TRICCAR

Rationale for a Revised Federal Cannabis Policy

March 2, 2017

BILL TOWNSEND, President & CEO
Townsend Rockefeller Institute of Cannabis Cultivation and Research
dba, TRICCAR Holdings, Inc.
848 N. Rainbow Blvd., #3254
Las Vegas, Nevada 89107

Table of Contents

Rationale for a Revised Federal Cannabis Policy

Purpose

This document is submitted to provide the Administration and Members of Congress a realistic plan to address the current state of cannabis (marijuana) use and sales in America.

It is submitted as a humble attempt to break through the rhetoric of what was once considered "Refer Madness" and to address the overwhelming public support for legalization while supporting states' rights, which is a promise of the Trump Administration. At the same time, it recognizes that cannabis is currently a DEA schedule I drug and simply rescheduling or decriminalizing it does not provide the right path to sound legislation that benefits America's citizens.

The Administration and United States Congress have an opportunity to set in place rulemaking and permitting/licensing at the federal level to ensure truth in labeling, uniform testing, and providing those who choose to consume cannabis—whether for medicinal or recreational use—products that are safer than what is currently found.

This document provides a comprehensive review of the history, classification and legal actions taken regarding the use and medical efficacy of cannabis

This document includes recommendations on greatly eliminating the black market and money laundering. It recommends bringing revenues obtained through state-legal cannabis sales into the light through nationwide access to banking.

It recommends a proposed new federal tax on the sale of recreational cannabis, federal permitting/licensing and associated fees, seed-to-store tracking of cannabis products, and suggestions on keeping possession or use of cannabis in states that have not legalized its use, a criminal act.

It addresses transportation, insurance, dietary supplements, labeling requirements, and other actions the federal government can take to bring its federal cannabis rules up to date with the wishes of the American people.

A General History of Cannabis in America

Marijuana—also called hemp and cannabis—has been used as an agent for achieving euphoria since ancient times. The first direct reference to a cannabis product as a psychoactive agent dates from 2737 BC, in the writings of the Chinese emperor Shen Nung. In these writings, the focus was on the powers of cannabis as a medication for rheumatism, gout, malaria, and oddly enough, absent-mindedness. Mention was made of the intoxicating properties, but the medicinal value was considered more important. Its use spread first from China to India and then to North Africa. From North Africa, the use of cannabis reached Europe at least as early as AD 500. In 1545, the Spanish brought cannabis to the New World. In 1611, the English introduced it in Jamestown, where it became a major commercial crop alongside tobacco. Cannabis was grown as a source of fiber for paper, textile, rope, canvas, and twine, and even used in animal bedding, insulation, animal feed, beer making, and fuel.

During the 17th century, the US Government encouraged the cultivation and production of hemp for the production of rope, sails, and clothing. How widespread was this? In 1619, the Virginia Assembly passed legislation requiring every farmer to grow hemp and hemp was exchanged as legal tender in not only Virginia, but Pennsylvania and Maryland as well. Hemp farming was even featured on the back of the $10 bill in the early 1900s.

Domestic production flourished until after the Civil War, when imports and other domestic materials replaced hemp for many products and uses. In the late nineteenth century, cannabis became a popular ingredient in many medicinal products and was sold openly in public pharmacies. Cannabis was freely available at drug stores in liquid form and as a refined product, hashish. Cannabis was also a common ingredient in turn-of-the-century patent medicines, which were over-the-counter medicines brewed to proprietary formulas.

Then, as now, it was difficult to clearly distinguish between medicinal and recreational use of a product whose purpose is to make you feel good. The hashish candy advertised in an 1862 issue of Vanity Fair as a treatment for nervousness and melancholy, for example, was also “a pleasurable and harmless stimulant.” “Under its influence all classes seem to gather new inspiration and energy,” the advertisement explained.

By 1890, cannabis had been replaced by cotton as a major cash crop in southern states. Some patent medicines during this era contained cannabis, but it was a small percentage compared to the number containing opium or cocaine. It was in the 1920’s that the use of marijuana began to catch on. Some historians say its emergence was brought about by Prohibition. Its recreational use was restricted to jazz musicians and people in show business. “Reefer songs” became the rage of the jazz world. Cannabis clubs, called tea pads, sprang up in every major city. These cannabis establishments were tolerated by the authorities because cannabis was not illegal and patrons showed no evidence of making a nuisance of themselves or disturbing the community. Cannabis was listed in the United States Pharmacopeia from 1850 until 1942 and was prescribed for various conditions including labor pains, nausea, and rheumatism.

After the Mexican Revolution of 1910, Mexican immigrants flooded into the U.S., introducing to American culture the recreational use of cannabis, most commonly referred to at the time as marihuana. The drug became associated with the immigrants, and the fear and prejudice directed at the Spanish-speaking newcomers became associated with marijuana. Anti-drug campaigners, largely led by warned

against the encroaching “Marijuana Menace” and terrible crimes were attributed to marijuana and the Mexicans who used it.

In 1930, Harry Ansinger was named Director of a new government agency, the Federal Bureau of Narcotics. Ansinger was overly ambitious in his goals for the new agency, and when he realized that opiates and cocaine wouldn’t be enough to help build his agency, he latched on to marijuana and started to work on making it illegal at the federal level. Anslinger immediately drew upon the themes of racism and violence to draw national attention to the problem he wanted to create, stating,

“There are 100,000 total marijuana smokers in the US, and most are Negroes, Hispanics, Filipinos, and entertainers. Their Satanic music, jazz, and swing, result from marijuana use. This marijuana causes white women to seek sexual relations with Negroes, entertainers, and any others.”

Anslinger received additional help from William Randolf Hearst, owner of a huge chain of newspapers. Hearst had lots of reasons to help. First, he had invested heavily in the timber industry to support his newspaper chain and didn’t want to see the development of hemp paper in competition. Second, he had lost 800,000 acres of timberland to General Pancho Villa and he hated Mexicans. Third, telling lurid lies about Mexicans (and the “devil weed” causing violence)—in what today would be called “Yellow Journalism—sold newspapers, making Hearst very rich. Combined, these two men did more to destroy the cannabis industry in America than anyone since; and sadly, the vast majority of the lies and mistruths about cannabis stuck in the minds of Americans and their elected representatives.

Anslinger and Hearst were then supported by Dupont chemical company and various pharmaceutical companies in the effort to outlaw cannabis. Dupont had patented nylon, and wanted hemp removed as competition. The pharmaceutical companies could neither identify nor standardize cannabis dosages, and besides, with cannabis, folks could grow their own medicine and not have to purchase it from large companies.

During the Great Depression, massive unemployment increased public resentment and fear of Mexican immigrants, escalating public and governmental concern about the problem of marijuana. This instigated a flurry of research which linked the use of marijuana with violence, crime and other socially deviant behaviors, primarily committed by “racially inferior” or underclass communities. Much of this research was dubious in nature but had the intended effect of convincing state governments to ban marijuana. By 1931, 29 states had outlawed marijuana.

Reefer Madness, a propaganda film released in 1936, had a storyline revolving around the melodramatic events that ensue when high school students are lured by pushers to try marijuana—from a hit and run accident, to manslaughter, suicide, attempted rape, hallucinations, and descent into madness due to marijuana addiction.

This set the stage for The Marijuana Tax Act of 1937, making marijuana illegal at the Federal level.

During World War II, imports of hemp and other materials crucial for producing marine cordage, parachutes, and other military necessities became scarce. In response, the U.S. Department of Agriculture launched its “Hemp for Victory” program, encouraging farmers to plant hemp by giving out seeds and granting draft deferments to those who would stay home and grow hemp. By 1943, American farmers registered in the program harvested over 375,000 acres of hemp.

In 1944, New York Academy of Medicine issued an extensively researched report declaring that, contrary to earlier research and popular belief, use of marijuana did not induce violence, insanity or sex crimes, or lead to addiction or other drug use. In the 1960s, reports commissioned by Presidents Kennedy and Johnson found that marijuana use did not induce violence nor serve as a gateway drug to the use of heavier drugs.

In 1972, the bipartisan Shafer Commission, appointed by President Nixon at the direction of Congress, considered laws regarding marijuana and determined that personal use of marijuana should be decriminalized. Nixon rejected the recommendation, but over the course of the 1970s, eleven states decriminalized marijuana and most others reduced their penalties. By 1977, the use of the drug seemed so commonplace and the fears so archaic that President Jimmy Carter called for the decriminalization of marijuana. As Carter pointed out in a message to Congress in 1977, anti-marijuana laws caused more harm to marijuana users than the drug itself.

In the mid-70s, a nationwide movement emerged of conservative parents' groups lobbying for stricter regulation of marijuana and the prevention of drug use by teenagers. Some of these groups became quite powerful and, with the support of the Drug Enforcement Agency and the National Institute on Drug Abuse (NIDA), were instrumental in affecting public attitudes which led to the 1980s War on Drugs.

President Reagan signed the Anti-Drug Abuse Act, instituting mandatory sentences for drug-related crimes. In conjunction with the Comprehensive Crime Control Act of 1984, the new law raised federal penalties for marijuana possession and dealing, basing the penalties on the amount of the drug involved. Possession of 100 marijuana plants received the same penalty as possession of 100 grams of the addictive drug heroin. A later amendment to the Anti-Drug Abuse Act established a “three strikes and you’re out” policy, requiring life sentences for repeat drug offenders, and providing for the death penalty for “drug kingpins.”

About 800,000 Americans are arrested annually for marijuana offenses, mostly simple possession. Few wind up in prison as a result of a first offense, but this encounter with the criminal justice system can have serious consequences, including the loss of eligibility for federal student financial aid and subsidized housing and difficulty in finding employment. “Three-strikes laws,” which 22 states and the federal government passed between 1993 and 1995 and which mandated stiff prison sentences for a person convicted of a third felony, ensure that marijuana offenses can lead to dire results.

Background: Drug Enforcement Agency

Drugs and other substances that are considered controlled substances under the Controlled Substances Act (CSA) are divided into five schedules. Substances are placed in their respective schedules based on whether they have a currently accepted medical use in treatment in the United States, their relative abuse potential, and likelihood of causing dependence when abused.

Schedule I Controlled Substances

Substances in this schedule have no currently accepted medical use in the United States, have a lack of accepted safety for use under medical supervision, and demonstrate a high potential for abuse. Some examples of substances listed in Schedule I include: heroin, lysergic acid diethylamide (LSD), marijuana (cannabis), peyote, methaqualone, and 3,4-methylenedioxymethamphetamine ("Ecstasy").

Schedule II/IIN Controlled Substances (2/2N)

Substances in this schedule have an accepted medical use in the United States, but have a high potential for abuse which may lead to severe psychological or physical dependence.

Examples of Schedule II narcotics include: hydromorphone (Dilaudid), methadone (Dolophine), meperidine (Demerol), oxycodone (OxyContin, Percocet), and fentanyl (Sublimaze, Duragesic). Other Schedule II narcotics include: morphine, opium, and codeine.

Examples of Schedule IIN stimulants include: amphetamine (Dexedrine, Adderall), methamphetamine (Desoxyn), and methylphenidate (Ritalin).

Other Schedule II substances include: amobarbital, glutethimide, and pentobarbital.

Schedule III/IIIN Controlled Substances (3/3N)

Substances in this schedule have a lower potential for abuse compared to substances in Schedules I or II and abuse may lead to moderate or low physical dependence or high psychological dependence.

Examples of Schedule III narcotics include: combination products containing less than 15 milligrams of hydrocodone per dosage unit (Vicodin), products containing not more than 90 milligrams of codeine per dosage unit (Tylenol with Codeine), and buprenorphine (Suboxone).

Examples of Schedule IIIN non-narcotics include: benzphetamine (Didrex), phendimetrazine, ketamine, and anabolic steroids such as Depo-Testosterone.

Schedule IV Controlled Substances

Substances in this schedule have a low potential for abuse relative to substances in Schedule III.

Examples of Schedule IV substances include: alprazolam (Xanax), carisoprodol (Soma), clonazepam (Klonopin), clorazepate (Tranxene), diazepam (Valium), lorazepam (Ativan), midazolam (Versed), temazepam (Restoril), and triazolam (Halcion).

Schedule V Controlled Substances

Substances in this schedule have a low potential for abuse relative to substances listed in Schedule IV and consist primarily of preparations containing limited quantities of certain narcotics.

Examples of Schedule V substances include: cough preparations containing not more than 200 milligrams of codeine per 100 milliliters or per 100 grams (Robitussin AC, Phenergan with Codeine), and ezogabine.

Removal or Rescheduling of Cannabis from Schedule I

Overview

The removal of cannabis from Schedule I of the Controlled Substances Act, the most tightly restricted category reserved for drugs that have "no currently accepted medical use," has been proposed repeatedly since 1972.

Rescheduling proponents argue that cannabis does not meet the Controlled Substances Act's strict criteria for placement in Schedule I and so the government is required by law to permit medical use or to remove the drug from federal control altogether. The US Government, on the other hand, maintains that cannabis is dangerous enough to merit Schedule I status. The dispute is based on differing views on both how the Act should be interpreted and what kinds of scientific evidence are most relevant to the rescheduling decision.

The Act provides a process for rescheduling controlled substances by petitioning the Drug Enforcement Administration (DEA). The first petition under this process was filed in 1972 to allow cannabis to be legally prescribed by physicians. The petition was ultimately denied after 22 years of court challenges, but a pill form of cannabis's psychoactive ingredient, Δ9-tetrahydrocannabinol, more commonly called “THC”, was rescheduled in 1985 to allow prescription under schedule II. In 1999, it was again rescheduled to allow prescription under schedule III. Therefore, cannabis, as a plant or the natural product derived from the plant, remains categorized by the DEA as a schedule I drug, however, the synthetic form is categorized two levels lower under schedule III. The syntheticform is called MARINOL® (dronabinol capsules, USP) and is controlled by the for-profit pharmaceutical company AbbVie, Inc. This in itself presents a conflict in categorization within the US Government. The natural plant is schedule I and the patent-applied for synthetic form is schedule III, yet only the latter is said to offer medical benefits.

Cannabis—whether inhaled, ingested, or topically applied—and prescription-based MARINOL have been proven effective treating nausea and vomiting that is associated with cancer chemotherapy in patients who have not responded to standard treatments for nausea and vomiting, as well for symptom relief in HIV/AIDS patients.

Legal History

In 1972, the National Commission on Marijuana and Drug Abuse released a report favoring decriminalization of cannabis. The Nixon administration took no action to implement the recommendation, however.

In 1972, the National Organization for the Reform of Marijuana Laws (NORML) petitioned the Bureau of Narcotics and Dangerous Drugs (BNDD) (now the Drug Enforcement Administration (DEA)) to transfer cannabis to Schedule II so that it could be legally prescribed by physicians. The BNDD declined to initiate proceedings on the basis of their interpretation of U.S. treaty commitments.

In 1974, the United States Court of Appeals for the District of Columbia Circuit ruled against the government and ordered them to process the petition (NORML v. Ingersoll 497 F.2d 654). The government continued to rely on treaty commitments in their interpretation of scheduling-related issues concerning the NORML petition. In 1977, the Court issued a decision clarifying that the Controlled Substances Act requires a full scientific and medical evaluation and the fulfillment of the rescheduling process before treaty commitments can be evaluated (NORML v. DEA 559 F.2d 735). On October 16, 1980, the Court ordered the government to start the scientific and medical evaluations required by the NORML petition (NORML v. DEA Unpublished Disposition, U.S. App. LEXIS 13100).

Meanwhile, some members of Congress were taking action to reschedule the drug legislatively. In 1981, the late Rep. Stuart McKinney introduced a bill to transfer cannabis to Schedule II. It was co-sponsored by a bipartisan coalition of 84 House members, including prominent Republicans Newt Gingrich (GA), Bill McCollum (FL), John Porter (IL), and Frank Wolf (VA). After the bill died in committee, Rep. Barney Frank began annually introducing nearly identical legislation. All of Frank's bills have suffered the same fate, though, without attracting more than a handful of co-sponsors.

On October 18, 1985, the DEA issued a Notice of Proposed Rulemaking to transfer "Synthetic Dronabinol in Sesame Oil and Encapsulated in Soft Gelatin Capsules"—a pill form of Δ9-tetrahydrocannabinol, the main psychoactive component of cannabis, sold under the brand name Marinol—from Schedule I to Schedule II (DEA 50 FR 42186-87). The government issued its final rule rescheduling the drug on 13 July 1986 (DEA 51 FR 17476-78). The disparate treatment of cannabis and the expensive, patentable Marinol prompted reformers to question the DEA's consistency.

In the summer of 1986, the DEA administrator initiated public hearings on cannabis rescheduling. The hearings lasted two years, involving many witnesses and thousands of pages of documentation. On 6 September 1988, DEA Chief Administrative Law Judge Francis L. Young ruled that cannabis did not meet the legal criteria of a Schedule I prohibited drug and should be reclassified. He declared that cannabis in its natural form is *"one of the safest therapeutically active substances known to man. (T)he provisions of the (Controlled Substances) Act permit and require the transfer of marijuana from Schedule I to Schedule II"*.

The conclusion was overruled by DEA Administrator John Lawn. Lawn said he decided against re-scheduling cannabis based on testimony and comments from numerous medical doctors who had conducted detailed research and were widely considered experts in their respective fields. Subsequent DEA Administrators upheld this conclusion even in the face of research that ruled cannabis to be of

medical benefit, non-addictive, and a safe alternative to more toxic opiates.. In 1994, the D.C. Court of Appeals finally affirmed the DEA Administrator's power to overrule Judge Young's decision (Alliance for Cannabis Therapeutics v. DEA. 15 F.3d 1131). The petition was officially dead. "Each of the doctors testifying on behalf of NORML claimed that his opinion was based on scientific studies, yet with one exception, none could identify, under oath, the scientific studies they relied on," DEA Administrator Thomas A. Constantine remarked in 1995.

On 10 July 1995, Jon Gettman and High Times Magazine filed another rescheduling petition with the DEA. This time, instead of focusing on cannabis' medical uses, the petitioners claimed that cannabis did not have the "high potential for abuse" required for Schedule I or Schedule II status. They based their claims on studies of the brain's cannabinoid receptor system conducted by the National Institute of Mental Health (NIMH) between 1988 and 1994. In particular, they claim that a 1992 study by M. Herkenham et al., "using a lesion-technique, established that there are no cannabinoid receptors in the dopamine-producing areas of the brain". Other studies, summarized in Gettman's 1997 report Dopamine and the Dependence Liability of Marijuana, showed that cannabis has only an indirect effect on dopamine transmission. This suggested that cannabis' psychoactive effects are produced by a different mechanism than addictive drugs such as amphetamine, cocaine, ethanol, nicotine, and opiates. The National Institute on Drug Abuse, however, continued to publish literature denying this finding. For instance, NIDA claims the following in its youth publication The Science Behind Drug Abuse:

> *"A chemical in marijuana, THC, triggers brain cells to release the chemical dopamine. Dopamine creates good feelings—for a short time. Here's the thing: Once dopamine starts flowing, a user feels the urge to smoke marijuana again, and then again, and then again. Repeated use could lead to addiction, and addiction is a brain disease."*

In reality, there is no clinical evidence for this conclusion. Millions of Americans use cannabis and stop cannabis use with no signs of addiction or withdrawal. The biggest consumers of cannabis find they need no more than 2 weeks to completely stop use, much less time than opiate and alcohol addiction and even cigarette use. This is not to say that marijuana is not addictive. For an unfortunate few, marijuana poses an increased risk of addiction. About 9 percent of people who use marijuana will become abusers, according to a study endorsed by the National Institute on Drug Abuse (NIDA). However, cannabis is different from a lot of other drugs of abuse in that although there usually are some subtle physiological signs of withdrawal when a chronic user stops smoking—mildly elevated pulse, irritability, and so on—these physical effects are generally fairly mild, and they are dramatically less obvious or powerful than those seen when a habitual user of alcohol, opiates (either heroin or any of the opioid pain pills), or benzodiazepines (such as Xanax or Klonopin) abruptly ceases use. In these latter instances, individuals in withdrawal can hallucinate, have greatly increased pulse and blood pressures, be visibly and dramatically uncomfortable, and in worst cases have seizures and even die. With cannabis addiction, most people can overcome addiction within two weeks of cessation of use, and as stated earlier, over 91% of users will never go through addiction withdrawal.

Millions of Americans use cannabis for all kinds of purposes—anxiety control, relief and treatment of cancer, pain reliever—without the drug becoming a problem in their lives.

In January 1997, the White House Office of National Drug Control Policy (ONDCP) asked the Institute of Medicine (IOM) to conduct a review of the scientific evidence to assess the potential health benefits

and risks of cannabis and its constituent cannabinoids. In 1999, the IOM recommended that medical cannabis use be allowed for certain patients in the short term, and that preparations of isolated cannabinoids be developed as a safer alternative to smoked cannabis. The IOM also found that the gateway drug theory was "beyond the issues normally considered for medical uses of drugs and should not be a factor in evaluating the therapeutic potential of marijuana or cannabinoids." Studies

Both sides claimed that the IOM report supported their position. The DEA publication Exposing the Myth of Smoked Medical Marijuana interpreted the IOM's statement, "While we see a future in the development of chemically defined cannabinoid drugs, we see little future in smoked marijuana as a medicine," as meaning that smoking cannabis is not recommended for the treatment of any disease condition. Cannabis advocates pointed out that the IOM did not study vaporizers, devices which, by heating cannabis to 185 °C, release therapeutic cannabinoids while reducing or eliminating ingestion of various carcinogens.

The DEA published a final denial of Gettman's petition on 18 April 2001. The U.S. Court of Appeals for the D.C. Circuit upheld the agency's decision on 24 May 2002, ruling that the petitioners were not sufficiently injured to have standing to challenge DEA's determinations in federal court (290 F.3d 430). Since the appeal was dismissed on a technicality, it is unknown what position the Court would have taken on the merits of the case.

On 9 October 2002, the Coalition for Rescheduling Cannabis filed another petition. The organization consisted of medical cannabis patients and other petitioners who would be more directly affected by the DEA's decision. On 3 April 2003, the DEA accepted the filing of that petition. According to Jon Gettman, "In accepting the petition the DEA has acknowledged that the Coalition has established a legally significant argument in support of the recognition of the accepted medical use of cannabis in the United States."

In a footnote to the majority decision in Gonzales v. Raich, Justice John Paul Stevens said that if the scientific evidence offered by medical cannabis supporters is true, it would "cast serious doubt" on the Schedule I classification.

On 23 May 2011, the Coalition for Rescheduling Cannabis filed suit in the District of Columbia Circuit Court of Appeals to compel the DEA to formally respond to its 2002 petition to have marijuana rescheduled under the provisions of the Controlled Substances Act (CSA). The writ of mandamus filed alleged that the lack of decision by DEA, "presents a paradigmatic example of unreasonable delay under Telecommunications Research & Action Ctr. v. FCC." In response to the suit, the DEA issued a Final Determination on the Petition for Rescheduling on 8 July 2011. The Petition for Writ of Mandamus was subsequently dismissed by the D.C. Circuit Court of Appeals as moot on 14 October 2011.

In response to the petition's denial, medical cannabis advocacy group Americans for Safe Access appealed to the D.C. Circuit on 23 January 2012. Oral arguments in the case *Americans for Safe Access v. DEA* were heard on 16 October 2012. On the same day the case was heard, the court ordered the plaintiffs (ASA) to clarify their arguments on standing. In response, ASA filed a supplemental brief on 22 October 2012, detailing how plaintiff Michael Krawitz was harmed by the federal government's policy on medical marijuana due to being denied treatment by the Department of Veterans Affairs. A ruling that

acknowledged Krawitz's standing, but ultimately the court stood by the DEA with its decision on 22 January 2013.

On 17 December 2009, Rev. Bryan A. Krumm, CNP, filed a rescheduling petition for Cannabis with the DEA arguing that "because marijuana does not have the abuse potential for placement in Schedule I of the CSA, and because marijuana now has accepted medical use in 13 states, and because the DEA's own Administrative Law Judge has already determined that marijuana is safe for use under medical supervision, the federal definition for a schedule I controlled substance, 21 U.S.C. § 812(b)(1)(A)-(C), no longer applies to marijuana and federal law must be amended to reflect these changes." Krumm demanded an expedited ruling in order to protect his health and welfare, as well as that of all citizens of United States who may benefit from this safe and effective medication.

Rev. Krumm did not request that cannabis be moved to any specific schedule of control under the Controlled Substances Act (CSA) and has reserved his right to challenge any incorrect findings by the FDA and/or DEA whether Cannabis should even be regulated under the CSA.

On 30 November 2011, Washington State Governor Christine Gregoire announced the filing of a petition with the U.S. Drug Enforcement Administration asking the agency to reclassify marijuana as a schedule II drug, which would allow its use for treatment—prescribed by doctors and filled by pharmacists. Gov. Lincoln Chafee (I-Rhode Island) also signed the petition.

On 23 December 2015, Tom Angell reported that the FDA had finally issued a recommendation to the DEA regarding both the 2009 and 2011 petitions. Requests have been made to both the DEA and FDA under the Freedom of Information Act to determine the details of that recommendation.

On 23 June 2011, Rep. Barney Frank (D-MA), along with 1 Republican and 19 Democratic cosponsors, introduced the Ending Federal Marijuana Prohibition Act of 2011. This act would have removed marijuana and THC from the list of schedule I controlled substances and would have provided that the Controlled Substances Act not apply to marijuana except when transported to a jurisdiction where its use is illegal. The bill was referred to committee but died when no further action was taken.

On 27 November 2012, after voters in the states of Colorado and Washington voted to legalize recreational use of marijuana, Rep. Diana DeGette (D-CO) introduced a bill referred to as *the 'Respect States and Citizens Rights Act'* which aimed to amend the Controlled Substances Act to exclude any state that has legalized marijuana (for medical OR recreational use) from marijuana provisions of the CSA, effectively giving state law precedence over federal law in cases where an individual (or commercial enterprise) is acting within the letter of state law regarding marijuana/cannabis. The bill was referred to committee but died when no further action was taken. The same bill was reintroduced later in the 113th and 114th Congresses, where it died each time.

On 20 February 2015, Rep. Jared Polis (D-CO), along with 1 Republican and 18 Democratic cosponsors, introduced the *'Regulate Marijuana Like Alcohol Act'*, which would have, among other provisions, directed the Attorney General to remove marijuana from all schedules of controlled substances under the Controlled Substances Act; prohibited transport of marijuana into a jurisdiction in which its possession, use, or sale is prohibited; and granted the Food and Drug Administration the same authorities with respect

to marijuana as it has for alcohol. The bill was referred to committee but died when no further action was taken.

A petition to change marijuana's schedule I classification, based on claims related to clinical studies, was denied in 2001. A rescheduling petition filed by medical cannabis advocates 2002 was denied by the DEA in July 2011, nine years after its filing. Subsequently, medical cannabis advocacy group Americans for Safe Access filed an appeal, *Americans for Safe Access v. Drug Enforcement Administration* in January 2012 with the District of Columbia Circuit, which was heard on 16 October 2012 and denied on 22 January 2013.

During the past three years, the FDA conducted an analysis, at the request of the DEA, on whether marijuana should be downgraded, said Douglas Throckmorton, Deputy Director for Regulatory Programs at the FDA, at a congressional hearing in June 2014. In August 2016 the DEA reaffirmed its position and refused to remove Schedule I classification.

In August 2016, the DEA rejected calls to reschedule marijuana, but indicated an increase in availability for research.

New Research: National Academies of Sciences, Engineering and Medicine

In January 2017, The National Academies of Sciences, Engineering and Medicine released a report entitled, 'The Health Effects of Cannabis and Cannabinoids. The Current State of Evidence and Recommendations for Research'. The committee was made up of leading experts, including:

Marie McCormick (Chair)
Harvard T.H. Chan School of Public Health

Donald I. Abrams
Zuckerberg San Francisco General Hospital

Margarita Alegría
Massachusetts General Hospital

William Checkley
Johns Hopkins University

R. Lorraine Collins
State University of New York at Buffalo

Ziva Cooper
Columbia University Medical Center

Adre J. Du Plessis
Children's National Health System

Sarah Feldstein Ewing
Oregon Health & Science University

Sean Hennessy
University of Pennsylvania

Kent Hutchison
University of Colorado Boulder

Norbert E. Kaminski
Michigan State University

Sachin Patel
Vanderbilt University Medical Center

Daniele Piomelli
University of California, Irvine

Stephen Sidney
Kaiser Permanente Northern California

Robert B. Wallace
University of Iowa College of Public Health

John Williams
Duke University Medical Center

Leigh Miles Jackson
Study Director

Jennifer Cohen
Program Officer

Kelsey Geiser
Research Associate

R. Brian Woodbury
Research Associate

Sara Tharakan
Research Associate

Hope Hare
Administrative Assistant

Matthew Masiello
Research Assistant

Marjorie Pichon
Senior Program Assistant

Kathleen Stratton
Scholar

Brownsyne Tucker-Edmonds
Norman F. Grant/American Board of Obstetrics and Gynecology Fellow

Rose Marie Martinez
Senior Board Director, Board on Population Health and Public Health Practice

The study was supported by multiple state and federal government entities, including:

CDC Foundation

Centers for Disease Control and Prevention

Food and Drug Administration
Mat-Su Health Foundation

National Cancer Institute—National Institutes of Health

National Highway Traffic Safety Administration

National Institute on Drug Abuse—National Institutes of Health

Oregon Health Authority

Alaska Mental Health Trust Authority

Arizona Department of Health Services

California Department of Public Health

Robert W. Woodruff Foundation

The Colorado Health Foundation

Truth Initiative

Washington State Dept. of Health

The committee conducted an extensive search of literature databases to identify relevant articles published since the 1999 release of the National Academies report Marijuana and Medicine: Assessing the Science Base. As a result of their search efforts, the committee considered more than 10,000 scientific abstracts for their relevance to the report. Given the large scientific literature on cannabis, the breadth of the statement of task, and other constraints of the study, the committee gave primacy to recently published systematic reviews and high-quality primary research for 11 groups of health topics and concerns, including therapeutic effects for a variety of diseases and conditions; cancer incidence; respiratory disease; prenatal, perinatal, and neonatal outcomes; psychosocial and mental health concerns, and others.

The committee was charged to conduct a comprehensive, in-depth review of health topics with the greatest public health impact rather than to conduct multiple systematic reviews, which would have required a lengthy and robust series of processes. The committee did, however, adopt key features of that process: a comprehensive literature search, assessments by more than one person of the quality of the literature and the conclusions, pre-specification of the questions of interest before conclusions were formulated, standard language to allow for comparisons between conclusions, and declarations of conflict of interest via the National Academies conflict-of-interest policies.

The committee arrived at nearly 100 different research conclusions related to cannabis or cannabinoid use and health, organizing these into 5 categories: conclusive, substantial, moderate, limited, and no/insufficient evidence. For a definition of these levels of evidence and a full listing of the conclusions, please see the “Committee’s Conclusions” document by visiting the report’s website at nationalacademies.org/CannabisHealthEffects.

Based on their research conclusions, the committee members formulated four recommendations that outline priorities to inform a research agenda. The recommendations prioritize research approaches and objectives to:

- Address current research gaps, highlighting the need for a national cannabis research agenda that includes clinical and observational research, health policy and health economics research, and public health and public safety research;
- Identify actionable strategies to improve research quality and promote the development of research standards and benchmarks;
- Highlight the potential for improvements in data collection efforts and the enhancement of surveillance capacity; and
- Propose strategies for addressing the current barriers to the advancement of the cannabis research agenda.

The committee concluded that this is a pivotal time in the world of cannabis policy and research. Shifting public sentiment, conflicting and impeded scientific research, and legislative battles have fueled the debate about what, if any, harms or benefits can be attributed to the use of cannabis or its derivatives. The report provides a broad set of evidence-based research conclusions on the health effects of cannabis and cannabinoids and puts forth recommendations to help advance the research field and better inform public health decisions.

The committee found that there is a medical use for cannabis, a finding in direct opposition the DEA's position that there are no medical uses for cannabis. The committee's report states:

"There **is conclusive or substantial evidence** that cannabis or cannabinoids are effective:

- For the treatment for chronic pain in adults (cannabis)
- As an antiemetic in the treatment of chemotherapy-induced nausea and vomiting (oral cannabinoids)
- For improving patient-reported multiple sclerosis spasticity symptoms (oral cannabinoids)

There is **moderate evidence** that cannabis or cannabinoids are effective for:

- Improving short-term sleep outcomes in individuals with sleep disturbance associated with obstructive sleep apnea syndrome, fibromyalgia, chronic pain, and multiple sclerosis (cannabinoids, primarily nabiximols)

There is **limited evidence** that cannabis or cannabinoids are effective for:

- Increasing appetite and decreasing weight loss associated with HIV/AIDS (cannabis and oral cannabinoids)
- Improving clinician-measured multiple sclerosis spasticity symptoms (oral cannabinoids)
- Improving symptoms of Tourette syndrome (THC capsules)
- Improving anxiety symptoms, as assessed by a public speaking test, in individuals with social anxiety disorders (cannabidiol)
- Improving symptoms of posttraumatic stress disorder (nabilone; one single, small fair-quality trial)

There is **limited evidence** of a statistical association between cannabinoids and:

- Better outcomes (i.e., mortality, disability) after a traumatic brain injury or intracranial hemorrhage

There is **limited evidence that cannabis or cannabinoids are *ineffective*, and thus, may be effective,for**:

- Improving symptoms associated with dementia (cannabinoids)
- Improving intraocular pressure associated with glaucoma (cannabinoids)
- Reducing depressive symptoms in individuals with chronic pain or multiple sclerosis (nabiximols, dronabinol, and nabilone)"

Of significant importance to the nation's policy on cannabis, The National Academies of Sciences, Engineering and Medicine found **conclusive evidence** of cannabis' application for therapeutic effects:

"There is strong evidence from randomized controlled trials to support the conclusion that cannabis or cannabinoids are an effective or ineffective treatment for the health endpoint of interest"

For other health effects, the report states:

"There is strong evidence from randomized controlled trials to support or refute a statistical association between cannabis or cannabinoid use and the health endpoint of interest. For this level of evidence, there are many supportive findings from good-quality studies with no credible opposing findings"; and that *"a firm conclusion can be made, and the limitations to the evidence, including chance, bias, and confounding factors, can be ruled out with reasonable confidence."*

This study and report, conducted by researchers from multiple renown universities and supported by US Government agencies including the Center for Disease Controls, National Institute of Health (NIH), National Institute on Drug Abuse (NIDA), National Highway Traffic Safety Administration, and the Food and Drug Administration (FDA), **clearly counterclaims the position of the DEA in its classification of cannabis as a schedule I drug which "has no currently accepted medical use in treatment in the United States".**

Cannabis: Hemp and Marijuana

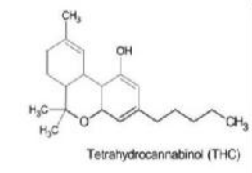

Figure 1: The structure of THC

Figure 2: The structure of CBD

Hemp and marijuana are two popular names for the cannabis plant. The difference is a largely misunderstood.

Hemp refers to strains of cannabis sativa that have been bred specifically for fiber used for clothing and construction, oils and topical ointments, nutritional benefits and a wide and growing variety of other purposes that don't involve intoxication. Hemp is a plant that has low THC and perhaps has a higher level of CBD.

Marijuana is a slang term coined by Hurst Newspapers to pin a negative connotation between cannabis and immigrant Mexicans. Today, marijuana is used to describe strains of cannabis sativa specifically bred for the potent resinous glands (trichomes) that grow on the flowers and some leaves (buds). The result is a confusing state-by-state legal redefinition of hemp from marijuana based on higher levels of the non-psychotropic cannabinoid cannabidiol (CBD) and the intoxicating Δ-9 tetrahydrocannabinol (THC).

The international definition of hemp as opposed to marijuana was developed by a Canadian researcher in 1971. Canadian scientist Ernest Small published a little-known but very influential book called *The Species Problem in Cannabis*. In it, he stated that "0.3 percent THC in a sifted batch of cannabis flowers was the difference between hemp and marijuana."

Dr. Small's arbitrary 0.3 percent THC limit has become standard around the world as the official limit for legal hemp. Small clearly noted that among the hundreds of strains he experimented with, 'plants cultivated for fibre [sic], oil and birdseed frequently had moderate or high amounts of THC'… thus the worldwide 0.3 percent THC standard divider between marijuana and hemp is not based on which strains

have the most agricultural benefit, nor is it based on an analysis of the THC level required for psychoactivity. It is based on an arbitrary decision of a Canadian scientist growing cannabis in Ottawa.

Hemp is thus classified as cannabis producing less than 0.3% THC. Marijuana produces anywhere between 5-20% THC on average, with some strains tipping the scale at 25-30% THC. A more realistic level of THC for classification of cannabis as hemp would be <1% THC.

The cannabis plant contains over 500 natural compounds. Cannabinoids happen to make up at least 85 of those compounds. While some cannabinoids are psychoactive, others are not. Hemp and marijuana plants contain an important cannabinoid: *cannabidiol* or *CBD*. Hemp plants produce more CBD than THC, while marijuana produces more THC than CBD. Research has shown that CBD acts to reduce the psychoactive effects of THC, separating hemp further from marijuana. CBD is a non-psychoactive cannabinoid and actually works to calm intoxication. It's also believed that CBD has numerous medicinal benefits, such as anti-inflammatory properties and the ability to protect neurons from injury or degeneration.

The human brain creates its own set of cannabinoids—similar to those found in cannabis—via the endocannabinoid system which is responsible for many important functions, such as appetite, sleep, emotion and movement. Cannabinoids work by interacting with specific receptors. These receptors are located within different parts of the body, such as the central nervous system and immune system, and activate two types of receptors: CB1 receptors, located within the nervous system, the brain and nerve endings, and CB2 receptors, located within the immune system.

Tetrahydrocannabinol (THC) is the most common psychoactive cannabinoid. It is best known for causing the high sensation one gets from smoking marijuana. However, it also seems to have a number of medical applications, such as pain relief and the ability to improve appetite, providing potentially important treatments to serious diseases including cancer, multiple sclerosis, ALS (Lou Gehrig's disease) and others.

Cannabidiol (CBD) is the second most common cannabinoid. Although it has no psychoactive effects, it appears to improve mood and alleviate pain. CBD has received a lot of attention lately because of its antipsychotic effect that calms the nervous system. Studies suggest that it may help with epilepsy, schizophrenia and a number of other ailments.

Cannabinol (CBN) is created from THC when cannabis is exposed to air—through a process called oxidization. CBN on its own provides a mild psychoactive effect, but when combined with THC can make one feel drowsy and induce sleep, thus assisting patients who have trouble getting the proper amounts of rest required to allow the body to fight infection and illness.

Cannabigerol (CBG) is a non-psychoactive cannabinoid and the building block for THC and CBD. It has been shown to reduce intraocular pressure, making it an ideal treatment for glaucoma patients.

While individual cannabinoids work independently, used together, they create an entourage effect, which multiplies the benefits of each individual cannabinoid.

The Public: A Shift in Attitudes

As of 28 February 2017, 28 states and Washington, D.C. have legalized the use of medical and/or recreational marijuana. These states include:

Alaska	Maine	New York
Arizona	Maryland	North Dakota
Arkansas	Massachusetts	Ohio
California	Michigan	Oregon
Colorado	Minnesota	Pennsylvania
Connecticut	Montana	Rhode Island
Delaware	Nevada	Vermont
Florida	New Hampshire	Washington
Hawaii	New Jersey	Washington, DC
Illinois	New Mexico	

In nearly every case involving ballot initiatives, the ballot measures passed with over 60% voter approval.

Recreational marijuana is legal in eight states, including the nation's most populous: California. Today, a total of about one quarter of the population lives in a place where voters have decided that adults should be able to consume cannabis much the same way they consume alcohol. All but six other states have legalized a non-psychoactive form of cannabis known as CBD, which people use to treat conditions like juvenile epilepsy, inflammation, and pain.

The fact is this: public opinion on marijuana is going in the opposite direction of the US Government’s stated position and is best served as a state’s rights issue.

While Democrats are generally more supportive of legalizing marijuana than Republicans, states of all shades—blue, purple and red—have embraced legal marijuana in some form, despite the fact that the federal government puts marijuana in the same class as heroin. Support for fully legalizing marijuana hit an all-time high of 60% in October 2016, according to Gallup.

Polls have found public support for medical cannabis to be nearly 90%.

Public-led efforts have legalized cannabis for medicinal and recreational use at the state level in more than half the United States and in some of the largest populated states in the nation. Many Americans hail these efforts as the triumph of average citizens over a draconian legal system that imprisons large numbers of nonviolent drug users unnecessarily. Here we are, over four decades since President Richard Nixon declared the “War on Drugs” in 1971 and over $1 trillion of taxpayer money has been spent. In the first 2 months of 2017 it is estimated that over $7 billion has already been spent. Clearly, these funds could be better utilized improving our infrastructure, schools, and healthcare.

An unresponsive regulatory regime that denies easily acquired relief to suffering patients has also led to increased citizen concern and discontentment with the federal government and the US healthcare system.

In 1996, California voters passed Proposition 215 allowing for the sale and medical use of marijuana for patients with AIDS, cancer, and other serious and painful diseases. On 1 January 2014, Colorado became the first state to permit marijuana dispensaries to sell pot for recreational use. As of 1 January 2017, Nevada passed recreational use and to date has the strictest laboratory testing regulations of any state, a series of standards that affect the entire cannabis lifecycle from growing to edibles and a worthwhile set of regulations that should be adopted nationwide.

Voters seem to have found a way around the twentieth-century quest for prohibition—a prohibition that has become increasingly difficult to explain or justify. Unlike alcohol, excessive cannabis consumption has not been unambiguously implicated in violent behavior or poor health. Cannabis has also been shown to not have a high potential for abuse and America's citizens have become more aware that the draconian War on Drugs, the media-perpetuated stories of addiction, overdosing, and "Reefer Madness" have been a waste of taxpayer dollars and the result of mass media disinformation campaigns, often led by our own Federal government.

Even the Democratic Party has called (through its 2016 platform) for removal of marijuana from schedule I of the Controlled Substances Act, "providing a reasoned pathway for future legalization" of marijuana. The Republican Party, mindful of states' rights, individual responsibility, consumer choice, improved healthcare options, and a decades' old failed War on Drugs should consider a reclassification of cannabis.

US Government's Marijuana Patent

As a schedule I drug, marijuana is considered to have no medical use, and yet, the US Government holds a patent on cannabis for medical treatment.

US Patent 6,630,507, states:

> *"Cannabinoids are useful in the treatment and prophylaxis of wide variety of oxidation associated with diseases, such as ischemic, age-related, inflammatory and autoimmune diseases. The cannabinoids are found to have particular application as neuroprotectants, for example in limiting neurological damage following ischemic insults, such as stroke and trauma, or in the treatment of neurodegenerative diseases, such as Alzheimer's disease, Parkinson's disease and HIV dementia."*

Sam Mendez, an intellectual property and public policy lawyer who serves as the executive director of the University of Washington's Cannabis Law & Policy Project, states, *"Naturally, it shows that there is a certain amount of hypocrisy that there is 'no accepted medical use' for cannabis according to federal law, and yet here you have the very same government owning a patent for, ostensibly a medical use for marijuana. It's certainly hypocritical, but there's no law against doing so."*

That one arm of the federal government is poised to make money from cannabis-derived compounds through patent licensing—and another arm has approved synthetic cannabinoid drugs such as Marinol and Syndros—tells a different story than that told by the DEA, which lumped together the hundreds of chemical compounds of cannabis as a schedule I substance.

Any safety aspects of consumption for medicinal and recreational use of cannabis that are of concern to the US Government can be addressed through Federal rulemaking while allowing states to determine their own course based on citizen desires.

The remainder of this document will outline areas where the US Government should take an active role and proposes a new classification, specifically for cannabis, called "schedule VI".

The Case for Changing the DEA's Schedule I Categorization of Cannabis

Even though hemp and marijuana provide dramatically different results when consumed, both hemp and marijuana's classification as schedule I drugs under the Controlled Substances Act means it remains Federally illegal to grow, productize, or consume, even though 28 states and the District of Columbia have exercised their states' rights to legalize cannabis. Outside the US, hemp is grown in more than 30 countries. It is actually legal to import hemp products into the United States. The top hemp-producing country in 2015 was China, followed by Chile and the European Union. According to the Hemp Industry Association, about $500 million worth of hemp product is imported every year to America.

Marijuana, on the other hand, remains illegal in most countries. A few, such as Israel and Canada, have recently started to regulate cannabis as a medicine and today, Israel leads the world in cannabis research. Researchers from Tel Aviv University and Hebrew University published in the *Journal of Bone and Mineral Research* the results of a study that proves cannabis' CBD helps fractures heal faster and even make the bones stronger than they were before. CBD has no psychotropic effects.

> *"We found that CBD alone makes bones stronger during healing, enhancing the maturation of the collagenous matrix, which provides the basis for new mineralization of bone tissue,"* researcher Yankel Gabet said. *"After being treated with CBD, the healed bone will be harder to break in the future."*

The US Government even grows cannabis for research purposes. For more than four decades, the University of Mississippi has had an exclusive license with the government to grow marijuana for federally sanctioned research. About $68 million in cannabis orders have flowed to the University of Mississippi in the past 5 years from federally approved researchers.

> Disclosure: In August 2016, the Drug Enforcement Administration announced it would grant permission to other growers—an effort, it said, to expand the supply and variety of marijuana available for research. TRICCAR intends to apply for a license to cultivate cannabis for research and to launch a research and development institute to conduct clinical studies of cannabis and its ingredients in seeking to uncover treatments for diseases wreaking havoc on the world's populations.
>
> Increasing evidence exists that marijuana helps cancer patients with appetite and pain, and that cannabinoids—CBDs—can alleviate seizures in epileptic patients, assist ALS patients in quality of life, and help patients as an analgesia, affecting cancer pain, post-operative pain, and phantom limb

pain. Cannabis' antiemetic effect assists in the prevention of nausea/vomiting caused by anticancer drugs and its bronchodilation may assist with the treatment of bronchial asthma. Appetite stimulation, which is important in palliative care for anorexia caused by opioids, antiviral drugs, AIDS-related illnesses or terminal cancer, may also be addressed through cannabis and cannabis-derived products. Decreased spasticity, ataxia and muscle weakness as often present in multiple sclerosis, cerebral palsy, spinal cord injuries, and negative effects of ALS such as tightening of the throat and breathing muscles and lack of sleep can be treated, as can glaucoma by decreasing intraocular pressure.

Terpenes that are modified chemically, such as by oxidation or rearrangement of the carbon skeleton, result in compounds generally referred to as terpenoids, which also have potential health benefits. Over 100 different terpenes have been identified in the cannabis plant, and every strain tends toward a unique terpene type and composition. The diverse palate of cannabis flavors is impressive enough, but arguably the most fascinating characteristic of terpenes is their ability to interact synergistically with other compounds in the plant, like cannabinoids. In the past few decades, most cannabis varieties have been bred to contain high levels of THC, and as a result, other cannabinoids like CBD have fallen to trace amounts. This has led many to believe that terpenes may play a key role in differentiating the effects of various cannabis strains. The effects these mechanisms produce vary from terpene to terpene; some are especially successful in relieving stress, while others promote focus and acuity. Myrcene, for example, induces sleep whereas limonene elevates mood. There are also effects that are imperceptible, like the gastroprotective properties of caryophyllene.

TRICCAR hopes to conduct the cultivation, research, and productizing necessary to undertake serious evaluation of cannabis and other natural substances in pursuit of remedies and cures to these maladies. It is because of these plans and our concern for consumer health that we have an interest in the federal government instituting rules around licensing, truth in labeling, and testing that will provide a level of consistency and safety for cannabis users.

America's Internal War: Opiate Addiction

According to Dr. Sanjay Gupta, "80-90% of the world's pain pills are consumed in the United States and accidental overdose is the # 1 cause of preventable death in America". Opiate addition had led to a dramatic increase in heroin use. In the 1960s, heroin users were usually young men, who started using around an average age of 16. They were most likely from low-income neighborhoods, and when they turned to opiates, heroin was their first choice.

More than 50 years later, a study from *JAMA Psychiatry* (May 2014) paints a very different picture.

Today's typical heroin addict starts using at 23, is more likely to live in white affluent suburbs and was likely unwittingly led to heroin through painkillers prescribed by his or her doctor.

While heroin is illicit and opioid pills such as OxyContin are FDA-approved, each is derived from the poppy plant. Their chemical structures are highly similar and they bind to the same group of receptors in the brain. (A few opioids, like fentanyl, are totally synthetic but designed to bind with those same receptors).

In any case, the various drugs produce the same result: an increase in pain tolerance and a sense of euphoria, along with drowsiness, occasional nausea and, at higher doses, a slowing of the user's breathing. All these drugs trigger "tolerance"—the need to take higher doses for the same effect—and a craving for the drug in its absence.

There is convincing evidence to suggest a relationship between increased non-medical use of opioid analgesics and heroin abuse in the United States.

It is precisely because there are so many similarities that pain pill addicts frequently turn to heroin when pills are no longer available to them. Heroin is usually cheaper than prescription drugs. Opiate pain medications cost the uninsured about $1 per milligram; so a 60-milligram pill will cost $60. A heroin user can obtain the equivalent amount of heroin for about one-tenth the price.

Heroin-related deaths—33,092 in 2016—have surpassed gun-related deaths. Deaths involving powerful synthetic opiates, like fentanyl, rose by nearly 75 percent from 2014 to 2015.

> "The epidemic of deaths involving opioids continues to worsen," said CDC Director Tom Frieden in a statement to the Washington Post. "Prescription opioid misuse and use of heroin and illicitly manufactured fentanyl are intertwined and deeply troubling problems."

The consequences of this abuse have been devastating and are on the rise. For example, the number of unintentional overdose deaths from prescription pain relievers has soared in the United States, more than quadrupling since 1999.

With cannabis, there has not been a single documented case of death by marijuana overdose. In reality—and this is supported by research—cannabis is not a gateway drug; it is a potentially effective exit strategy for opiate addiction.

Advocates of marijuana legalization argue that the budgetary impact of removing cannabis from schedule I and legalizing its use in the United States could save billions by reducing government spending for prohibition enforcement in the criminal justice system. By taking the recommendations in this document, the nation could reallocate funds from criminal justice and law enforcement of marijuana to more important areas such as homeland security and the exploding heroin epidemic.

Additionally, advocates for legalizations argue that billions in annual tax revenues could be generated through proposed taxation and regulation. Patient advocates argue that by reclassifying cannabis, millions of Americans who are currently prevented from using medical cannabis would be able to benefit from its therapeutic value. Cultivators, testing laboratories, dispensaries and product manufacturers want to provide their products to consumers wherever states have legalized cannabis and federal guidelines and rulemaking would help ensure consumer safety.

Schedule VI: A Recommended Solution for Cannabis Cultivation, Distribution, Commercialization and Use

Currently classified as a schedule I drug, the preponderance of available research suggests that cannabis has since been proven to not fit this classification. Substances in this schedule have no currently accepted medical use in the United States, a lack of accepted safety for use under medical supervision, and a high potential for abuse. Cannabis has proven medical uses, is rapidly attaining a reputation as a safe alternative to harmful opiates, chemotherapy, radiation and other widely accepted disease treatments, and has a low potential for abuse when compared to alcohol and opiates.

Counter to the schedule I criteria, the January 2017 report from The National Academies of Sciences, Engineering and Medicine has shown cannabis does in fact have a potential role in medical use and cannabinoids may provide even further health benefits.

Cannabis use has been shown to be an alternative and adjunct to pain management, essentially equating its use to that of someone taking an over the counter medicine such as Tylenol, Advil or aspirin, but without the risk of stomach and intestinal discomfort.

By rescheduling cannabis into a new category, important research can be conducted to ensure the benefits of the plant are understood and the concentrations of THC, CBD, and terpenes are matched to best address an illness or health issue.

The removal of the schedule I designation of cannabis will result in many advancements and benefits for the United States. It is recommended that this removal be completed under a new category that requires adherence to federal guidelines to engage in the cannabis industry, but gives states the right to offer or not offer medical or recreational cannabis products—and still upholds federal penalties for the illegal sale or possession of cannabis. The advancements and benefits that would result may include:

- New research towards disease treatment and prevention
- New companies creating jobs and boosting the economy (Colorado, for one, added nearly $2.4 billion to the state's economy in one year)
- New technologies that apply to cannabis but could be adapted for general agriculture use
- Increased tax revenues for the federal government and states (the US Government should consider levying a sales tax on cannabis, such as 0% for medical and 10% for recreational use)
- A recognition of States' Rights by the Administration (supported by the message President Trump delivered to governors during a private breakfast at the White House on 27 February 2016)
- Reuse of existing infrastructure helping inner cities and underserved populations (for example, the opportunity to convert abandoned warehouses and manufacturing facilities into cannabis cultivation centers and laboratories)
- A significant elimination of black market sales by shedding light on the cannabis industry
- A reduction in funds required to support police departments, the judicial system, and the already overcrowded prison system
- A means to dramatically decrease money laundering, through the passage of laws to enable banks and credit unions to offer accounts and accept deposits and transactions from cannabis-related

businesses (much like alcohol, the more light that can be shined on the industry, the fewer criminal elements it will produce)
- Product safety levels that are currently not able to be attained due to competing state testing and cultivation rules
- Uniform labeling rules for cannabis and its related products, giving consumers vital information to make informed decisions
- Protection for those under 21 years of age and especially children
- Global leadership in cannabis cultivation, testing, research and product development

Schedule VI

Rescheduling sets forth a federal process to administer and regulate cannabis. It is recommended that cannabis be removed from Schedule I and placement in a proposed new category, schedule VI. It is further recommended that schedule IV be defined in the following manner:

> *Substances in this schedule have a medical use, a low potential for abuse relative to substances listed in Schedules I, II, III, IV, and V, and consist primarily of cannabis plant material, cannabis-infused, or derived products. The term cannabis shall include hemp and marijuana, as well as indica, sativa and hybrid strains of the cannabis plant and pertains to the consumption or application via topical or oral ingestion of cannabis and cannabis-infused or derived products.*

Schedule VI amends the Controlled Substances Act to: (1) provide that schedules I, II, III, IV, and V shall consist of the drugs and other substances that are set forth in the respective schedules in part 1308 of title 21 of the Code of Federal Regulations; (2) exempt cannabis from such schedules, and reclassify cannabis as schedule VI, providing federal rules for the cultivation, research and sale of cannabis and cannabis-related products; (3) provide states the ability to regulate the sale of medical and recreational cannabis provided state laws include the provisions of schedule VI; (4) instruct the Attorney General to revise the definition of “felony drug offense” to exclude conduct relating to the legal possession and sale of cannabis; (5) eliminate cannabis from provisions setting forth penalties applicable to prohibited conduct under schedules I, II, III, IV, and V of such Act; and (6) prohibit shipping or transporting marijuana from any place outside a jurisdiction of the United States into such a jurisdiction in which its possession, use, or sale is prohibited.

Schedule VI will eliminate marijuana as: (1) a controlled substance for purposes of the Controlled Substances Import and Export Act or the National Forest System Drug Control Act of 1986, (2) a dangerous drug for purposes of federal criminal code provisions authorizing interception of communications, and (3) a targeted drug for purposes of provisions of the national youth anti-drug media campaign under the Office of National Drug Control Policy Reauthorization Act of 1998.

Subjects cannabis to the provisions that apply to: (1) the Fair Packaging and Labeling Act, the Webb-Kenyon Act, and the Victims of Trafficking and Violence Protection Act of 2000.

Under the Fair Packaging and Labeling Act, Schedule VI directs the Federal Trade Commission and the Food and Drug Administration to issue regulations requiring that all cannabis products be labeled to disclose net contents, identity of commodity, and name and place of business of the product's manufacturer, packer, or distributor, the THC, CBD and Terpene content, the laboratory test result identifying test numbers with the unaltered test results available for public inspection on the manufacturer's website, the packaging date and the expiration date.

Federal Licensing

The US Government has a role in ensuring the safety of its citizens and as such should require permitting (or licensing) of companies and individuals engaged in business in the cannabis industry. Schedule VI amends the Federal Alcohol Administration Act to set forth procedures for the issuance and revocation by the Drug Enforcement Agency of permits (aka, licenses), not to exceed a cost of $10,000 per year per category, for the following categories (suggested fees are included after each category):

1. Cultivation [$10,000]
2. Research & Development [$3,500]
3. Transportation and Distribution [$7,500]
4. Combined License: Cultivation, Research, Product Development, Production and related Distribution [$20,000]
5. Purchasing for resale to the public [$7,500]
6. Purchasing for resale for medical sales (e.g., dispensaries) [$5,000]
7. Importing, shipping or selling in foreign commerce [$10,000]
8. Producing and/or packaging cannabis-infused products, including edibles, topicals, vapeliquids, shatter, hashish, and other non-flower products [$7,500]
9. Home growing of up to 8 plants for personal consumption (the selling or distribution of which remains illegal). [$1,000 for a 5-year permit]

For example, a cultivation operation which self-distributes its products to medical dispensaries would pay $17,500 per year in federal permit fees (1. Cultivation and 3. Transportation and Distribution). A dispensary that only sells medical marijuana would pay $5,000 per year (6. medical sales). A company making liquids for vape cigarettes and a company producing hemp clothing would each pay $7,500 per year (8. Producing and Packaging). Combined with state permitting/licensing fees, these financial levels would not be detrimental to the growth of the industry and would keep fly-by-night operators from trying to operate outside the system knowing they could be prosecuted for cultivation, productizing or retail sales of cannabis and cannabis products.

Schedule VI prohibits any person from engaging in such conduct without a permit, subject to a $20,000 fine. Schedule VI sets forth criteria for ineligible applicants and disqualifying offenses, including money laundering and illegal sales (to be determined by the DEA and/or Department of Justice).

Access to Banking

In 2016, the cannabis industry **surpassed $7 billion in sales** and much of that money was processed in cash transactions because under current banking regulations, banks and credit unions refuse to support state-legal companies in the cannabis industry. Fewer than 3 percent of the nation's 11,954 federally regulated banks and credit unions are serving the cannabis industry, resulting in a huge black market for cash transactions.

The cannabis industry includes growers and facilities that produce a variety of marijuana products like tinctures, extracts and edibles, along with the companies that supply equipment to those operations. It also includes the chemists and labs who conduct safety and quality testing to confirm that marijuana products contain what they say they do—and don't have any deadly hidden surprises, like pesticides or mold. Companies that manufacture smoking apparatus and other equipment such as lighting, nutrients, fertilizer, and planters fall under this category as well, as do transportation companies, security firms, distributors and a host of other businesses that are connected with the industry.

As a growing number of states legalize recreational and/or medical cannabis, the question of how companies can conduct business when federal law still strictly outlaws cannabis becomes complicated.

The banking industry tends to be risk-averse, and handling money associated with federally illegal actions carries risks such as the bank becoming subject to specialized reporting requirements, auditing of their operations, and potential forced cooperation in asset seizures.

Most banks don't want the headache of accepting cash and check deposits from marijuana-based businesses, or processing credit card transactions, however, there are a lot of clear advantages for everyone when it comes to allowing marijuana-based businesses to access the banking system. For example, it's a net gain for public safety when businesses aren't storing large amounts of cash on site. In addition, it's easier to track financial activity, which means it's easier to enforce tax laws, and thus ensure everyone in the industry is paying their required taxes.

In 2009 and 2011, U. S. Department of Justice issued guidance to federal prosecutors regarding marijuana enforcement under the Controlled Substances Act. Then, in August 2013, James M. Cole, the Deputy Attorney General, issued new guidance regarding marijuana enforcement. This memo is currently written and referred to as the "Cole Memo."

The Cole Memo, states that the Department of Justice is committed to enforcing the CSA. In enforcing the CSA, the Departments of Justice is placed enforcement on the following priorities: preventing the distribution of marijuana to minors, preventing revenue from the sale of marijuana from going to criminal enterprises, games, and cartels, preventing the diet version of marijuana from states where it is legal under state law in some form to other states, preventing state-authorized marijuana activity from being used as a cover or pretext for the trafficking of other illegal drugs or other illegal activity, preventing violence and the use of firearms in the cultivation and distribution of marijuana, preventing drugged driving and the exacerbation of other adverse public health consequences associated with marijuana use, preventing the growing of marijuana on public lands in the attendant public safety and environmental dangers posed by marijuana production on public lands, and preventing marijuana possession or use on federal property.

Essentially, the Cole Memo states that jurisdictions that have legalized marijuana in some form are less likely to be a threat to the federal priorities under the CSA if they have implemented strong and effective regulatory and enforcement systems to control marijuana growth and distribution. The Cole Memo also gives wide prosecutorial discretion whether to prosecute state legal marijuana enterprises and hinted that it is probably not efficient use of federal resources to focus enforcement on state legal businesses.

After the Cole Memo, the Department of the Treasury's Financial Crimes Enforcement Network ("FinCEN"), published its own expectations regarding marijuana-related businesses guidelines. This guidance specifically references the Cole Memo and its priorities. And while the FinCEN guidelines provides for financial institutions to service state legal marijuana businesses, it reiterates that financial institutions must file a suspicious activity reports if the financial institution knows, suspects, or has reason to suspect that a transaction conducted or attempted by, at, or through the financial institution: involves funds derived from illegal activity or is an attempt to disguise funds derived from illegal activity, is designed to abate regulations promulgated under the Bank Secrecy Act, or lacks a business or parent lawful purpose. In essence, a financial institution is required to file a suspicious activity report involving any marijuana related business because federal law still prohibit the distribution and sale of marijuana.

As banks are not in the business of determining where a depositor's funds originate, the FinCEN guidelines were simply too onerous for banks to follow and they instead decided to ignore the cannabis industry.

Creating a clear banking framework reduces the risk that money will end up being funneled into criminal enterprises. Those in the cannabis industry will likely not enter risky criminal partnerships and transactions—or try to launder money—when it can be legally banked. Having more money on deposit also allows banks to offer more favorable loans, too, which can help economically revitalize communities.

In May 2014, lawmakers authorized a new class of financial institution called a cannabis credit co-operative, which wouldn't have to acquire and maintain deposit insurance. But no such institutions have been formed so far, partly because the Federal Reserve isn't likely to approve them.

Later that year, lawmakers authorized a credit union for the cannabis industry. But the Fed denied the credit union access to a master account, which is necessary for transferring money, and the National Credit Union Administration refused to insure its deposits.

Senator Elizabeth Warren (D-MA) is leading an effort to make banking more available to cannabis industry participants. She and her colleagues have requested that the Federal Crimes Enforcement Network reevaluate the way it approaches the question of marijuana-based businesses and banking.

Why should the Trump Administration get behind this effort? Allowing the cannabis industry access to highly regulated banking, just as every other company can do, enforces accurate reporting of sales, makes tax collection easier, ensures employees are covered under Social Security and Worker's Compensation rules, and reduces crime such as money laundering and burglary.

> *All the cash floating around makes cannabis businesses targets for crime. Since Colorado fully legalized marijuana in January 2014, the Denver Police Department has logged over 200 burglaries at marijuana businesses, as well as shoplifting and other crimes.)*

If the Trump Administration does not believe Congress will work to make banking accessible to the industry, it may consider issuing an Executive Order that does the following:

> This Executive Order provides a safe harbor for depository institutions providing financial services to a cannabis-related legitimate business insofar as it prohibits a federal banking regulator from: (1) terminating or limiting the deposit or share insurance of a depository institution solely because it provides financial services to a cannabis-related licensed business; or (2) prohibiting, penalizing, or otherwise discouraging a depository institution from offering such services.
>
> A federal banking regulator may neither recommend, motivate, provide incentives, nor encourage a depository institution to refuse to offer financial services to an individual, nor downgrade or cancel financial services offered to an individual, solely because the individual: (1) is a manufacturer, producer, owner or operator of a cannabis-related legitimate business; or (2) the depository institution was not aware that the individual is the owner or operator of a cannabis-related business.
>
> A federal banking regulator may not take any adverse or corrective supervisory action, solely because of the business involved, on a loan made to an owner or operator of: (1) a cannabis-related legitimate business, or (2) real estate or equipment that is leased to a cannabis-related licensed business.
>
> Immunity from federal criminal prosecution or investigation is granted, subject to certain conditions, to a depository institution that provides financial services to a cannabis-related legitimate business in a state or one of its political subdivisions that allows the cultivation, production, manufacture, sale, transportation, display, dispensing, distribution, or purchase of cannabis and cannabis-derived products. Neither the depository institution nor its officers, directors, nor employees may be held liable under federal law or regulation solely for providing such financial services or further investing income derived from those services.
>
> The Department of the Treasury must require any suspicious activity report filed by a financial institution regarding a cannabis-based business to comply with specified guidance of the Financial Crimes Enforcement Network.

Seed to Sale Tracking

To ensure safety and to find the source of potential problems—similar to what happens when a salmonella outbreak occurs—federal licensing should require that every pot-producing cannabis plant be through each stage of its life, from cultivation to point of sale.

In Colorado, officials launched a first-of-its-kind computer schema, the Marijuana Enforcement Tracking, Reporting, and Compliance system— better known as METRC. The METRC database stores highly detailed information, such as a specific plant's size and location in a facility, and who buys the products of a certain plant. The tracking is done in real-time, and is reportedly fail-safe. A federal program could track the same information and when testing is done on the initial crop or end product, the results of those tests could be instantly updated in a national database (this would dramatically reduce the current

cheating that sometimes occurs when one lab does not pass a specimen and the grower takes the specimen to a more "friendly" lab that will provide a passing report). In Colorado, if any marijuana products are contaminated, officials can use METRC to track the tainted pot back to the growers and sellers. The state-mandated system promotes public safety, and though time-consuming, costly, and susceptible to human error, is needed to ensure tracking of tainted crops and products can be completed in a timely manner.

The seed-to-sale program also provides states the ability to conduct random cannabis inspections. During these unannounced visits—typically done by state enforcement officials—inspectors check the number of plants, how much product is being dried and cured, and can determine if a cultivation operation is growing more plants than it is reporting.

Cannabis plants can be tracked through radio frequency identification (RFID), the same technology that tracks pets, or bar codes and scanners. Each RFID tag or barcode file should contain a unique 24- to 36-digit ID number that's updated at every step of production. This number becomes the end product's batch number and identifies the cultivator, product company, and would link to lab testing results.

In order to meet these requirements, many clinics will label a plant with more than 20 pieces of information, including when it was planted, each time it was weighed, the strain's THC, CBC, and Terpene levels, its intended products if being converted into products (non-flower use), and the endpoint distributor, dispensary or retailer.

Uniform Testing

While there has not been a single documented case of death by marijuana overdose, there have been deaths due to molds and toxins in cannabis. The February 2017 death of a cancer patient in California has been linked to fungus in medical marijuana. Dr. Joseph Tuscano of the University of California, Davis Cancer Center believes the patient was already in a very serious cancer fight when that fight suddenly became much more complicated with a relatively rare but particularly lethal fungal infection and died from contaminated marijuana. Dr. Tuscano and Dr. Donald Land gathered 20 samples of medical marijuana from across California and took them apart, pulling out a range of dangerous bacteria and fungi which they analyzed down to their DNA. California is already known for lax testing requirements and the results of Dr. Tuscano and Dr. Land's tests indicated that ninety percent (90%) of those samples had DNA of some pathogens. "The cannabis was contaminated with many bacteria and fungi, some of which was compatible with the infections that I saw in my patients," Tuscano said.

Currently, there are no federal standards for testing and state testing is all over the map. California tests very little. Colorado tests some. Nevada tests the most and has the most stringent testing protocols. Herein lays the problem with cannabis: there are no federal testing guidelines to ensure consumers receive what they are told they are purchasing. Any plans for reclassification of cannabis must include uniform testing requirements.

It is important that cannabis is tested for not only potency, but also for contaminants, such as mold, fungus, and pesticides, as well. More and more patients are demanding testing and after the recent death in California of a cancer patient dying from contaminated marijuana, the importance of testing is evident.

Many patients have suppressed immune systems that make them particularly susceptible to many common contaminants. Most are interested in medicine to treat specific ailments or side effects from other treatments they receive, and federal testing standards will provide that safety net.

Potency and cannabinoid testing provides doctors and patients with important information to aid in selecting the product that best suits their needs. Tetrahydrocannabinol (THC), cannabidiol (CBD), cannabinol (CBN), THC acid (THCA), cannabidiolic acid (CBDA), tetrahydrocannabivarin (THCV), and cannabigerol (CBG) are just a few of the many cannabinoids in cannabis. Studies have found that differing levels of these compounds will determine how effective a particular cannabis strain is for treating a patient's specific symptoms. However, now dispensaries are marketing untested cannabis extracts and tinctures which were recommended by doctors for many different complaints including pain, cough and asthma, and as a sedative agent. With an absence of federal testing standards, it becomes difficult—if not impossible—to provide product consistency and treatment efficacy. Without these standards, consumers are left to the whim of manufacturers. By knowing not only that the product is safe, but also what its THC, cannabinoid (CBD), and terpene make up is, doctors and patients will be able to make informed decisions. Additionally, dispensary employees will be more informed and thus able to ensure their patients that the medicine they are purchasing is effective, safe and a well-tolerated treatment.

Because of the current and past legal status for growers of cannabis, there is little known about the sources, growing and curing conditions, or pesticide use for medicine available for purchase. While many growers and dispensaries take care to provide a safe, effective product, there are numerous reports of the presence of pesticides and molds in purchased medicine. The current legal landscape subjects patients to the ethics and whims of people they largely do not know and may never be able to contact. The only solution at present to ensure the safety and efficacy of cannabis is reliable testing. It can be argued that testing by laboratories owned or closely affiliated with specific growers or dispensaries might not have the interest of the patients as their top priority. For this reason, independently owned and operated laboratories are the best solution. At present, only a very small fraction of medicinal cannabis is tested. It could be argued that, since testing is not yet mandatory across the United States, producers and dispensaries could self-select to make sure that "suspicious" samples not be submitted for testing. Thus, it is impossible to accurately estimate the number of tainted samples being sold. Thus, a federal requirement that all lots of 10 plants be tested and that finished products be tested, should include four elements:

1.Tested by a federally permitted laboratory;

2.Tested for pesticides known to be used in the cannabis industry and those that are not permitted. Abamectin is one particularly hazardous substance that is not approved for use on edibles in the US, but, nevertheless, as an effective miticide, is sometimes used by unscrupulous growers in danger of losing a crop to mites. Others include bifenazate, bifenthrin, and even common household bleach.

3.Tested for mycotoxins; Mycotoxins are among the most toxic substances known. They are byproducts of some molds and fungi and can remain even after the molds/fungi die off. The most important for cannabis are ochratoxin and the four aflatoxins: B1, B2, G1, and G2.

4. Tested for potencies of THC, CBD, and Terpenes, the active ingredients in cannabis.

Tests that should be required through federal rulemaking:

Product	Tests Required
Usable cannabis (hemp and marijuana). All cannabis plant material must be tested through a certified laboratory before sale or use in making cannabis-derived products. For flowers, a lot equivalent to 10 plants or fewer grown from one or more seeds or cuttings that are planted and harvested at the same time (or 20 pounds of trim). Six (6) grams of product from each lot to be provided to a certified testing laboratory for completion of a full battery of tests. "Lot" defined. "Lot" means: 1. The flowers from one or more marijuana plants of the same strain, in a quantity that weighs 10 pounds or less; or 2. The leaves or other plant matter from one or more marijuana plants, other than full female flowers, in a quantity that weighs 20 pounds or less.	1. Moisture content 2. THC analysis (percentage) 3. CBP analysis (percentage) 4. Terpene analysis (percentage) 5. Foreign matter inspection 6. Microbial screening 7. Mycotoxin screening 8. Heavy metal screening 9. Pesticide residue screening 10. Bleach screening
Extracts of cannabis (non-solvent) like kief, hashish bubble hash, or oils or fats derived from natural sources For edible products or cannabis-infused products, a facility for the production of edible marijuana products or marijuana-infused products shall select three random samples of completed products from each batch for testing by an independent testing laboratory. Each batch shall be labelled with a unique production number, packaging date and expiration date. "Batch" defined. "Batch" means a specific lot of marijuana grown from one or more seeds or cuttings that are planted and harvested at the same time and used to infuse or make a product intended to be sold to a medical or recreational cannabis consumer.	1. THC analysis 2. CBD analysis 3. Terpene analysis 5. Foreign matter inspection 6. Microbial screening (only if using cannabis that failed the initial test)
Extracts of cannabis (solvent-based) made from naphtha, CO_2, alcohol, n-butane, isobutene, propane, heptane, or other solvents or gases approved by the State(s) for use in distillation/evaporative processing	1. THC analysis 2. CBD analysis 3. Terpene analysis 5. Foreign matter inspection 6. Microbial screening (only if using cannabis that failed the initial test) 7. Residual solvent test
Extracts of cannabis made with food grade ethanol	1. THC analysis 2. CBD analysis

	3. Terpene analysis 4. Microbial screening (only if using cannabis that failed the initial test)
Extracts of cannabis made with food grade glycerin or propylene glycol	1. THC analysis 2. CBD analysis 3. Terpene analysis 4. Microbial screening (only if using cannabis that failed the initial test)
Edible cannabis-infused products	1. THC analysis 2. CBD analysis 3. Terpene analysis 4. Foreign matter inspection 5. Microbial screening (only if using cannabis that failed the initial test)
Liquid cannabis-infused products, including, without limitation, soda or tonic, or products used in vapes, e-cigarettes, or other inhaling devices	1. THC analysis 2. CBD analysis 3. Terpene analysis 4. Foreign matter inspection 5. Microbial screening (only if using cannabis that failed the initial test)
Topical cannabis-infused products	1. THC analysis 2. CBD analysis 3. Terpene analysis

Federal testing guidelines should indicate cannabis samples be exposed to liquid chromatography (LC) to identify cannabinoids (potency agents), pesticides, and mycotoxins (toxic byproducts from certain fungi and molds that may be present even if the fungi and molds themselves are undetectable). Some form of chromatography is necessary to separate all of the otherwise similar compounds to allow their individual identification and quantitation. There are three common methods for this. One is thin layer chromatography (TLC). While very inexpensive to set up and use, TLC does not give much information about the wide range of different compounds in the medicine and the accuracy of the amounts determined is very dependent on conditions that are often beyond the control of the analyst. Additionally, the compounds needed to carry out the separation and subsequent visualization of the results can be very toxic. Gas chromatography (GC) is another method commonly used, but, because a fundamental step in the beginning of this analysis uses high heat to vaporize the sample, most of the compounds actually present in the medicine are decomposed and not detected. As a consequence, to date, testing labs using this method only report THC, CBD, and CBN content, and the accuracy of these results is in question because some of the original compounds in the sample decompose and form more of these three compounds. The efficiency of this transformation depends on the temperature and even the flow characteristics in the injector, so it is not possible to know what amounts were in the original sample using gas chromatography. In liquid chromatography, the plant material is dissolved in liquid solvents and separated while still in the liquid. Thus, the compounds are never exposed to any heat and the analysis reveals the true content of all of the compound present in the original sample.

From the time that a batch has been homogenized for sample testing and eventual packaging and sale to a medical marijuana dispensary, facility for the production of edible marijuana products or marijuana-infused products or, if applicable, another cultivation facility, until the independent testing laboratory

provides the results from its tests and analysis, the facility which provided the sample shall segregate and withhold from use the entire batch, except the samples that have been removed for testing.

If a lot (or batch) of usable cannabis fails a quality assurance test, any cannabis plant trim, leaf and other usable material from the same plants automatically fails the quality assurance test. A second test, performed by the same testing laboratory, may be requested and if it is found the lot passes, then the plant trim, leaf and other usable material from the same plants qualifies as passing the quality assurance test.

If a lot of marijuana fails a quality assurance test twice, it may be used to make a CO_2, ethanol, or solvent-based extract. After processing, the CO_2 or solvent-based extract must pass all required quality assurance tests.

Recreational Use and Limits

The cannabis plant usually creates THC levels of 10-25% with some strains reaching the high 20s. There are currently no known varieties of cannabis naturally producing more than 35% THC potency. Any products that state they are over 35% are either misinforming the public or are altered in such a manner as to artificially increase THC levels.

In order to maintain safety across the nation, federal rules should limit recreational cannabis and its related by-products to no more than 35% THC potency.

Specifically, the sale of cannabis flower, leaves, hashish, shatter, wax, butane hash oil, vape oil or edibles for recreational use should be limited to no more than 35% THC potency. Shatter, a cannabis extract with about 80 percent THC content, is legal for recreational use in states such as Colorado and Washington, sold in medical marijuana dispensaries in other states, and is faster-acting and far more easily concealed than marijuana flowers or buds: it has thus become a favorite of Millennials.

Those under the age 35 have turned to shatter and dabbing as a discrete way to ingest cannabis without the negative smell associated with smoking cannabis. Because these products are not effectively labelled, with accurate THC potency often not revealed, the end user can ingest too much, leading to anxiety, paranoia, a sense of distorted time, rapid heartbeat and heart attack, erratic behavior, and random thinking. Drinking, operating a motor vehicle, or engaging in risky behavior can be negatively affected by high THC levels. While high levels of THC may have medical applications, offering anything higher than 35% THC potency for recreational users should be considered bad public policy.

Any company selling cannabis or cannabis products over 35% THC content for the purpose of inhalation, whether through smoking, vape, dab, edibles or other methods delivering a dosage to the lungs, to the recreational market shall be subject to loss of federal permit/license and a fine not to exceed $500,000.

There shall be no limits for THC potency in medical cannabis which is more closely controlled and prescribed.

Edibles

Federal rules are required to protect children, underage and adult non-users from accidentally consuming cannabis-infused edibles.

The cannabis industry has a long history of making edibles appear like common foods found in the kitchen or stores, including brownies and lollipops. To combat the mimicking of these common foods, federal rules should state that edibles may not share the appearance of children's candies, including lollipops, ring pops, gummy bears, Tootsie Rolls, Swedish Fish, nor children's cereal or beverages. Edibles may also not employ naming conventions that are alternative spellings or plays on trademarked names of common grocery candy, cookies, crackers, or cereal.

Edibles in the form of candy bars, cookies, brownies, cakes, or similar format must be individually wrapped with appropriate labeling as defined under the guidance of the Federal Trade Commission and the Food and Drug Administration and must clearly show its THC, CBD, and Terpene content as expressed by a percentage of weight of the edible.

All edibles' packaging must be labeled with a green cross and the words "CAUTION CANNABIS", as shown at right, printed in a standardized color (Process: C84, M13, Y99, K2 or PMS #342 C) and reproduced at a size of at least one-quarter inch in height (1/4").

Dietary Supplements

Cannabas-based dietary supplements must be clearly labeled under the guidance of the Federal Trade Commission and the Food and Drug Administration and must clearly show its THC, CBD, and Terpene content as expressed by a percentage.

Dietary supplements may not contain more than 5% THC.

Dietary supplements include such ingredients as vitamins, minerals, herbs, amino acids, and enzymes. Dietary supplements are marketed in forms such as tablets, capsules, softgels, gelcaps, powders, and liquids, oils, tinctures, edibles, or formulated drinks.

Supplements may not be provided in injectable forms. Products requiring injection must be approved by the FDA's Center for Drug Evaluation and Research (CDER) before bringing to market and will be classified as pharmaceutical drugs available only by prescription.

Manufacturers and distributors of cannabis-derived dietary supplements and dietary ingredients are prohibited from marketing products that are adulterated or misbranded. The Food and Drug Administration is responsible for taking action against any adulterated or misbranded dietary supplement product after it reaches the market.

Under existing law, including the Dietary Supplement Health and Education Act passed by Congress in 1994, the FDA can take action to remove products from the market, but the agency must first establish

that such products are adulterated (e.g., that the product is unsafe) or misbranded (e.g., that the labeling is false or misleading).

Cannabis supplements may not make health claims and must contain the following statement on all labels *"This product is not intended to treat, diagnose, prevent, or cure diseases."*

All dietary supplement packaging must be labeled with a green cross and the words "CAUTION CANNABIS" as shown at right, printed in a standardized color (Process: C84, M13, Y99, K2 or PMS #342 C) and reproduced at a size of at least one-quarter inch in height (1/4").

Recall reporting and practices shall be determined by the FDA.

Truth in Labeling

In order for consumers to make informed choices of the myriad of cannabis plants and products, federally-mandated minimum labeling requirements should include:

- Cannabis plant strain name(s)
- THC content as a percentage of volume
- Cannabinoid content as a percentage of volume
- Terpene content as a percentage of volume
- Specific cannabinoid names testing over 1% of volume
- Grower origin (state and country, province and country, or comparable classification)
- Company manufacturing the product, address, telephone number and website URL (if available)
- 24- to 36-digit lot or batch number
- Date of packaging
- Expiration date

Transportation and Distribution

While cannabis has been legalized in 28 states and the District of Columbia, it is still illegal under federal law and the DEA's schedule I classification. As a result, transporting marijuana across state lines could result in federal criminal prosecution. Thus, the need for a federal permit/license for transporting cannabis across state lines is necessary. Rules that should apply to the federal permit/license include:

Transportation and distribution of cannabis plants, seeds, and products for the purposes of cultivation, distribution, or product development must be transported in locked cases with the transporting individual or company having possession of the batch numbers of each lot being transported.

Distributors, courier companies, individuals or other transportation services (such as delivery to and from laboratories) are required to possess a federal permit/license and to fill out shipping manifests to move

cannabis from growing warehouses to store shelves. The federal permit/license under schedule VI would give these couriers additional powers, such as temporary storage of cannabis if an unexpected storm hits, mechanical breakdown, or other impediment to delivery, and the product can be safely delivered to its designation within 72 hours. If the product cannot be delivered in that time window, it must be returned to the grower or manufacturer within 24 hours.

Transportation via US Mail and private carriers such as UPS and FedEx must be made from the permit holder's address and must be signed by the recipient. For shipping via United States Postal Service, shipment must be made via registered, insured, or Priority mail and require the recipient's signature.

Transportation via airline, train, bus or other commercial carrier must be done so with the cannabis and/or cannabis-based products stored in hard sided boxes or transport crates with TSA approved locks attached and the name of the grower/transporter, address, and telephone number printed on the outside of the box. Tags, because they can be removed, are not an acceptable form of identification.

Medical marijuana license holders may transport cannabis based upon their doctor's recommendation via air, railway, bus, car or other transport, provided the destination to which the patient is travelling is a state that has approved medical and/or recreational cannabis.

The legal implications of transporting cannabis within a particular state will depend on the laws of the individual state. First of all, if marijuana is illegal in a particular state, the transportation of the drug will also be illegal in that state. In states that have made marijuana legal, on the other hand, the laws related to the transportation of marijuana are different depending on if the person is a business or an individual. States that have legalized marijuana require businesses to be licensed by the state before they can legally transport cannabis. For example, in order for a person to transport marijuana within Colorado for his or her business, the person needs to have a license from the State Licensing Authority as well as from the relevant local authorities. In Washington, transporting marijuana requires a person to have a marijuana retailer license and comply with specific transportation requirements.

Since these requirements differ from state to state, it's important that a federal permit/license be available to help track the movement of cannabis seeds, plants and products.

Insurance

Any holder of a federal permit/license, with the exception of an individual holding a permit for home growing, must carry a minimum product liability insurance policy of $1,000,000 per incident.

Proof of insurance will be required when applying for a license and upon renewal.

Summary

This document is not meant to address every part of the cannabis legalization question, but to give an outline of the key elements that will ensure cannabis is regulated at the federal level, has clear and accurate labeling, contains warnings to help prevent underage kids and teens from consuming cannabis products, gives states the authority and power to legalize the medical and recreational sale of cannabis and related products based on the wishes of their citizens, provides for a nationwide testing protocol to ensure product safety, and seed-to-store tracking to provide a trail should bad products reach the market.

While cannabis has been legalized in 28 states and the District of Columbia, it is still illegal under federal law and the research completed to date has been largely restricted by limited federal access to the myriad of cannabis strains available around the world. In addition, confusing regulations have kept many research scientists and universities that receive federal funding from participating in research projects.

Researchers know that cannabidiol and THC balance each other, and yet, more research is needed to see how these interact with the more than 500 compounds in cannabis that interact and work with each other (commonly called the "entourage effect").

The cannabis industry worries that there is a possibility that the Trump Administration may not be friendly to the industry. Attorney General John Session's vocal opposition to cannabis is well known. The Administration's former spokesman, Sean Spicer's, comments about enforcing federal laws related to marijuana has fueled the fires of concern. Consequently, regulatory reforms to bring the industry into the light may take a backseat to the enforcement of federal law, though the War on Drugs has proven to be a losing proposition.

From a purely legal standpoint, the federal government cannot require states to prohibit marijuana, nor can it force states to enforce federal law. While the Drug Enforcement Administration could go into any state and arrest every single dispensary owner, at least in theory, the state and local police would be under no clear legal obligation to help. In the past, the feds have focused more on big fish and with the increase in heroin use across America, federal focus on getting control of that drug is more important than efforts and expending taxpayer funds to chase after marijuana enforcement which has historically been shown to do very little in limiting access to cannabis.

Moving the cannabis industry from largely unregulated industry with black market banking and non-uniform product safety testing to an industry of common regulations, uniform testing, federal oversight and state regulation, will generate tremendous tax revenues, bring safety and standardized protocols to every state wishing to legalize medical or recreational cannabis, plus create the opportunity for new avenues in research into cannabis' pharmaceutical potential including the possibility of the development of clinically proven treatments for some of the nation's most debilitation diseases such as PTSD, obesity, depression, cancer, ALS, multiple sclerosis, epilepsy, opiate addiction, and more.

Research has proven that cannabis is not a gateway drug; and it likely holds promise as an exit strategy for opiate addiction. It has the potential to treat the symptoms of dozens of illnesses and until it can be brought out of the shadows through federal rules and permitting/licensing, increased oversight, collection of all required tax revenues, and providing safety measures equal or greater than what consumers receive through the global dietary supplements market—a market size of $122.08 billion in 2015—cannabis will remain an enforcement and safety issue.

It is our belief that the will of the people should be recognized and the federal government has a role in ensuring consumers the safest cannabis and cannabis-derived products possible.

Cannabis should not be declassified, but reclassified by the Drug Enforcement Agency into its own category, schedule VI, with the permitting, taxing, labeling oversight, and testing requirements defined at the federal level and implemented by states that wish to pass medical or recreational cannabis use.

Respectfully submitted,

Bill Townsend, President & CEO
TRICCAR Holdings, Inc.
848 N. Rainbow Blvd., #1888
Las Vegas, NV 89131
Email: Townsend@triccar.com