The Future State of Medical Cannabis Legalization: The US Must Move Past Absurdity and into Healing

Intro

Regulation of medical cannabis in the United States has always been a racial, moral, and political crusade, rather than a concerted effort to encourage and protect public health and safety, rooted in scientific and medical research. Evidence demonstrating the high value and relative low risk of medical cannabis is plentiful, but the federal government continues to mire itself in exceptionally contradictory policy choices, which have produced absurd results that arguably cannot stand from a legal standpoint.

What this means is the current state of medical cannabis legality in the country is a tangled web of prohibitionist federal laws; statements from the Executive branch (remember Ogden, Cole I, Cole II, and Sessions?) and actions by Congress in opposition to those laws; and widely varying, permissive state laws.

The result: millions of Americans are denied access to a natural, safe substance that promotes homeostasis in the human body; certain communities negatively impacted by the war on drugs continue to suffer significant, intergenerational consequences; duly licensed medical cannabis operators operating in compliance with state laws are prevented from earning legitimate profits; and many more. (Not?) Shockingly, there is one group who may lawfully profit from medical cannabis within the current system, and who may authorize others to profit from the same – the federal government itself.

Now, amid changes to the legality of medical cannabis enacted globally by the United Nations (UN), and the <u>imminent rescheduling of cannabis</u> in the U.S., medical cannabis is again in the spotlight. In August 2023, the Department of Health and Human Services (HHS) responded to President Biden's request that it review how marijuana is scheduled under federal law with a letter recommending its rescheduling from Schedule I to Schedule III under the Controlled Substances Act (CSA). In May 2024, the Drug Enforcement Agency (DEA) announced it would begin the rulemaking process to formally reschedule cannabis to Schedule III.

Interestingly, in January 2024, HHS released for the first time its complete, unredacted, 252-page Schedule III recommendation, including a detailed analysis of eight factors it considered regarding cannabis' potential for abuse, pharmacological effects, current scientific knowledge, history and current pattern of about, scope, duration, and significance of abuse, risk to public health, potential for psychic or physiological dependence, and whether it is a precursor to other controlled substances. The report is illuminating, and vindicating: HHS determined that cannabis is *safer* than alcohol, recognized, for the first time, state-level (v. solely federal) data regarding cannabis' currently accepted medical uses, and expressed cannabis' utility and vitality as a medicine.

The Two Lanes of "Medical Cannabis"

Today, we see medical cannabis delivered to patients via two separate and distinct "lanes," which adds no small amount complexity to public opinion, discourse, policy, and legislation around its safety and legality. The first is the *traditional medical/pharmaceutical route*, in which pharma companies isolate specific compounds of the plant, like cannabinoids

(including THC and CBD), conduct double-blind clinical studies, and use approved cannabinoids or compounds as *ingredients* in prescription medication formulations. The basis of this lane is a belief that specific cannabinoids contained in cannabis (like CBD) are "good," while others (like THC) are "not good," and that the specific *genetics* of the plant determine its medical value. Even if cannabis is never rescheduled, this type of development is sure to continue – cannabinoids will continue to be studied and approved for use as ingredients in pharmaceutical drugs.

The second lane, which is as yet unaddressed comprehensively from a medical safety and efficacy standpoint, is the *medical dispensary* route, whereby patients with qualifying conditions are authorized to consume cannabis flower in its whole botanical form (or any other form, for that matter) with the authorization of a physician. In this lane, doctors and patients don't necessarily care about the individual genetics of the plant – rather, they look holistically at the plant and recognize it naturally contains a spectrum of ingredients which, taken together, contribute to the patient's healing. But the fact that medical cannabis users often use cannabis in the exact same way that nonmedical (also known as adult-use or recreational) cannabis users do seems to frustrate conversations about cannabis' medical value.

All of this is underpinned by the fact that the human body contains within it an endocannabinoid system, which regulates and controls many critical bodily functions. This means our brains and immune cells actually have *built-in cannabinoid receptors*. Different tissues in the body produce *endocannabinoids*, which bear an uncanny structural resemblance to cannabinoids found in cannabis. Some scholars even believe that THC may be able "to compensate for a deficiency or defect in the production or functions of [human] endocannabinoids."

Without knowing any more than that, doesn't it seem a little **absurd** that lawmakers insist that a plant that delivers its (overwhelmingly pleasant) effects into a perfectly designed system within the human body is fundamentally unsafe for humans?

"Avoiding Absurdity"

Within our system of government, the "separation of powers" doctrine is used to describe the U.S. Constitution's delegation of certain powers to each of the three branches of government, so that no one branch is all-powerful. With respect to the laws themselves, the legislative branch, comprised of Congress, *makes* the laws; the executive branch, comprised of the President and the appointed heads of myriad federal agencies, *enforces* the laws; and the judicial branch, comprised of the Federal Courts, including the U.S. Supreme Court, *interprets* the laws.

But why do laws need interpretation? Statutes are the laws themselves, passed by a legislature and written down somewhere in a federal, state, or local code. Because the English language is imperfect at best, this often means that the precise words used in

¹ Nagarkatti, Mitzi and Prakash Nagarkatti. *People produce enocannabinoids – similar to compounds found in marijuana – that are crucial to many bodily functions*. The Conversation. 22 February 2023. Accessed 18 April 2024. https://theconversation.com/people-produce-endocannabinoids-similar-to-compounds-found-in-marijuana-that-are-critical-to-many-bodily-functions-198220.

drafting a statute can be vague, confusing, contradictory, or *ambiguous*, meaning the same statute can be read to have more than one logical meaning or understood in multiple ways. This means that courts, tasked with *interpreting the laws*, are brought in when statutes are ambiguous to interpret the true meaning of the words, or of the drafters' intent, to ultimately make a determination as to what the statue means as applied to the current circumstances under which the question arose.

The process of statutory interpretation is a concept well known to attorneys, legal scholars, and pained first-year law students alike, whereby judges apply a set of historical "canons of construction," or rules, to the ambiguous text at issue. Among these canons is the concept of "avoiding absurdity," which at its core counsels that "[a] statute should be interpreted in a way that avoids absurd results." (Emphasis supplied.) "Absurd" is defined by Merriam-Webster as "ridiculously unreasonable, unsound, or incongruous."

Putting these concepts together, this means that *courts are tasked with interpreting laws to avoid ridiculously unreasonable, unsound, or incongruous results*. When applied to the knot of prohibitionist, conflicting laws and policy around medical cannabis in the U.S., it becomes clear that we have been led straight into absurdity, which as a purely legal concept, *cannot stand*.

Where We Started

The United States' treatment of cannabis with respect to its medical benefits has been **absurd** since the beginning of its regulation.

"In the early days of the Republic, it would have been unthinkable that Congress could prohibit the local cultivation, possession, and consumption of marijuana."⁴ – Clarence Thomas.

The Cannabis sativa L. plant, varieties of which can be considered what we currently define as "hemp" or "marijuana," has been grown in the U.S. before the country even existed. It was widely cultivated as a cash crop in the early days of colonial America. At one point, hemp was even considered legal tender in Pennsylvania, Virginia, and Maryland.⁵ By the late 1800s, cannabis was a popular ingredient in medicinal products and was openly sold in pharmacies all over the country.⁶

In 1937, Congress enacted the Marihuana Tax Act, over objections from the American Medical Association (AMA). Harry J. Anslinger, head of the Federal Bureau of Narcotics (the precursor to the modern DEA), both drafted the initial bill and led the charge to convince Congress to pass it. In Anslinger's testimony before Congress, he relied on intense, fear-

² U.S. v. Dauray, 215 F.3d 257, 264 (2d Cir. 2000).

³ Absurd, Merriam-Webster Dictionary (online ed. 2024).

⁴ Gonzales v. Raich, 545 U.S. 1, 59 (2005). (Thomas, C., dissenting).

⁵ Marijuana Timeline, Frontline, PBS.org. Accessed 18 April 2024. https://www.pbs.org/wgbh/pages/frontline/shows/dope/etc/cron.html

based media propaganda that portrayed cannabis users as "violent addicts," which Congress accepted as fact.

One of the only medical practitioners to speak during the deliberations was Dr. William C. Woodward, Legislative Counsel for the AMA.⁷ During his testimony, Dr. Woodward questioned why the medical profession had not been consulted in drafting the bill, stated that the AMA opposed restrictions on prescribing medical cannabis under the Act, and suggested a number of federal agencies which should have been called as sources of information to substantiate the negative effects of cannabis the bill was trying to protect the public from (including the Bureau of Prisons, the Children's Bureau, the Office of Education, and the Public Health Service).

Does it not seem **ridiculously unsound (absurd)** to enact sweeping, prohibitive legislation out of concern for the safety of the effects of a plant used for centuries *for medical purposes*, without consulting the medical community?

Following the passage of the Marihuana Tax Act, in 1938, the then-mayor of New York City, Fiorello LaGuardia, concerned with media coverage and rumors concerning "the smoking of marihuana by large segments of our population and even by school children," appointed a special committee to engage in a thorough sociological and scientific investigation of the impacts of the substance.⁸ In the Foreword to the special committee's final report, Mayor LaGuardia himself wrote, "I am glad that the sociological, psychological, and medical ills commonly attributed to marihuana *have been found to be exaggerated* insofar as the City of New York is concerned."⁹ (Emphasis supplied.) The report found "presumptive evidence that there is no true addiction in the medical sense associated with the use of marihuana," and that the "gateway drug" effect was "extremely rare where the habit of marihuana smoking is associated with addiction to these other narcotics." The committee interviewed many law enforcement officers at the federal, state, and local level, who reported "no proof that major crimes are associated with the practice of smoking marihuana."¹⁰

At the global level, in 1961, the UN passed the Single Convention of Narcotic Drugs. ¹¹ This convention, plus a network of other international treaties, requires countries to control cannabis, specifically to "limit exclusively to medical and scientific purposes for the production, manufacture, export, import, distribution of, trade in, use and possession of

⁷ Galliher, John F., and Allynn Walker. "The Puzzle of the Social Origins of the Marihuana Tax Act of 1937." *Social Problems*, vol. 24, no. 3, 1977, pp. 367–76. JSTOR, https://doi.org/10.2307/800089. Accessed 16 Feb. 2024.

⁸ LaGuardia, Fiorello. "LaGuardia Committee Report on Cannabis." Schaffer Library of Drug Policy. Druglibrary.net, 2024. 2 April 2024. https://www.druglibrary.net/schaffer/Library/studies/lag/lagmenu.htm.

⁹ *Id*.

¹⁰ Id. at "The Mental Attitude of the Marihuana Smoker Toward Society and Marihuana"

¹¹ United Nations, <u>Treaty Series</u>, <u>vol. 520</u>, p. 151, <u>vol. 557</u>, p. 280 (corrigendum to the Russian text), <u>vol. 570</u>, p. 346 (procès-verbal of rectification of the authentic Russian text), and vol. 590, p. 325 (procès-verbal of rectification of the authentic Spanish text).

drugs."¹² (Emphasis supplied.) The U.S. was initially in 1961, and still is, a party to the convention; its laws must appropriately control substances as scheduled by the Convention.

In 1970, Congress under the Nixon administration enacted the Controlled Substances Act, and placed "marihuana" among the most dangerous substances (such as heroin), within Schedule I, the category reserved for substances with high potential for abuse, **no** currently accepted medical use, and no acceptable safety for the substance under medical supervision. Under the framework of the CSA, substances listed in Schedule I are *never* legal, and are subject only to stringent criminal sanctions for "trafficking," including production, distribution, and possession of cannabis. Medical cannabis has remained on Schedule I since 1970, and today is *always illegal* at the federal level.

But why was cannabis given a Schedule I, no medical value designation in the U.S. when just nine years prior, the U.S. joined the Single Convention of Narcotic Drugs, which only required it to limit the use of cannabis exclusively to medical and scientific purposes? Those two decisions seem **incongruous** (absurd), don't they?

In comparison, cocaine, methamphetamine, OxyContin, and fentanyl are *currently scheduled* in the CSA's Schedule II, indicating these substances are less dangerous and subject to less control, oversight, and penalties than medical cannabis. This means the federal government currently believes medical cannabis is more dangerous than fentanyl, though we see headlines like these¹⁴ with alarming frequency. Objectively, this makes no sense, right? In the legal world, we call that **unreasonable (absurd)** legislation.

Just in case you weren't convinced yet that there was something more to cannabis' scheduling than considerations of safety and potential for abuse, in 1994, John Ehrlichmann, former White House Counsel to President Nixon, admitted on the record to a Harper's Magazine journalist that the CSA's schedules were assembled to engender bias and disrupt certain communities outright:

"We knew we couldn't make it illegal to be either against the war or black, but by getting the public to associate the hippies with marijuana and blacks with heroin, and then criminalizing both heavily, we could disrupt those communities. We could arrest their leaders, raid their homes, break up their meetings, and vilify them night after night on the evening news. Did we know we were lying about the drugs? Of course we did."15

So there we have it – proof, on the record, that cannabis was not placed on Schedule I out of genuine concern for public health and safety. Instead, it was vilified to disenfranchise

¹² *Id.* at Art. 4(1)(c)

^{13 21} USCS § 812(b)(1)

¹⁴ Richter, Felix. *Fentanyl Fuels Surge in U.S. Drug Overdose Deaths*, Statista.com, 16 April 2024. Accessed 23 April 2024, https://www.statista.com/chart/18744/the-number-of-drug-overdose-deaths-in-the-us/.

¹⁵ Baum, Dan. *Legalize it All*, Harper's Magazine. April 2016, pp. 22-32. Accessed 23 April 2024. https://harpers.org/archive/2016/04/legalize-it-all/.

communities exercising their constitutional right to peaceful protest. **How ridiculously unsound, unreasonable, and incongruous. How absurd.**

States' Rights: The CSA v. States' Recognition of Medical Cannabis' Value

In 1996, California became the first state to legalize medical cannabis through a voter-initiated referendum vote, Proposition 215. The law's mandate recognized the medical value of cannabis, "seriously ill Californians'" right to this medicine, and placed the discretion to determine safe use of medical cannabis in the hands of physicians:

To ensure that seriously ill Californians have the right to obtain and use marijuana for medical purposes where that medical use is deemed appropriate and has been recommended by a physician who has determined that the person's health would benefit from the use of marijuana in the treatment of cancer, anorexia, AIDS, chronic pain, spasticity, glaucoma, arthritis, migraine, or any other illness for which marijuana provides relief. (Emphasis supplied.)

But if the federal government has expressly prohibited the use of cannabis for medical purposes, how did this happen?

This is where constitutional law concepts of supremacy and preemption come into play. In a nutshell, the U.S. Constitution contains the "Supremacy Clause," which establishes that, when state and federal laws are in conflict with one another, the federal laws control. Preemption stands for the proposition, among others, that the federal government may choose to "preempt," or choose to *exclusively* regulate, an entire "field" of legislation, often those fields subject to complex regulatory schemes.

Interestingly, the CSA did not "preempt" the field of controlled substance regulation and enforcement – in fact, it contains a provision expressly stating otherwise. This is due to the federal government's relative lack of resources when it comes to law enforcement, resulting in a reliance on state and local governments to enforce criminal drug laws. Even though the CSA did not preempt the field of controlled substances, the CSA's prohibition on medical cannabis meant (and still means) that California's medical cannabis law was unlawful at the federal level.

As such, California cannabis laws have been subject to many legal challenges since they were enacted. Though the statutes legalizing cannabis have never been invalidated or overruled under federal law, the *Gonzales v. Raich* Court held that cannabis grown in the homes of medical patients, which never left the state, nevertheless impacted interstate commerce and was within the jurisdiction of the DEA to regulate.¹⁷ In her dissent, Justice O'Connor discussed the role of states as "laboratories" to promote innovation and experimentation, and that medical cannabis laws exemplified the need for such innovation.¹⁸

¹⁶ Cal Health & Saf Code § 11362.5(b)(1)(A)

¹⁷ See Gonzales v. Raich, 545 U.S. 1, 42 (2005).

¹⁸ *Id*. at 42

Thanks to California paving the way, in 2012, Colorado became the first state to legalize recreational, or adult-use, cannabis.

Where We Are Now

Medical cannabis laws and policy in the United States are incongruous, confusing, and contradictory; though 88% of adult Americans believe that cannabis should be legal for medical and/or recreational use.¹⁹

As of the date of this article, forty states and the District of Columbia have implemented some kind of medical cannabis program.

Some states' medical cannabis statutes are instructive as to its medical value. For instance, Minnesota's cannabis statues define a "qualifying medical condition" for medical cannabis patients to include a diagnosis of twenty conditions: Alzheimer's disease; autism spectrum disorder; cancer; chronic motor or vocal tic disorder; chronic pain; glaucoma; HIV or AIDS; intractable pain; obstructive sleep apnea; PTSD; Tourette's syndrome; amyotrophic lateral sclerosis; seizures or epilepsy; severe and persistent muscle spasms or multiple sclerosis; inflammatory bowel syndrome or Chrohn's disease; irritable bower syndrome; obsessive-compulsive disorder; sickle cell disease; terminal illness; or "any other medical condition or its treatment approved by the office."²⁰

But why such a gap between and the conclusions of 40 states' legislators and the CSA about the value of medical cannabis? One of the major challenges to combatting the Schedule I status of medical cannabis is that to obtain an "approved medical use" designation under federal law, traditional, double-blind clinical studies must be conducted to validate safety and efficacy of the substance. Under the CSA, the DEA holds exclusive authority to register or license participants to grow cannabis to use in clinical studies.

For many years, the CSA made it nearly impossible for researchers to obtain safe cannabis to use in research. Until 2020, the University of Mississippi held the *sole* federally granted license to cultivate cannabis for clinical trials. Dr. Sue Sisley made headlines beginning in 2020 for exposing the problem with cannabis grown by Ole Miss – the cannabis she was sent in order to conduct a clinical trial of cannabis' efficacy for treating PTSD was *moldy and unsafe for human consumption*. When Sisley applied for her own DEA license to cultivate cannabis for clinical trials and was stonewalled, she sued the DEA. In 2020, the DEA amended it regulations to facilitate the cultivation of cannabis for research purposes.

Today, there are eight DEA-approved bulk manufacture cannabis growers: Biopharmaceutical Research Company LLC; Bright Green Corporation; Groff NA Hemplex LLC; Irvine Labs, Inc.; Maridose, LLC; National Center for Development of Natural Products; Royal Emerald Pharmaceuticals Research and Develop; and the Scottsdale Research Institute (founded and run by Dr. Sisley):

¹⁹ Schaeffer, Katherine. 9 facts about Americans and marijuana, Pew Research Center, 10 April 2024. Accessed 18 April 2024. https://www.pewresearch.org/short-read/2024/04/10/facts-about-marijuana/

²⁰ Minn. Stat. § 342.01(63)

- Biopharmaceutical Research Company LLC the company's website states it is "developing phytocannabinoid-based treatments for the unmet medical needs of many." Planned and upcoming clinical trials include autoimmune/inflammatory disease, pain, and neurological diseases.²¹
- Bright Green Corporation "As the first publicly traded company (BGXX) in almost a century to receive federal authorization for the production of Schedule I and Schedule II plant-based drugs and APIs* for pharmaceutical applications, we are building on operational strongholds to establish and scale a reliable domestic supply chain for APIs."²² Regarding cannabis, "Through strict oversight, Bright Green's environmentally controlled greenhouse-cultivated medical cannabis is cost-effective, regulated, and more dependable than outdoor cultivation."²³
- Groff NA Hemplex LLC "GNA sells its cannabis products for federally authorized research, drug development, drug manufacturing, and export. Groff NA is one of only three commercially-focused cannabis companies with Schedule 1 registrations from the U.S. Drug Enforcement Administration for bulk cultivation of marijuana, and the only company to further possess registration for patient dose manufacturing (capsules, tinctures, lotions, etc)."24
- Irvine Labs, Inc. the company is developing a pipeline of therapeutics for both people and animals. For people, the pipeline includes drugs for insomnia, pain, topical pain, atopic dermatitis (eczema), and opioid abuse disorder.²⁵
- Maridose, LLC appears to be seeking investors and strategic partners.²⁶
- National Center for Development of Natural Products this is the group within Ole Miss that obtained the original license for Schedule I cannabis cultivation. "We are a university-based, academic research entity devoted to the discovery and development of new pharmaceutical and agrochemical technologies based on the amazing chemical diversity of living organisms – plants, animals and microbes."²⁷
- Royal Emerald Pharmaceuticals "As a registered DEA Schedule 1 Bulk Drug Manufacturer, Importer, and Exporter, we provide global access to a varied array of Schedule 1 substances, supporting medical researchers and developers in their pursuit of botanical drug formulations."²⁸

²¹ https://biopharmaresearchco.com/pipeline

²² https://brightgreen.us/

²³ https://brightgreen.us/services/#

²⁴ https://groffna.com/about-us/

²⁵ https://irvinelabs.com/science/pipeline/for-people/

²⁶ https://maridose.com/

²⁷ https://pharmacy.olemiss.edu/ncnpr/about/welcome/

²⁸ https://royalemeraldpharma.com/services/

• The Scottsdale Research Institute – this is Dr. Sisley's institute. "Once our Phase 1 Trial is complete, certain patients will be eligible for federally legal access to treatments including Psilocybin and Cannabis."²⁹

The HHS' US Patent No. 6,630,507

What if I told you that in complete contradiction to cannabis' designation as a Schedule I substance with no medical value, the federal government itself was able to profit off the medical use of ingredients found in cannabis?

Consider the following: the U.S. Department of Health and Human Services currently holds US Patent No. 6,630,507, granted in 2003.³⁰ The goal of the patent is stated as "to provide a new class of antioxidant drugs, that have particular application as neuroprotectants, although they are generally useful in the treatment of many oxidation associated diseases."³¹ Interestingly, Patent 6,630,507 also references *twelve* other U.S. patents related to cannabis.

One of the reasons for obtaining a patent is the potential revenue stream from licensing patented materials. Through the patent system, a patent holder can license its patent, for a fee, to other parties at its discretion. HHS has done this, and licensed its cannabinoid patent out to pharmaceutical companies, who have ultimately developed chemically synthesized, lab-created cannabinoids. As a result, both the federal government and pharmaceutical companies have been able to profit from cannabinoids. It is **unreasonable (absurd)** for the federal government to criminalize cannabis and prevent industry participants from profiting from it, while the federal government and its chosen pharmaceutical partners may profit.

Legal Pharmaceutical Synthetics (?!)

Ironically, synthetically produced cannabinoids or forms of THC are explicitly prohibited in many states' cannabis and hemp guidelines. But, as a result of the federal government's patent, several pharmaceutical synthetic cannabinoid-based medications serve as the *only* lawful medical cannabis available today.

Cannabis prohibitionist advocates often cite that synthetic cannabinoids have caused deaths to support the claims that cannabis is dangerous to human health. However, what these prohibitions fail to recognize is that these deaths were caused by true synthetic analogues of cannabinoids and THC – that is, those that did not derive (ever) from the Cannabis sativa

²⁹ https://www.scottsdaleresearchinstitute.org/

³⁰ Hampson, et al., Cannabinoids as antioxidants and neuroprotectants, US Patent 6630507 B1 (issued October 7, 2003).

³¹ *Id*. at 11.

L. plant – such as street drugs "Spice," "K2," or other types of "fake weed." In extreme case, these substances have been found to include rat poison.³²

However, consider the following – Dronabinol is an entirely *synthetic* form of THC that is the active ingredient in the prescription pill Marinol, and in the prescription eyedrop Syndros. Marinol and Syndros are two of the only FDA approved cannabinoid-based medications in the U.S. It is **incongruous and unreasonable (absurd)** that the U.S. views cannabinoids *derived from cannabis* as Schedule I substances with no recognized medical value, but expressly condones *synthetic* cannabinoids *developed in a lab* by pharmaceutical companies.

Further, the FDA has approved the medical use of Epidiolex, a cannabis plant-derived CBD medication developed in the UK, but has yet to approve any cannabis-derived formulations developed by U.S. researchers.

The Rohrabacher-Farr Amendment: DOJ Spending Rider Section 538

In 2014, and every year since, Congress has included a provision in its omnibus spending bill that states:

None of the funds made available in this Act to the Department of Justice may be used, with respect to [those states that have legalized medical marijuana] to prevent such States from implementing their own State laws that authorize the use, distribution, possession, or cultivation of **medical marijuana**.³³ (Emphasis supplied.)

This provision means that the federal government is prohibited from using any funds to prevent states from implementing medical marijuana programs. Combined with Ogden, Cole I, and Cole II, this law renders the CSA **ambiguous**, because it is impossible to square the CSA's assertion that cannabis has no medical value with the actions of Congress and the states that suggest otherwise. And an **ambiguous law which produces absurd results** is ripe for challenge.

2018 Farm Bill Legalizes "Hemp"

In December of 2018, the 2018 Farm Bill was signed into law. The 2018 Farm Bill changed the definition of "hemp" under 7 USC 1639(o) to define hemp as "Cannabis sativa L. and any part of that plant, including 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% on a dry weight basis." (Emphasis supplied.) This definition removed hemp, cannabis seeds, and derivatives of cannabis with no more than 0.3% delta-9 THC on a dry weight basis from the definition of marijuana in the CSA, effectively legalizing hemp and hemp-derived products throughout the U.S.

³² Powell, Devin. "The Spice of Death: The Science behind Tainted "Synthetic Cannabis." Scientific American, 17 April 2018. 4 April 2024 https://www.scientificamerican.com/article/the-spice-of-death-the-science-behind-tainted-synthetic-cannabis/

³³ H.Amdt.332 to H.R.2578

While this was great news for the cannabis industry at large, which I discussed in my fivepart series, and great news for patients seeking access to hemp-derived, CBD-rich medications, it had the effect of creating even more absurdity

For one, as the Farm Bill states, hemp and marijuana are not two different plants – they are the same exact plant, *Cannabis sativa L*. Under the Farm Bill, what separates lawful hemp from unlawful marijuana can be a *tenth of a percent* of delta-9 THC, detectable only through sophisticated gas chromatography or similar processes. In reality, this means it's nearly impossible for consumers, operators, regulators, and law enforcement to tell the difference between the two products.

In addition, the Farm Bill authorized states to implement their own regulatory framework for hemp, and authorized the FDA to regulate the safety of hemp products nationwide (which it has refused to do using the existing framework). Six states chose not to regulate hemp within their borders, relying on the USDA's plan. As a result, this means that 46 states and the USDA have different systems for regulating hemp products – which, for an industry participant, is ridiculously incongruous (absurd) and from a law enforcement perspective, is unsound (absurd). Most of these states use different definitions for important scientific concepts, such as "synthetic," leaving room for confusion, bad actors, and some legal "loopholes" that allow enterprising hemp operators to synthesize large amounts of hemp-derived CBD into hemp-derived THC and sell products that look, feel, and produce effects like cannabis. On top of that, there is no way to comply with all 50 states' regulations around hemp products at the same time.

What the Rest of the World is Doing

On December 2, 2020, recognizing recommendations from the World Health Organization (WHO), the UN voted to remove cannabis for medicinal purposes from a category of the world's most dangerous drugs. Recommendation 5.1 set forth that cannabis and cannabis resin, which were then included in Schedule I and Schedule IV of the Single Convention on Narcotic Drugs of 1961, be controlled only under the least restrictive category - Schedule I. For the purpose of clarity, Schedule I in the Single Convention on Narcotic Drugs of 1961 is a lesser restricted set of drug controls than Schedule IV. (This is, of course, is different than the Schedule I designation under the United States Controlled Substances Act which is the most restrictive category or control.)

With this vote, in one fell swoop, the notion that cannabis is a drug with a high potential for abuse and no therapeutic benefits was stricken from the tenets of global drug policy, and the fact that cannabis is "deleterious to society" - a notion underlying the 1961 Convention – was struck a tremendous blow.

The US voted in favor of Recommendation 5.1, explaining that due to recent, well-controlled clinical trials, "the legitimate medical use of a cannabis preparation has been established through scientific research, and *cannabis no longer meets the criterion for placement in Schedule IV of the Single Convention.*"³⁴ (Emphasis supplied).

³⁴https://www.unodc.org/documents/commissions/CND/CND Sessions/ CND 63Reconvened/ECN72020 CRP24 V2007524.pdf page 12

But if, according to the US itself, cannabis no longer meets the criterion for the Convention's Schedule IV, why is it still a Schedule I substance under the CSA? And is it not wildly **incongruous (absurd)** that the US *voted for* the reclassification of medical cannabis at the global level, but continues to assert, via the CSA, that cannabis has no recognized medical value?

On April 1, 2024, Germany became the latest country to enact laws affirmatively legalizing personal possession of cannabis. In Germany, citizens may possess up to 25g of dried cannabis, and cultivate up to three cannabis plants in their homes. In doing so, Germany joined a small group of countries where cannabis is a legal substance for recreational use, joining Uruguay (legalized in 2013), Georgia (2018), South Africa (2018), Canada (2018), Mexico (2021), Malta (2021), Thailand (2022), and Luxembourg (2023).

Of course, the medical use of cannabis is much broader around the globe, with close to fifty countries that have legalized medical cannabis. Still more countries are testing out strategies to decriminalize or legalize cannabis.

In March 2024, <u>Swiss company Alpen Group and Boulder, CO-based Wana Brands announced a new partnership</u> where Alpen will manufacture Wana's edible cannabis gummies, as part of Switzerland's Art. 8a NarcA cannabis pilot program "designed to deliver insights on the impact of measures, usefulness of instruments and effectiveness of approaches regarding the use of non-medicinal cannabis."³⁵

Despite more states and countries creating legal pathways for medical cannabis, there is much more to be done in terms of scientific and medical research around its value. As discussed above, the current system's two lanes include both the pharmaceutical route, isolating and using cannabinoids as *ingredients*, and the medical dispensary route, focusing on using the plant *holistically* to leverage its natural construction, and how cannabis interacts with the human endocannabinoid system. The latter path is where much more research is needed.

While some have touted the <u>"entourage effect"</u> of cannabis, which is the idea that the *combination* of the cannabinoids, terpenes, and phytocannabinoids working in concert that produce the "high" a consumer experiences, there is little known about the potential medical benefits of the entourage effect for medical cannabis.

And those benefits can be game-changing. Ohio lawmakers are considering adding Female Orgasmic Disorder as a qualifying condition for the state's medical cannabis program. The cannabis flavonoid Caflanone, derived from a rare Jamaican cannabis strain Black Swan, was granted Orphan drug status by the FDA in 2019 and is being used in pancreatic cancer treatment trials. Rick Simpson has suggested that his high-potency Phoenix Tears oil is effective at treating ailments from skin cancer to Crohn's disease. With a nation so afflicted by cancer and opioid addiction, the possibilities in front of us appear endless.

Conclusion

³⁵ <u>Switzerland Federal Office of Public Health FOPH – Authorisation of pilot trails under Art.</u> <u>8aNarcA</u>

Reviewing the history of the U.S.' prohibition of medical cannabis, it becomes clear that the federal government knew about cannabis' medical value hundreds, if not thousands of years, yet it led us straight into absurdity when it chose, time and again, to legislate otherwise. As a legal concept, I would argue these laws cannot stand.

But beyond that, what the U.S.' behaviors around the use of medical cannabis indicate – through licensing its patent on cannabinoids (to allow it and pharmaceutical companies to profit) and fully accepting the use of fully synthesized cannabis-based drugs (which allow pharmaceutical companies to profit) – is that they actually are not concerned with "safety," but are, as always, concerned with the interests of a small few.

So, what ultimately happens when the DEA reschedules cannabis to Schedule III under the CSA? Well first, cannabis does not become automatically legal – the DEA tightly controls Schedule III substances through a registered supply chain. But at least some industry afficionados assert that one interpretation of Section 8.29 of the CSA is that Schedule III substances may be legally dispenses by a "practitioner" through an "order" that could ostensibly be filled at a pharmacy (or dispensary-like pharmacy) without a "physician" writing a "prescription."

Second, finances become somewhat easier, as cannabis operators will be immediately freed from IRS Code Section 280E, which forbids the deduction of ordinary and necessary business expenses for tax purposes, resulting in an impossible to maintain effective tax rate. But more will be needed for the current industry, whose operators are in desperate need of capitalization and don't have access to traditional banking or investment – though rescheduling sends a signal of legitimacy from the federal government.

Hopefully, rescheduling paves the way for legislative action to further correct the absurdity of our medical cannabis laws and policy – and leads us towards true healing.