pain relief, control of nausea and vomiting, and appetite stimulation ... While there are a variety of ways of supplying marijuana for medical use, serious consideration should be given to the 1997 recommendation ... that the FDA reclassify marijuana from Schedule I and provide a consistent, safe supply.”

New York County Medical Society

“The American Medical Student Association strongly urges the United States Government ... to meet the treatment needs of currently ill Americans by restoring the Compassionate (Investigational New Drug) program for medical marijuana, and ...

reschedule marijuana to Schedule II of the Controlled Substances Act, and ... end the medical prohibition against marijuana."

American Medical Student Association

"The National Nurses Society on Addictions urges the federal government to remove marijuana from the Schedule I category immediately, and make it available for physicians to prescribe. NNSA urges the American Nurses' Association and other health care professional organizations to support patient access to this medicine."

National Nurses Society on Addictions

"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 US 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."

American Cancer Society

Action from Congress and the Administration is necessary to harmonize current conflict between state and federal medical cannabis laws and regulations. While both the Administration and Congress have taken small steps towards addressing the conflict over the past several years, including the DOJ and Treasury guidance memos and the adoption of the Rohrabacher-Farr amendment, there is still more to be done.

5. THE GATEWAY THEORY DISPROVEN

The "gateway drug" theory is often used as a reason to block medical cannabis efforts. This argument is not relevant to medical cannabis because it is a direct conflation of medical versus recreational use. When we speak of medical cannabis, we are talking about a medicine. As such, we are not advocating for teen or adult recreational use, but rather, a decision between a doctor and a patient to treat a condition using a cannabis-based therapy. Therefore, recreational abuse should not enter into the argument at all. However, since it has, it should be noted that recent research has disproven the validity of this theory. In fact, the DEA in its denial of petitions to reschedule cannabis stated, "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."² One example of the research studies which lend support to this statement by the DEA was from researchers at Columbia University in NY, who conducted a longitudinal study of 708 adolescents that concluded that early onset cannabis use did not lead to problematic drug use.³

² **Drug Enforcement Administration.** Denial of Petition To Initiate Proceedings To Reschedule Marijuana. *Federal Register*. August 2016; 53687-53766. 81 FR 53687.

³ Kandel, D., 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.



A May 2016 poll by Quinnipiac University surveying 1,561 registered voters nationwide found support of medical cannabis at 89%. This poll closely mirrors the results of a 2014 CNN/ORC national poll, which showed the support level at 88%.



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 in the largest national member-based organization of patients, medical professionals, scientists and concerned citizens promoting safe and legal access to cannabis for therapeutic use and research, ASA works to overcome political, social and legal barriers by creating policies that improve access to medical cannabis for patients and researchers through legislation, education, litigation, research, grassroots empowerment, advocacy and services for patients, governments, medical professionals, and medical cannabis providers.

ASA and our members have moved public policy forward by light years by incorporating strategies across many

disciplines. ASA has brought together policy experts, public health experts, attorneys, lobbyists, scientists, industry associations and medical professionals to create the campaigns, projects and programs that have broken down political, social, academic, and legal barriers across the US.

Ensuring safe and legal access to cannabis means:

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

Become a part of History! Join us today @ AmericansForSafeAccess.org/Join



Americans for Safe Access

1624 U Street, NW, Suite 200 Washington, DC 20009

Tel: 202.857.4272

AmericansForSafeAccess.org