

# A Modern State-Federal Framework for a Regulated U.S. Cannabis Industry

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## ABSTRACT

Based on the regulatory status of cannabis (*Cannabis* spp., Cannabaceae) in the United States, the premise of the proposed federal framework is to create a regulatory model that is specific to a plant-based end product that can be used for both social and therapeutic purposes. Cannabis products are currently being regulated at the state level, with the exception of US Food and Drug Administration (FDA)-approved drug products such as Epidiolex<sup>®</sup> (GW Pharmaceuticals; Cambridge, UK).

The proposed framework by design defers to the existing state regulated infrastructures by leaving state autonomy intact to the greatest degree possible, with minimal federal entanglement. Importantly, the framework also sets forth that the federal interface would be conducted via the U.S. Department of Agriculture (USDA) and the Cannabis plant would not be a federally scheduled substance. This article will explain why this proposed dynamic is integral to the long-term success of the regulated Cannabis market, and will address why commonly-cited frameworks, such as the alcohol and tobacco models, are not appropriate for a modern regulated Cannabis market. The scope of the proposed framework does not include the production, manufacture, or regulation of no- or low-THC hemp or any crop cultivated under the provisions of the Agriculture Improvement Act of 2018 (the 2018 Farm Bill).<sup>2</sup>

This article will expound on the three critical data points and underlying considerations used in developing the proposed regulatory structure. Firstly, a review of the history, evidence, and science of the plant to understand the plant's properties and true safety concerns. Secondly, an understanding of the landscape of today's U.S. regulated cannabis markets and recognition of any safety gaps, pressure points and other market vulnerabilities. Finally, an assessment of several existing national regulatory pathways to market and identification of why these existing pathways may not be best suited for the regulated Cannabis market.

The Cannabis plant has a long history of human use for different purposes and is one of several hundred botanicals with therapeutic properties supported by clinical data and traditional use. The proposed framework is a 21st century pathway to market for plant-based products that respects the efforts of the states and balances an appropriate federal intersection with long-term market interests.

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<sup>2</sup> The 2018 Farm Bill defines the term “hemp” as “the plant *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.” One Hundred Fifteenth Congress of the United States of America. Agriculture Improvement Act of 2018. Public Law 115-334. January 3, 2019. Available at: [www.govinfo.gov/content/pkg/BILLS-115hr2enr/pdf/BILLS-115hr2enr.pdf](https://www.govinfo.gov/content/pkg/BILLS-115hr2enr/pdf/BILLS-115hr2enr.pdf).

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## Introduction

This article proposes a state-federal framework to resolve the current conflict between the U.S. federally scheduled status of the cannabis plant under the U.S. Controlled Substances Act (CSA)<sup>3</sup> and the state-enacted cannabis programs.<sup>4</sup> The proposed framework is intended to, 1) create market stability for the regulated cannabis industry, 2) enhance the integrity and competitiveness of the existing regulated markets, and 3) place the stakeholders from the regulated cannabis industry on a level playing field with other regulated, tax-paying businesses.

This paper asks the reader to consider a federal framework that is designed for a plant-based product and a framework that supports the existing structure of the domestic regulated cannabis market, addresses market vulnerabilities and facilitates entry into the global market.

For purposes of this paper, the term “cannabis” shall be used in lieu of the term “marihuana” as referenced in the CSA,<sup>5</sup> or the term “marijuana” which is a common name or street vernacular for the plant, unless citing statutory use of the term. The latter two terms are frequently used interchangeably by law makers, regulators, and the general public when referencing the plant. However, the proper botanical nomenclature for the plant subject of this paper is *Cannabis* L. (inclusive of *Cannabis sativa* and *C. indica*).<sup>6</sup> Use of the proper botanical nomenclature is more accurate and will build integrity into the regulated industry by disassociation with street terms having an illegal drug connotation.<sup>7</sup>

The currently used Latin scientific names for the plant species that are the subject of this article were assigned in the 18<sup>th</sup> century. In the 1753 publication *Species Plantarum*, Swedish botanist Carl Linnaeus (1707-1778) named the plant species *Cannabis sativa* L., stating its habitat as India.<sup>8</sup> Thirty years later, French botanist Jean-Baptiste Lamarck (1744-1829) described a related species as *Cannabis indica* Lam., which he referred to as “*chanvre des Indes*” (Indian hemp).<sup>9</sup> In the geographic origin of the species, cannabis preparations have a long history of use in the traditional Indian systems of medicine (such as Ayurveda, Siddha, and Unani medicine, respectively) with officinal monographs published in the currently valid editions of the *Ayurvedic Pharmacopoeia of India*,<sup>10</sup> *Siddha Pharmacopoeia of India*,<sup>11</sup> and *Unani Pharmacopoeia of India*.<sup>12</sup>

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<sup>3</sup> Controlled Substances Act (CSA), Title II of the Comprehensive Drug Abuse Prevention Substances Act of 1970 (CSA, 21 U.S.C. §801 *et seq.*); Schedules of U.S. Controlled Substances, 21 U.S.C. §812(c), Schedule I(c).

<sup>4</sup> Which also includes regulated markets in the District of Columbia (D.C.), Guam, and Puerto Rico.

<sup>5</sup> ‘Marihuana’ is a Scheduled I substance under the Controlled Substances Act (CSA). 21 U.S.C. §802(16); 21 U.S.C. §812(c), Schedule I (c); 21 C.F.R. §1308.11(d)(22, 30).

<sup>6</sup> Roy Upton et al., *Cannabis Inflorescence. Cannabis spp. Standards of Identity, Analysis, and Quality Control*. American Herbal Pharmacopoeia®, (Revision 2014).

<sup>7</sup> See Alan Piper, *The Mysterious Origins of the Word ‘Marihuana’*, 153 SINO-PLATONIC PAPERS (2005).

<sup>8</sup> CARL LINNAEUS, *Species plantarum : exhibentes plantas rite cognitatas, ad genera relatas, cum differentiis specificis, nominibus trivialibus, synonymis selectis, locis natalibus, secundum systema sexuale digestas* 1017 (1753).

<sup>9</sup> JEAN-BAPTISTE LAMARCK & JEAN-LOUIS-MARIE POIRET, *ENCYCLOPÉDIE MÉTHODIQUE. BOTANIQUE. TOME PREMIER* 695 (1783-1808).

<sup>10</sup> AYURVEDA PHARMACOPOEIA COMMITTEE, *THE AYURVEDA PHARMACOPOEIA OF INDIA, PART I, VOLUME I* 125-126 (1989).

<sup>11</sup> SIDDHA PHARMACOPOEIA COMMITTEE, *THE SIDDHA PHARMACOPOEIA OF INDIA, PART I, VOLUME I* 63-64 (2008).

<sup>12</sup> UNANI PHARMACOPOEIA COMMITTEE, *THE UNANI PHARMACOPOEIA OF INDIA, PART I, VOLUME I* 72-73 (2007).

In addition to utilizing the term “cannabis,” the term “adult-use” will be used in lieu of the terms “recreational” or “retail” to indicate the state-sanctioned cannabis programs designed for social use (versus the medical programs).

## I. OVERVIEW OF THE U.S. REGULATED CANNABIS INDUSTRY

This section provides condensed information on the domestic regulated cannabis industry to provide context for the proposed federal framework. Further details on the domestic market will be developed later in this article.

The U.S. regulated cannabis market currently consists of 46 states, the D.C., Puerto Rico, and Guam, all of which have enacted medical cannabis programs, and ten states<sup>13</sup> with adult-use markets.<sup>14</sup> The number of states with regulated markets is on the rise and the scope of each market within a state continues to expand.<sup>15</sup> These state-sanctioned programs have been uniquely structured by the lawmakers and citizens of each state (or territory) and their respective regulatory agencies. The market reach for the plant and any products that have been developed under the state frameworks is limited to intrastate commerce.

The U.S. regulated markets are currently valued at \$10 plus billion, have created 150-200k+ taxable jobs,<sup>16</sup> have played a mitigating role in the opioid crisis,<sup>17</sup> and have provided access to medical cannabis for over two million patients.<sup>18</sup> The benefits from the regulated markets have exceeded expectations.

Additionally, with the increase in the number of states enacting regulated markets, state regulatory agencies and outside interest groups have tracked data to assess any change in societal impact. Fortunately, the data has shown that the regulated markets have not resulted in an increase in youth use,<sup>19</sup>

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<sup>13</sup> At the time of this writing, Illinois is about to become the 11<sup>th</sup> state with an adult-use cannabis program. House Bill 1438 passed on 31 May 2019 and was sent to Gov. J.B. Pritzker, who has pledged to sign it, after which it would come into force on 01 January 2020.

<sup>14</sup> The 33 states with comprehensive medical programs: Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Hawaii, Illinois, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, Utah, Vermont, Washington, and West Virginia; and 13 states with high-CBD, low-THC programs (also referred to as ‘limited programs’): Alabama, Georgia, Indiana, Iowa, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee, Texas, Virginia, Wisconsin, and Wyoming. The 10 states with adult-use programs: Alaska, California, Colorado, Maine, Massachusetts, Michigan, Nevada, Oregon, Vermont, and Washington.

<sup>15</sup> North Dakota Secretary of State, Initiated Statutory Measure No. 3: Pertaining to the Legalization of Marijuana (2018); Missouri Secretary of State, Proposition C (2018); Utah Lieutenant Governor Elections, Utah Medical Cannabis Act (Proposition #2) (2018).

<sup>16</sup> NBC News, [Legal marijuana industry had banner year in 2018 with \\$10B worth of investments](#), (Dec.27, 2018); Susan Gunelius, [Research Reveals Surprises in International Marijuana Markets](#), Cannabiz Media (Jul. 20, 2018), <https://cannabiz.media/international-marijuana-markets/>.

<sup>17</sup> Richard Harris, [Opioid Use Lower in States that Eased Marijuana Laws](#), Minnesota Public Radio News (Apr. 2, 2018, 11:45 AM), <https://www.npr.org/sections/health-shots/2018/04/02/598787768/opioid-use-lower-in-states-that-eased-marijuana-laws>; Mark Zdechlik, [Analysis: Medical Cannabis Users Find Pain Reduction](#), Minnesota Public Radio News, (Mar. 1, 2018), <https://www.mprnews.org/story/2018/03/01/medical-cannabis-users-find-pain-reduction>.

<sup>18</sup> Americans for Safe Access, [A Patient-Focused Analysis of the Patchwork of State Laws](#). 2018 Annual Report, p. 4.

<sup>19</sup> Gregory Austin et al., *School climate, substance use, and student well-being in California, 2015-17. Results of the Sixteenth Biennial Statewide Student Survey, Grades 7, 9, and 11* (2018).; Yuyan Shi, Sharon E. Cummins & Shu-Hong Zhu, *Medical Marijuana Availability, Price, and Product Variety, and Adolescents' Marijuana Use*, 63 J. ADOLESC. HEALTH, 88-93 (2018).

nor an increase in crime rates.<sup>20</sup> Impaired driving continues to be a topic of interest by all parties including regulators, industry stakeholders, lawmakers and the general public. In July 2017, the National Highway Traffic Safety Administration (NHTSA) submitted a report to Congress, stating that while there is evidence that cannabis use impairs psychomotor skills, lane tracking, and cognitive functions, its role as a potential cause of crashes is not yet clear. The NHTSA Report recommended that the collection of data on prevalence and effects of cannabis-impaired driving should be increased.<sup>21</sup>

There have also been reports of indictments and criminal prosecutions for product diversion across state lines.<sup>22</sup> These incidents are unfortunate; however, the fact that the activity was detected is an indication that the tracking systems and other enforcement measures within the state regulatory frameworks are effective.

For the most part – and certainly for the states that have enacted regulated programs within the past five years – the state regulatory frameworks are comprehensive and prescriptive with licensure requirements, agricultural practices and good manufacturing practices (GMPs), dispensary and laboratory requirements, labeling and advertising standards, and numerous enforcement measures. The state frameworks are detailed on the front end to provide ample instruction to the stakeholders on how to operate in a compliant manner, and extensive on the back end to ensure regulatory authorities have the power to enforce with significant consequences for failure to comply. The intended uses and allowable product dosage formats, as well as the design of the program, are unique and novel to each intrastate market, with certain safety parameters that are common across all state programs.

In addition to the tremendous growth of the state-regulated markets, the state-sanctioned cannabis programs have the support from a majority of the U.S. population:

- a) 93% support medical cannabis legalization,
- b) 63% support full legalization,
- c) 70% oppose federal interference in the state-authorized markets.<sup>23</sup>

As this paper will outline, the U.S. regulated domestic cannabis market is young in years; however, the comprehensiveness of the individual state regulatory frameworks and the market growth of the industry have been exceptional. To date, the integrity and strength of the state programs have been pivotal in garnering support from the general public, and both of these attributes will be key to continue to win over policy and law makers and in the ongoing success of the regulated industry.

## II. THE ROAD TO 2019

The modern regulated cannabis market has been in the making for decades. For a true appreciation of what shaped the regulated domestic market to its current landscape, an understanding of the history of the plant and its different chemotype cultivars historically used for fiber, food or medicine purposes<sup>24</sup> in the

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<sup>20</sup> Yu-Wei Luke Chu & Wilbur Townsend, *Joint Culpability: The Effects of Medical Marijuana Laws on Crime*, J. ECON. BEHAV. ORGAN. (2018).

<sup>21</sup> Richard P. Compton, *Marijuana-Impaired Driving - A Report to Congress* (DOT HS 812 440) (July 2017).

<sup>22</sup> Denver Post, [Drug ring bust a huge wake-up call for Colorado cannabis regulators](#). The Denver Post Editorial Board, 16.Jun.2017; 4CBS Denver, [Former Pot Officer, Entrepreneur Charged in Trafficking Ring](#). 13.Jun.2017.

<sup>23</sup> [Quinnipiac University Poll](#), 26.Apr.2018.

<sup>24</sup> See JOSHUA A. HARTSEL et al., CHAPTER 53: CANNABIS SATIVA AND HEMP, NUTRACEUTICALS 735-754 (2016); and DAN JIN et al., CANNABIS CLASSIFICATION SYSTEMS AND GROWTH TRENDS OF THE NORTH AMERICAN MEDICAL CANNABIS INDUSTRY, published in conference journal “*The Second Annual Academic Conference of the Specialty Committee of TCM Pharmacognosy of the World Federation of Chinese Medicine Societies*”, 23-27 (2015).

U.S. is instructive.<sup>25</sup> This section provides considerable background on the plant and an exploration of other influences that played a role in shaping today's current market.

The medicinal use of the cannabis plant in Asia has been documented from about 2700 B.C.E.; however, the medicinal use in the U.S. dates to the early 1800s and that is where the historic timeline for purposes of this paper begins.

### *Pharmacopoeia of the United States of America*

The U.S. enjoys a rich history with plants used as food, fiber and herbal medicine. The first publication of the *Pharmacopoeia of the United States of America* (USP) in 1820 included 254 botanical substances as well as monographs for 246 herbal drug preparations, together accounting for over 80% of USP entries.<sup>26</sup> Subsequently in 1833, the USP served as the basis for the first edition of the *Dispensatory of the United States of America* (USD).<sup>27</sup>

In combination, the USD and USP monographs provided pharmacists and physicians with essential information on quality, indications and posology for officinal botanical drugs and preparations made from them. A listing for 'Extractum Cannabis' (alcoholic extract of the dried flowering tops of *Cannabis sativa*, variety *Indica*) first appeared in the secondary list of Materia Medica of the USP in its third decennial revision in 1850.<sup>28</sup> It was quickly elevated to the primary list of Materia Medica in the fourth

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<sup>25</sup> Of relevance to this discussion is the relation of industrial hemp to the cannabis plant. The cannabis plant, which is in the botanical genus of *Cannabis*, has more than one species and each species has distinguishing botanical, chemical, and pharmacological properties. Each species has unique chemotypes and cultivars with chemical variations. One such 'fiber-type' chemotype is the source of industrial hemp (hemp), an agricultural crop with no psychoactive properties (or at a level with no effect) that can be used for multiple commercial purposes, for example making rope or clothing. Another is the so-called 'drug-type' chemotype that is referenced in the CSA and is the subject of this paper. These two types do have a similar morphology and outward appearance; however, they are distinct and have been the subject of confusion for the past several decades. Industrial hemp has been documented to have arrived in the U.S. in the early 1600s- specifically, in Jamestown as part of the North American British colony, where the farming of industrial hemp was an invaluable crop. The fiber was used to make ropes, canvas- and purportedly America's first flags. Quite interestingly, hemp was a sought after crop during Revolutionary War times for maritime use for lines, rigging, and sail canvas and again, purportedly the first drafts of the Declaration of Independence were written on hemp paper. The cultivation of industrial hemp was prohibited under the CSA (as the two types were conflated) and remained prohibited until the Agricultural Act of 2014, commonly referred to as the 2014 Farm Bill, and specifically, §7606 which provided for state-initiated pilot programs of domestic hemp production. [sans a brief period during WWII to support war efforts. In 1942, the USDA released a motion picture titled "Hemp for Victory," which "shows how the war cut off our supply of East Indian coarse fibres, and the urgent need for American-grown hemp for our Army and Navy as well as for civilian uses. Portrays farm practices of hemp growers in Kentucky and Wisconsin, where hemp has long been a staple crop. Designed to encourage farmers in other States to grow hemp to meet the war emergency."]. In December of 2018, the Agriculture Improvement Act of 2018 was enacted (2018 Farm Bill, S.3042, H.R.2), which removed hemp from the Controlled Substances Act, provided a definition of hemp with a maximum upper limit of <0.3% delta-9 tetrahydrocannabinol (THC) on a dry weight basis, and fully legalized the domestic production of hemp. At the time of this article, the hemp production provisions in the 2018 Farm Bill had yet to be fully implemented. The USDA is tasked with the issuance of regulations and guidance to implement a hemp production program. Interestingly, during the several decades when industrial hemp could not be cultivated in the U.S., hemp was being legally imported into the U.S. either as a raw material or as part of a finished product. Even though industrial hemp and cannabis have very distinct chemical variations, the two species have been conflated for decades, which highlights the magnitude of misunderstanding – intentional or not – of the plant.

<sup>26</sup> UNITED STATES PHARMACOPOEIAL CONVENTION, *THE PHARMACOPOEIA OF THE UNITED STATES OF AMERICA* (1820); John S. Haller, *The United States Pharmacopoeia: It's Origin and Revision in the 19<sup>th</sup> Century*, 58 *BULL. N.Y. ACAD. MED.* 480–492 (1982).

<sup>27</sup> GEORGE B. WOOD & FRANKLIN BACHE, *THE DISPENSATORY OF THE UNITED STATES OF AMERICA* (1833).

<sup>28</sup> UNITED STATES PHARMACOPOEIAL CONVENTION, *THE PHARMACOPOEIA OF THE UNITED STATES OF AMERICA, THIRD DECENNIAL REVISION* 50 (1851).

decennial revision of the USP in 1860.<sup>29</sup> In 1854, therapeutic monographs for ‘Extractum Cannabis Indicae’ and ‘Tinctura Cannabis Indicae’ entered the tenth edition of the USD.<sup>30</sup>

Interestingly, the fifth decennial revision of the USP in 1870 included entries for both ‘Cannabis Americanae’ (the flowering tops of *Cannabis sativa* cultivated in North America) and ‘Cannabis Indicae’ (the flowering tops of the female plant of *Cannabis sativa*, variety *Indica*; from India) as well as monographs for their respective dosage form preparations ‘Extractum Cannabis Americanae USP’ and ‘Extractum Cannabis Indicae USP’,<sup>31</sup> indicating that cannabis had become important enough to domesticate the species for commercial cultivation in the U.S. to supply pharmacies rather than sole reliance on imports of wild cannabis raw materials from India. And, in 1888, both ‘Extract of Indian Cannabis’ and ‘Tincture of Indian Cannabis’ were included as components of several multi-ingredient preparations monographed in the first issue of the American Pharmaceutical Association’s National Formulary (N.F. I).<sup>32</sup> Today, the National Formulary is produced by the United States Pharmacopeial Convention.

Cannabis remained as a listed substance in the USP until the twelfth decennial revision of 1940, published in 1942 (USP XII). The USP XII did not include cannabis (or Extractum Cannabis), and unfortunately, the revision notes<sup>33</sup> that were prepared by the Convention between the USP XI and USP XII did not reference cannabis; however, there has been speculation that the USP received outside pressure from individuals with a prohibition mindset towards the plant. In addition to the potential outside influences on the Convention, during the early 1900s, the U.S. experienced a general shift away from botanical-based medicines and a greater interest towards pharmaceutical drugs often made of synthetic substances. The move towards synthetic drugs was accelerated by the enactment of the Pure Food and Drugs Act of 1906 and subsequently, the Federal Food, Drug, and Cosmetic Act of 1938.

Fast forward 74 years, and in February of 2016, the USP published a ‘stimuli to the revision process’ article for public comment on the topic of advisability and feasibility of developing new USP quality standards monographs for medical cannabis. As a result of legalization of the medical use of cannabis in several U.S. states and internationally, and in the absence of modernized quality standards monographs, the USP has been requested to develop such standards.<sup>34</sup> USP monographs are not only official compendia of the U.S. but are used and incorporated by reference into drug regulations in many countries of the world, especially those lacking their own national pharmacopoeia (e.g. Australia and Canada), for specifications and quality control of medicines. Subsequently, in September 2016, a ‘USP Expert Panel on Medical Cannabis’ was established comprised of scientific experts in areas of cannabis testing, procedure development and validation, and compendial procedures.<sup>35</sup>

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<sup>29</sup> UNITED STATES PHARMACOPEIAL CONVENTION, THE PHARMACOPEIA OF THE UNITED STATES OF AMERICA, FOURTH DECENNIAL REVISION 28 (1860).

<sup>30</sup> GEORGE B. WOOD & FRANKLIN BACHE, THE DISPENSARY OF THE UNITED STATES OF AMERICA, TENTH EDITION, 338-340, 1223 (1854).

<sup>31</sup> UNITED STATES PHARMACOPEIAL CONVENTION, THE PHARMACOPEIA OF THE UNITED STATES OF AMERICA, FIFTH DECENNIAL REVISION 23, 135, 303 (1870).

<sup>32</sup> AMERICAN PHARMACEUTICAL ASSOCIATION COMMITTEE ON NATIONAL FORMULARY, THE NATIONAL FORMULARY OF UNOFFICIAL PREPARATIONS. FIRST ISSUE 87, 88, 102, (1888).

<sup>33</sup> Revision notes are the transcripts from the Conventions that captured the reasoning for the addition or removal of substances from the USP.

<sup>34</sup> Gabriel I. Giancaspro et al., *The Advisability and Feasibility of Developing USP Standards for Medical Cannabis*, 42 PHARMACOPEIAL FORUM (Jan.–Feb. 2016).

<sup>35</sup> USP EXPERT PANEL ON MEDICAL CANNABIS (Aug. 30, 2016), <https://www.uspnf.com/notices/usp-expert-panel-medical-cannabis>



Today, almost 200 years since the first publication of the USP, the cannabis plant is once again part of the vernacular in the medical community within the U.S. and within the USP. Completion of a modern-day USP quality standards monograph to serve as the basis for specifications on quality control and testing of medical cannabis is anticipated.

### *Initial Scheduling of the Plant*

Technically, there are two bodies of law that remain in conflict with the state-driven cannabis initiatives: the U.S. Controlled Substances Act and the United Nations Single Convention on Narcotic Drugs of 1961. Under both, the cannabis plant is a scheduled substance. Most interestingly is the dynamic leading up to the cannabis plant being initially placed on Schedule I of the CSA, and on Schedules I and IV of the Single Convention on Narcotic Drugs of 1961 and the Convention on Psychotropic Substances of 1971.<sup>36</sup> The following several paragraphs further elaborate on this dynamic and the authors ask the reader to bear with as the historic excerpts provide important context.

### *U.S. Controlled Substances Act*

Prior to the enactment of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (P.L. 91-513), and specifically, Title II, the Controlled Substances Act (CSA), there was great confusion over the actual risk of harm from the plant.<sup>37</sup> This state of confusion and uncertainty about the plant is reflected in the numerous Congressional bills that were introduced, and during the several hearings and debates that were held on how best to proceed to effectively control the growth of the broader illicit drug market and what role cannabis plays, if any, in actual social harm. Congressional debates explored the actual dangers of the cannabis plant, what types of criminal penalties should be imposed for offenses committed by youth, adults and addicts, and how best to approach cannabis in general.

Quite remarkably even in the late 1960s, there were data to indicate that incarceration and traditional law enforcement measures were ineffective in controlling ‘marihuana.’ The following are several excerpts from Congressional floor debates and hearings that highlight the uncertainty on the risk of harm from the plant prior to the plant becoming a Scheduled I substance.

For example, a December 1969 Senate Report on controlled substances legislation that would become the law that remains in effect today included language regarding the failure of the existing criminal penalty structure of the time:

‘The penalty provision was added based on evidence developed through subcommittee investigations and hearings which indicated that the penalties provided in S. 2637 were inconsistent as compared with the harmfulness, abuse characteristics and their social implications of the several classes of drugs. *For example, to impose the same high mandatory penalties for*

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<sup>36</sup> United Nations Treaty Collection, [Chapter VI, 18. Narcotic Drugs and Psychotropic Substances](#), Single Convention on Narcotic Drugs, 1961, as amended by the Protocol amending the Single Convention on Narcotic Drugs, 1961. New York, 8 August 1975. (site 23.Aug.2018); United Nations Treaty Collection, [Chapter VI, 16. Narcotic Drugs and Psychotropic Substances](#), Convention on psychotropic substance, Vienna, 21 February 1971. (site 23.Aug.2018). Both treaties are also referenced in the U.S. Controlled Substances Act (21 U.S.C. §801 et seq.).

<sup>37</sup> The state of confusion on the cannabis plant dates back even further to 1937 when the Marihuana Tax Act of 1937 (H.R. 6385) was introduced and enacted. Hearings before the House Committee on Ways and Means (April 27-30, May 4, 1937) included a lively debate between Congressional Members and Dr. Woodward, legislative counsel for the American Medical Association. Dr. Woodward attempted to dispel some of the sensationalist media reports and advocate for the medicinal value of the plant.



*marihuana-related offenses as for LSD and heroin offenses is inequitable in the face of a considerable amount of evidence that marihuana is significantly less harmful and dangerous than LSD or heroin.*

It had also become apparent that the severity of penalties including the length of sentences does not affect the extent of drug abuse and other drug-related violations. *The basic consideration here was that the increasingly longer sentences that had been legislated in the past had not shown the expected overall reduction in drug law violations. The opposite had been true notably in the case of marihuana.* Under Federal law and under many State laws marihuana violations carry the same strict penalties that are applicable to hard narcotics, yet, marihuana violations have almost doubled in the last 2 years alone.

In addition, the severe drug laws specifically as applied to marihuana have helped create a serious clash between segments of the youth generation and the Government. These youths consider the marihuana laws hypocritical and unjust. Because of these laws the marihuana issue has contributed to the broader problem of alienation of youth from the general society and to a general feeling of disrespect for the laws and the judicial process.

The main thrust of the change in the penalty provisions is to eliminate all mandatory minimum sentences for drug law violations except for a special class of professional criminals. The field of penology has maintained the position that mandatory sentences hamper the process of rehabilitation of offenders. It has equally been maintained that such penalties infringe on the judicial function by not allowing the judge to use his discretion in individual cases.<sup>38</sup>

The same Senate Report also included statements on the overall confusion on the plant and the wide-ranging opinions on ‘marihuana:’

‘The third new provision directs the Attorney General to appoint a committee of experts to study the marihuana problem.

As it will be pointed out below, marihuana offenses make up the bulk of drug arrests throughout the Nation. *This drug has created greater controversy than any of the other substances of abuse. And the present marihuana laws have embittered, confused and disillusioned a large segment of this Nation's young people, including those who do not use any drugs at all.* The marihuana controversy is baffling to the general public and to the parents as well as the young people.

The span of arguments on this drug ranges *from the death penalty to complete legalization of the drug.* The gross ignorance and misunderstanding regarding this problem aggravates it and makes it worse than it already is.

It was determined that an authoritative report from a group of experts on this matter is needed to *dispel the irrational fears of the public regarding marihuana and to provide better understanding with respect to the substantial dangers associated with this drug.*<sup>39</sup>

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<sup>38</sup> Senate Report No. 91-613. 16.December.1969, Controlled Dangerous Substances Act of 1969, Report of the Committee on the Judiciary United States Senate, Together with Additional Views To Accompany S. 3246, pp. 1-2, 91<sup>st</sup> Congress 1<sup>st</sup> Session (*emphasis added*). The referenced bill (S. 3246) is the same legislation that would become the current law in the U.S. (Pub. L. 91-513).

<sup>39</sup> *Id.* (*emphasis added*).

The following month during another Senate debate<sup>40</sup> on the same bill, Senator Thurmond (R-SC) stated,

‘Mr. President, even though we have spent a great deal of time and effort in formulating this legislation to control dangerous substances such as marihuana, *we actually know little about marihuana. Even the experts are in conflict as to its nature and potential for harm.* Since the use of marihuana has become a phenomenon in present day American society, we should learn as much as possible about its nature.

Therefore, title VIII provides for the establishment of a committee of experts to study all aspects of marihuana and its use. The Attorney General and the Secretary of HEW are authorized to appoint this committee, and it shall conduct an *extensive examination into the medical and social aspects of its use.* This study must be completed within 2 years, at which time a report shall be made to the President and to Congress.’<sup>41</sup>

During the same Senate debate, Senator Dole (R-KS) reiterated the need for an objective review of the cannabis plant:

‘One other aspect of the bill deserves special mention. Title VIII establishes a blue-ribbon committee to study marihuana. *Phenomenally increased marihuana use in recent years has not been accompanied by a comparable increase in our understanding of the drug. Many social, medical, and legal problems can be traced to this deficiency. An authoritative, comprehensive, and unemotional investigation of marihuana is a matter of high national importance,* for we can only begin to deal effectively with this drug when we have a *fundamental grasp of all its potentials for good and for ill.*’<sup>42</sup>

The following is an excerpt of another Senate debate on the same bill regarding the role and purpose of the Committee on Marihuana by Senator Hughes (D-IA) and the general state of the affairs concerning the plant:

‘Mr. Hughes: Mr. President, title VIII of S. 3246 establishes a Committee on Marihuana, which is directed to review the available information on marihuana use, carry out studies in this area, and within 24 months submit a comprehensive report on its findings, together with its recommendations as to the nature of the controls which should be exercised over the use of marihuana. As you know, Mr. President, *a number of bills* have been introduced in both Houses to establish some form of independent commission or committee of experts to evaluate and make recommendations concerning marihuana use.

The fact that an estimated 8 to 10 million Americans have used this drug makes the appointment of such a committee a matter of vital concern. There is an unquestionable need to evaluate the scientific information, *which is available,* about the use and effects of this drug. *We also need to reappraise the efficacy of traditional enforcement efforts to deter marihuana use. There has been ample testimony before committees of the Congress that our current techniques for dealing with marihuana use have failed.* Certainly the mechanism of using an impartial commission or

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<sup>40</sup> Congressional Record-Senate, 26.Jan.1970, Senate debate on the Controlled Dangerous Substances Act of 1969, pp. 1159-1183.

<sup>41</sup> *Id.*, p. 1182 (*emphasis added*).

<sup>42</sup> *Id.*, p. 1183 (*emphasis added*).

committee is a useful way to reevaluate our stance in this area. However, I have a number of concerns about the Committee on Marihuana established by S. 3246.

...

Mr. President, I am also concerned that the mandate given by this title of S. 3246 will result in inefficient and unnecessary duplication of efforts which are already underway. Specifically, Health, Education and Welfare *has already devised and is implementing an extensive program of research in the area of marihuana*. As the Senator from Colorado (Mr. Dominick) pointed out on the Senate floor on December 1, Health, Education and Welfare currently *has underway or has recently completed over 65 research projects* in this area. HEW witnesses have testified that given adequate fiscal support, this target of research efforts will begin to produce new knowledge concerning the use and effects of marihuana within 2 years. I would prefer seeing this program expedited rather than having us develop a brandnew [sic] parallel effort.<sup>43</sup>

Also of interest is a House Report<sup>44</sup> that was issued in September of 1970 on the House counterpart bill reiterating the degree of misinformation on the plant that was being perpetuated. The below chart on fable and fact was created by Dr. Stanley F. Yolles, who was the Director of the National Institute of Mental Health:<sup>45</sup>

‘The extent to which marihuana should be controlled is a subject upon which opinions diverge widely. There are some who not only advocate its legalization but would encourage its use; at the other extreme there are some States which have established the death penalty for distribution of marihuana to minors. During the hearings, Dr. Stanley F. Yolles, who was the Director of the National Institute of Mental Health, submitted a chart of fable and fact concerning marihuana.’

That chart is presented below as Figure A.

#### **FIGURE A: DR. STANLEY F. YOLLES CHART OF FABLE AND FACT CONCERNING MARIHUANA**

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<sup>43</sup> Senate floor debate on the Controlled Dangerous Substances Act of 1969, Congressional Record, January 28, 1970, p. 1637 (*emphasis added*).

<sup>44</sup> House Report No. 91-1444 (Part 1), Comprehensive Drug Abuse Prevention and Control Act of 1970, Report of the Committee on Interstate and Foreign Commerce, House of Representatives Together with Individual Views To Accompany H.R. 18583, pp. 12-13, 10.Sept.1970, 91<sup>st</sup> Congress, 2d Session.

<sup>45</sup> *Id.*, pp.12-13.

## MARIHUANA

FABLE	FACT
1. Marihuana is a narcotic.	1. Marihuana is not a narcotic except by statute. Narcotics are opium or its derivations (like some synthetic chemicals with opium-like activity).
2. Marihuana is addictive.	2. Marihuana does not cause physical addiction, since tolerance to its effects and symptoms on sudden withdrawals does not occur. It can produce habituation (psychological dependence).
3. Marihuana causes violence and crime.	3. Persons under the influence of marihuana tend to be passive. It is true that sometimes a crime may be committed by a person while under the influence of marihuana. However, any drug which loosens one's self-control is likely to do the same and relates primarily to the personality of the user.
4. Marihuana leads to increase in sexual activity.	4. Marihuana has no aphrodisiac property.
5. Marihuana is harmless.	5. Instances, of acute panic, depression, and psychotic states are known, although they are infrequent. Certain kinds of individuals can also become over-involved in marihuana use and can lose their drive. We do not know the effects of long-term use.
6. Occasional use of marihuana is less harmful than occasional use of alcohol.	6. We do not know. Research on the effects of various amounts of each drug for various periods is underway.
7. Marihuana use leads to heroin.	7. We know of nothing in the nature of marihuana that predisposes to heroin abuse. It is estimated that less than 5% of chronic users of marihuana go on to heroin use.

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FABLE	FACT
8. Marihuana enhances creativity.	8. Marihuana might bring <i>fantasies</i> of enhanced creativity but they are illusory, as are "instant insights" reported by marihuana users.
9. More severe penalties will solve the marihuana problem.	9. Marihuana use has increased enormously in spite of the most severely punitive laws.
10. It is safe to drive while under the influence of marihuana.	10. Driving under the influence of any intoxicant is hazardous.

In the bill as recommended by the administration and as reported by the committee, marihuana is listed under schedule I, as subject to the most stringent controls under the bill, except that criminal penalties applicable to marihuana offenses are those for offenses involving nonnarcotic controlled substances.

The committee requested recommendations from the Department of Health, Education, and Welfare concerning the appropriate location of marihuana in the schedules of the bill, and by letter of August 14, 1970 (printed in this report under the heading "Agency Reports"), the Assistant Secretary for Health and Scientific Affairs recommended "that marihuana be retained within schedule I at least until the completion of certain studies now underway."

In addition, section 601 of the bill provides for establishment of a Presidential Commission on Marihuana and Drug Abuse. The recommendations of this Commission will be of aid in determining the appropriate disposition of this question in the future.

The chart of fable and fact that was prepared by Dr. Yolles in 1970 – now nearly 50 years on - is still remarkably accurate. Two noteworthy examples: Firstly, the ‘Fact’ as identified by Dr. Yolles that marihuana is not a gateway substance to heroin use (Number 7). The gateway theory has long had skeptics; however, the theory was widely circulated and used in support of continuing the scheduled status of the plant. Fortunately, the theory is now more universally accepted as debunked as is reflected by the U.S. Drug Enforcement Agency’s (DEA) recent removal of such statements from its website.<sup>46</sup> To the contrary that cannabis is a gateway substance, contemporary data and evidence has been shown to actually support the role of cannabis in treating addiction.<sup>47</sup> Secondly, the ‘Fact’ that ‘serious punitive laws’ are not effective in addressing the use and availability of cannabis (Number 9). Now available are years of data to support the accuracy of this Fact that was set forth in 1970.<sup>48</sup>

The same House Report includes a letter from the Department of Health, Education and Welfare (HEW) that underscores the ‘void’ of knowledge about the cannabis plant and the loss of knowing on how to classify the plant – if at all- reads as follows:

’August 14, 1970

Hon. Harley O. Staggers, Chairman Committee on Interstate and Foreign Commerce, House of Representatives, Washington, D.C.

Dear Mr. Chairman: In a prior communication, comments requested by your committee on the scientific aspects of the drug classification scheme incorporated in H.R. 18583 were provided. *This communication is concerned with the proposed classification of marihuana.*

It is presently classed in schedule I(C) along with its active constituents, the tetrahydrocannabinols and other psychotropic drugs.

Some question has been raised whether the use of the plant itself produces “severe psychological or physical dependence” as required by a schedule I or even schedule II criterion. *Since there is still a considerable void in our knowledge of the plant and effects of the active drug contained in it*, our recommendation is that marihuana be retained within schedule I at least until the completion of certain studies now underway to resolve this issue. If those studies make it appropriate for the Attorney General to change the placement of marihuana to a different schedule, he may do so in accordance with the authority provided under section 201 of the bill.

We are advised by the Office of Management and Budget that there is no objection to the presentation of this report from the standpoint of the administration’s program.

Sincerely yours, Roger O. Egeberg, M.D., Assistant Secretary for Health and Scientific Affairs.’<sup>49</sup>

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<sup>46</sup> Americans for Safe Access. [DEA Removes Marijuana Misinformation from Website After Months of Public, Legal Pressure](#). 13.Feb.2017 (as posted on site 06.Oct.2018, 10:29 a.m.).

<sup>47</sup> PubMed, U.S. National Library of Medicine National Institutes of Health: Philippe Lucas et al., *Substituting Cannabis for Prescription Drugs, Alcohol and other Substances among Medical Cannabis Patients: The Impact of Contextual Factors*, 35 *DRUG ALCOHOL REV.* 326-333 (2016). doi: 10.1111/dar.12323. Epub 2015 Sep 14.

<sup>48</sup> American Civil Liberties Union, [Marijuana Arrests by the Numbers](#). (as posted on site, 06.Oct.2018 at 10:49 a.m.). The material posted on the site captures data from 2001-2010; The Washington Post, [More people were arrested last year over pot than for murder, rape, aggravated assault and robbery- combined](#). Ingraham, Christopher. 26.Sept.2017.

<sup>49</sup> See House Report No. 91-1444, p. 61. Letter dated 14.Aug.1970 (*emphasis added*).

**Point being**, the above excerpts demonstrate there was great uncertainty as to what type of controls (if any) needed to be placed on the plant. The overall sense was to place cannabis on Schedule 1 contingent upon further instruction from the Commission on Marihuana and Drug Abuse (Commission).<sup>50</sup> Hence by default and as a temporary placement, cannabis was included on Schedule I of CSA until the Commission completed a comprehensive review of the plant.

The Commission that Congress was to rely upon was charged with conducting a comprehensive study on marihuana and to subsequently submit a report with policy recommendations to the President. The exact charge was as follows:

‘(d) (1) The Commission shall conduct a study of marihuana including, but not limited to, the following areas:

- (A) the extent of use of marihuana in the United States to include its various sources of users, number of arrests, number of convictions, amount of marihuana seized, type of user, nature of use;
- (B) an evaluation of the efficacy of existing marihuana laws;
- (C) a study of the pharmacology of marihuana and its immediate and long-term effects, both physio- logical and psychological;
- (D) the relationship of marihuana use to aggressive behavior and crime;
- (E) the relationship between marihuana and the use of other drugs; and
- (F) the international control of marihuana.

...

(e) The Commission shall conduct a comprehensive study and investigation of the causes of drug abuse and their relative significance. The Commission shall submit to the President and the Congress such interim reports as it deems advisable and shall within two years after the date on which funds first become available to carry out this section submit to the President and the Congress a final report which shall contain a detailed statement of its findings and conclusions and also such recommendations for legislation and administrative actions as it deems appropriate. The Commission shall cease to exist sixty days after the final report is submitted under this subsection.’<sup>51</sup>

The Commission consisted of thirteen members, of which *nine were appointed by President Nixon*, and two Members of the Senate were appointed by the President of the Senate and two Members of the House of Representatives were appointed by the Speaker of the House of Representatives. The Commission completed a comprehensive report in 1972 and this report is commonly referred to as the 1972 Shafer Commission Report (Report)<sup>52</sup> since the chair of the Commission was former Pennsylvania Governor Raymond P. Shafer.

Overall, the tone of the Shafer Report was one of caution yet clearly dispelled the several myths about the plant that were being rampantly circulated among lawmakers and the public. The Report was comprehensive and methodical in its analysis of marihuana and the impact on society. The wording of the 22.Mar.1972 letter from the Chairman of the Commission to President Nixon and Congress that accompanied the Report, was indicative of the pragmatic and non-hysterical approach in developing the Report:

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<sup>50</sup> The Commission on Marihuana and Drug Abuse was created under the Controlled Substances Act, §601, in 1970; Pub. L. 91-513 as amended by Pub. L. 92-13, 14.May.1971.

<sup>51</sup> Pub. L. 91-513, §601(d, e).

<sup>52</sup> *A Signal of Misunderstanding*, First Report of the National Commission on Marihuana and Drug Abuse (March 1972); *Drug Use in America: Problem in Perspective* (1973).

‘Whatever the facts are we have reported them. Wherever the facts have logically led us, we have followed and used them in reaching our recommendations. We hope this Report will be a foundation upon which credibility in this area can be restored and upon which a rational policy can be predicated.’<sup>53</sup>

In rendering its findings, the Commission considered individual freedoms, the actual risk of harm of the cannabis plant, and measures that are considered to be in the broader best interests of society. The 200 plus page Report noted that, “Any psychoactive drug is potentially harmful to the individual, depending on the intensity, frequency and duration of use. Marijuana is no exception.”<sup>54</sup> However, the Report also noted that the concern for the risk of harm from cannabis lies in the ‘heavy, long-term use of the drug, particularly of the most potent preparations’ - in part, because heavy users tend to use drugs other than marijuana.<sup>55</sup> The Commission went on to note that the ‘predominant pattern of use in the United States is experimental or intermittent use of less potent preparations of the drug.’<sup>56</sup>

The following is an excerpt of the Shafer Report addressing the Commission’s finding of a lack of causal relationship between the use of marijuana and crime:

‘In sum, the weight of the evidence is that marijuana does not cause violent or aggressive behavior; if anything, marijuana generally serves to inhibit the expression of such behavior.’<sup>57</sup>

‘In essence, neither informed current professional opinion nor empirical research, ranging from the 1930’s to the present, has produced systematic evidence to support the thesis that marijuana use, by itself, either invariably or generally leads to or causes crime, including acts of violence, juvenile delinquency or aggressive behavior. Instead the evidence suggests that sociolegal and cultural variables account for the apparent statistical correlation between marijuana use and crime or delinquency.’<sup>58</sup>

‘We conclude that some users commit crimes more frequently than non-users not because they use marijuana but because they happen to be the kinds of people who would be expected to have a higher crime rate, wholly apart from the use of marijuana. In most cases, the differences in crime rate between users and non-users are dependent not on marijuana use *per se* but on these other factors.

In summary, although the available evidence suggests that marijuana use may be statistically correlated with the incidence of crime and delinquency, when examined in isolation from the other variables, *no valid evidence was found to support the thesis that marijuana, by itself, either inevitably, generally or even frequently causes or precipitates the commission of crime, including acts of violence, or juvenile delinquency.*

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<sup>53</sup> National Commission on Marijuana and Drug Abuse, Letter from Chairman Raymond P. Shafer to President Nixon and Members of Congress, dated 22.Mar.1972, accompanied the Report titled, ‘*Marijuana, A Signal of Misunderstanding.*’

<sup>54</sup> *Id.* (Signal of Misunderstanding, March 1972, p. 65)

<sup>55</sup> *Id.*, p. 66, 96.

<sup>56</sup> *Id.*, p. 166.

<sup>57</sup> *Id.*, p. 73.

<sup>58</sup> *Id.*, p. 76.



Within this framework, *neither the marihuana user nor the drug itself can be said to constitute a danger to public safety*. For, as two researchers have so cogently stated for the Commission, “Whatever an individual is, in all of his cultural, social and psychological complexity, is not going to vanish in a puff of marihuana smoke.”<sup>59</sup>

The Commission also concluded that the use of marihuana did not necessarily lead to use of harder drugs, and that small amounts of cannabis should be decriminalized. Interestingly, the Commission did not explicitly recommend a reclassification of marihuana from Schedule 1 of the CSA. The sense of the Commission was to not encourage use, and hence, marihuana should continue to be classified as contraband. However, the Commission did recommend that personal use of marihuana should no longer be an offense, and that ‘casual distribution’ of marihuana for no (or an insignificant amount of) remuneration should no longer be an offense.<sup>60</sup>

The Commission recommended continued research: into the therapeutic benefits of the plant and specifically cited investigations for the treatment of glaucoma, migraine, alcoholism, and terminal cancer;<sup>61</sup> and into methods to detect impairment, which were underway at the time by the Department of Transportation and other federal agencies.<sup>62</sup>

The Shafer Report concluded with:

‘We have carefully analyzed the interrelationship between marihuana the drug, marihuana use as a behavior, and marihuana as a social problem. Recognizing the extensive degree of misinformation about marihuana as a drug, we have tried to *demythologize* it. Viewing the use of marihuana in its wider social context, we have tried to *desymbolize* it.

Considering the range of social concerns in contemporary America, marihuana does not, in our considered judgment, rank very high. We would *deemphasize* marihuana as a problem.

The existing social and legal policy is out of proportion to the individual and social harm engendered by the use of the drug. To replace it, we have attempted to design a suitable social policy, which we believe is fair, cautious and attuned to the social realities of our time.’<sup>63</sup>

**In sum**, as the above excerpts from Congressional records indicate, the initial treatment of marihuana in the CSA in 1970 was contingent upon the Commission’s review and report on the plant- and at the conclusion, ‘make recommendations with respect to the degree of control to be exercised over marihuana use.’<sup>64</sup> Even though President Nixon appointed nine of the 13 members of the Commission, ultimately, the President declined to follow the recommendations of the Commission and in effect, continued on a path almost completely counter to the Commission’s pragmatic recommendations. Once again remarkably, the findings of the Report are just now being implemented in the U.S. some 45 plus years from the date the Commission issued the policy recommendations.

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<sup>59</sup> *Id.*, p. 77-78 (*emphasis added*).

<sup>60</sup> *Id.*, p. 152.

<sup>61</sup> *Id.*, p. 176.

<sup>62</sup> *Id.*, p. 175.

<sup>63</sup> *Id.*, p. 167.

<sup>64</sup> House Report 91-1444, Part 1, 91<sup>st</sup> Congress, 2d Session, p. 66, as stated in a 14.Apr.1970 letter from the Department of Health, Education, and Welfare to Chairman Staggers, Committee on Interstate and Foreign Commerce, House of Representatives.

## 1961, 1971 Conventions

Another interesting backstory is the international scheduling of cannabis under the 1961 Single Convention on Narcotic Drugs, and the 1971 Convention on Psychotropic Substances (collectively referred to as the Conventions). The Conventions are two of the leading international treaties on drugs, abuse and trafficking, of which the U.S. is a signatory to – and bound by – both treaties.

Cannabis is currently a scheduled substance under the Conventions, which has provided an additional ‘out’ for stateside regulators in addressing any serious reforms to policy on cannabis. However, in 2014, the Expert Committee on Drug Dependence (ECDD) – the committee within the World Health Organization (WHO)<sup>65</sup> that reviews substances and makes scheduling recommendations – made a critical discovery. The ECDD reported to the WHO – which is the organization that makes recommendations to the UN on which substances should be subject to international control that:

‘cannabis had never been subject to pre-review or critical review by the ECDD.’<sup>66</sup>

The importance of this discovery cannot be overstated and highlights the convoluted treatment of the plant. These two Conventions are under the purview of the United Nations Office on Drugs and Crime (UNODC), and more specifically, the Commission on Narcotic Drugs (CND) within UNODC. WHO – based on the work of the ECDD – makes recommendations to CND regarding which narcotic drugs and psychotropic substances should be placed under international control. Fortunately, the ECDD made the discovery and was transparent about the finding that cannabis had never been properly vetted to support the initial scheduling- and perhaps most importantly, to support the continued scheduled status of the plant.

The ECDD is ‘an independent group of experts in the field of drugs and medicines’ that ‘assesses the health risks and benefits of the use of psychoactive substances’, and during the ECDD 36<sup>th</sup> Meeting in 2014, the ECDD made the following discovery:

*‘After World War II, WHO became responsible for the health functions of the League of Nations. The Expert Committee on Drugs Liable to Produce Addiction, later called the Expert Committee on Addiction-Producing Drugs (and today called the ECDD) spoke out against the medical use of cannabis repeatedly (e.g. fifth (1955), 11th (1960), 14th (1965) and 16th Meetings (1968)). However, in none of these cases was there a review of the dependence-producing properties of the substance. WHO published a literature review on the physical and mental effects of cannabis in 1955, which was prepared by a former WHO staff member for the Commission on Narcotic Drugs. However, it is not clear if this report was discussed by the Expert Committee on Drugs Liable to Produce Addiction, because it is not mentioned or cited in the Expert Committee’s reports.*

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<sup>65</sup> ‘The World Health Organization (WHO) is the specialized agency of the United Nations that conducts the medical, scientific and public health evaluation of psychoactive substances under the Single Convention on Narcotic Drugs, 1961 (the 1961 Convention), as amended by the 1972 Protocol, and the Convention on Psychotropic Substances, 1971 (the 1971 Convention).’ WORLD HEALTH ORGANIZATION, *Guidance on the WHO review of psychoactive substances for international control* (2010), p.7.

<sup>66</sup> *International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; Cannabis Plant and Resin; Extracts and Tinctures of Cannabis; Delta-9-Tetrahydrocannabinol; Stereoisomers of Tetrahydrocannabinol; Cannabidiol; Request for Comments*. U.S. Federal Register, Vol. 83, No. 68, 09.Apr.2018.

Because of their inclusion in the 1925 Opium Convention, cannabis and cannabis resin were included in Schedule I of the Single Convention on Narcotic Drugs. When the Schedules of the Single Convention were drawn up, the Expert Committee on Addiction-Producing Drugs stated that it “believed that the composition of the schedules [on the draft list for the Single Convention] should be most carefully reviewed before they become an established part of the new Convention”. However, the Expert Committee’s tenth report only mentions that substances in Schedule III were reviewed individually. *No reference can be found to a review of cannabis and/or its resin.* The Expert Committee’s 13th Report also mentions a review of substances for the Single Convention, but again, *no specific reference to a review of cannabis or cannabis resin is made.*<sup>67</sup>

...

In the last fifteen years, many countries have allowed the medical use of cannabis. Its current scheduling in Schedule IV is *based on the assumption that there is little or no therapeutic role for cannabis.*<sup>67</sup>

Per the ECDD in 2014:

‘Cannabis and cannabis resin has not been scientifically reviewed by the Expert Committee since the review by the Health Committee of the League of Nations in 1935.’<sup>68</sup>

Rather remarkably, after eight plus decades of the cannabis plant being a scheduled substance, there is an acknowledgement on the failure of a proper assessment. Since the discovery by the ECDD in 2014, the ECDD has undertaken such review which in brief, is a two-prong analysis. The first is a pre-review of the substance and if the data from the pre-review analysis meets the criteria then the substance (i.e., the cannabis plant) advances to a critical review.

The purpose of a pre-review is ‘to determine whether current information justifies an Expert Committee critical review’ and shall ‘recommend a critical review if it finds that information may justify the scheduling or a change in the scheduling of the substance in the 1961 or 1971 Conventions ...’<sup>69</sup> The categories of information collected and researched under a pre-review are the same as that for a critical review; however, a final determination to control a substance is not made at the pre-review stage.

On July 23, 2018, the WHO Director-General provided an update on the pre-review process. The ECDD recommended that *cannabidiol (CBD), a constituent of the cannabis plant, should not be scheduled under the Conventions,*<sup>70</sup> and that the other four substances of interest (i.e., cannabis plant and

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<sup>67</sup> [Cannabis and cannabis resin, Information Document, Agenda item 8.2](#), Expert Committee on Drug Dependence, Thirty-sixth Meeting, Geneva, 16-20 June 2014, World Health Organization. pp. 3-4 [*emphasis added*].

<sup>68</sup> Expert Committee on Drug Dependence, [Cannabis and cannabis resin Information Documents](#), World Health Organization, Thirty-six meeting, Geneva, 2014.

<sup>69</sup> [WORLD HEALTH ORGANIZATION, Guidance on the WHO Review of Psychoactive Substances for International Control](#) (2010), p.10.

<sup>70</sup> Regulators and law makers frequently point to the restrictions under the Conventions as the reason behind any meaningful policy reform on cannabis. However, an interesting timeline is currently unfolding on cannabidiol (CBD), and the long-term implications are yet to be determined. In May of 2018, the U.S. FDA issued a letter to the U.S. DEA recommending that cannabidiol (CBD) be moved to Schedule V of the CSA, citing the Conventions as to why CBD must remain scheduled. In [June of 2018 the FDA approved Epidiolex](#), a pharmaceutical of a purified cannabidiol for the treatment of ‘seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome.’ In July of 2018, the ECDD recommended CBD not be a scheduled substance, of which the Commission on Narcotic Drugs (CND, within the UN) was slated

resin, extracts and tinctures of cannabis, delta-9 THC, and isomers of THC) should advance to a critical review phase.<sup>71</sup>

The purpose of a critical review is ‘to consider whether the Expert Committee should advise the Director-General to recommend the scheduling of, or amending of the scheduling status of, a substance.’<sup>72</sup> The critical review will provide comprehensive evidence-based data on the following categories:

1. substance identification by International Nonproprietary Name (INN), chemical or other common name and trade names, other identifying characteristics, Chemical Abstracts Service (CAS) registry number;
2. chemistry, including general information on synthesis, preparation and properties;
3. ease of convertibility into controlled substances;
4. general pharmacology, including pharmacokinetics and pharmacodynamics;
5. toxicology,
6. adverse reactions in humans;
7. dependence potential;
8. abuse potential;
9. therapeutic applications, extent of therapeutic use and epidemiology of medical use;
10. listing on the WHO Model List of Essential Medicines;
11. marketing authorizations (as a medicine);
12. industrial use;
13. non-medical use, abuse and dependence;
14. nature and magnitude of public health problems related to abuse and dependence;
15. illicit production, consumption and international trade;
16. illicit manufacture and traffic, and related information;
17. current international controls and their impact;
18. current and past national controls;
19. other medical and scientific matters relevant for a recommendation on the scheduling of the substance.<sup>73</sup>

The ECDD convened on November 12-16, 2018, to undertake the critical review of the cannabis plant and resin, extracts and tinctures of cannabis, delta-9 THC, and isomers of THC. The implications from ECDD’s recommendations could be vast. As referenced in this paper, several countries and several states within the U.S. have established regulated cannabis markets and a recommendation from the ECDD - and adoption of same by CND - that is counter to the established premise of these regulated markets (i.e., products within the regulated frameworks are safe) could create considerable market confusion.

In January of 2019, the WHO issued a letter to the Secretary-General of the UN addressing the review of cannabis and cannabis-related substances. Largely, the WHO recommendations include a change in the level of control of cannabis such as, cannabis and cannabis resin should be deleted from Schedule IV of

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to consider this recommendation in March of 2019 in Vienna during their annual meeting; however, the CND delayed the vote to allow Member States additional time for consideration. In [September of 2018, the DEA announced the CBD FDA-specific formulation will be moved to Schedule V of the CSA](#). 2019 may bring exciting news – and perhaps meaningful shifts with the current dated policy.

<sup>71</sup> [World Health Organization letter](#) to the Secretary-General of the United Nations dated 23 July 2018, (*emphasis added*).

<sup>72</sup> [WORLD HEALTH ORGANIZATION](#), *Guidance on the WHO Review of Psychoactive Substances for International Control* (2010), p. 11.

<sup>73</sup> *Id.*

the 1961 Convention, extracts and tinctures to be deleted from Schedule I, while THC would be added to Schedule I. Furthermore, of note, WHO recommended that ‘Preparations containing predominantly cannabidiol and not more than 0.2 percent of delta-9-tetrahydrocannabinol are not under international control.’ The complete recommendations are found in the Jan.2019 WHO letter and the Feb.2019 CND summary.<sup>74</sup>

These recommendations were slated for consideration by CND during its March of 2019 meeting; however, there was a delay in the consideration and a date certain to reconvene has yet to be established at the time of this article.

Aside from the Conventions, of relevance and to provide further context of the political climate surrounding the cannabis plant in the late 19<sup>th</sup> through late 20<sup>th</sup> centuries, several expert reports were prepared for British as well as U.S. federal and state commissions.<sup>75</sup> There have also been other international conventions and treaties with references to cannabis.<sup>76</sup> Point being, the cannabis plant has been a substance of global interest and the subject of extensive debates for decades. This plant is not a novel substance.

### *State-driven initiatives*

Just as the medical community shifted in its attitude towards botanicals in the early 20<sup>th</sup> century, the U.S. was also facing strong political currents as it entered the era of prohibition. Several states had outlawed alcohol in the early 1900s which resulted in alcohol prohibition on the federal level from 1920 until 1933, when the 18<sup>th</sup> Amendment was repealed by the 21<sup>st</sup> Amendment. Once the prohibition of alcohol was repealed in 1933, interests shifted over the next several decades towards drugs, which included ‘marihuana.’

Interestingly, as the states are leading the contemporary effort to liberate the plant, it was the state-led initiatives in the early 1900s that initially prohibited cannabis and eventually prompted federal restrictions. Starting in 1937, ‘marihuana’ – which included the industrial hemp chemotype – became the subject of various federal statutes including the Marihuana Tax Act. As noted in a House Report at that time, there were several inaccurate beliefs on the use of the cannabis plant and the impact on society:

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<sup>74</sup> [World Health Organization letter to Secretary-General of the United Nations, 24.January.2019](#); Commission on Narcotic Drugs, Implementation of the international drug control treaties: changes in the scope of control of substances, [Changes in the scope of control of substances: proposed scheduling recommendations by the World Health Organization on cannabis and cannabis-related substances](#). E/CN.7/2019/12, 01.February.2019.

<sup>75</sup> The Indian Hemp Commission Report of 1894 was produced by a committee formed to study the use of ‘ganja’ in India at the direction of British officials. The seven-volume, three-thousand plus page report found no correlation between the use of ganja and “moral injury” among other similar type findings; *The La Guardia Committee Report: The Marihuana Problem in the City of New York*, Mayor’s Committee on Marihuana, by the New York Academy of Medicine (1944). The report was prepared by a committee of doctors and scientists from the New York Academy of Medicine and refuted the claims that the use of cannabis resulted in violence and that cannabis was a gateway substance. The Report also recommended further research into the medicinal properties of the plant; 1967 (February), *The Challenge of Crime in a Free Society*, authored by President Johnson’s Commission on Law Enforcement and Administration of Justice (now referred to as the Katzenbach Commission), recommended continued research on all aspects of marihuana by the National Institutes of Mental Health; 1973-78: *Marijuana and Health Reports*, U.S. Department of Health, Education and Welfare; *Marijuana A Study of State Policies & Penalties*, National Governors’ Conference Center for Policy Research and Analysis, November 1977.

<sup>76</sup> 1912 Hague International Opium Convention; Geneva International Opium Convention 1925; Geneva Convention for Limiting the Manufacture and Regulating the Distribution of Narcotic Drugs, 1931; Geneva Convention for Suppression of Illicit Traffic in Dangerous Drugs, 1936; and United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988.

‘Under the influence of this drug the will is destroyed and all power of directing and controlling thought is lost. Inhibitions are released. As a result of these effects, it appeared from testimony produced at the hearings that many violent crimes have been and are being committed by persons under the influence of this drug. Not only is marihuana used by the hardened criminals to steel them to commit violent crimes, but it is also being placed in the hands of high-school children in the form of marihuana cigarettes by unscrupulous peddlers. Cases were cited at the hearings of school children who have been driven to crime and insanity through the use of this drug. Its continued use results many times in impotency and insanity.’<sup>77</sup>

These beliefs continued for the next several decades on both the state and federal level until the CSA came into effect in 1970, which included cannabis on Schedule 1 - the most restrictive of the 5 available schedules. From the mid-1960s forward, state-initiatives reversed course from the strict prohibition mindset towards the cannabis plant and engaged in another decades-long effort to either decriminalize the plant, reduce criminal penalties for a small possession of the plant or enact medical programs.

The state-led efforts to correct the regulatory course of the cannabis plant over the span of 50 plus years did experience incremental successes along the way although the first notable break-through came in 1996.

The first state-regulated medical cannabis program was enacted in 1996 in California via Proposition 215, the Compassionate Use Act.<sup>78</sup> Proposition 215 (Prop 215) was truly groundbreaking in light of the decades long misinformation being disseminated by the federal government, the harsh criminal penalties for possession of Cannabis that were in place on both the state and federal level, and the various pro-prohibition interests engaged on the state level. The path to success for the Compassionate Use Act was neither easy nor straight-forward. Even after the passage of Prop 215, California continued to experience resistance from players within the state and on the federal level. Fortunately, activists and patients on the ground in California were steadfast in their resolve to ensure the patient-physician relationship was respected. The years-long effort to implement Prop 215 frequently included arrests, incarceration and litigation.

California set the foundation – and perhaps gave permission – for other states to follow Prop 215’s now chartered territory. Subsequent state measures were achieved through both ballot initiatives and legislative efforts.

The second most notable regulated market was enacted in 2012 when the citizens of Colorado voted on Amendment 64. The ballot initiative provided the guardrails for a state-regulated adult-use market. As with California’s medical cannabis program, resistance and skepticism surrounded Amendment 64; however, the initiative prevailed, and Colorado launched its adult-use program 14 months after Amendment 64 passed.

Since 2012, the number of states that have implemented medical cannabis and adult-use programs has soared. Data may be a considerable driver behind the proliferation of the regulated markets. Certainly, the

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<sup>77</sup> Commission on Marihuana, March 1972, p. 105, referencing 1937 House Report to Ways and Means Committee.

<sup>78</sup> The first compassionate use scenario was actually established at the federal level in 1978 during the presidency of Jimmy Carter. The Compassionate Investigational New Drug program was ended in 1991 by President George H.W. Bush, although the surviving patients were grandfathered into the program and continued to receive cannabis grown at the University of Mississippi in Oxford, Mississippi. The contract with the University of Mississippi funds the growing, harvesting and storage of cannabis. It also funds potency monitoring and other services for the DEA. See National Institute on Drug Abuse (NIDA). Provision of Marijuana and Other Compounds For Scientific Research - Recommendations of The National Institute on Drug Abuse National Advisory Council (January 1998).

lack of data to demonstrate that a regulated market will result in an uptick in social harms – as suggested by the opposition – has been critical in advancing the regulated industry’s agenda. Additionally, the demonstrated financial cost to communities and the enforcement of failed drug policies have highlighted the need for fiscal responsibility. Perhaps most impactful have been the countless personal testimonies shared by patients, caretakers and doctors on the role cannabis has played in medical treatments. With access to contemporary data and powerful stories, politicians and regulators appear to now have the capacity and interest to study and view cannabis through a modern lens, which means to objectively look at the science behind the plant without the hyperbole and hysteria of the ‘reefer madness’ propaganda campaigns.<sup>79</sup>

The unique dynamic in the U.S. now includes a majority of the country living in a jurisdiction with some type of a regulated cannabis market even though the substance remains federally scheduled under the CSA.

### *Cannabis as Part of the Broader Botanical Industry*

The cannabis plant has endured several challenging and negative influences; however, one beneficial influence for the plant has been from the broader botanical industry.<sup>80</sup> Since the time of the so-called ‘herbal renaissance’ in the U.S., starting in the early 1970’s a rekindling of interest in plant-based remedies and products blossomed and became mainstream by the 21<sup>st</sup> century. In this timeframe a legal framework for the clinical practice of medical herbalism, for example by Licensed Acupuncturists (L.Ac.) and Naturopathic Doctors (N.D.), came into force in nearly every state.

To parallel the implementation of legal frameworks for the clinical practice of medical herbalism, the U.S. market also experienced an increase in consumer demand and interest in natural products. The natural products category has been on a steady incline trajectory over the past several decades and has exploded in the past 10 years.

For example, one of the more prominent natural product categories is the dietary supplement category. The dietary supplement industry is valued at close to a \$50 billion a year industry in 2018, with an overall economic impact on the U.S. economy of \$122 billion in 2016.<sup>81</sup> The botanical-based supplement products within this category surpassed \$8 billion in 2017<sup>82</sup> and show no sign of slowing. As noted in a 2018 article on herbal supplement sales,

‘Strongest sales growth in more than 15 years bolstered by continued popularity of Ayurvedic herbs and new formulations of botanicals with general health and nutrition benefits.’<sup>83</sup>

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<sup>79</sup> *Reefer Madness* was a film distributed in the mid-1930s and depicted individuals in a state of complete hysteria after consumption of cannabis. The term ‘reefer madness’ now connotes the pure propaganda based on complete misinformation that was disseminated throughout the U.S. over the last several decades.

<sup>80</sup> The broader botanical industry is inclusive of companies that manufacture and market plant-based cosmetic products, dietary supplement products, food and beverage products, and medical food products.

<sup>81</sup> [\*Economic Impact of the Dietary Supplement Industry\*](#), as reported by the Council for Responsible Nutrition in Jun.2016. [\*2016 Economic Impact of the Dietary Supplement Industry, Methodology and Documentation\*](#).

<sup>82</sup> The Journal of the American Botanical Council, *Herbalgram*, Number 119 July-Sept 2018, pp. 62-71, citing SPINS | IRI data.

<sup>83</sup> *Id.*



Another natural products category that is experiencing hyper-growth is the plant-based foods and beverages category. This industry is currently valued at \$3.3 billion<sup>84</sup> with year-over-end significant growth. This category includes meat and cheese alternatives, non-dairy beverages, tofu, and other vegan-type products. Other natural product categories include, plant-based cosmetics (personal care products) which accounted for \$11.5 billion in global retail sales in 2017,<sup>85</sup> apparel (hemp and bamboo clothing), and hemp-based building materials to name a few.

Several drivers behind the growth of the natural products market include:

- a) a better understanding of the nexus between flavorants, colorants, preservatives, fillers and food allergies, food sensitivities;
- b) the availability of environmental impact data from the conventional food industry,
- c) the awareness of the inhumane treatment of animals in the conventional agricultural model,
- d) failures of conventional pharmacotherapy (e.g., extensive side effects, treatment of the symptoms not the condition, high costs, overprescribing, and medical errors; a Johns Hopkins study reports that medical errors are now the third leading cause of death in the U.S.<sup>86</sup>).

In light of above considerations, consumers look for alternatives and fortunately, the marketplace has provided viable alternatives at an approachable price point. When given a choice, a growing number of consumers opt for the ‘natural’ and plant-based products that are perceived to be a healthier option for their bodies and friendlier to the earth.<sup>87</sup>

The cannabis plant and cannabis-based products are now part of the broader botanical industry. The regulated cannabis industry can benefit from the momentum of the broader botanical industry and perhaps most importantly, the cannabis industry can look to the expertise and learned experiences from the broader botanical industry on topics that range from how best to cultivate, test, and handle plant material. The cannabis industry can also look to the regulatory and market place challenges previously faced by the broader botanical industry to better understand how to avoid or overcome these challenges (e.g., supply chain integrity).

### *Global Regulated Market*

Another data point to further understand the influences on the U.S. regulated cannabis market is the global market, which is well underway. The global regulated cannabis market is comprised of heavily funded and cutting-edge research, a nascent import-export trade of finished product and raw material, and robust international stock exchanges. Estimates on the current and potential size of the global market vary considerably depending, in part, on assumptions of speed of expected changes in regulatory frameworks, and, in part, on inclusion criteria, i.e., which level of the value chain from raw material to extracts and derivatives to finished products. A 2017 *Forbes* article conservatively estimated the global legal market at

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<sup>84</sup> Nielsen Retail Sales Data, 52-week period ending June.2018, [as reported by the Plant Based Foods Association](#); Nielsen Retail Sales Data, 52-week period ending 12.Aug.2017, as reported by the [Plant Based Foods Association](#); [Plant-based Food Options are Sprouting Growth for Retailers](#), as reported by Nielsen on 13.Jun.2018.

<sup>85</sup> [Global Natural & Organic Personal Care Market 2018-2026: Growth Trends, Key Players and Competitive Strategies](#), PR Newswire (Jul. 02, 2018, 09:00 ET), <https://www.prnewswire.com/news-releases/global-natural--organic-personal-care-market-2018-2026-growth-trends-key-players-and-competitive-strategies-300675255.html>

<sup>86</sup> Martin Makary & Michael Daniel, *Medical Error—the Third Leading Cause of Death in the US*, 353 *BMJ* (2016).

<sup>87</sup> For example, an estimated 80% of aquatic pharmaceutical pollution comes from medicines used at home via urinary excretion. Corrinne Burns, *What Happens to the Excreted Drugs you Flush Down the Toilet?* [THE GUARDIAN](#) (Aug. 8, 2014, 02.00 EDT), <https://www.theguardian.com/science/blog/2014/aug/08/drugs-toilet-pharmaceutical-pollution>

\$8 billion.<sup>88</sup> A February 2019 *Bloomberg* article reported that New York-based investment bank Jefferies Group LLC, assigned an estimated value of the current global legal cannabis market at US\$12.3 billion, and the global illicit market at between US\$150 billion to US\$200 billion.<sup>89</sup> A May 2019 report by Grand View Research stated that the “global legal marijuana market size was estimated at USD 13.8 billion in 2018 and is projected to expand at a CAGR of 23.9% by 2025.”<sup>90</sup>

The global regulated market is comprised of countries that offer a wide range of markets from limited medical cannabis programs where the medicine can only be obtained with a valid prescription from a physician to full adult-use programs. The global market is as much of a patchwork as the U.S. regulated market.

Germany is at the forefront of the medical cannabis market share and Uruguay is leading the experiment as the first country to allow adult-use of the plant. There are currently over 30 countries with medical programs, including Australia, Canada, Czechia, Israel, Italy, Jamaica, and the Netherlands. The stakeholders in the global market have also experienced challenges and for the most part, have successfully navigated these challenges as their programs and individual markets become more mature.

The recent shift in international policies toward cannabis has been notable and has accelerated the global growth. For example, prior to Canada enacting a national adult-use program in 2018,<sup>91</sup> a comprehensive report was conducted by Health Canada to assess the viability; in part, the report concluded as follows:

‘Despite enforcement efforts under these treaties, cannabis remains the most widely used illicit drug in the world. Although the ultimate aim of the drug treaties is to ensure the “health and welfare of humankind,” there is growing recognition that cannabis prohibition has proven to be an ineffective strategy for reducing individual or social harms, including decreasing burdens on criminal justice systems, limiting negative social and public health impacts, and minimizing the entrenchment of illicit markets, which in some cases support organized crime and violence. Thus, a growing number of governments are interested in alternative approaches to cannabis control that promote and protect the health, safety and human rights of their populations.’<sup>92</sup>

This shift in policy can be seen in other countries as well as they continue to move away from a prohibition era mindset into a regulated market especially for medical or therapeutic uses. The following provides a glimpse of four global counterparts as a flavor on the range of global regulated markets.

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<sup>88</sup> Mona Zhang, [The Global Marijuana Market Will Soon Hit \\$31.4 Billion But Investors Should Be Cautious](#), Forbes (Nov. 7, 2017, 08:00 AM); Reuters, [Hot Stocks, 23.Jan.2018](#).

<sup>89</sup> David George-Cosh, [Global cannabis market could be worth up to US\\$130B by 2029](#); Jefferies, BNN Bloomberg (Feb. 25, 2019).

<sup>90</sup> GRAND VIEW RESEARCH, [Legal Marijuana Market Size, Share & Trends Analysis Report By Type \(Medical Cannabis, Recreational Cannabis\), By Product Type, By Medical Application \(Cancer, Mental Disorders\), And Segment Forecasts, 2019 – 2025](#), May 2019.

<sup>91</sup> HEALTH CANADA, the *Cannabis Act* (S.C. 2018, c. 16) went into effect on 17.Oct.2018.

<sup>92</sup> *A Framework for the Legalization and Regulation of Cannabis in Canada. The Final Report of the Task Force on Cannabis Legalization and Regulation*, November 30, 2016. Health Canada, Government of Canada.

## Germany

Germany has long been a leader with botanicals and botanical-based medicines for cultural reasons. In Germany, botanical drugs have never been considered alternative medicine but rather have always been an integral part of healthcare. Use of cannabis as a therapeutic agent in Europe was first documented in the 18<sup>th</sup> century. But it was not until 1830 that the first known comprehensive account of its therapeutic uses in Europe were documented by German pharmacist and botanist Friedrich Ludwig Nees von Esenbeck (1787-1837).<sup>93</sup>

One of the factors that propelled Germany to lead the medical cannabis industry is the fact that Germany has a very long history of developing pharmacopoeial standards for the testing of herbal drug identity and quality in pharmacies. For example, in the 18<sup>th</sup> century, monographs for ‘Cannabis sativae seminis’ (Cannabis seed/fruit) were included in several German state pharmacopoeias such as the first edition of the Württembergian ‘*Pharmacopoea Wirttembergica*’ in 1741,<sup>94</sup> and the Prussian ‘*Pharmacopoea Borussica*’ published in 1799.<sup>95</sup> In 1872, the first German national pharmacopoeia, ‘*Pharmacopoea Germanica*’ was published, which included monographs for ‘Fructus Cannabis’ (hemp seed), ‘Herba Cannabis Indicae’ (Indian hemp; flowering tops of female plants), ‘Tinctura Cannabis Indicae’ (tincture of Indian hemp herb), and ‘Extractum Cannabis Indicae’ (thick, viscous extract of Indian hemp herb).<sup>96</sup>

In 2016, in view of pending new legal requirements for medical use of cannabis in Germany, new *German Drug Codex* (DAC) monographs, describing pharmaceutical quality cannabis flowers and refined and standardized cannabis oleoresin,<sup>97</sup> with advanced analytical methodologies, were developed by the Federal Union of German Associations of Pharmacists (ABDA) in collaboration with the German Federal Institute for Drugs and Medical Devices (BfArM). At the same time, near identical quality standards monographs were developed by the German Pharmacopoeia Commission for 2017 publications in the official *German Pharmacopoeia* (DAB).<sup>98</sup>

In March of 2017, Germany enacted a comprehensive medical cannabis program where patients could now receive a prescription for use of the plant and obtain the medicine from a pharmacy (versus obtaining an exemption from BfArM), and companies could domestically cultivate the plant. One nimble characteristic of the program was that BfArM allowed the legal import of product until German cultivators were able to produce quality cannabis. Germany’s medical cannabis market also allows insurance reimbursement which may have played a role in building a robust market.

Even though Germany has considerable experience in the regulation and marketing authorization of botanical-based medicinal products (i.e., anthroposophical, balneotherapeutic, homoeopathic, well-established-use herbal medicinal products, and traditional herbal medicinal products), Germany was not the first to the global medical cannabis market. However, due to Germany’s established reputation in

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<sup>93</sup> THEODOR FRIEDRICH LUDWIG NEES VON ESENBECK & CARL HEINRICH EBERMAIER, *HANDBUCH DER MEDICINISCH-PHARMAZEUTISCHEN BOTANIK* (1830); Manfred Fankhauser, *CANNABIS AS MEDICINE IN EUROPE IN THE 19TH CENTURY*, IN: EMCDDA, *A CANNABIS READER: GLOBAL ISSUES AND LOCAL EXPERIENCES*, MONOGRAPH SERIES 8, VOLUME 1, 5-14 (2008).

<sup>94</sup> *PHARMACOPOEA WIRTTENBERGICA* 64 (1741).

<sup>95</sup> *PHARMACOPOEA BORUSSICA* 61 (1799).

<sup>96</sup> HERMANN HAGER, *PHARMACOPOEA GERMANICA. DEUTSCHE PHARMAKOPÖE*, 113, 164, 180 (1872).

<sup>97</sup> *DEUTSCHER ARZNEIMITTEL CODEX / NEUES REZEPTUR-FORMULARIUM* (DAC/NRF) (2016)

<sup>98</sup> Michael Hörmig, *Die DAC-Monographie „Cannabisblüten“ - The DAC monograph „Cannabis flowers“*, 5 *PHARMAKON* 130-136 (2017).

working with plants, once Germany enacted a regulated medical market, other countries have followed suit.<sup>99</sup>

## *Uruguay*

In 2013, Uruguay enacted Law N°. 19,172 and became the first country to legalize and regulate a national adult-use market which allows the purchase of non-medical cannabis product from either a pharmacy, a cannabis club, or via a home grow. Under the program, Uruguay permits the cultivation, distribution and consumption of cannabis by those 18 and over.<sup>100</sup> In large part, the program has been a success and continues to evolve to address market challenges.

As the first country to enact an adult-use program, Uruguay caught the attention of and faced pushback from the International Narcotics Control Board (INCB). The INCB is the compliance watchdog over international drug treaties. As noted in the INCB's 2016 Report,

‘Once again, the Board wishes to draw the attention of all Governments that measures permitting the non-medical use of cannabis are contrary to the provisions of the international drug control conventions, specifically article 4, paragraph (c), and article 36 of the 1961 Convention as amended by the 1972 Protocol, and article 3, paragraph 1(a), of the 1988 Convention. INCB also reiterates that the limitation of the use of controlled substances to medical and scientific purposes is a fundamental principle that lies at the heart of the legal framework for international drug control, and admits no exception.’<sup>101</sup>

Yet Uruguay persisted.

Another challenge faced by stakeholders in the regulated market in Uruguay occurred in August of 2017 when Bank of America and Citibank took a highly publicized action against the stakeholders.<sup>102</sup> Due to the U.S. federally scheduled status of cannabis, traditional banking institutions have been reluctant to engage with the U.S. regulated industry. A global ramification of this occurred when U.S. banks issued cease and desist letters to the banks in Uruguay that serviced the pharmacies that sold cannabis products. The U.S. banks cited that by engaging with these pharmacies the Uruguayan banks were in violation of the, *Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (USA Patriot Act) Act of 2001*.<sup>103</sup> To avoid having their bank accounts closed, the pharmacies either stopped selling cannabis products or turned to operating in cash. Thus far, Uruguay is the only country that has reported receiving cease and desist letters from U.S. banks.

## *Jamaica*

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<sup>99</sup> Denmark, 01.Jan.2018 launched a medicinal Cannabis pilot program under the [Danish Medicines Agency](#).

<sup>100</sup> Uruguay, Ley No. 19.172, [http://archivo.presidencia.gub.uy/sci/leyes/2013/12/cons\\_min\\_803.pdf](http://archivo.presidencia.gub.uy/sci/leyes/2013/12/cons_min_803.pdf).

<sup>101</sup> International Narcotics Control Board. [Report of the International Narcotics Control Board for 2016](#), Chapter III, B. p. 68, paragraph 535.

<sup>102</sup> US News, [Uruguay's Experience With Its Marijuana Law](#), *A U.S. anti-terrorism law passed after 9/11 is acting as a financial blockage to wider use*. Tegel, Simeon. 22.Jun.2018, 9:42 a.m.; The New York Times, *Pot Was Flying Off the Shelves in Uruguay*. Then U.S. Banks Weighed In., Londoño, Ernesto, 25.Aug.2017.

<sup>103</sup> [PUBLIC LAW 107-56](#)—Oct. 26, 2001.

In 2015, as a result of the decriminalization of cannabis use in Jamaica, the Cannabis Licensing Authority (CLA), a new agency of the Ministry of Industry, Commerce, Agriculture and Fisheries, was established with the following specific mandates:<sup>104</sup>

- To create regulations to guide the development of an orderly legal ganja and hemp industry in Jamaica, for the use of the plant and its by-products for medical, therapeutic and scientific purposes.
- To ensure that regulations created and activities within the industry are in keeping with Jamaica's international obligations.
- To issue licenses, permits and authorisation for the handling of hemp and ganja.

By May of 2016, regulations were passed providing for an interim cannabis licensing regime under the authority of the Jamaica CLA to function “until more fulsome regulations are made.”<sup>105</sup> Two of the attractive traits from this market include an unlimited number of licenses for the variety of business categories and both Jamaican citizens and tourists have access to medical cannabis.

### *Canada*

Canada enacted a medical cannabis program in 2001,<sup>106</sup> and in 2013, Health Canada outlined information for health care professionals on the therapeutic uses of cannabis and cannabinoids that covered a wide range of conditions from arthritis to psychiatric disorders. Evidence was found to be effective in treating several of the reviewed conditions to include, chemotherapy-induced nausea and vomiting, epilepsy, multiple sclerosis, spinal cord injury, pain states (acute and chronic), increase in appetite, palliative care and sleep disorders.<sup>107</sup> Canada's acceptance of cannabis as a medicine is not surprising as Health Canada has long had a framework to license natural products,<sup>108</sup> which included a compendium of hundreds of monographs<sup>109</sup> for both single ingredient (i.e., *Arnica montana* L. (Asteraceae)) and product specific (i.e., diaper rash products).

Canada has also captured global attention because as of June 2018, Canada became the second country in the world to fully legalize adult-use cannabis with the passage of Bill C-45, the Cannabis Act, by the Senate of Canada.<sup>110</sup>

‘The Cannabis Act creates a strict legal framework for controlling the production, distribution, sale and possession of cannabis across Canada. The Act aims to accomplish 3 goals:

- keep cannabis out of the hands of youth
- keep profits out of the hands of criminals

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<sup>104</sup> CANNABIS LICENSING AUTHORITY JAMAICA, Overview (2016), <http://cla.org.jm/about/overview>

<sup>105</sup> THE DANGEROUS DRUGS (CANNABIS LICENSING) (INTERIM) REGULATIONS, 2016, CXXXIX The Jamaica Gazette Supplement. Proclamations, Rules and Regulations (May 5, 2016).

<sup>106</sup> Health Canada, Marihuana Medical Access Regulations (2001), subsequently replaced by the Access to Cannabis for Medical Purposes Regulations (2016).

<sup>107</sup> HEALTH CANADA, INFORMATION FOR HEALTH CARE PROFESSIONALS: CANNABIS (MARIHUANA, MARIJUANA) AND THE CANNABINOIDS (2013), [http://www.hc-sc.gc.ca/dhp-mps/alt\\_formats/pdf/marihuana/med/infoprof-eng.pdf](http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/marihuana/med/infoprof-eng.pdf)

<sup>108</sup> Health Canada's Natural Health Products Directorate (NHPD) recently underwent a reorganization | modernization and is now referred to as the Natural and Non-prescription Health Products Directorate (NNHPD).

<sup>109</sup> Health Canada, [Listing of Monographs](#), retrieved from site 13.Oct.2018 at 9:51 a.m. ET.

<sup>110</sup> SENATE OF CANADA, Bill C-45, the Cannabis Act (2018), <https://sencanada.ca/en/sencaplus/news/cannabis-act/>

- protect public health and safety by allowing adults access to safe, legal cannabis.’<sup>111</sup>

Canada’s adult-use program launched on 17.Oct.2018, and thus, the details, successes, and anticipated litigation from the adult-use program have yet to be seen. Canada is currently home to a very dynamic cannabis stock market and as more countries enter the global sector, its long-term ranking has yet to be determined.

**In sum**, the global regulated cannabis market may be young *per se*; however, the market is thriving. A few key considerations that have allowed such growth in the overall global market include, research is easier to conduct on foreign soil than in the U.S., and in turn, easier to develop valuable intellectual property portfolios. At times, research is even government-driven such as in Israel. Most countries outside the U.S. have access to banking resources, which translates to the establishment of energetic stock exchanges and merger-acquisition transactions. Finally, even with certain restrictions on the import-export of cannabis material (product) among the global community, the restrictions are workable and great market opportunities have been created.

The global community has also had the benefit of observing jurisdictions with regulated medical cannabis programs and realizing that the result of these regulated medical markets has not been disastrous. The U.S. (via California since 1996) has provided 20 plus years of empirical data, and Canada has provided 15 plus years of observation. During this time, patients have benefited from having access to medical cannabis and economic opportunities have been created. The success of the medical markets has further signaled – with caution – that a regulated adult-use market is possible.

As the above Section II identifies, the road to the 2019 regulated Cannabis market has been anything but straightforward and there have been several influences that helped pave the road for today’s regulated cannabis industry.

### III. PROPOSED STATE-FEDERAL FRAMEWORK

The public and political sentiment toward cannabis within the United States has changed dramatically over the past several years. The United States has a vibrant regulated cannabis industry that has been built on more than 46 intrastate markets. Today’s emergent regulated landscape is a new consideration when discussing how best to approach contemporary cannabis policy. Because the United States has a robust regulated intrastate cannabis market — where a majority of the country’s population now resides in a jurisdiction with some type of regulated market — the conversation is ripe to review federal cannabis policy.

Understanding the historic, albeit winding, road to 2019 provides useful guidance as to what the map to the future could look like. Similar to female hop (*Humulus lupulus*, Cannabaceae) flowers that are used in therapeutic products such as sleep aids and alcoholic beverages such as beer,<sup>112</sup> the cannabis plant possesses various psychoactive, physiological, and therapeutic properties. Therefore, this paper sets forth the position that the plant should be subject to an appropriate regulatory framework rather than as a controlled substance under the Controlled Substances Act (CSA). The proposed framework also sets forth a limited federal interface to ensure minimal disruption to the existing state-regulated industry, with the

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<sup>111</sup> GOVERNMENT OF CANADA, DEPARTMENT OF JUSTICE, *Cannabis Legalization and Regulation* (2018), <http://www.justice.gc.ca/eng/cj-jp/cannabis/>

<sup>112</sup> ZHENGYI WU, ZHE-KUN ZHOU & BRUCE BARTHOLOMEW. Cannabaceae. In: Wu ZY, Raven PH, Hong DY, eds. *FLORA OF CHINA*. Vol 5. Science Press, Beijing, and Missouri Botanical Garden Press, St. Louis; 2003:74-75.

states retaining a majority of control over their respective programs. The states should also remain active participants in developing the direction of US cannabis policy. The proposed framework is designed to advance both innovation and inclusion by incorporating forward-thinking principles to ensure the regulated industry is diverse and allows access to all interested stakeholders. Finally, the framework allows entry into the global market, fosters responsible use, and subjects the market to minimal federal standards and technical assistance (for crop quality assurance and export marketing support) as needed to support the long-term integrity of the regulated industry.

### *States Retain Autonomy*

The proposed federal framework sets forth as a foundational premise that state interests must be protected and at the forefront. The stakeholders that faced the greatest risk by engaging in these state-authorized “laboratories of democracy” should reap the benefits from laying the foundation for a multi-billion dollar regulated industry that serves both patients and consumers.

The significant investments made by the individual states to enact their programs — coupled with the considerations that the state programs are comprehensive and have been generally successful — underscore the importance of a federal interface that causes minimal disruption to the existing regulated markets. As explained in Section IV, the market vulnerabilities faced by the industry due to the design of the individual state programs are being addressed on the state level, and other market vulnerabilities (e.g., market stability, production and marketing controls [referred to as “volume controls” in USDA guidelines], pesticide use, solvent use, etc.) could be resolved with technical assistance via the federal government. The federal interface would be less of a primary authoritative regulator and, instead, would provide the needed technical assistance for the state-regulated markets.

The proposed federal model allows individual states to decide if a regulated cannabis market is appropriate for their state. The only federal override of this measure is that a state must recognize a valid prescription for medical cannabis regardless if such state has implemented a regulated medical cannabis program. This mandate is included to resolve the issue of “patient refugees,” where patients seeking medical cannabis have relocated from their home jurisdiction that does not have a regulated medical program to a jurisdiction that does.

Thus, the individual state frameworks would largely remain intact, with the additional administrative responsibility of engagement with the federal interface and the advisory committee, both as defined below.

### *Federal Interface*

This proposed framework delegates primary federal oversight of the regulated cannabis market to the USDA. After reviewing the strengths and vulnerabilities of the intrastate markets, the authors of this article found that the most common need was technical assistance, which is a service already provided through USDA programs for other crops (e.g., hops).

Concerning cash commodity crops (e.g., food, cosmetics, fiber, and medicine), the USDA has the technical expertise to work with plant material and help create market stability for plant-based products. Because of this expertise, and that the USDA currently operates in all 50 states and US territories, it is the best-suited federal agency to work in collaboration with the relevant state regulatory agencies and the individual state stakeholders in the cannabis industry. Furthermore, the USDA has Cooperative Extension System offices situated in each land-grant university (LGU; there are one or more LGUs in each state and territory that provide a network of scientists, extension staff, and volunteers to carry out USDA programs) as well as Farm Service Agency offices operating in



each state.<sup>113</sup> The Agriculture Marketing Service (AMS) within the USDA is particularly well-suited to serve as the proposed federal interface.

The AMS was created in the late 1930s to facilitate “the efficient, fair marketing of US agricultural products, including food, fiber, and specialty crops.”<sup>114</sup> The AMS engages with industry-driven initiatives that support particular agricultural sectors with technical assistance. The reach of the expertise within AMS is vast and extends to both domestic and global markets. AMS is versed in specialty crops that are experiencing rapid growth, as is the case with cannabis. This growing sector would benefit from technical assistance to help stabilize the market. As noted by AMS on the role and value of its services:

‘AMS quality standards, grading, certification, auditing, and inspection are voluntary tools and services that industry can use to help promote and communicate quality and wholesomeness to consumers. These services assist businesses in differentiating themselves from their competition.

Examples of USDA grades include USDA Prime, USDA Grade A, and US No. 1. Annually, AMS grades, audits, certifies and/or inspects over \$150 billion worth of agricultural products, ensuring the quality of domestic goods and helping American farms and businesses export goods.’<sup>115</sup>

The services provided by AMS include:

- Establishing data collection practices
- Collecting production and price data
- Distributing statistical data
- Inspection services
- Establishing standards and quality grading systems
- Calculating supply and demand levels
- Marketing and branding efforts
- Research efforts
- Enforcement measures with impact
- Establishing good agricultural and collection practices (GACPs) for an industry
- Monitoring and facilitating import/export transactions
- Providing scientific and analytical support
- Monitoring pesticide use (the Environmental Protection Agency approves crop-specific pesticides for human and/or animal food crops)

One attractive consideration for the state-regulated cannabis industry to work with AMS is the expertise of AMS on how to position unique crops as regional specialties. This branding ability is highly desirable as a means to establish a single recognizable grading system and secure the place of US cannabis-based products in a rapidly developing global market. This type of branding, marketing, and development of standards will drive interest from investors and buyers for US products and, ideally, when the United States enters the global market, demand for US products will already exist. AMS possesses the requisite expertise in international market intelligence for exported crops, which should help US farmers secure market share prior to the United States’ entering the global market. AMS could facilitate the

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<sup>113</sup> *USDA Local Offices*, [www.outreach.usda.gov/USDALocalOffices.htm](http://www.outreach.usda.gov/USDALocalOffices.htm) (retrieved on 13.Apr.2019).

<sup>114</sup> *About AMS*, [www.ams.usda.gov/about-ams](http://www.ams.usda.gov/about-ams) (retrieved on 13.Apr.2019).

<sup>115</sup> *Services*, [www.ams.usda.gov/services](http://www.ams.usda.gov/services) (retrieved on 13.Apr.2019).

positioning of state-branded products (e.g., “California-grown”) from the US-regulated market as high-value regional specialty crops.

Another appealing trait of the AMS is its existing expertise to navigate multiple pathways to market for finished products. The regulated cannabis industry is composed of products for medical use and patient populations, adult-use and social consumers, and veterinary use for pets and livestock.<sup>116</sup> The USDA understands plant material and is able to develop programs that are tailored to the specific plant and end user(s).

Finally, several of the current state-regulated cannabis markets already include the state counterpart to USDA. Examples include the Utah Department of Agriculture and Food (“the agency responsible for implementing and enforcing many of the new cannabis-related laws”<sup>117</sup>) and the Oregon Department of Agriculture, which works with two other state agencies that are the lead regulators for Oregon’s medical and adult-use programs.<sup>118</sup> State departments of agriculture commonly address issues such as pesticide limits, fertilizer use, and cultivation practices.<sup>119,120,121</sup> The AMS is the obvious complement to state regulatory agencies.

The range of industries with which AMS engages is extensive and includes various fruits, cotton (*Gossypium* spp., Malvaceae), dairy products, eggs, lumber, plant oils, specialty crops (e.g., medicinal herbs), and vegetables. The relationship between AMS and the American ginseng (*Panax quinquefolius*, Araliaceae) root and spearmint (*Mentha spicata*, Lamiaceae) essential oil industries are prime examples of the inherent value that AMS can bring to an industry.

The American ginseng plant is used both in culinary and medicinal applications, and the marketplace is highly competitive to the point that federal legislation was introduced in 2002 that banned the use of the name “ginseng” in US commerce unless the plant material is from the genus *Panax*.<sup>122,123,124</sup> The AMS currently works with ginseng producers in Wisconsin and has developed grading standards for American ginseng and Asian ginseng (*P. ginseng*). The US standards for quality grades of cultivated ginseng roots developed by AMS are fit for purpose<sup>125</sup> and have helped create a

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<sup>116</sup> Edie Lau, [Cannabis for veterinary patients gets research attention, funding. Stigma begins to lift but legal questions persist](#), *VIN News Service*. March 29, 2018.

<sup>117</sup> UTAH DEPARTMENT OF AGRICULTURE AND FOOD. [Cannabis Laws](#) (retrieved from UDAF site on 08.Oct.2018 at 3:57 p.m.)

<sup>118</sup> OREGON DEPARTMENT OF AGRICULTURE. [Cannabis \(marijuana\)](#) (retrieved from ODA site on 08.Oct.2018 at 4:36 p.m.)

<sup>119</sup> WASHINGTON STATE DEPARTMENT OF AGRICULTURE. *Pesticide and Fertilizer Use for the Production of Marijuana in Washington*, <https://agr.wa.gov/pestfert/pesticides/pesticideuseonmarijuana.aspx> (retrieved on 13.Apr.2019)

<sup>120</sup> ILLINOIS DEPARTMENT OF AGRICULTURE. *Medical Cannabis Pilot Program - Frequently Asked Questions*, <https://www2.illinois.gov/sites/mcpp/ Documents/mcppfaq-Updated-2-19-15.pdf> (retrieved on 13.Apr.2019)

<sup>121</sup> COLORADO DEPARTMENT OF AGRICULTURE. *Cannabis Pesticide Education*, [www.colorado.gov/pacific/agplants/cannabis-pesticide-education](http://www.colorado.gov/pacific/agplants/cannabis-pesticide-education) (retrieved on 13.Apr.2019).

<sup>122</sup> SENATE AND HOUSE OF REPRESENTATIVES OF THE UNITED STATES OF AMERICA. *Farm Security and Rural Investment Act of 2002, Public Law 107-171, §10806(b), Ginseng Labeling*. Washington, DC: US Government Publishing Office; May 13, 2002.

<sup>123</sup> UNITED STATES DEPARTMENT OF AGRICULTURE. 7 CFR § 65.145 - Ginseng. In: *Code of Federal Regulations*. Washington, DC: US Government Printing Office; 2018.

<sup>124</sup> OFFICE OF THE LAW REVISION COUNSEL. 21 USC 343: Misbranded food. In: *United States Code*. Washington, DC: US House of Representatives; 2018.

<sup>125</sup> United States Department of Agriculture, the [United States Standards for Grades of Cultivated Ginseng](#), 07.May.2012.

dynamic marketplace. The net result is that ginseng marketed with a “Wisconsin Ginseng Seal®” fetches a premium in foreign markets, particularly in the People’s Republic of China. The Ginseng Board of Wisconsin is managed by an elected board of seven Wisconsin ginseng producers. The board functions under a marketing order managed by the Wisconsin Department of Agriculture, Trade & Consumer Protection.<sup>126</sup>

Spearmint is another popular plant with culinary and therapeutic applications that is cultivated in various regions of the United States. AMS has engaged with producers of spearmint in Idaho, Oregon, Nevada, Utah, and Washington. The producers are organized under the Far West Spearmint Oil Administrative Committee, and AMS is authorized to support research and promotion programs, and volume control (supply and demand). Accounting for more than 50% of total global production of spearmint oil, the northwestern United States (the “Far West”) is the premier spearmint-producing area in the world.<sup>127</sup>

The previous two examples provide a preview of the potential benefits for a single-crop industry. The regulated cannabis industry would benefit greatly from a defined grading structure, and possible marketing order volume controls,<sup>128, 129</sup> among the other services offered by AMS.

Additionally, the illicit market will continue to thrive until the price point within the regulated cannabis market is approachable. Access to a quality product in a regulated market is critical for reducing (and ultimately eliminating) the illicit market.

It is also relevant that USDA has played a supportive role for industrial hemp farmers in different states in the past. The *Yearbook of the United States Department of Agriculture 1895*, for example, provided guidance to farmers on agricultural methods for the *Cannabis sativa* crop.<sup>130</sup> It is worth noting that the state of Kentucky was the predominant industrial hemp-farming state in the 19th century and, in the summer of 2018, US Senate Majority Leader Mitch McConnell of Kentucky pushed to allow more US farmers to grow hemp legally, which could play a role in meeting the production demands for high-value cannabidiol (CBD). Most Kentucky growers are already geared toward CBD production as opposed to growing hemp as a fiber crop.<sup>131</sup> The USDA understands and has the plant expertise for both industrial hemp and the cannabis plant. AMS will reengage with hemp farmers in 2019, as the 2018 Farm Bill (Section 10113) directs the USDA to issue regulations and guidance for a commercial hemp production program.

Logistically, under AMS guidelines, the cannabis plant would be considered a specialty crop, and the cost for states to partner with AMS would be absorbed by the state regulatory agencies and stakeholders. The AMS is currently structured to engage with an industry on a voluntary basis;

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<sup>126</sup> GINSENG BOARD OF WISCONSIN (GBW), [www.ginsengboard.com/](http://www.ginsengboard.com/) (retrieved on 09.Oct.2018 at 2:10 p.m. ET)

<sup>127</sup> FAR WEST SPEARMINT OIL ADMINISTRATIVE COMMITTEE, *Marketing Order*, [www.farwestspearmint.org/marketing-order.html](http://www.farwestspearmint.org/marketing-order.html) (retrieved on 09.Oct.2018 at 2:59 p.m. ET)

<sup>128</sup> Jane Wells, Washington has more pot than it can smoke. *CNBC.com*, 11.Feb.2015.

<sup>129</sup> Matt Stangel & Katie Shepherd . Oregon Grew More Cannabis Than Customers Can Smoke. Now Shops and Farmers Are Left With Mountains of Unwanted Bud. It turns out Oregonians are good at growing cannabis—too good. *Willamette Week*. 18.Apr.2018.

<sup>130</sup> YEARBOOK OF THE UNITED STATES DEPARTMENT OF AGRICULTURE 1895, 198-199, 215-222 (1896).

<sup>131</sup> Amanda Chicago Lewis, *Mitch McConnell: Drug Warrior. CBD Champion?*, *Rolling Stone*, June 29, 2018 7:12PM ET, <https://www.rollingstone.com/politics/politics-features/mitch-mcconnell-drug-warrior-cbd-champion-667089/>

however, under the proposed framework, engagement with AMS by the states that have regulated markets would be a mandate.<sup>132</sup>

The eight-decade-long evolution of US cannabis regulation largely has been defined by the unjustified treatment and a lack of willingness by federal authorities to either correct course or objectively review evidence on the plant. Due to this history, the authors sought viable alternatives outside the FDA to take the lead as the federal interface. However, the key deciding factor to structure the proposed framework within the USDA was the department's breadth of expertise, specifically within the AMS, in working with plants and crops. The state programs have existing infrastructures, and the AMS is equipped to engage with these existing state markets via regulatory agencies and individual stakeholders to create long-term market stability while continuing to drive innovation without over-commercialization.

### *Advisory Committee*

An elected advisory committee (AC) is envisaged to act as the authoritative intermediary between the states and the federal interface. It is further proposed that the AC should consist of nine individuals, with seven representatives from the state perspective (including industry stakeholders) and two from the federal perspective, at least one of whom must be from the AMS. The AC would serve as experts of the regulated cannabis industry and field inquiries and concerns from state and federal stakeholders.

The AC would be responsible for:

- adopting or establishing baseline quality and laboratory standards, scientifically valid analytical methods — possibly in collaboration with the United States Pharmacopeia (USP), American Herbal Pharmacopoeia (AHP), AOAC International, NSF International, or ASTM International — and minimum labeling requirements;
- creating a national educational message/tagline/symbol (e.g., “Smart Colorado”); and
- establishing social equity measures that merge innovation and inclusion (e.g., gender analysis on each policy issued).

The execution of the above three items will be instrumental in maintaining integrity in the regulated industry. Most importantly, an impactful educational campaign is critical for the responsible use of cannabis-based products and to thwart potential societal harms from uninformed consumption and misuse. Education is central to all industries and product categories; however, in light of the decades of misinformation about cannabis, a clear and sound educational message is all the more important.

Other areas of interest and concern that may be addressed by the AC include targeted research efforts, community re-investment measures, diversity and inclusion measures, and other social justice issues. The latter two have been addressed to varying degrees by local and state authorities; however, at a minimum, these matters could be referenced as part of the AC's charter. The AC must include the appropriate expertise and balance of perspectives to ensure the US-regulated cannabis market is as robust as possible while continuing to honor and support the existing state platforms.

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<sup>132</sup> At a minimum, a state's engagement with AMS would be a mandate prior to global entry.

## *Diversity and Small Business Provision*

The regulated industry was built by individual efforts that over time joined forces in garnering support for a reasonable path forward. Today, the domestic and global regulated cannabis industry is experiencing hyper-growth. With such growth, promises of high returns on investments are rampant, which in turn has attracted larger players to seize the potential benefits. However, the efforts that built the industry must be considered when developing the path forward.

As a measure to ensure the industry maintains diversity and a range of business sizes, the proposed federal framework will include a section to protect and secure an opportunity for these interests to remain competitive in the regulated market. Furthermore, the inclusion of a provision to protect the roles of diversity and small businesses in the regulated industry is another means of honoring the existing individual state structures and the participating stakeholders and acknowledging the impact from the historic treatment of the plant.

Some municipalities, like Oakland, California, are experimenting with cannabis licensing scenarios that aim to address racial inequity and take into consideration the failed war on drugs that disproportionately incarcerated the impoverished and minority communities. As reported in *USA Today*, Oakland's "Equity Applicant" system "aims to help poor, longtime Oakland residents — including those with convictions for illegally selling marijuana — get started in a business that otherwise has remained stubbornly white, male and middle class across the USA."<sup>133</sup>

As such, the city of Oakland now requires that at least half of all cannabis permits for cultivators, delivery-only dispensaries, distributors, testing laboratories, manufacturers, and transporters must be issued to Equity applicants:

- Equity — Applicants who qualify for fee waivers plus technical and financial assistance based on income level and residential location or cannabis conviction.
- General — All other applicants. A General applicant who incubates an Equity applicant by providing them with three years of free rent and security measures, has priority over other General applicants.<sup>134</sup>

The success of these types of licensing scenarios<sup>135</sup> has yet to be fully realized; however, the Oakland program has met challenges in the early days of its program.<sup>136,137</sup> The advantage of local jurisdictions' retaining autonomy over the marketplace within their border is that experiments with different types of social equity models can be undertaken to find the most appropriate and effective path forward. A requirement in the federal framework that acknowledges the importance of these measures bolsters local and state efforts, which is the intended design of the federal framework.

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<sup>133</sup> Trevor Hughes, California City to Use Pot Shops to Fight Racial Inequities, *USA Today*, July 31, 2017, 3:06 a.m. ET, <https://www.usatoday.com/story/news/nation/2017/07/31/marijuana-oakland-california-shop-owners/507008001/>

<sup>134</sup> City of Oakland, California, City Administration, Cannabis Permits, 2018, <http://www2.oaklandnet.com/government/o/CityAdministration/cannabis-permits/index.htm>

<sup>135</sup> San Francisco is another example of a local jurisdiction with a social equity program. "San Francisco's Cannabis Equity Program is designed to lower barriers to cannabis licensing for those hardest hit by the War on Drugs." See San Francisco Office of Cannabis, retrieved from site on October 12, 2018: <https://officeofcannabis.sfgov.org/equity>.

<sup>136</sup> San Francisco Chronicle, [\*Oakland's marijuana equity program is hurting those it was supposed to help\*](#), 15.Jun.2018, Otis Taylor Jr.

<sup>137</sup> Reason, [\*Oakland's Weed Equity Program Not Helping Intended Recipients\*](#), 19.Jul.2018, Wolfe, Liz.

Also of interest, the term “small business” does not have a universal, accepted definition and has been in large part defined by individual industries. For example, the US Small Business Administration (SBA) develops size standards per economic activity sector or industry.<sup>138</sup> In addition to the number of employees and average annual receipts, the SBA requires a small business to meet several other criteria, including:

- being organized for profit,
- having a place of business in the United States,
- operating primarily in the US market or making a significant contribution to the US economy,
- being independently owned/operated, and
- not being dominant within one’s industry on a national level.

Depending on the industry, the SBA defines a small business as having no more than 1,500 employees and less than \$38 million in average annual receipts.

Another example of how small businesses can be defined is identified in regulations from a modern piece of legislation regarding food safety standards. Under the Food Safety Modernization Act (FSMA),<sup>139</sup> categories for “small businesses” and “very small businesses” were established to account for businesses with typically smaller budgets, fewer employees and resources, and limited bandwidth. Under FSMA, generally a small business is defined as a business with fewer than 500 employees.<sup>140</sup>

The primary point is that the term “small business” can go beyond a sole proprietor operating a business from her or his home. The range of parameters on how to define a small business is vast, and appropriate criteria to reflect the regulated cannabis industry will need to be identified by the AC. Possible measures for the AC to consider as a means to protect small businesses include a reduced tax rate, or additional tax credits for meeting the defined criteria of a small business. Measures that call for the reduction of or exemption from quality control standards should only be allowed if product integrity and safety are not compromised. The critical consideration is that small business interests are protected and that barriers to enter the market for smaller entities are not excessive.

### *Eligibility for Insurance Coverage*

Of great relevance is that data from the US-regulated programs support the eligibility of medical cannabis for insurance coverage. The 46-plus medical cannabis programs currently serve more than two million patients,<sup>141</sup> and the cost for the medicines received via the state programs has been absorbed 100% out-of-pocket by the patient. The individual patient has been paying out of pocket for her or his medical cannabis since 1996, when California enacted a medical program.

Since that time, data have suggested that regulated cannabis markets correlate with positive health outcomes and reduced health care costs:

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<sup>138</sup> 13 C.F.R. §121, Small Business Size Regulations.

<sup>139</sup> U.S. Food Safety Modernization Act, Public Law 111-353, 111<sup>th</sup> Congress (2011).

<sup>140</sup> Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food; Final Rule. FEDERAL REGISTER, 2015;80(180):55908-56168.

<sup>141</sup> *Medical Marijuana Access in the United States – A Patient-Focused Analysis of the Patchwork of State Laws*. 2018 Annual Report prepared by Americans for Safe Access.

- States with medical cannabis programs have a 25% lower opioid mortality rate.<sup>142</sup>
- Availability of medical cannabis has correlated with reductions in Medicare Part D spending.<sup>143</sup>
- Medical cannabis laws are associated with significant reductions in opioid prescribing in the Medicare Part D population.<sup>144</sup>

An example of data generated from a state-specific program with notable effect comes from the Minnesota medical cannabis program. Minnesota enacted a medical cannabis program in 2014 and is considered a fairly conservative program. Recently released data from the Minnesota Department of Health, the agency that oversees Minnesota’s medical cannabis program, demonstrated that patients with “difficult-to-control pain of moderate and high levels reported medical cannabis provided significant relief.”<sup>145,146</sup> The data also indicated a reduction or elimination of opioid use by half of the participants after six months of use of medical cannabis.

Opioids are commonly prescribed for pain<sup>147</sup> and, in light of the opioid crisis faced by the United States right now,<sup>148</sup> the promising early data on the use of medical cannabis for the treatment of pain are quite notable. This is even more true considering that more than 25 of the US medical cannabis programs list “pain” (with varying types of pain including moderate-to-severe, severe, chronic, intractable, and debilitating) as a qualifying condition. The use of medical cannabis instead of opioids for the treatment of pain continues to gain momentum on the state level as certain states even have enacted legislation as a means to reduce the use of opioids<sup>149</sup> or have expanded their existing medical cannabis programs to include qualifying conditions that could be treated with an opioid.<sup>150</sup>

Hence, medical cannabis programs appear to correlate with improved health outcomes and decreased health care costs. The above is one example that demonstrates the potential role of medical cannabis in the opioid crisis. The state programs have several qualifying conditions and there is a confidence among the scientific and medical community that other conditions can successfully be treated with cannabis. To date, medical cannabis has been established as a safe and effective treatment for certain conditions and thus should be eligible for insurance coverage.<sup>151,152</sup>

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<sup>142</sup> Marcus A. Bachhuber, Brendan Saloner, Chinazo O. Cunningham & Colleen L. Barry, Medical cannabis laws and opioid analgesic overdose mortality in the United States, 1999-2010, *JAMA INTERN MED.* 2014;174(10):1668-1673.

<sup>143</sup> Ashley C. Bradford & W. David Bradford, Medical marijuana laws reduce prescription medication use in Medicare Part D. *HEALTH AFF (MILLWOOD)*. 2016;35(7):1230-1236.

<sup>144</sup> Ashley C. Bradford, W. David Bradford, Amanda Abraham & Grace Bagwell Adams, Association between US state medical cannabis laws and opioid prescribing in the Medicare Part D population. *JAMA INTERN MED.* 2018;178(5):667-672.

<sup>145</sup> *Analysis: Medical cannabis users find pain reduction.* Zdechlik, Mark. 01.Mar.2018, *MPR News*.

<sup>146</sup> *What are we learning about medical marijuana?* Mulcahy, Mike & Erickson, Jo. 06.Mar.2018. *MPR News*.

<sup>147</sup> Deborah Dowell, Tamara M Haegerich & Roger Chou, CDC guideline for prescribing opioids for chronic pain — United States, 2016. *MMWR Recomm Rep.* 2016;65(No. RR-1):1-49. doi: <http://dx.doi.org/10.15585/mmwr.rr16501e15581>

<sup>148</sup> *US DEPARTMENT OF HEALTH AND HUMAN SERVICES. HHS Acting Secretary Declares Public Health Emergency to Address National Opioid Crisis.* 26.Oct.2017 (retrieved from HHS site, 12.Oct.2018, 1:47 p.m. ET).

<sup>149</sup> ABC 7 Eyewitness News, Chicago, *Rauner signs bill legalizing medical marijuana as opioid alternative*, 28.Aug.2018. Wall, Craig.

<sup>150</sup> *NEW YORK STATE DEPARTMENT OF HEALTH, New York State Department of Health Announces Opioid Replacement Now a Qualifying Condition for Medical Marijuana.* 12.Jul.2018.

<sup>151</sup> Caroline A. MacCallum & Ethan B. Russo, Practical considerations in medical cannabis administration and dosing. *EUR J INT MED.* 2018;49:12-19.

## *Scheduled Status of Cannabis*

With the implementation of a federal framework to interface with the existing state-regulated markets, the cannabis plant should be removed from the CSA. This proposed federal framework is not a legalization measure. Individual states retain the autonomy to determine what type of regulated market is appropriate for their individual state, and the proposed federal framework is structured to defer to the state-led initiatives. Both AMS and the AC will ensure that the state programs provide adequate instruction and oversight of cannabis-based products.

If a state does not have a regulatory framework that provides a pathway to bring a cannabis-based product to market, then such product would not be allowed in that jurisdiction but for the mandate to recognize a medical cannabis product that was obtained via a valid prescription in a jurisdiction with a regulated medical program.

Each of the five schedules of the CSA have certain criteria that must be met before a substance is placed in a schedule, and each schedule is based on the premise that there is a need to regulate a substance. As this article sets forth a proposed federal framework specific to cannabis-based products that are also subject to state regulatory models, there is no need for the cannabis plant to remain in any schedule of the CSA.

Even without a specific federal framework for cannabis-based products, the plant should not be included in Schedule I of the CSA. This is in part due to the lack of proper review of the plant before the plant was scheduled in 1970,<sup>153</sup> and, more importantly, the well-established medicinal value and safety profile of the plant. The criteria for a substance to be placed in Schedule I and II are:

(1) Schedule I. —

- The drug or other substance has a high potential for abuse.
- The drug or other substance has *no currently accepted medical use* in treatment in the United States.
- There is a *lack of accepted safety* for use of the drug or other substance under medical supervision.

(2) Schedule II. —

- The drug or other substance has a high potential for abuse.
- The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.
- Abuse of the drug or other substances *may lead to severe psychological or physical dependence*.<sup>154</sup>

As explained in the section of this paper titled “Evidence and Science of the Plant,” there is ample evidence to support the medical applications of the plant, and it has an accepted safety profile. The remaining schedules of the CSA are less restrictive than Schedules I and II, but they are still based on the premise that the substances need to be controlled. As stated, with a federal framework designed for cannabis-based products there is not a need for the plant to be scheduled.

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<sup>152</sup> NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE. *The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research* (2017).

<sup>153</sup> UNITED STATES COMMISSION ON MARIHUANA AND DRUG ABUSE. *Marihuana: A signal of misunderstanding; First report* (1972).

<sup>154</sup> 21 U.S.C. §812(b)(1), Schedule of Controlled Substances.



The pathway to market for cannabis-based products in the United States will be determined by the individual state frameworks, which are subject to the standards developed by the AC and the requirements identified by the AMS. The state-regulated pathway to market for cannabis-based products will coexist with the drug pathways under the FDA.

### *Funding mechanism*

Funding for the federal interface with AMS (and the AC, if needed) will be absorbed by the individual state programs.

### *Use of Technology*

As is practical, both the AMS and the AC are encouraged to use modern technology platforms to facilitate the tracking, collection, and analysis of data. Public health trends and additional therapeutic uses of cannabis can be determined with methodical monitoring and collection of data from the state-regulated markets. Blockchain is one example of modern technology that may facilitate review of real-time data. The concept of big data to better inform health research and patient outcomes is gaining momentum. Other types of analytic data are driving innovation to meet patient and consumer demands. The use of modern technologies to understand consumer and patient uses of the plant along with any impacts on society will be instrumental in keeping pace with burgeoning market influences (e.g., consumer demands, investment opportunities, global interests, and overall market growth).

In sum, the guardrails for the proposed framework are not overly prescriptive, yet are intended to provide adequate structure and substance to the federal interface to ensure the long-term vitality of the regulated cannabis industry.

## **IV. THE BASIS FOR THE PROPOSED FRAMEWORK**

The following considerations were taken into account in developing the proposed federal framework. In brief, this section explores a scientific assessment of the plant, the strengths and vulnerabilities of the intrastate markets, and the range of currently available regulatory pathways to market. These factors taken as a whole determined the role of the federal government.

As a starting point, what is the safety profile of the cannabis plant?

### *Evidence and Science of the Plant*

The cannabis plant is not novel in that the plant has considerable levels of scientific evidence to support a pathway to market. The cannabis plant has documented uses dating thousands of years.<sup>155</sup> One of the advantages of a lengthy recorded historic use of the plant – which is referred to as traditional use evidence- is that the traditional use evidence lays a foundation for a greater degree of contemporary confidence on the safety profile of the plant.

### *Traditional Use Evidence*

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<sup>155</sup> National Center for Complementary and Integrative Health, National Institutes of Health within U.S. Department of Health & Human Services, [landing page on website 24.Aug.2018](#); Claudius Galen, an influential Greek physician, second century AD, one suggested medical use was for ‘ears’ pains’.

One type of evidence to support the safety and efficacy of a plant is referred to as, ‘traditional use evidence.’ Herbal medicine – or plant-based medicines – is often supported by traditional use evidence due to the centuries of use:

‘Herbal medicines include herbs, herbal materials, herbal preparations and finished herbal products, that contain as active ingredients parts of plants, or other plant materials, or combinations. Traditional use of herbal medicines refers to the long historical use of these medicines. Their use is well established and widely acknowledged to be safe and effective, and may be accepted by national authorities.’<sup>156</sup>

Traditional use evidence can be captured in literature, scientific writings and pharmacopoeias. The traditional use evidence of the cannabis plant dates at least 3000 years.<sup>157</sup> Archaeobotanical literature provides evidence of cannabis flower used as a pharmacological agent from the excavation of a 2700-year-old grave of a shaman, buried with a large cache of cannabis, in the Gobi Desert, Xinjiang Uyghur Autonomous Region.<sup>158</sup> In another excavated tomb in the same region, estimated at 2800 to 2400 years old, thirteen nearly entire female cannabis plants were found as a burial shroud on the deceased, indicating ritual and/or medicinal use.<sup>159</sup> Indian, Chinese and Middle East cultures have documented uses dating thousands of years. In the ancient Indian system of healthcare known as Ayurveda (possibly one of the world’s oldest codified systems of medicine), cannabis preparations are used for treatment of ‘*agnimandya*’ (digestive impairment), ‘*anidra*’ (insomnia), ‘*atisara*’ (diarrhea), ‘*klaibya*’ (male impotence), and ‘*grahani roga*’ (malabsorption syndrome).<sup>160</sup>

In the Dravidian system of Siddha medicine, also one of the oldest systems of medicine recognized in India, cannabis preparations are used for treatment of ‘*orraitalaivali*’ (hemicranias/migraine), ‘*vantipeti*’ (vomiting and diarrhea), ‘*mikupaci*’ (excessive appetite), ‘*narampuvali*’ (neuralgia), ‘*perumpatu*’ (menorrhagia), and ‘*kakkirumal*’ (whooping cough).<sup>161</sup> In China, the premodern classic ‘*Shen Nong Ben Cao Jing*’ (Divine Farmer’s Classic of Materia Medica, 神農本草經), compiled in the first century CE,<sup>162</sup> attributed to Emperor Shen Nong although he is believed to have lived 2737-2697 BCE,<sup>163</sup> recommended cannabis for more ‘than a hundred ailments, including ‘female weakness, gout, rheumatism, malaria, constipation, beri-beri, and absent-mindedness.’<sup>164</sup>

In traditional Chinese medicine (TCM), while it is mainly the seed-like fruit that is used in formulations, ancient indications for use of cannabis female inflorescence include pain relief, seizures and conditions related to mental illness. It is suggested that the ancient Chinese indications for use may

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<sup>156</sup> WHO Essential Medicines and Health Products Information Portal, as cited on [website 24.Aug.2018](#).

<sup>157</sup> As cited on the Medical Marijuana page of National Center for Complementary and Integrative Health [website](#), dated 20.Aug.2018.

<sup>158</sup> Ethan B. Russo et al., *Phytochemical and Genetic Analyses of Ancient Cannabis from Central Asia*, 59 J. EXP. BOT. 4171–4182 (2008).

<sup>159</sup> Hongen Jiang et al., *Ancient Cannabis Burial Shroud in a Central Eurasian Cemetery*, 70 ECON. BOT. 213–221 (2016).

<sup>160</sup> AYURVEDA PHARMACOPOEIA COMMITTEE, *THE AYURVEDA PHARMACOPOEIA OF INDIA, PART I, VOLUME I* 125-126 (1989).

<sup>161</sup> SIDDHA PHARMACOPOEIA COMMITTEE, *THE SIDDHA PHARMACOPOEIA OF INDIA, PART I, VOLUME I* 63-64 (2008).

<sup>162</sup> Si-Yuan Pan, Shu-Feng Zhou, Si-Hua Gao, et al., *New Perspectives on How to Discover Drugs from Herbal Medicines: CAM's Outstanding Contribution to Modern Therapeutics*, *EVID-BASED COMP. ALT. MED.* (2013) Article ID 627375, 25 pages.

<sup>163</sup> Subhuti Dharmananda, *The Lessons of Shennong. The Basis of Chinese Medicine* (2004).

<sup>164</sup> *Smoke Signals, A Social History of Marijuana – Medical, Recreational, and Scientific*. Lee, Martin. (2012).

correspond to current cannabinoid research.<sup>165</sup> And, in Unani medicine, a system of medicine introduced in India by Arabs and Persians around the 11<sup>th</sup> century, cannabis preparations are used in the treatment of conditions including ‘*ishal*’ (diarrhea), ‘*kasrat-e-tams*’ (polymenorrhagia; excessive or frequent menstruation), ‘*bawaseer*’ (piles), ‘*sual*’ (bronchitis), ‘*waj-ul-kabid*’ (hepatalgia; liver pain), and ‘*qulanj*’ (colic).<sup>166</sup>

The plant was introduced into European western medicine in the early 19<sup>th</sup> century and as discussed earlier in this paper, in 1830, German pharmacist and botanist Friedrich Ludwig Nees von Esenbeck is believed to be the first European to comprehensively document the medical value of the plant.<sup>167</sup> In 1840 a notable Irish physician working in India, by the name of William B. O’Shaughnessy (1809-1889), documented various medical uses of the plant to include, tetanus and other convulsive disorders.<sup>168</sup> The plant was also documented as a medical treatment for pain, insomnia, and as a sedative.<sup>169</sup> Some of the medical properties of ‘*Extractum Cannabis USP*’ described in a monograph of the *Dispensatory of the United States of America* (USD) in 1854 included ability to produce sleep, to allay spasm, to compose nervous inquietude, and to relieve pain, especially useful in treating conditions related to neuralgia, gout, rheumatism, tetanus, hydrophobia, epidemic cholera, convulsions, chorea, hysteria, mental depression, insanity, and uterine hemorrhage.<sup>170</sup>

Several countries listed *Cannabis* species plant parts and preparations in their respective national pharmacopoeias and therapeutic compendia. Chronologically, these include the first listing of ‘*Extractum Cannabis*’ in the third decennial revision of the U.S. Pharmacopoeia (USP III) in 1850,<sup>171</sup> monographs for ‘*Extractum Cannabis Indicae*’ and ‘*Tinctura Cannabis Indicae*’ entering the tenth edition of the U.S. Dispensatory (USD X) in 1854,<sup>172</sup> monographs for ‘*Fructus Cannabis*,’ ‘*Herba Cannabis Indicae*,’ ‘*Tinctura Cannabis Indicae*,’ and ‘*Extractum Cannabis Indicae*’ included in Germany’s first national pharmacopoeia (DAB I) in 1872,<sup>173</sup> monographs for both *Cannabis indica* flower (for preparation as a narcotic tincture) and *Cannabis sativa* seed emulsion (for use as an emollient in inflammations of mucous membranes) in the first edition of the ‘*Nueva Farmacopea Mexicana*’ in 1874,<sup>174</sup> and, in 1888, both ‘*Extract of Indian Cannabis*’ and ‘*Tincture of Indian Cannabis*’ appearing in the first issue of the National Formulary (NF I) of the United States.<sup>175</sup>

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<sup>165</sup> E. Joseph Brand & Zhongzhen Zhao, *Cannabis in Chinese Medicine: Are Some Traditional Indications Referenced in Ancient Literature Related to Cannabinoids?* 8 FRONT. PHARMACOL. 1-11 (2017).

<sup>166</sup> UNANI PHARMACOPOEIA COMMITTEE, THE UNANI PHARMACOPOEIA OF INDIA, PART I, VOLUME I 72-73 (2007).

<sup>167</sup> EMCDDA (2008), *A cannabis reader: global issues and local experiences*, Monograph series 8, Volume 1, European Monitoring Centre for Drugs and Drug Addiction, Lisbon.

<sup>168</sup> William Brooke O’Shaughnessy, *New Remedy for Tetanus and other Convulsive Disorders*, 23 BOSTON MED. SURG. J. 153-155 (1840).

<sup>169</sup> Bernard Fronmuller, 1869 (referenced in EMCDDA 2008, p. 8)

<sup>170</sup> GEORGE B. WOOD & FRANKLIN BACHE, THE DISPENSATORY OF THE UNITED STATES OF AMERICA, TENTH EDITION, 338-340, 1223 (1854).

<sup>171</sup> UNITED STATES PHARMACOPOEIAL CONVENTION, THE PHARMACOPOEIA OF THE UNITED STATES OF AMERICA, THIRD DECENNIAL REVISION 50 (1851).

<sup>172</sup> GEORGE B. WOOD & FRANKLIN BACHE, THE DISPENSATORY OF THE UNITED STATES OF AMERICA, TENTH EDITION, 338-340, 1223 (1854).

<sup>173</sup> HERMANN HAGER, PHARMACOPOEIA GERMANICA. DEUTSCHE PHARMAKOPÖE, 113, 164, 180 (1872).

<sup>174</sup> SOCIEDAD FARMACÉUTICA DE MÉXICO, NUEVA FARMACOPEA MEXICANA, 1<sup>a</sup> Ed. 73, 154 (1874).

<sup>175</sup> AMERICAN PHARMACEUTICAL ASSOCIATION COMMITTEE ON NATIONAL FORMULARY, THE NATIONAL FORMULARY OF UNOFFICIAL PREPARATIONS. FIRST ISSUE 87, 88, 102 (1888).

**In brief**, there is ample traditional use evidence of the cannabis plant that underscores the long history of use, and the safety and efficacy of the plant.

### *Modern Science*

In addition to the vast amount of traditional use evidence, there is abundant modern scientific data that support the plant's safety and efficacy which can be layered on top of the centuries of traditional use evidence. There is also a significant amount of data from authoritative resources that provide further insight into the plant's chemistry, pharmacology, toxicology, and applications. As noted by the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) in 2008 regarding cannabis,

‘Interestingly, long-proven indications have more recently been scientifically documented.’<sup>176</sup>

One of the more significant scientific breakthroughs on the cannabis plant in modern times occurred in 1963-64 when cannabidiol (CBD) and  $\Delta^9$ -tetrahydrocannabinol ( $\Delta^9$ -THC) - two of the most sought-after compounds in today's market - were successfully isolated. The discovery was made by Dr. Raphael Mechoulam and his team of scientists in Israel while conducting research on the plant.<sup>177</sup> Interestingly, Dr. Mechoulam's research was subsidized by the U.S. National Institutes of Health (NIH).<sup>178</sup>

Furthermore, cannabis was the subject of hundreds of clinical trials during the second half of the 20<sup>th</sup> century<sup>179</sup> and authoritative bodies have developed monographs to provide standards for the regulated industry. The USP was previously mentioned and the American Herbal Pharmacopoeia (AHP) published a *Cannabis Inflorescence* standards of identity, analysis, and quality control monograph in 2014.<sup>180</sup> The AHP is another known source for authoritative scientific and traditional data on plants, and the publication of a monograph elevates the conversation on the plant. The AHP Cannabis monograph has already been recognized in regulations of some states for quality control testing purposes,<sup>181</sup> including Washington<sup>182</sup> and Massachusetts.<sup>183</sup>

The cannabis plant – as is true for all plant material – is complex. The plant consists of over 750 constituents, and over 120 cannabinoids.<sup>184,185</sup> Commercially available varieties of cannabis raw materials

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<sup>176</sup> EMCDDA (2008), *A cannabis reader: global issues and local experiences*, Monograph series 8, Volume 1, European Monitoring Centre for Drugs and Drug Addiction, Lisbon.

<sup>177</sup> *Cannabinoid pharmacology: the first 66 years*. *BR. J. PHARMACOL* (2006 Jan); 147(Suppl 1): S163-S171.

<sup>178</sup> Lee, *Smoke Signals*, p. 80-82.

<sup>179</sup> The Journal of the American Botanical Council, Herbalgram, *Review Finds Substantial Evidence Supporting Some Medicinal Benefits of Cannabis and Cannabinoids*, Number 119, July-Sept.2018 (Grotenhermen F, Müller-Vahl K. Medicinal uses of marijuana and cannabinoids. A literature review of 140 controlled clinical trials published from 1975-2015).

<sup>180</sup> Roy Upton et al., *Cannabis Inflorescence. Cannabis spp. Standards of Identity, Analysis, and Quality Control*. *AMERICAN HERBAL PHARMACOPOEIA®*, (Revision 2014).

<sup>181</sup> Gabriel I. Giancaspro et al., *The Advisability and Feasibility of Developing USP Standards for Medical Cannabis*, 42 *PHARMACOPEIAL FORUM* (Jan.–Feb. 2016).

<sup>182</sup> Tyler Smith, American Herbal Pharmacopoeia Publishes Historic Monograph on Cannabis, *HERBALEGRAM*: Volume 11, Issue 1 (January 2014).

<sup>183</sup> Association of Public Health Laboratories, *Guidance for State Medical Cannabis Testing Programs* (May 2016), <https://www.aphl.org/aboutAPHL/publications/Documents/EH-Guide-State-Med-Cannabis-052016.pdf>

<sup>184</sup> *Id.*

contain (-)-trans- $\Delta^9$ -Tetrahydrocannabinol ( $\Delta^9$ -THC) and (-)-trans-cannabidiol (CBD) in various concentrations from <1 to 22 %  $\Delta^9$ -THC and <1 to 7 % CBD. Although  $\Delta^9$ -THC and CBD are the most often referenced active compounds, they are formed (via heating process) from precursors occurring in the plant, cannabinolic acids  $\Delta^9$ -THC acid and CBD acid.<sup>186</sup> The plant also consists of secondary metabolites, to include ‘terpenoids, non-cannabinoid phenols, nitrogenous compounds, as well as other more common plant compounds, all of which are non-psychoactive.’<sup>187</sup>

The discovery of cannabinoid receptors at a St. Louis University in 1988 and the discovery of the endocannabinoid system (ECS) in 1992<sup>188</sup> have provided great insight into the brain and the controls impacting an individual’s intricate molecular network. These two modern-day discoveries have assisted in a better understanding of the interplay between cannabis (and cannabinoid-based) products and the lengthy list of conditions previously identified in this paper.<sup>189</sup>

Regarding toxicology, cannabis is a relatively safe substance. A 2018 report by the World Health Organization (WHO) Expert Committee on Drug Dependence stated,

‘Most of the evidence on the toxicology of cannabis comes from observational population studies from which causation cannot be inferred.’<sup>190</sup>

Furthermore, a January of 2017 report by the National Academies of Science, Engineering and Medicine (NASEM) reached a conclusion that,

‘There is no or insufficient evidence to support or refute a statistical association between cannabis use and: All-cause mortality (self-reported cannabis use)(9-1), ..., Death due to cannabis overdose (9-4a).’<sup>191</sup>

Even though a wide safety margin has been established for the cannabis plant, several questions remain to further understand the role of Cannabis on numerous functions (e.g., fertility).

Modernized analytical methods for specifications and quality control of cannabis raw material and preparations made from it have been developed by standards-setting organizations including the American Herbal Pharmacopoeia<sup>192</sup> and the German Pharmacopoeia Commission,<sup>193</sup> and are presently in development by the United States Pharmacopoeial Convention.

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<sup>185</sup> WHO Expert Committee on Drug Dependence Pre-Review, *Cannabis plant and cannabis resin*. Section 1: Chemistry, 2018.

<sup>186</sup> Michael Hörnig, Die DAC-Monographie „Cannabisblüten“ - The DAC monograph „Cannabis flowers“, 5 *PHARMAKON* 130-136 (2017).

<sup>187</sup> Upton (AHP).

<sup>188</sup> *BR. J. PHARMACOL.* *Cannabinoid pharmacology: the first 66 years*, Pertwee, Roger. 2006 Jan; 147(Suppl 1): S163-S171; *Cerebrum, Getting High on the Endocannabinoid System*, Alger, Bradley. 2013 Nov-Dec; 2013: 14 (located on NIH PMC).

<sup>189</sup> WHO 37<sup>th</sup> ECDD (2015) Agenda Item 6.2, *Update of Cannabis and its medical use*. Madras, B.

<sup>190</sup> WHO Expert Committee on Drug Dependence, [fortieth report](#). Geneva: World Health Organization, 2018 (WHO Technical Report Series, No. 1013), p. 20. Licence: CC BY-NC-SA 3.0 IGO.

<sup>191</sup> The National Academies of Sciences, Engineering, and Medicine. 2017. *The health effects of cannabis and cannabinoids: Current state of evidence and recommendations for research*. Washington, DC: The National Academies Press. [See Committee’s Conclusions](#).

<sup>192</sup> Upton (AHP).

<sup>193</sup> *DEUTSCHE ARZNEIBUCH-KOMMISSION, DEUTSCHES ARZNEIBUCH* (2017)

Therapeutic applications have been elaborated by several governmental health agencies, such as Australia, Canada, Israel, Germany, the Netherlands, and Switzerland, among others. For example, in Switzerland, in 2013, a product containing a combination of two extracts of cannabis leaf and flower (*cannabis sativae folii cum flore extractum spissum*), one standardized to contain 61-71% delta-9-tetrahydrocannabinol (THC) and the other standardized to contain 60-71% cannabidiol (CBD), received marketing authorization indicated for treating adults with moderate to severe spasticity due to multiple sclerosis (MS).<sup>194</sup>

**In sum**, due to the extensive amount of traditional use evidence and modern science on the plant, and that the plant and preparations made from it have sufficient evidence to support the safety (and efficacy) requirements for marketing authorization in other advanced countries, the proposed federal regulatory framework does not necessitate an invasive and overly prescriptive mandate on how the states should operate their respective programs. The cannabis plant is well researched and state regulators, law makers, and stakeholders have access to considerable contemporary scientific data as well as traditional use evidence for reference in developing their respective programs.

### *The Maturity of Today's Regulated Market*

The individual states have been self-regulating cannabis programs within their respective borders for over two decades. Today the U.S. regulated industry consists of 46 plus state-authorized medical cannabis programs that provide medicine to over two million patients, and ten (soon eleven as explained earlier) state-sanctioned adult-use markets- taken together these regulated markets have created a vibrant economic opportunity. These markets and economic advancements have been achieved without a fundamental change on federal policy towards the cannabis plant since the enactment of the CSA in 1970. The regulated market translates to a majority of our country currently residing in a jurisdiction with some type of a regulated cannabis market. With more than 20 years of self-regulating sans a safety crisis, the state-sanctioned market has proven itself sophisticated and mature.

Additionally, the states that have taken the lead on developing infrastructures have invested significant time, expertise, and resources to enact their respective comprehensive programs.<sup>195</sup> The state-sanctioned regulatory structures are comprehensive and include seed-to-sale tracking, reporting requirements, good manufacturing practices, strict labeling requirements, and laboratory and testing protocols. The following are six examples of state-enacted cannabis programs:

State-regulated Cannabis programs	Type of program: Medical (M)   Adult-Use (AU)	Year enacted (M, AU)	Oversight   State regulatory agencies	Diversion measures	Labeling measures
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<sup>194</sup> Almirall AG, Sativex®, in: *Fachinformation des Arzneimittel-Kompendium der Schweiz*® (2016), <http://www.kompendium.ch/mpro/mnr/24719/pdf/de#page1>

<sup>195</sup> Colorado Department of Regulatory Agencies, *2014 Sunset Review: Colorado Medical Marijuana Code*, Office of Policy, Research and Regulatory Reform, 15.October.1014; Colorado Department of Revenue, Enforcement Division – Marijuana, *Report to the Joint Budget Committee and the Joint Finance Committees of the Colorado General Assembly*, 01.Apr.2015; Minnesota *Medical Cannabis Therapeutic Use Program Impact Assessment Report*, 01.Feb.2017 (medical Cannabis manufacturer ‘lost a significant amount of money in 2015.’ Combined loss in excess of \$5 million).

Alaska	M, AU	1998, 2014	Department of Health and Social Services – <u>Division of Public Health</u> ; Dept. of Commerce, Community, and Economic Development – <u>Alcohol &amp; Marijuana Control Office</u> , Marijuana Control Board	✓	✓
<u>Arkansas</u>	M	2016	<u>Arkansas Medical Marijuana Commission</u> ; Department of Health; Alcoholic Beverage Control	✓	✓
Colorado	M, AU	2000, 2012	Department of Public Health and Environment; <u>Department of Revenue</u> – Marijuana Enforcement Division; Department of Agriculture	✓	✓
<u>Minnesota</u>	M	2014	Department of Health – Office of Medical Cannabis	✓	✓
North Dakota	M	2017	North Dakota Department of Health; <u>Division of Medical Marijuana</u>	✓	✓
<u>Texas</u>	M	2015	<u>Department of Public Safety</u>	✓	✓

Due to the strength of the state regulatory frameworks, a great degree of federal oversight is not warranted. To the contrary, if a proper balance is not established in the state-federal relationship, the federal interface may be disruptive and create chaos to the high-functioning state markets. The federal interplay with the state-enacted programs must give deference to the well-established and successfully operating state infrastructures.

In addition to the significant investment of resources made by the individual states and stakeholders to enact a program, these same interests did so as they faced the risk of criminal prosecution and civil asset forfeiture.<sup>196</sup>

‘Today, marijuana is still categorized as a Schedule I controlled substance and *is therefore subject to the most severe restrictions contained within the CSA*. Pursuant to the CSA, the unauthorized cultivation, distribution, or possession of marijuana is a federal crime. Although various factors contribute to the ultimate sentence received, the mere possession of marijuana generally constitutes a misdemeanor subject to up to one year imprisonment and a minimum fine of \$1,000.

...

Moreover, property associated with the offense may be confiscated without or with any prior or accompanying criminal conviction.

<sup>196</sup> 18 U.S.C. §981, Civil forfeiture; 21 U.S.C. §881, Forfeitures.

...

Section 511 of the CSA (21 U.S.C. §881) makes a *wide array of property associated with violations of the CSA subject to seizure* by the Attorney General and forfeiture to the United States. Property subject to the CSA's civil forfeiture provision includes any controlled substance that has been manufactured, distributed, dispensed, acquired, or possessed in violation of federal law, as well as any equipment, firearm, money, mode of transportation, or real property used or intended to be used to facilitate a violation of the CSA. In order to seize the covered property, the government need only show that the property is subject to forfeiture by a preponderance of the evidence. Once forfeited, the Attorney General may destroy the controlled substances seized, and sell the other property at public auction.

...

Forfeiture proceedings are generally *less resource intensive than a criminal prosecution and have been used in the past against medical marijuana dispensaries.*<sup>197</sup>

The stakes in establishing and participating in the intrastate markets were extraordinary for the states and individual stakeholders.

As such, the individual states that have developed and implemented these programs at the direct request of the citizens within its borders and the individuals that operated within the programs should reap the reward from taking these risks. Hence, states are to retain significant autonomy and control within the state-federal framework.

### *Vulnerabilities and Market Challenges Within the Regulated Cannabis Market*

There have been vulnerabilities and market pressure points within the state programs, of which certain challenges are due to the design of the program while other pressure points are due to the federally scheduled status of the plant.

#### *Vulnerabilities Due to State Frameworks*

Fortunately, due to the nimbleness and the close monitoring of each program, most of the vulnerabilities due to the design of the intrastate program have been quickly identified and resolved or, at a minimum have been subject to regulatory attention.

Product diversion has been a key consideration when drafting laws and regulations for the state regulated markets. The concern of cannabis products being transported from a jurisdiction that allows product into a jurisdiction where cannabis is not permitted is valid. One of the measures incorporated into recently enacted state regulatory frameworks to address this concern has been a seed to sale tracking mechanism. This entails a comprehensive tracking protocol that follows a seed through harvest, through the manufacturing phase and up until the time a finished product leaves a dispensary. As previously mentioned in this paper, there have been reported incidents of product diversion and subsequent criminal

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<sup>197</sup> CRS Report R43435, *Marijuana: Medical and Retail – Select Legal Issues*, by Garvey, T., Doyle, C., Carpenter, D. (08.Apr.2015) [*emphasis added*].



actions ensued. Product diversion continues to be a priority for regulators that hail from a state sanctioned program.<sup>198</sup>

The lack of readily available laboratory standards has created challenges for the state markets. Laboratory standards create greater consistency, which in turn results in better product quality. Both state regulators and stakeholders appreciate the need for and are in support of laboratory standards. As proposed in this paper, the AC and AMS would address the need for harmonized laboratory standards in the regulated cannabis industry.

Cannabis-impaired driving is another concern and due to the unique traits of the cannabis plant, detection of impairment via blood sample is not reliable since cannabis remains in the blood long after any effect of impairment.<sup>199</sup> To address the concern of impaired driving, strong responsible use campaigns that discourage the use of product (medicine) before driving are recommended and being implemented, and the use of Drug Recognition Experts (DRE) by law enforcement to detect impairment (versus a blood sample) has been the optimal detection method to date.

Finally, the intricate balance of market supply and demand ultimately impacts product availability (shortages or excesses) and product price points. The individual state markets have encountered this challenge due to a variety of reasons ranging from too few dispensaries to laboratory restrictions. As proposed in this paper, the AMS has great expertise in creating market stability and will ideally resolve the market pressure points in the event a state (or region) has yet to resolve.

**In sum**, the above identifies certain of the vulnerabilities and market challenges within the state regulated markets due to the design of individual state program. If the vulnerabilities are not addressed by the stakeholders and state authorities, this proposed framework is designed to provide the technical assistance to resolve.

### *Vulnerabilities Due to Federally Scheduled Status*

Several other intrastate market challenges are due to the conflict in the classification of cannabis between the state laws in jurisdictions that have enacted regulated programs and current federal law. The proposed federal framework would resolve the below identified market challenges. Until the conflict between state and federal law is reconciled, the state-authorized stakeholders will have limitations and will not be operating at 100% as other lawful, tax-paying businesses within their states.

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<sup>198</sup> States currently absorb a majority of enforcement measures in general. As noted in a 2014 Congressional Research Service Report, 'The majority of drug crimes known to U.S. law enforcement are dealt with at the state level (100). In the United States in 2012, the U.S. Drug Enforcement Administration (DEA) arrested 30,476 suspects for federal drug offenses while state and local law enforcement arrested 1,328,457 suspects for drug offenses (101). In many cases, federal agencies assist state and local agencies with drug arrests, and suspects are referred for state prosecution, and vice-versa.' *Drug Enforcement in the United States: History, Policy, and Trends*. 02.Oct.2014, Sacco, Lisa. Congressional Research Service, R43749.

<sup>199</sup> Further data collection is recommended. In a study looking at Fatality Analysis Reporting System (FARS) data between 1993 to 2014, nearly one-quarter of fatal crash drivers tested positive for alcohol, 8.8% of drivers tested positive for Cannabis, followed by stimulants (6.1%), narcotics (4.2%), depressants (3.6%), and other illicit drugs (0.3%). The author suggested that analyses of any geographic association between dispensary locations and Cannabis-related driving infractions should be included in future research. Eric L. Seigny, *The Effects of Medical Marijuana Laws on Cannabis-involved Driving*, 118 ACCIDENT. ANAL. PREV. 57-65 (2018); Additionally, in its 2017 report to Congress, the National Highway Traffic Safety Administration made recommendations to increase collection of data on prevalence and effects of Cannabis-impaired driving. Richard P. Compton, *Marijuana-Impaired Driving - A Report to Congress* (DOT HS 812 440) (July 2017).

The most commonly cited concern is the shortage of traditional financial institutions that will provide banking services to the regulated industry. Due to the federally scheduled status of cannabis under the CSA, financial transactions within the state-regulated markets are considered unlawful, and therefore, the money laundering provisions and several other federal statutes create statutory barriers and significant risk for financial institutions to engage with state-authorized stakeholders.<sup>200, 201</sup> The Financial Crimes Enforcement Network (FinCEN) within the U.S. Department of Treasury reported in September of 2017 that approximately 400 banks provide services to the regulated cannabis industry.<sup>202, 203</sup> This translates to a significant portion of the regulated industry being unbanked and operating on a cash-basis. The proposed framework resolves this issue as cannabis would be removed from the CSA, and therefore, financial transactions and activity within the regulated markets would no longer be considered ‘unlawful.’

Another significant hurdle due to the scheduled status of cannabis is the application of a 1982 tax provision – commonly referred to as 280E – that has been applied to certain stakeholders within the regulated industry. The application of Internal Revenue Code (IRC) §280E to state-sanctioned businesses has resulted in an exorbitant tax rate on certain stakeholders. This IRC provision was intended to disallow deductions for businesses engaged in trafficking. The proposed framework removes cannabis from the CSA, and therefore, the Internal Revenue Service could no longer apply 280E to lawfully operating stakeholders within the regulated industry.

The United States Patent and Trademark Office (USPTO) has refused to issue federal trademark protections for cannabis-related trademarks based on the goods or services of the application are an ‘unlawful activity’ under the CSA. Additionally, veterans have faced certain limitations in accessing medical cannabis and in having fully transparent discussions with their physician within the Veterans Affairs system – even if they reside in a jurisdiction with a state-authorized medical program.<sup>204</sup> Fortunately, the Department of Veterans Affairs has updated its internal directives which has provided partial relief.<sup>205</sup> However, once cannabis is no longer a scheduled substance as proposed, both of these issues would be fully resolved.

There are also several social justice matters that need to be addressed. With decades of data since the cannabis plant became a scheduled substance, there are ample data that demonstrate the disproportionate arrest and incarceration rates among minorities. The trickle-down effect and impact of the biased implementation of criminal penalties for cannabis-related offenses has resulted in the denial of employment, housing, and financial aid for higher education. The more intangible effects are the stigma and shame that can accompany an arrest or conviction. To date, local jurisdictions as previously mentioned in this paper and individual states have been in the best position to make an immediate impact

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<sup>200</sup> Money laundering provisions under, 18 U.S.C. §1956, 1957. Provisions within the Bank Secrecy Act (31 U.S.C. §5311-5330) regarding ‘illegal activity’ and 18 U.S.C. §1960 (Prohibition of unlicensed money transmitting businesses) among other federal statutes.

<sup>201</sup> Another collateral implication can be found with a policy adopted by the U.S. Small Business Administration (SBA) that sets forth Cannabis-related businesses are ineligible for SBA funds. This policy has the potential to create a further divide in this burgeoning industry between larger players and small businesses due to the elimination of a means for small businesses to enter a market and/or remain competitive in a market. See SBA SOP 50 10 5 (K).

<sup>202</sup> Financial Crimes Enforcement Network (FinCEN), 30.Sept.2017, *Marijuana Banking Update*.

<sup>203</sup> Financial Crimes Enforcement Network (FinCEN), Department of the Treasury, 14.Feb.2014, Guidance: *BSA Expectations Regarding Marijuana-Related Businesses*.

<sup>204</sup> DEPARTMENT OF VETERANS AFFAIRS, VETERANS HEALTH ADMINISTRATION, Access to Clinical Programs for Veterans Participating in State-Approved Marijuana Programs, VHA Directive 2011-004, 31.Jan.2011.

<sup>205</sup> DEPARTMENT OF VETERANS AFFAIRS, VETERANS HEALTH ADMINISTRATION, Access to VHA Clinical Programs for Veterans Participating in State-Approved Marijuana Programs, VHA Directive 1314, 08.Dec.2017.

on certain of these social harms. Expungement of federal use and possession offenses need to be addressed on the federal level at the direction of the Advisory Committee as proposed.

**In sum**, the market vulnerabilities that can be addressed by the state authorities are being given the attention to resolve and states should retain the autonomy to resolve certain market pressure points. The market challenges due to the current federally scheduled status of the plant will be resolved under this proposed framework. The proposed framework also includes measures to address future market challenges such as entering the global market.

### *Existing Pathways to Market*

The U.S. market has several regulatory pathways to market for conventional food and beverages, and therapeutic products. However, after a review of each regulatory paradigm and an assessment of the implementation of each, this paper sets forth that existing regulatory pathways to market are not best suited for a cannabis-based product. Especially since the U.S. regulated cannabis industry is built on intrastate markets (versus starting with a federal program) and in at least 10 states, the intrastate markets include two sub-pathways to market (i.e., medical, adult-use).

As this paper sets forth, the state markets are fairly established and comprehensive and therefore, a heavy-handed federal component is not warranted. Furthermore, the federal interface needs to strike a balance with the state markets to avoid unnecessary disruption of the current regulated industry which has done exceptionally well to date. This paper also sets forth that the originators of the current market (i.e., individual states and stakeholders within each market) should be rewarded by protecting their interests within a federal framework. Using these two considerations - minimal disruption to the state programs and that states are to retain control - as the cornerstones of the proposed federal framework, the following presents a review of five of the current available pathways to market.

The following subheadings discuss pros and cons of possible frameworks in order of least desirable to most desirable, namely Botanical Drug, Alcohol and Tobacco, Botanical Dietary Supplement, and Pharmacy Compounding.

#### *Botanical Drug*

The Botanical Drug<sup>206</sup> pathway – although by title seems promising for a cannabis-based medicine - has only brought two botanical drugs<sup>207</sup> to market in the U.S. after 600 plus pre-investigational new drug and investigational new drug (IND) submissions.<sup>208</sup>

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<sup>206</sup> Botanical Drug Development Guidance for Industry, U.S. Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (CDER), December 2016 Revision 1. The first FDA guidance on botanical drug development was issued in 2004.

<sup>207</sup> Veregen, approved 31.Oct.2006 (green tea, green tea extract | indication: genital/perianal warts), sponsored by MediGene, Inc. based in Germany; Fulyzaq | Crofelemer, approved 31.Dec.2012 (*Croton lechleri* | indication: HIV related diarrhea), sponsored by Salix Pharmaceuticals.

<sup>208</sup> However, FDA has approved drug products through the conventional new drug pathway that contain either a constituent or synthetic derivative of the cannabis plant. See [FDA and Marijuana: Questions and Answers](#): “The FDA has approved Epidiolex, which contains a purified drug substance cannabidiol, one of more than 80 active chemicals in marijuana, for the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients 2 years of age and older. That means the FDA has concluded that this particular drug product is safe and effective for its intended indication. The agency also has approved Marinol and Syndros for therapeutic uses in the United States, including for the treatment of anorexia associated with weight loss in AIDS patients. Marinol and Syndros include the active ingredient dronabinol, a synthetic delta-9-tetrahydrocannabinol (THC) which is considered the psychoactive component of marijuana. Another FDA-approved drug, Cesamet, contains the active ingredient nabilone, which has a chemical structure similar to THC and is synthetically derived.” (Question 2, accessed via FDA website 26.Nov.2018).

There are several unique traits of a botanical drug (versus a non-botanical drug) which include, variation in raw materials, complex heterogeneous mixture (versus a single molecule), the active constituents may not be fully identified, and of natural origin. Due to these unique traits, the conventional model of review that FDA employs for non-botanical drugs (e.g., Chemistry, Manufacturing, and Controls (CMC)) does not easily translate to an applicable regulatory pathway for botanical drugs.

For example, one of the challenges with the U.S. botanical drug pathway is working with crude plant material (i.e., dried leaves, buds), versus a well-characterized mixture of compounds of botanical origin. Even though the FDA Botanical Drug pathway does not require the drug sponsor to isolate, purify and identify the active ingredient(s), the guidance calls for a pharmacokinetic analysis<sup>209</sup> which is not possible without knowing the active ingredient(s).

The safety and efficacy of botanical-based medicines are often substantiated by traditional use evidence. U.S. regulatory agencies have not yet been willing to accept the validity of this type of evidence (i.e., long history of safe human use with well-documented clinical observation). In general, regulatory agencies in the U.S. have been slow to embrace the benefits of plant-based products and medicines. Of note, several developed countries have successfully implemented herbal and traditional herbal medicine pathways via marketing authorizations and other licensing frameworks,<sup>210</sup> including Australia, Canada, Japan, Mexico, and European Union member states.

FDA revised the Botanical Drug Guidance document in 2016, and by degrees this pathway is more accepting of the complexity of plant material. For example, the FDA is now taking a ‘totality of the evidence’ approach. However, accepted traditional use evidence has yet to be fully acknowledged and weighted at par with conventional clinical investigation protocols. The botanical drug pathway will continue to exist; however, this paper sets forth that the botanical drug model is not appropriate as the federal interface for the cannabis-based medicines being developed and brought to market under the state-regulated programs.

### *Alcohol and Tobacco*

Of the existing regulatory pathways to market, the alcohol and tobacco models are two commonly cited regulatory frameworks that the cannabis industry should look to adopt.<sup>211</sup>

This paper sets forth that the regulated cannabis industry should not adopt – or even associate with – the alcohol and tobacco frameworks. The primary reason is that the shadow effect from these two categories predisposes the regulated cannabis industry for failure from both the general public and the regulators perspective. The alcohol and tobacco industries are successful at generating revenue and tax dollars. However, both industries fall short on consumer safety and social impact. The following are topline statistics on the impact that these two industries have on the U.S. population and economy.

The alcohol and tobacco industries are responsible for hundreds of thousands of deaths every year,

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<sup>209</sup> FDA 2016 Botanical Drug Development Guidance for Industry, p. 14.

<sup>210</sup> German Federal Institute for Drugs and Medical Devices (BfArM), Division Complementary and Traditional Medicinal Products; 2004 Directive 2004/24 EC “Traditional herbal medicinal products”

<sup>211</sup> Ira P. Robbins, *Guns N’ Ganja: How Federalism Criminalizes the Lawful Use of Marijuana*, 51 U.C.DAV. L.REV. 1784-1825 (2018); Ittleman, Andrew, Esq., Tuazon, Jessika, Esq., *Federal Marijuana Regulation: Why is Flexibility Critical in the Dawn of Legalization?*, Food and Drug Law Institute’s Food and Drug Policy Forum, V. 4, Issue 12, 19.Dec.2014.

‘Cigarette smoking is responsible for more than 480,000 deaths per year in the United States, including more than 41,000 deaths resulting from secondhand smoke exposure.’<sup>212</sup>

‘Excessive alcohol use led to approximately 88,000 deaths ... from 2006-2010.’<sup>213</sup>

‘Excessive drinking contributes to more than 4,300 deaths among people below the age of 21 in the U.S. each year.’<sup>214</sup>

The alcohol and tobacco industries cost billions of dollars in economic and healthcare costs,

‘The economic costs of excessive alcohol consumption in 2010 were estimated at \$249 billion, or \$2.05 a drink.’<sup>215</sup>

‘Total economic cost of smoking is more than \$300 billion a year, ...’<sup>216</sup>

Products from both of these industries have resulted in serious societal harms such as addiction, disease and emotional well-being issues. Both industries have been less than truthful with the public and policy makers about the effects from their products.<sup>217</sup>

In addition to the far-reaching negative shadow effect from both industries,<sup>218</sup> the regulatory frameworks for each are not appropriate either. Both industries do encompass a state-federal regulatory partnership; however, this article sets forth the partnerships have not been successful.

The alcohol model was developed in the 1930s post-prohibition<sup>219</sup> which transitioned an alcohol beverage from a strictly prohibited substance to a regulated industry.<sup>220</sup> The alcohol industry for the most part operates on a three-tier system that consists of three separate and independent interests: producers, distributors, and retailers. The system was designed to avoid monopolies and corruption in a post-prohibition era; however, in modern-times this system has been subject to great debate as if the initial goals are being met. For example, craft producers have struggled to maintain market access due to a few

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<sup>212</sup> Centers for Disease Control and Prevention (CDC), Data and Statistics, [Smoking & Tobacco Use](#) (retrieved from site 14.Oct.2018).

<sup>213</sup> Centers for Disease Control and Prevention (CDC), Alcohol and Public Health: [Alcohol-Related Disease Impact \(ARDI\)](#) (retrieved from site 14.Oct.2018).

<sup>214</sup> Centers for Disease Control and Prevention (CDC), [Alcohol and Public Health](#) (retrieved from site 14.Oct.2018).

<sup>215</sup> Centers for Disease Control and Prevention (CDC), Alcohol and Public Health: [Alcohol Use and Your Health](#) (retrieved from site 14.Oct.2018).

<sup>216</sup> Centers for Disease Control and Prevention (CDC), Data and Statistics, [Smoking & Tobacco Use](#) (data based on 2014 Surgeon General’s Report | retrieved from site 14.Oct.2018, 1:47 p.m. E.T.).

<sup>217</sup> United States v. Philip Morris USA, Inc. (2006), U.S. District Court for District of Columbia, Civil Action No. 99-2496 (e.g., denied act of intentionally manipulating levels of nicotine to result in addiction, denied causal relationship between cigarette smoking and disease); U.S. National Institutes of Health, PubMed, [How alcohol industry organizations mislead the public about alcohol and cancer](#) (2018). Petticrew M., Maani Hessari N., Knai C., Weiderpass E., 2018 Mar;37(3):293-303.

<sup>218</sup> The Guardian, [Alcohol causes one in 20 deaths worldwide, says WHO](#). Davis, Nicola. 21.Sept.2018.

<sup>219</sup> Twenty-first Amendment, 05.Dec.1933; Federal Alcohol Administration Act (FAA Act) (1935) (27 U.S.C. §8); Department of Treasury, Alcohol and Tobacco Tax and Trade Bureau (TTB).

<sup>220</sup> Under the FAA Act, individual states retained the authority to regulate the production, sale and distribution of alcohol within its borders. Certain states today even have counties that are dry and do not allow any alcohol sales within its jurisdiction (e.g., Arkansas, Texas). Similarly as proposed by this paper, states would also retain the authority on how to regulate Cannabis within their border.

large players that now control the industry. As this paper is not a debate on the appropriateness of the three-tier system for the alcohol industry and pros and cons can be set forth for the system, the point of distinction for the cannabis industry is that there isn't a need for the three-tiers. The cannabis industry is entering a post-federal prohibition era; however, the regulated cannabis industry is already subjected to defined regulatory requirements under their respective state programs.<sup>221</sup> Unless a state program requires or allows a 'distributor' (e.g., California), there isn't a need to mandate a three-tier system on a federal level.

The tobacco industry as of 2009 came under the regulatory purview of the FDA.<sup>222</sup> The Tobacco Control Act places controls on the sale of tobacco products which includes to name a few, age and advertisement restrictions, labeling requirements, manufacturing standards, premarket product review and registration, and user fees imposed on the tobacco companies are the funding mechanism. The tobacco industry was clearly in need of extensive federal oversight in light of the social harms the industry inflicted<sup>223</sup> and the lack of meaningful measures undertaken by industry to address the harms. Hence, the extensive reach of the Tobacco Control Act. As a point of distinction, the regulated cannabis industry is already subject to extensive regulatory requirements under their respective state frameworks to ensure only safe products are placed into commerce, the products are properly labeled and that controls are in place to avoid youth access. As with the alcohol model, the federal regulatory requirements for the tobacco industry are not warranted for the regulated cannabis industry.

As the societal harms remain from these two industries and the lack of a state-federal effort to mitigate or to reduce the societal harms via prevention strategies,<sup>224</sup> the net result is indicative of a less-than-successful state-federal partnership model.

The regulated cannabis industry should not be associated with the alcohol and tobacco regulations because the cannabis plant does not need to endure the shadow effect from these industries. The cannabis plant is barely recovering from 100 plus years of unwarranted stigma and to give the plant its due - and to give the nascent industry a chance – this paper recommends that the federal regulatory interface starts with a blank slate. Therefore, although there are parallels with certain regulatory controls in the alcohol and tobacco industry, on the whole the development of a federal regulatory framework uniquely designed for the 21<sup>st</sup> century regulated cannabis industry is the sound path forward.

### *Botanical Dietary Supplement*

We do not see the framework established for botanical dietary supplements to be appropriate for cannabis. The dietary supplement category is regulated predominantly by the FDA but also by the individual state food and drug branches. The industry is subject to good manufacturing practices (GMPs), serious adverse event reporting, ingredient restrictions (i.e., pre-1994 status of old dietary supplement, post-1994 new dietary ingredient) and labeling requirements.

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<sup>221</sup> Another requirement under the FAA Act involves a federal permitting system; however, as proposed in this paper, the state regulated industry does not need a federal registration system other than as proposed by the Advisory Committee or the AMS for supply and demand needs.

<sup>222</sup> Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (22.Jun.2009).

<sup>223</sup> In addition to disease, deaths and economic impact caused by the tobacco industry, tobacco products were also used to facilitate and finance criminal activities.

<sup>224</sup> As noted by the CDC, 'State spending on tobacco prevention and control does not meet CDC-recommended levels. States have billions of dollars from tobacco taxes and tobacco industry legal settlements to prevent and control use. However, states currently use a very small amount of these funds for tobacco control programs.' Centers for Disease Control and Prevention (CDC), Data and Statistics, [Smoking & Tobacco Use](#) (retrieved from site 14.Oct.2018).

The dietary supplement industry consists of products that promote health and well-being yet are not intended to treat disease conditions. The permissible dosage formats range from powders to capsules to beverages; however, the products must be ingested (versus a topical, for example) to be considered a supplement. The dietary supplement industry is regulated almost exclusively on the federal level under the Dietary Supplement Health and Education Act of 1994 (DSHEA)<sup>225</sup> within the U.S. Food, Drug, and Cosmetic Act. However, prior to DSHEA, dietary supplement products faced numerous market access challenges which is to a degree, a commonality with the cannabis industry.

For example, at one time, certain Members of Congress and the FDA tried to regulate the supplement industry as ‘food additives’- a pathway which was designed to identify safe substances that could be used in food products.<sup>226</sup> However, the nutritional products that consumers wanted did not consist of mere substances to be added to food. The products that consumers wanted were in and of themselves therapeutic. After years of debates and challenges and attempts of being forced into an existing regulatory framework, DSHEA was finally enacted as a comprehensive framework specific to dietary supplement products. Dietary supplements are regulated by the FDA and herbal supplements (botanical supplements) are considered a sub-category within the dietary supplement category. The supplement industry is the reverse of the cannabis industry in that supplements are regulated primarily on the federal level with the occasional one-off state regulation impacting a supplement product’s market access.<sup>227</sup>

On the whole, the supplement product category model is not appropriate for the cannabis industry due to the supplement category being regulated almost exclusively on the federal level, the range of non-botanical products in this category, and the permissible intended uses of supplement products (i.e., to support health and well-being). Lessons can be extracted on how the dietary supplement product category came to be, how to avoid the continued rifts that exist between agency and the supplement industry, and perhaps most importantly, how to avoid the general public’s great misunderstanding of this category.

### *Pharmacy Compounding*

The practice of pharmacy compounding is a means to prepare a medication for a patient that is not readily available in the marketplace. For example, a patient may have allergies to the fillers in a currently available prescription drug and to meet this individual patient’s need, a medication must be prepared without the fillers. A compounding pharmacy fills that patient need by preparing a compounded medication that does not include the fillers that cause the allergic reaction.

This particular model is attractive in that it is based on the concept of individualized medicine. Furthermore, traditional compounding pharmacies (503A operations) are predominantly regulated by state authorities and more specifically, by individual state boards of pharmacy and the board’s unique regulatory framework.<sup>228</sup> The traditional pharmacy compounding model also looks to the USP for quality standards in how to prepare compounded medications. Hence, at first glance this paradigm seems appealing for the state-regulated cannabis industry as the parallels between the two industries are striking. The individual state boards of pharmacy equate to the state regulatory agency(ies) that have oversight of

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<sup>225</sup> Dietary Supplement Health and Education Act of 1994, Public Law 103-417, 103<sup>rd</sup> Congress.

<sup>226</sup> U.S. Food, Drug and Cosmetic Act (FDCA), §§401 (Standards), 409 (Food Additives).

<sup>227</sup> For example, California’s Proposition 65, Safe Drinking Water and Toxic Enforcement Act of 1986, that mandates additional labeling with a warning if the product contains a chemical listed under this Act.

<sup>228</sup> U.S. Food, Drug, and Cosmetic Act (FDCA) §503A (21 U.S.C. §353a).

the regulated cannabis programs, and both models look to USP for instruction. The model also includes a licensing mechanism, controls on which active pharmaceutical ingredients (API) can be used in a compounded medication, sanitary conditions and other manufacturing requirements.

An often cited concern with the 503A model is that FDA exceeds their limited statutory authority. FDA also often sets forth that pharmacy compounding is less safe or not safe. Hence, there is a tension between industry and agency, and at times, this translates to mixed messages for the public.

This model is driven by patient access and need, and a delicate balance between the practice of medicine and FDA involvement is key to the success of this model. Parallels can be drawn and borrowed from the construct of the pharmacy compounding model. However, perhaps the working knowledge that can be taken from the pharmacy compounding model is that a state-regulated industry is possible, and an appropriate federal interface with a collaborative approach towards the state-regulated industry is vital for its sustainability.

**In sum**, the above cited regulatory pathways that are currently available in the U.S. provide instruction for the regulated cannabis industry; however, these pathways are not best suited for the cannabis industry. The existing federal pathways to market for the numerous product categories can successfully coexist with the proposed framework for the cannabis industry, and in doing so, will ensure the long-term success of the regulated cannabis industry.

## CONCLUSION

The cannabis plant has an extraordinary history and is one of several hundred botanicals with demonstrated therapeutic properties. This proposed framework is designed specifically for plant-based products that will work for the cannabis plant and the existing state-sanctioned cannabis programs. After careful consideration of the current regulated stateside landscape and the existing federal pathways to market, an original framework is the most appropriate option. The proposed federal framework intentionally defers to the state-driven regulated markets. This is in large part based on a review of the historic trajectory of the cannabis plant in the U.S., the ample science available on the plant and the detailed nature of the individual state regulatory frameworks.

These laboratories of democracy should be a true experiment under the direction of state leadership.

A regulatory framework that fosters collaboration between stakeholders, state agencies and the federal interface is forward-thinking. The states have made significant investments to enact and implement their unique regulatory frameworks. The proposed framework is a modern approach that reconciles the current dated federal policy with the state landscape and respects what the states have achieved to date. The federal interface should bolster and support via technical assistance the thus far quite successful state-led efforts in bringing cannabis-based products to market without being overly intrusive.

This proposed plant-forward framework is a 21<sup>st</sup> century pathway to market that is designed to provide stability within the current regulated markets, establish harmonized baseline quality standards, and ultimately strengthen and build integrity into the state-regulated markets. The future of the regulated market depends on appropriate controls that strike a balance between innovation and oversight, and the proposed framework fulfills that critical obligation.



## *Future*

A final consideration for the future: in addition to creating an environment that allows the regulated cannabis industry to grow in the marketplace, and foster opportunities to discover therapeutic applications and innovative technologies – are the state-regulated markets a viable model to bring other plant-based products at therapeutic levels to market? The infrastructures are in place and the consumer interest, demand and need may warrant an expansion of the state frameworks to include other botanicals. The existing state-led regulated landscape may be an opportunity for the U.S. market to explore a viable pathway to market for other botanical-based products at therapeutic levels.