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ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT (FEBRUARY 3, 2020)

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

MARVIN WASHINGTON, DEAN BORTELL, as Parent of Infant ALEXIS BORTELL, ALEXIS BORTELL, JOSE BELEN, SEBASTIEN COTTE, as Parent of Infant JAGGER COTTE, JAGGER COTTE, CANNABIS CULTURAL ASSOCIATION INC.,

Plaintiffs-Appellants,

v.

WILLIAM PELHAM BARR, In His Official Capacity as United States Attorney General, UNITED STATES DEPARTMENT OF JUSTICE UTTAM DHILLON, In His Official Capacity as the Acting Administrator of the Drug Enforcement Administration, UNITED STATES DRUG ENFORCEMENT ADMINISTRATION, UNITED STATES OF AMERICA,

Defendants-Appellees.

Docket No. 18-859

Before: DENNIS JACOBS, GUIDO CALABRESI, Circuit Judges., Jed S. RAKOFF, District Judge.*

On May 30, 2019, we gave Appellants six months to file a petition with the Drug Enforcement Administration to reclassify marijuana under the Controlled Substances Act, noting that a failure to do so would result in affirmance of the district court's judgment dismissing the case. On January 3, 2020, we denied Appellants' motion for an 18-month extension to file their petition. Moreover, on January 17, 2020, Appellants informed us that they do not plan to file a petition. Accordingly, it is hereby ORDERED that the district court's judgment is AFFIRMED and the case is DISMISSED with prejudice.

For the Court:

/s/ Catherine O'Hagan Wolfe
Clerk of Court

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* Judge Jed S. Rakoff, of the United States District Court for the Southern District of New York, sitting by designation.

OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT (MAY 30, 2019)

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

MARVIN WASHINGTON, DEAN BORTELL,
as Parent of Infant ALEXIS BORTELL,
JOSE BELEN, SEBASTIEN COTTE,
as Parent of Infant JAGGER COTTE,
CANNABIS CULTURAL ASSOCIATION INC.,

Plaintiffs-Appellants,

v.

WILLIAM PELHAM BARR, in His Official Capacity
as United States Attorney General, UNITED
STATES DEPARTMENT OF JUSTICE
UTTAM DHILLON, in His Official Capacity as the
Acting Administrator of the Drug Enforcement
Administration, UNITED STATES DRUG
ENFORCEMENT ADMINISTRATION,
UNITED STATES OF AMERICA,

Defendants-Appellees.[1]

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[1] The Clerk of Court is respectfully requested to amend the official caption as set forth above.

Docket No. 18-859

Before: JACOBS, CALABRESI, Circuit Judges., RAKOFF, District Judge.[2]

GUIDO CALABRESI, Circuit Judge:

This is the latest in a series of cases that stretch back decades and which have long sought to strike down the federal government's classification of marijuana as a Schedule I drug under the Controlled Substances Act (CSA), 21 U.S.C. § 801 *et seq. See, e.g.*, *Krumm v. Drug Enforcement Admin.*, 739 F. App'x 655 (D.C. Cir. 2018) (mem.); *Ams. for Safe Access v. Drug Enforcement Admin.*, 706 F.3d 438 (D.C. Cir. 2013); *Alliance for Cannabis Therapeutics v. Drug Enforcement Admin.*, 15 F.3d 1131 (D.C. Cir. 1994) (mem.). The current case is, however, unusual in one significant respect: among the Plaintiffs are individuals who plausibly allege that the current scheduling of marijuana poses a serious, life-or-death threat to their health. We agree with the District Court that Plaintiffs should attempt to exhaust their administrative remedies before seeking relief from us, but we are troubled by the Drug Enforcement Administration (DEA)'s history of dilatory proceedings. Accordingly, while we concur with the District Court's ruling, we do not dismiss the case, but rather hold it in abeyance and retain jurisdiction in this panel to take whatever action might become appropriate if the DEA does not act with adequate dispatch.

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[2] Judge Jed S. Rakoff, of the United States District Court for the Southern District of New York, sitting by designation.

STANDARD OF REVIEW

The trial court granted Defendants' motion under Federal Rules of Civil Procedure 12(b)(1) and (6) to dismiss Plaintiffs' case. We therefore review its decision *de novo*, accepting as true all of the complaint's well-pleaded facts. *See d'Amico Dry Ltd. v. Primera Maritime (Hellas) Ltd.*, 886 F.3d 216, 222 (2d Cir. 2018); *Harris v. Mills*, 572 F.3d 66, 71 (2d Cir. 2009).

BACKGROUND

A. Parties

As this case reaches us at the motion to dismiss stage, we must treat the well-pleaded facts alleged in Plaintiffs' complaint as true. According to their pleadings, Plaintiffs are several individuals and a membership organization with an interest in the regulation of marijuana. They assert that the classification of cannabis as a Schedule I substance under the CSA harms them in one or more ways.

Marvin Washington is an African-American businessman working in the medical marijuana space. He would like to expand his business into whole-plant cannabis products and take advantage of the federal Minority Business Enterprise Program, but, he alleges, he is impeded from so doing by the drug's scheduling.

Alexis Bortell and Jagger Cotte are children with dreadful medical problems. Bortell suffers from chronic and intractable seizures; Cotte from Leigh's disease. They allege that they exhausted traditional treatment options before finding success medicating with cannabis. They claim that marijuana has saved their lives. Because of its Schedule I classification, however, they cannot bring their life-saving medicine

with them when they travel onto federal lands or into states where marijuana is illegal. For Bortell, these travel limitations also mean that she cannot take full advantage of the veteran's benefits to which she is entitled through her father. In addition, both Bortell and Cotte live in constant fear that their parents might be subject to arrest and prosecution for their involvement in their children's medical treatment.

Jose Belen is a veteran of the war in Iraq and suffers from post-traumatic stress disorder. After his honorable discharge, he became suicidal and was adjudged 70% disabled. He alleges that he pursued conventional therapies unsuccessfully. In despair, he turned to medical marijuana. This, he claims, has allowed him to manage his symptoms. He further asserts, like Bortell, that marijuana's Schedule I classification restricts his ability to travel and to take full advantage of his veteran's benefits.

The Cannabis Cultural Association, Inc. (CCA) is a not-for-profit organization dedicated to assisting people of color develop a presence in the cannabis industry. CCA is particularly focused on the way past convictions for possession, cultivation, distribution, and use of marijuana have disproportionately affected people of color and prevented minorities from participating in the new state-legal marijuana industry.

Defendants are the United States, the Attorney General, the Department of Justice, the Acting Administrator of the DEA, and the DEA itself. They are responsible for implementing the CSA and, more particularly, for updating the classification of controlled substances. *See* 21 U.S.C. § 811(a); 28 C.F.R. § 0.100(b).

B. Proceedings below

Plaintiffs initiated the instant suit in the Southern District of New York in July 2017 and filed the amended complaint now at issue on September 6, 2017. Plaintiffs raised numerous arguments for re– or deschedule marijuana, including, as relevant to this appeal, (a) that the classification of marijuana as a Schedule I drug exceeded Congress's powers under the Commerce Clause and was without a rational basis, (b) that the classification was arbitrary and capricious, (c) that marijuana's inclusion in the CSA was racially animated and is an act of viewpoint discrimination, and (d) that the law, as applied to Plaintiffs, violates variously their (or, in CCA's case, its members') First, Fifth, and Ninth Amendment rights, including, *inter alia*, substantive due process and the fundamental right to travel.

The crux of Plaintiffs' case is that new facts related to the acceptance of medical marijuana treatment regimens and the federal government's own involvement in medical marijuana research require a reexamination of marijuana's scheduling under the CSA. The complaint seeks declaratory relief, as well as an injunction restraining Defendants from enforcing the CSA with respect to cannabis. In reply, Defendants moved to dismiss.

After argument, the District Court granted the government's motion and dismissed Plaintiffs' suit. It further held that amending the complaint would be futile. As a threshold matter, the Court determined that Plaintiffs had failed to exhaust their administrative remedies and that they did not qualify for an exception to the exhaustion rule. On the merits, the Court did not find Plaintiffs' arguments persuasive

and deemed their claims to be either foreclosed by precedent or without legal authority. The Court additionally held that CCA failed to establish that it had standing to pursue its claim, since the relief it sought would not redress the injury its members had allegedly suffered. The District Court entered judgment on February 26, 2018, and this appeal timely followed.

DISCUSSION

We resolve this case without reaching most of Plaintiffs' disparate arguments. As the District Court correctly observed, Plaintiffs challenge the current classification of marijuana as a Schedule I substance under the CSA but did not first bring this challenge to the agency that has the authority to reschedule marijuana, the DEA.[3] Although the CSA does not expressly mandate the exhaustion of administrative remedies, our precedents indicate that it is generally to be required as a prudential rule of judicial administration. We agree with the District Court that exhaustion was

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[3] The CSA places in the Attorney General the power to schedule, reschedule, or deschedule drugs. *See* 21 U.S.C. § 811(a). The Attorney General has promulgated rules delegating this power to the head of the DEA. *See* 28 C.F.R. § 0.100(b). The CSA further requires that, before scheduling, rescheduling, or descheduling a drug, the Attorney General "shall . . . request from the Secretary [of Health and Human Services] a scientific and medical evaluation [of the drug], and [the Secretary's] recommendations, as to whether such drug or other substance should be so controlled or removed," which "shall be binding on the Attorney General as to such scientific and medical matters." 21 U.S.C. § 811(b). The process for reviewing a drug's scheduling can be initiated by the Attorney General, the Secretary of Health and Human Services, or "on the petition of any interested party." *Id.* § 811(a).

appropriate here. But in light of the allegedly precarious situation of several of the Plaintiffs, which at this stage of the proceedings we must accept as true, and their argument that the administrative process may not move quickly enough to afford them adequate relief, we retain jurisdiction of the case in this panel, for the sole purpose of taking whatever action might become appropriate should the DEA not act with adequate dispatch. We wish to make clear, however, that, in doing so, we express no view whatever on the merits of Plaintiffs' case—that is, on whether marijuana should be listed or not.

A. Exhaustion of Administrative Remedies Is Appropriate Here

The administrative state is a topic of much debate these days. *See* Gillian E. Metzger, *The Supreme Court, 2016 Term—Foreword: 1930s Redux: The Administrative State Under Siege*, 131 Harv. L. Rev. 1 (2017). Distinguished jurists and scholars have been critical of its expansion. *See, e.g.*, *Gutierrez-Brizuela v. Lynch*, 834 F.3d 1142, 1149 (10th Cir. 2016) (Gorsuch, *J.*, concurring); Philip Hamburger, *Is Administrative Law Unlawful?* (2014). Others understand it as a central part of our modern republic. *See generally* Stephen Skowronek, *Building a New American State: The Expansion of National Administrative Capacities, 1877-1920* (1982); *see also* Jerry L. Mashaw, *Creating the Administrative Constitution: The Lost One Hundred Years of American Administrative Law* (2012) (tracing the roots of the administrative state back to the Founding). Regardless of one's point of view, it remains at the moment a key part of our legal regime. The doctrines that regulate the relationship between courts and administrative agencies are thus

of particular importance. They attempt to reconcile the advantages of expertise, flexibility, and efficiency with the safeguards of government under law. *See* Daniel R. Ernst, *Tocqueville's Nightmare: The Administrative State Emerges in America, 1900-1940* (2014).

Exhaustion of administrative remedies is one such doctrine. It holds that federal courts should refrain from adjudicating a controversy if the party bringing suit might obtain adequate relief through a proceeding before an administrative agency. *See Woodford v. Ngo*, 548 U.S. 81, 88-89 (2006) ("[N]o one is entitled to judicial relief for a supposed or threatened injury until the prescribed administrative remedy has been exhausted.") (internal quotation marks and citations omitted). The duty to exhaust administrative remedies can spring from legislation or from judicial decision. "Where Congress specifically mandates [it], exhaustion is required." *McCarthy v. Madigan*, 503 U.S. 140, 144 (1992), *superseded by statute on other grounds as recognized in Porter v. Nussle*, 534 U.S. 516 (2002). "But [even] where Congress has not clearly required exhaustion," a court may still impose it as an act of "sound judicial discretion." *Id.*

Before requiring exhaustion as a "rule of judicial administration," *Myers v. Bethlehem Shipbuilding Corp.*, 303 U.S. 41, 50 (1938), a court should, however, look to "legislative purpose, which is of paramount importance." *Patsy v. Bd. of Regents of State of Fla.*, 457 U.S. 496, 501 (1982). Simply put, "a court should not defer the exercise of jurisdiction under a federal statute unless it is consistent with [congressional] intent." *Id.* at 501-02; *see also id.* at 502 n.4 ("Even where the statutory requirement of exhaustion is not explicit, courts are guided by congressional intent in

determining whether application of the doctrine would be consistent with the statutory scheme.").

Although the CSA does not mandate exhaustion of administrative remedies, we agree with the court below that exhaustion here is consistent with congressional intent and is therefore appropriate. This judgment flows from our analysis of the text and structure of the Act.

The text of the CSA shows that Congress sought to favor administrative decision-making. In several places, the words of the statute either presume or create an administrative process to review the classification of drugs under the

Act's schedules. Thus, 21 U.S.C. § 811(a) instructs the Attorney General to schedule, reschedule, or deschedule drugs under the Act by rules "made on the record after opportunity for a hearing pursuant to the rulemaking procedures prescribed" by the Administrative Procedure Act, 5 U.S.C. § 551 *et seq*. Similarly, 21 U.S.C. § 811(b) details the procedures the Attorney General should follow when scheduling, rescheduling, or descheduling drugs, including a duty to defer to the Secretary of Health and Human Services on certain medical and scientific matters. And § 811(c) lists several factors the Attorney General must consider before initiating classification. *See generally Ams. for Safe Access*, 706 F.3d at 439-41.

These provisions, among others, establish that Congress intended to implement scheduling decisions under the CSA through an administrative process. Requiring would-be plaintiffs to exhaust that process before turning to the courts is consonant with that intent. Were plaintiffs able to go directly to federal

court to pursue reclassification, the language Congress devised to erect an administrative review process would be rendered a nullity. It follows that construing the Act to allow such behavior as a matter of course would violate a basic canon of statutory interpretation: that, if possible, every provision of a statute must be given effect. *See, e.g.*, *Williams v. Taylor*, 529 U.S. 362, 404 (2000).

The structure of the Act reinforces the language used and hence our conclusion that Congress wanted aggrieved parties to pursue reclassification through agencies, and not, in the first instance, through the federal courts. The CSA relies on an administrative process to operate effectively. When Congress enacted the CSA, it put, by legislative fiat, certain drugs directly into schedules. *See* Controlled Substances Act, Pub. L. No. 91-513, § 202, 84 Stat. 1236, 1247-52 (1970) (codified at 21 U.S.C. § 812); *see also Gonzales v. Raich*, 545 U.S. 1, 14 (2005). But the statute contemplated that these initial lists would be regularly revised and updated by the Attorney General, in consultation with the Secretary of Health and Human Services, and that this would be done according to a specific procedure and set of standards. *See* 21 U.S.C. §§ 811(a)-(c). The Act thus incorporates an administrative process into its structure. Indeed, its logic and design depend on administration and agency actions to realize its aims. Not to require exhaustion in the ordinary case would therefore undermine the text and structure of the CSA.

In addition, requiring exhaustion is eminently sensible here. The Supreme Court has told us that exhaustion furthers two important goals. First, it "protect[s] administrative agency authority." *McCarthy*, 503

U.S. at 145. By "defer[ing] to Congress' delegation . . . to coordinate branches of Government," exhaustion recognizes "that agencies . . . have primary responsibility for the programs that Congress has charged them to administer." *Id.* Second, exhaustion "promotes judicial efficiency" by giving an administrative agency a chance to resolve a dispute, thus either rendering controversies moot or "produc[ing] a useful record for subsequent judicial consideration." *Id.*

Both purposes are advanced by requiring exhaustion in the instant case. The Supreme Court has recognized that protecting agency authority is a particularly compelling aim where "the agency proceedings in question allow the agency to apply its special expertise." *Id.* (citing *McKart v. United States*, 395 U.S. 185, 194 (1969)). That is the situation in the case before us now. At its root, the question raised by Plaintiffs' suit is whether developments in medical research and government practice should lead to the reclassification of marijuana. This is precisely the kind of question that calls for the application of special knowledge. Exhaustion here "protect[s] administrative agency authority" by leaving this decision in the first instance to the specialists at the DEA and the Department of Health and Human Services. *Id.*

Administrative exhaustion will also promote judicial efficiency in the ways identified by the Supreme Court. It is conceivable that, in response to a petition from Plaintiffs along the lines advanced before us now, the DEA would reschedule marijuana, rendering the current case moot. And if the DEA did not, the administrative process would generate a comprehensive record that would aid in eventual judicial review. The Supreme Court has observed that the creation of

such a record can be "especially" beneficial "in a complex or technical factual context," *id.*, which is the context involved in the case at bar. *Accord Shenandoah v. U.S. Dep't of Interior*, 159 F.3d 708, 713 (2d Cir. 1998); *City of New York v. Heckler*, 742 F.2d 729, 737 (2d Cir. 1984).

Moreover, we think that the kinds of arguments Plaintiffs advance make this case well suited to administrative evaluation and inappropriate for federal court determination in the first instance. Plaintiffs do not contend that a decisive event or singular discovery has rendered the previous classification of marijuana under the CSA indefensible. Rather, Plaintiffs claim that a shift over time in our understanding of the uses and dangers of marijuana warrants a change in marijuana's classification. This argument raises a complex policy question: whether the extant regulatory regime continues to advance the CSA's goals in light of the current state of our knowledge about the drug. It is possible that the current law, though rational once, is now heading towards irrationality; it may even conceivably be that it has gotten there already. Courts are not especially good at dealing with situations of this sort by themselves. In such circumstances, dialogue between courts and other law-defining institutions, like agencies, often works best. *See United States v. Then*, 56 F.3d 464, 468-69 (2d Cir. 1995) (Calabresi, *J.*, concurring).

A sensible response to our evolving understanding about the effects of marijuana might require creating new policies just as much as changing old ones. This kind of constructive governmental work, mixing adjudication and program-design, creating policy through the balancing of competing legitimate interests, is not

generally best accomplished by federal courts on their own; it is, however, the stock-in-trade of administration. *See, e.g.*, James M. Landis, *The Administrative Process* (1938). Assuming, of course, that one can get the administrative agency to act.

For the foregoing reasons, requiring exhaustion is appropriate in the instant case. Although not mandated by Congress, it is consistent with congressional intent, as manifested in the CSA's text and structure. And it advances the goals that the Supreme Court has announced the doctrine serves. The District Court's decision to require exhaustion here was therefore correct.

B. None of the Recognized Exceptions to the Doctrine Govern This Case at This Time

Even where exhaustion is seemingly mandated by statute or decisional law, the requirement is not absolute. The Supreme Court itself has recognized exceptions to the exhaustion requirement under "three broad sets of circumstances." *McCarthy*, 503 U.S. at 146.

First, exhaustion may be unnecessary where it would be futile, either because agency decision-makers are biased or because the agency has already determined the issue. *Id.* at 148. It does not appear, however, that this futility exception currently applies here. Plaintiffs cite to various public statements by former Attorney General Jefferson Beauregard Sessions III and former Acting Administrator of the DEA Charles Philip Rosenberg to suggest that the administrative process would be biased against them. But Plaintiffs' evidence, even if given the interpretation they suggest, does not qualify them for the exception, since

the public statements relied on do not implicate the relevant decision-maker. Neither Sessions nor Rosenberg remains part of the review process. Nor, indeed, would they have been the relevant decision-makers at the time Plaintiffs initiated their suit. On the medical and scientific claims central to Plaintiffs' argument, it is the opinion of the Secretary of Health and Human Services that matters, not the judgment of the Attorney General or the head of the DEA. *See* 21 U.S.C. § 811(b) (stating that "[t]he recommendations of the Secretary to the Attorney General shall be binding on the Attorney General as to [the] scientific and medical" evaluation of substances considered for scheduling). Plaintiffs make no plausible allegations of bias on the part of the Secretary. Futility on account of bias has, therefore, not been adequately alleged.

The Supreme Court has further stated that exhaustion may be unnecessary where the administrative process would be incapable of granting adequate relief. *See McCarthy*, 503 U.S. at 147. That second exception, too, is inapposite at the moment. Although Plaintiffs style their claims in many different ways, the gravamen of their argument is that marijuana should not be classified as a Schedule I substance under the CSA. Were a court to agree, the remedy would be to re– or deschedule cannabis. It cannot be seriously argued that this remedy is not available through the administrative process. It is precisely the remedy provided under 21 U.S.C. § 801 *et seq*. Plaintiffs are therefore not currently entitled to bypass exhaustion under this second exception either.

Finally, exhaustion may be unnecessary where pursuing agency review would subject plaintiffs to

undue prejudice. *McCarthy*, 503 U.S. at 146-47. In particular, "an unreasonable or indefinite timeframe for administrative action" may sufficiently prejudice plaintiffs to justify a federal court in taking a case prior to the complete exhaustion of administrative remedies. *Id.* at 147. Not every delay will be sufficiently severe to justify waiver, however. Although, in most cases, "respondents would clearly prefer an immediate appeal . . . rather than the often lengthy administrative review process," a mere preference for speedy resolution is not enough. *Heckler v. Ringer*, 466 U.S. 602, 619 (1984). "[T]hreatened or impending irreparable injury flowing from delay incident to following the prescribed [administrative] procedure" militates in favor of waiving exhaustion, but only if there is a "strong showing . . . both [of] the inadequacy of the prescribed procedure and of impending harm." *Aircraft & Diesel Equip. Corp. v. Hirsch*, 331 U.S. 752, 773-74 (1947).

Despite the apparently dire situation of some of the Plaintiffs, they do not yet meet the requirement for this exception to the exhaustion requirement. In point of fact, the existing classificatory scheme has not prevented Plaintiffs Bortell, Cotte, or Belen from obtaining their allegedly life-saving medication. Nor have Plaintiffs otherwise explained how pursuing agency review would subject them to an additional "irreparable injury flowing from delay incident" to the administrative process itself. *Id.* at 773. Accordingly, despite their concededly difficult position, Plaintiffs are not currently entitled to bypass agency review.

C. *United States v. Kiffer* Does Not Require That We Waive Exhaustion Here at the Moment

The exhaustion requirement under the CSA is, however, prudential, not jurisdictional. It is not mandated by the statute. Rather, it is a judicially-created administrative rule, applied by courts in their discretion.

This explains why this Court has, on at least one previous occasion, considered a challenge to the scheduling of marijuana under the CSA without requiring exhaustion, in *United States v. Killer*, 477 F.2d 349 (2d Cir. 1973). That case is readily distinguishable, however, and its holding does not mean that exhaustion should not be required in the current case at this time. The *Killer* Court began by observing that "timely and successful use of th[e] administrative [process] would have obtained for [the] appellants [in that case] the very relief they seek from us—a declaration either that mari[j]uana should not be subject to the [CSA] or that it should be covered only in another schedule." *Id.* at 351. The Court began, then, with the assumption that exhaustion did apply. It waived the normal requirement only because of two factors that do not obtain in the instant case: first, because the "application of the . . . doctrine [of exhaustion] to criminal cases is generally not favored," *id.* at 352, and, second and more significantly, because, at the time *Kiffer* was heard, the federal government had taken the position that it did not have the power to re- or deschedule marijuana at all, as a result of foreign treaty commitments, *id.* at 351. Under those circumstances, where "there [wa]s some doubt whether appellants in fact [had] an administrative remedy," the Court declined to require exhaustion. *Id.* The instant

case is different. It is, of course, civil. And, as the D.C. Circuit has since held, foreign treaty commitments have not divested the Attorney General of the power to re- or deschedule marijuana. *See Nat'l Org. for Reform of Marijuana Law (NORML) v. Drug Enforcement Admin.*, 559 F.2d 735 (D.C. Cir. 1977). *Kiffer*'s result is therefore not controlling. In fact, the case's logic reinforces our conclusion that Plaintiffs should attempt to exhaust their administrative remedies before seeking relief from us. But *Kiffer* also makes clear that, when appropriate, we do have the power to act even if the administrative agency has not.

D. Strong Interests Compel This Court to Retain Jurisdiction

This case reaches us as an appeal from a ruling on a motion to dismiss. Under settled principles of adjudication, we must, therefore, accept the well-pleaded facts in the complaint as true. Taking the facts as alleged, and, accordingly, taking the supposed benefits some Plaintiffs have experienced from marijuana as true as well, we—like the District Court below—are struck by the transformative effects this drug has assertedly had on some Plaintiffs' lives. As a result, we are troubled by the uncertainty under which Plaintiffs must currently live. Plaintiffs claim that marijuana has extended their lives, cured seizures, and made pain manageable. If true, these are no small things. Plaintiffs should not be required to live indefinitely with uncertainty about their access to allegedly life-saving medication or live in fear that pursuing such medical treatment may subject them or their loved ones to devastating consequences.

Plaintiffs argue that the administrative process will prolong their ordeal intolerably. And their argument is not without force. Plaintiffs document that the average delay in deciding petitions to reclassify drugs under the CSA is approximately nine years. Such long delays cast doubt on the appropriateness of requiring exhaustion. *Accord Gibson v. Berryhill*, 411 U.S. 564, 575 n.14 (1973). And where, as here, health is involved, delay can be even more problematic. *See Abbey v. Sullivan*, 978 F.2d 37, 46 (2d Cir. 1992) (observing that, "if the delay attending exhaustion would subject claimants to deteriorating health . . . then waiver [of exhaustion] may be appropriate").

Indeed, on the alleged facts, which, we repeat, we must for now take as true, undue delay by the agency might make applicable each of the three exceptions to exhaustion that the Supreme Court has recognized and which we discussed earlier. Specifically, undue delay, if it in fact results in catastrophic health consequences, could make exhaustion futile. Moreover, the relief the agency might provide could, because of undue delay, become inadequate. And finally, and obviously, Plaintiffs could be unduly prejudiced by such delay.

To be clear, Plaintiffs have not alleged that they will necessarily suffer sufficient harm as a result of the time it would take to pursue the administrative process to justify an exception to exhaustion now. Plaintiffs do, however, plausibly raise the specter of delay and plausibly suggest that the delay could become problematic. And although agencies, like legislatures, are often the best decision-makers, this is so only when they actually do decide.

Courts have, moreover, on occasion deemed it proper to encourage prompt decision-making. Thus, where agencies have a history of dilatory proceedings, federal courts have sometimes retained jurisdiction of related cases to facilitate swift review. In *Telecommunications Research and Action Center v. F.C.C.*, 750 F.2d 70 (D.C. Cir. 1984), our sister circuit retained jurisdiction of a case in part because of the failure of a federal agency to act with adequate speed. *See* 750 F.2d at 80-81. "Whether or not the[] [agency's] delays would justify mandamus," the court stated, they were significant enough that it should retain jurisdiction to promote a quick resolution. *Id.* at 81; *see also, e.g.*, *In re Pesticide Action Network N. Am.*, 532 F. App'x 649, 652 (9th Cir. 2013) (summary order) (observing that "it is well established that we may retain jurisdiction over [a case] to ensure that [the agency] acts expediently"); *cf. Then*, 56 F.3d at 468-69 (2d Cir. 1995) (Calabresi, *J.*, concurring).[4]

We think it possible that future action by us may become appropriate here. Plaintiffs have not asked for—and we do not even consider issuing—a writ of mandamus to force the DEA to act. But we exercise our discretion to keep jurisdiction of the case in this panel, to take whatever action may become appropriate if Plaintiffs seek administrative review and the DEA fails to act promptly. And we note that, under

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[4] Some courts in other jurisdictions have gone even further in asserting a role for courts to ensure prompt action by lawmakers. *See Vincent v. Pabst Brewing Co.*, 177 N.W.2d 513, 517 (Wis. 1970); Corte Cost., 24 ottobre 2018, n. 207 (It.); *see generally* Guido Calabresi, *A Common Law for the Age of Statutes* (1982), especially *id.* at 35-37. We wish to make clear that we make no such assertion of power in the federal courts generally.

the unusual health-related circumstances of this case, what has counted as appropriate speed in the past may not count as appropriate speed here.

In doing this, we specify that we are not retaining jurisdiction to review the actions the agency may take. Jurisdiction over those may well lie solely in another circuit. Nor do we intend to retain jurisdiction indefinitely. Unless the Plaintiffs seek agency review and so inform us within six months, we will affirm the District Court's judgment dismissing this case. (And if only some Plaintiffs seek agency review, we will dismiss the complaint as to those who do not.) But if Plaintiffs do seek agency review, and the agency fails to act with alacrity, Plaintiffs may return directly to us, under our retained jurisdiction.[5]

To be clear, we repeat that this case remains in our purview only to the extent that the agency does not respond to Plaintiffs with adequate, if deliberate, speed. In other words, we retain jurisdiction exclusively for the purpose of inducing the agency to act promptly.

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[5] Because Plaintiffs' allegations with respect to the catastrophic harm they are facing are not implausible, we must take them as true at this stage of the litigation. Should the agency fail to act, we would, before proceeding further, however, have to look into the allegations more deeply. Accordingly, should the case return to us, it may be appropriate to remand to the District Court for further fact-finding. At that time, if Plaintiffs have not at least raised a disputed issue of material fact as to the veracity of their allegations, summary judgment against them would be appropriate.

CONCLUSION

Because Plaintiffs failed to exhaust their administrative remedies and do not at this time qualify for an exception to the exhaustion doctrine, the District Court did not err in requiring Plaintiffs to bring their claims to the relevant agency first. But, in light of the unusual circumstances of this case, we hold the case in abeyance and retain jurisdiction in this panel to take whatever further action might become appropriate should Plaintiffs initiate administrative review and the administrative process fail to operate with adequate dispatch.

DISSENTING OPINION BY JUDGE DENNIS JACOBS

DENNIS JACOBS, Circuit Judge, dissenting:

The plaintiffs seek a declaration that the classification of marijuana as a Schedule 1 substance is unconstitutional because it does not reflect contemporary learning regarding the drug's medicinal uses. I agree with the District Court that this case must be dismissed for failure to exhaust administrative remedies in the Drug Enforcement Agency ("DEA"). The majority opinion does not actually disagree, though it seems to treat lack of jurisdiction as a prudential speed bump. I dissent from the majority opinion's decision to hold the case in abeyance so that we may turn back to it if, at some future time, we get jurisdiction.

The majority posits that jurisdiction may materialize if the plaintiffs, claiming emergency, do not obtain a prompt decision on their not-yet filed petition to the DEA-but this seems to be no all-fired emergency, given that the plaintiffs are afforded half a year to file a petition on which hang supposed "serious, life-or-death" consequences. Majority Op. 3. For the following reasons, the plaintiffs' claims of emergency are tenuous, and constitute a further argument against retaining jurisdiction that we do not have in order to hurry along an administrative decision on a petition that has not been filed.

- Plaintiffs Dean Bortell and Sebastien Cotte sue on behalf of their severely ill children, who rely on marijuana for treatment. Bortell and Cotte concede that their children get all the treatment they need, including marijuana, and

dwell in states that do not outlaw it or that do not enforce any vestigial prohibition; their grounds for claiming urgency are that their children are unable to take that medicine with them if they travel onto federal lands or into states where marijuana is illegal. The parents add that they suffer fear they might be subject to federal prosecution because they are involved in their children's medical treatment. I view these claims as contrived and fanciful. Nobody need fear severe consequences for administering medical marijuana to sick children.

- Jose Belen is a veteran with post-traumatic stress disorder who successfully uses marijuana to manage his symptoms, but complains that his travel is restricted and that he cannot take full advantage of his veterans benefits (presumably for the government to pay for the marijuana).
- Plaintiff Marvin Washington asserts that he is impeded from seeking federal aid to expand his business so that he can sell cannabis products. No emergency here, and likely no standing either.
- Finally, the Cannabis Cultural Association assists people of color who wish to participate in the cannabis industry but who cannot because they jumped the gun, and have been arrested or convicted for cannabis use. I cannot see that this Association has standing to challenge the classification of marijuana under the

> nation's drug laws, let alone to seek an emergency resolution of that issue.
>
> [* * *]

As to the Judgment below, which dismissed the claims for failure to exhaust administrative remedies, I agree with the District Court-and with the majority opinion, which agrees that exhaustion is required (at least for now).

I part company with the majority opinion insofar as it holds the case in abeyance with the expectation of taking some measures if the DEA fails to act with "adequate dispatch." Majority Op. 27. Our failure to dismiss the case now is error for several reasons that are easily stated.

First, it is common ground that the case was properly dismissed under 12(b)(1) for failure to exhaust remedies; so neither this Court nor the District Court has jurisdiction to grant a remedy. And we cannot simply decide to wait for jurisdiction that (as we are properly ruling) we do not have. Our job as a circuit court is to issue mandates. We do not fulfill the requirements of the job by holding a case in abeyance on the off chance that we may get jurisdiction to decide it in the future.

Second, the terms of the hold on this case are without content: we may take "whatever further action" if the agency fails to act "promptly" or "with adequate dispatch" or "[with] appropriate speed" or "with alacrity". Majority Op. 25-27. This is of no help-the DEA is unlikely to discern what "adequate dispatch" or "appropriate speed" may mean for an

issue that (as the majority opinion observes) "stretch[es] back decades".[1] Majority Op. 2.

[* * *]

Given all this, it would be surprising if solid precedent supported this procedural invention. The majority opinion adduces none. The majority thinks that *United States v. Kiffer*, 477 F.2d 349 (2d Cir. 1973), "makes clear that, when appropriate, we do have the power to act even if the administrative agency has not." Majority Op. 22. But in that case, the Court excused administrative exhaustion only because the defendant had shown that exhaustion would be futile and unduly prejudicial. *Id.* at 351-352 ("[I]t appears now that the administrative route for [the defendants] would at best provide an uncertain and indefinitely delayed remedy . . . [and impose on them a] severe burden."). Accordingly, *Kiffer* stands only for the uncontroversial proposition that exhaustion may be excused where it would be futile or unduly prejudicial; it does not condone waiting around until an exception is met. The majority opinion (correctly) concludes that the plaintiffs do not meet the requirements for either exception. The relevance of *Kiffer* ends there.

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[1] The majority opinion also limits its "purview" to a failure of the agency to act with "adequate, if deliberate, speed." Majority Op. 26. The echo of that phrase from *Brown v. Board of Education II* is unfortunate, however, given that, in the many decades since, school integration is an unfinished project. The phrase seems to be derived from Admiralty law in the days of sail, which likewise offers no useful context. And in Francis Thompson's "Hound of Heaven," "deliberate speed" is the pace by which God pursues us. No help there either.

The majority opinion relies on *Telecommunications Research & Action Center v. F.C.C.*, 750 F.2d 70 (D.C. Cir. 1984) ("*TRAC v. F.C.C.*"); but that Court decided a mandamus petition (none is before us here). Moreover, the court did not hold the case in abeyance, but retained jurisdiction (that it already had) only to ensure that the agency fulfilled its *sua sponte* promise to address the issue expeditiously. And the court gave the agency specific direction. *Id.* at 80-81 (directing the agency to advise the Court of its progress every 60 days).

The majority opinion's "*e.g.*" cite to a single Ninth Circuit summary order does not bespeak a wealth of examples. In that case as well, the court considered a mandamus petition. It decided that a writ of mandamus was not warranted, and *declined* to retain jurisdiction, citing only *TRAC v. F.C.C.* for the proposition that it *could* have retained jurisdiction if it wanted to. *In re Pesticide Action Network N. Am.*, 532 F. App'x 649, 652 (9th Cir. 2013). (The parenthetical quote from Pesticide classifies itself as "well-established"-often a tell that the point is a novation.) The majority's remaining authority, a concurring opinion by Judge Calabresi, advances the speculative idea that courts may prod government when laws outlive the views of the *Bien pensant* community. None of these cases supports the idea that a court is permitted to hold a case in abeyance because the court may on contingency gain jurisdiction to hear it, and can bully the agency in the meantime. As near as I can make it out, the holding of the majority opinion is: a court without jurisdiction should proceed with caution.

[* * *]

I doubt that the DEA will be hurrying its work on an application that these plaintiffs have not yet filed, seeking administrative action on an old and ramified controversy. Unless the panel opinion precipitates a swift administrative rejection, there is no reason to anticipate a swift ruling that entails the assessment of countervailing risks, the pendency of legislation, and the eliciting of opinions on issues of medicine and public health. So I fully expect to see further proceedings in this appeal. No one can tell what this panel could do then, or (more accurately) would do. In the meantime, the one thing that will not happen is the issuance of the mandate, since I presume the majority will not thus oust this panel and this Court of the ability to take "whatever further action" may be necessary. Majority Op. 26. As and when this case returns to this Court and this panel, I will be an interested and bemused spectator.

A True Copy:

/s/ Catherine O'Hagan Wolfe
Clerk of Court

ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT DENYING PLANTIFF'S MOTION TO EXTEND (JANUARY 1, 2020)

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

MARVIN WASHINGTON, DEAN BORTELL, as Parent of Infant ALEXIS BORTELL, ALEXIS BORTELL, JOSE BELEN, SEBASTIEN COTTE, as Parent of Infant JAGGER COTTE, JAGGER COTTE, CANNABIS CULTURAL ASSOCIATION INC.,

Plaintiffs-Appellants,

v.

WILLIAM PELHAM BARR, In His Official Capacity as United States Attorney General, UNITED STATES DEPARTMENT OF JUSTICE UTTAM DHILLON, In His Official Capacity as the Acting Administrator of the Drug Enforcement Administration, UNITED STATES DRUG ENFORCEMENT ADMINISTRATION, UNITED STATES OF AMERICA,

Defendants-Appellees.

Docket No. 18-859

Before: DENNIS JACOBS, GUIDO CALABRESI, Circuit Judges., Jed S. RAKOFF, District Judge.*

Appellants move for an 18-month extension of time to file a petition with the Drug Enforcement Agency to de-schedule cannabis under the Controlled Substances Act.

IT IS HEREBY ORDERED that the motion is DENIED.

For the Court:

/s/ Catherine O'Hagan Wolfe
Clerk of Court

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* Judge Jed S. Rakoff, of the United States District Court for the Southern District of New York, sitting by designation.

OPINION AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK GRANTING MOTION TO DISMISS (FEBRUARY 26, 2018)

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MARVIN WASHINGTON, ET AL.,

Plaintiffs,

v.

JEFFERSON BEAUREGARD SESSIONS, III, ET AL.,

Defendants.

No. 17 Civ. 5625 (AKH)

Before: Alvin K. HELLERSTEIN,
United States District Judge.

ALVIN K. HELLERSTEIN, U.S.D.J.:

Plaintiffs Marvin Washington, Dean Bortell, Alexis Bortell, Jose Belen, Sebastien Cotte, Jagger Cotte, and the Cannabis Cultural Association, Inc. ("Plaintiffs") filed this action on July 24, 2017. Broadly stated, plaintiffs assert an as-applied constitutional challenge to the Controlled Substances Act ("CSA"), 21 U.S.C. § 801 *et seq.,* which classifies marijuana as a Schedule

I drug—the highest level of drug classification. Plaintiffs attempt to demonstrate the CSA's constitutional infirmity in a number of ways, but the gravamen of the complaint is that the current scheduling of marijuana violates due process because it lacks a rational basis.

On September 8, 2017, plaintiffs moved the Court for an order to show cause why a temporary restraining order should not issue. The Court denied plaintiffs' motion that same day, and issued a summary order confirming that result on September 11, 2017. *See* Order Denying a Temporary Restraining Order, ECF 26. After initially indicating a willingness to proceed into discovery, the Court reconsidered and entered a briefing schedule advancing defendants' motion to dismiss the complaint, *see* Order, ECF 33, filed October 13, 2017 under Federal Rules 12(b)(1) and 12(b)(6). The Court held oral argument on February 14, 2018. For the reasons discussed in this opinion, the defendants' motion to dismiss the complaint is granted.

BACKGROUND

In response to President Nixon's "war on drugs," Congress passed the Comprehensive Drug Abuse and Control Act of 1970. *Gonzales v. Raich,* 545 U.S. 1, 10 (2005). "Title II of the Act, codified at 21 U.S.C. § 801 *et seq.,* is the Controlled Substances Act ('CSA'), and it 'repealed most of the earlier antidrug laws in favor of a comprehensive regime to combat the international and interstate traffic in illicit drugs.'" *United States v. Green,* 222 F. Supp. 3d 267, 271 (W.D.N.Y. 2016) (quoting *Raich,* 545 U.S. at 7, 12). Congress made a number of findings associated with the CSA, including

that "[t]he illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people." 21 U.S.C. § 802(2).

"The Act covers a large number of substances, each of which is assigned to one of five schedules; this statutory classification determines the severity of possible criminal penalties as well as the type of controls imposed." *United States v. Kiffer,* 477 F.2d 349, 350 (2d Cir. 1973); *see also* 21 U.S.C. § 812(a). When the CSA was enacted, Congress classified marijuana as a Schedule I drug. "This preliminary classification was based, in part, on the recommendation of the Assistant Secretary of [the Department of Health, Education, and Welfare] that marihuana be retained within schedule I at least until the completion of certain studies now underway." *Raich,* 545 U.S. at 14 (internal quotation marks omitted). In order to fall within Schedule I, Congress determined that a drug must have: (1) "a high potential for abuse," (2) "no currently accepted medical use in treatment in the United States," and (3) "a lack of accepted safety for use of the drug or other substance under medical supervision." 21 U.S.C. § 812(b)(1). The chart below describes the GSA's various schedules and the findings required for each:

	Statutory Factors	Examples
Schedule I	High potential for abuse, no currently accepted medical use in treatment, and a lack of accepted safety for use of the drug under medical supervision. *See* 21 U.S.C. § 812(b)(l).	Heroin, LSD, Marijuana
Schedule II	High potential for abuse, some currently accepted medical use in treatment, and abuse may lead to severe psychological or physical depen-dence. *See* 21 U.S.C. § 812(b)(2).	Morphine, Codeine, Amphetamine (Adderall ®), Methamphetami ne (Desoxyn ®)
Schedule III	Potential for abuse less than substances in Schedules I and II, some currently accepted medical use in treatment, and abuse may lead to moderate or low physical dependence or high psychological dependence. *See* 21 U.S.C. § 812(b)(3).	Tylenol with Codeine ® Ketamine, Anabolic Steroids

Schedule IV	Potential for abuse less than substances in Schedule III, some currently accepted medical use in treatment, and abuse may lead to limited physical or psychological dependence. *See* 21 U.S.C. § 812 (b)(4).	Alprazolam (Xanax ® Diazepam (Valium ®)
Schedule V	Potential for abuse less than substances in Schedule IV, some currently accepted medical use in treatment, and abuse may lead to limited physical or physical dependence. *See* 21 U.S.C. § 812(b)(5).	Robitussin AC ®

After placing marijuana in Schedule I, "Congress established a process for reclassification, vesting the Attorney General with the power to reclassify a drug 'on the record after opportunity for a hearing.'" *Green,* 222 F. Supp. 3d at 271 (quoting 21 U.S.C. § 811(a)). Before beginning the reclassification process, the Attorney General must seek a scientific and medical evaluation from the Secretary of Health and Human Services ("HHS"), whose findings are binding on the Attorney General. *Id.* § 811(b). In the relevant implementing regulations, the Attorney General has delegated this reclassification authority to the Drug Enforcement Agency ("DEA"). *See* 28 C.F.R. § 0.100(b).

The CSA also provides an avenue for interested parties to petition the DEA to reclassify drugs, consistent with the medical and scientific data provided by HHS. *See* 21 U.S.C. § 811(a) (providing that the Attorney General may reclassify drugs after an on the record hearing "on the petition of any interested party"); *see also* 21 C.F.R. § 1308.43(a). If a petitioner receives an adverse ruling from the DEA, 21 U.S.C. § 877 provides for judicial review of the DEA's determination in the D.C. Circuit, or another appropriate Circuit:

> All final determinations, findings, and conclusions of the Attorney General under this subchapter shall be final and conclusive decisions of the matters involved, except that any person aggrieved by a final decision of the Attorney General may obtain review of the decision in the United States Court of Appeals for the District of Columbia or for the circuit in which his principal place of business is located upon petition filed with the court and delivered to the Attorney General within thirty days after notice of the decision. Findings of fact by the Attorney General, if supported by substantial evidence, shall be conclusive.

"Despite considerable efforts to reschedule marijuana, it remains a Schedule I drug." *Raich,* 545 U.S. at 15. "As of 2005, the D.C. Circuit Court of Appeals had reviewed petitions to reschedule marijuana on five separate occasions over the course of 30 years, [and upheld] the DEA's determination in each instance." *Green,* 222 F. Supp. 3d at 272. In 2011, the DEA denied a rescheduling petition, *see* Denial of

Petition to Initiate Proceedings to Reschedule Marijuana, 76 Fed. Reg. 40,552 (July 8, 2011), and the D.C. Circuit upheld the DEA's determination in *Americans for Safe Access v. Drug Enforcement Administration,* 706 F.3d 438, 449 (D.C. Cir. 2013). The DEA denied another rescheduling petition as recently as 2016. *See* Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 81 Fed. Reg. 53,767 (Aug. 12, 2016).[1]

DISCUSSION

Defendants filed a motion to dismiss the complaint under Federal Rules 12(b)(1) and (b)(6). In ruling on a motion to dismiss, the court must accept the factual allegations in the complaint as true and draw all reasonable inferences in favor of the nonmoving party. *Gregory v. Daly,* 243 F.3d 687, 691 (2d Cir. 2001), *as amended* (Apr. 20, 2001). In order to survive a motion to dismiss, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft,* 556 U.S. at 678 (quoting *Bell Atl. Corp. v. Twombly,* 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.*

A. Exhaustion and Plaintiffs' Rational Basis Claim

Properly understood, plaintiffs have raised a collateral challenge to the administrative decision not to reclassify marijuana. As such, plaintiffs' claim

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[1] It appears that one challenge to the DEA's determination was filed in the Tenth Circuit, but the petition was dismissed as untimely. *See* Order, *Krumm v. DEA*, 16-9557 (10th Cir. Dec. 15, 2016).

premised on the factors found in Section 812 of the CSA is barred because plaintiffs failed to exhaust their administrative remedies. Even if the Court were to reach the merit of plaintiffs' rational basis claim, I hold that plaintiffs have failed to state a claim under Rule 12(b)(6).

The parties first present a threshold question of statutory interpretation, the resolution of which illustrates that plaintiffs' claim is an administrative one, not one premised on the constitution. Plaintiffs contend that, in analyzing the rationality of the CSA, Congress should be bound by the factors set out in 21 U.S.C. § 812(b)(1), which include a finding that a drug has "no currently accepted medical use in treatment in the United States." Alternatively, defendants suggest that the Section 812 factors apply only to reclassification determinations by the Attorney General, as set forth in 21 U.S.C. § 811(a). Put differently, the question is whether the statutory factors outlined in Section 812(b)(1) are imputed into the constitutional analysis, thereby binding Congress to particular factors in conducting rational basis review.

A fair reading of the statute reveals that the factors set out in Section 812 apply only to the Attorney General's reclassification proceedings-they do not bind Congress on rational basis review. As explained above, 21 U.S.C. § 811(a) vests the Attorney General with the authority, through his or her designated agent, to reclassify particular drugs if he or she: (1) "finds that such drug or other substance has a potential for abuse, and," (2) "makes with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of this title." And 21

U.S.C. § 812(b) states that "[t]he findings required for each of the schedules are as follows," and thereafter lists the three relevant factors, including, as relevant here, whether the drug has any currently accepted medical uses. Read in context with Section 811(a), it is clear that the factors listed in 21 U.S.C. § 812(b)(1) were intended to apply only to the executive officials in reclassification proceedings.

More fundamentally, as a constitutional matter I am persuaded by the logic of the opinion of Judge Wolford of the Western District of New York in *United States v. Green,* who analyzed this question as follows:

> It is difficult to conclude that marijuana is not currently being used for medical purposes—it is. There would be no rational basis to conclude otherwise. And if that were the central question in this case, Defendants' argument would have merit—but it is not the central question. . . . The issue is not whether it was rational for Congress or the DEA to conclude that there is no currently accepted medical use for marijuana—that would be the issue if a claim were brought in a circuit court challenging the DEA's administrative determination. Rather, the constitutional issue for equal protection purposes is, simply, whether there is any conceivable basis to support the placement of marijuana on the most stringent schedule under the CSA.

222 F. Supp. 3d at 275-80.

By framing their claim in terms of the statutory factors outlined in Section 812(b)(1), plaintiffs' lawsuit is best understood as a collateral attack on the various administrative determinations not to reclassify marijuana into a different drug schedule. As such, plaintiffs' claim is barred because plaintiffs failed to exhaust their administrative remedies. The exhaustion rule generally requires "that parties exhaust prescribed administrative remedies before seeking relief from the federal courts." *McCarthy v. Madigan,* 503 U.S. 140, 144-45 (1992); *see also Beharry v. Ashcroft,* 329 F.3d 51, 56 (2d Cir. 2003), *as amended* (July 24, 2003) ("The general rule is that 'a party may not seek federal judicial review of an adverse administrative determination until the party has first sought all possible relief within the agency itself.' (quoting *Howell v. INS,* 72 F.3d 288, 291 (2d Cir. 1995))). "Exhaustion is required because it serves the twin purposes of protecting administrative agency authority and promoting judicial efficiency." *McCarthy,* 503 U.S. at 145. However, because federal courts have a "virtually unflagging obligation to exercise the jurisdiction given them," three exceptions to the exhaustion requirement have emerged. *Id.* at 146 (internal quotation marks omitted) (quoting *Colorado River Water Conservation Dist. v. United States,* 424 U.S. 800, 817-18 (1976)). The Supreme Court has explained these exceptions as follows:

> First, requiring resort to the administrative remedy may occasion undue prejudice to subsequent assertion of a court action. Such prejudice may result, for example, from an unreasonable or indefinite timeframe for

> administrative action. . . . Second, an administrative remedy may be inadequate because of some doubt as to whether the agency was empowered to grant effective relief . . . . Third, an administrative remedy may be inadequate where the administrative body is shown to be biased or has otherwise predetermined the issue before it.

Id. 145-49 (internal quotation marks omitted) (quoting *Gibson v. Berryhill,* 411 U.S. 564,575 n.14 (1973)). None of these exceptions applies here.

Plaintiffs first suggest that the relief they seek—a declaration that the CSA is unconstitutional—differs from the relief available in an administrative forum, which is limited to rescheduling based on the criteria in 21 U.S.C. § 812(b)(1). But while framed in different terms, these two remedies are ultimately two sides of the same coin. Although plaintiffs couch their claim in constitutional language, they seek the same relief as would be available in an administrative forum—a change in marijuana's scheduling classification—based on the same factors that guide the DEA's reclassification determination. As a district court in this Circuit recently explained, "[w]hen [this] argument is dissected, it essentially becomes an attack on the scheduling of marijuana based on the criteria set forth in the statute." *Green*, 222 F. Supp. 3d. at 273. The exhaustion requirement therefore bars plaintiffs' claims.

To avoid this result, plaintiffs rely on *United States v. Kiffer,* 477 F.2d 349 (2d Cir. 1973). Plaintiffs do so in error. In *Kiffer,* criminal defendants convicted of marijuana possession challenged the constitutionality of the CSA under the rational basis test. *Kiffer,*

477 F.2d at 350. Responding to this very exhaustion claim, the Second Circuit held that "the administrative route for these appellants would at best provide an uncertain and indefinitely delayed remedy," and declined to require administrative exhaustion. *Id.* at 351-52. But at the time *Kiffer* was decided, the designated executive official had taken the position that he was barred by a treaty from even considering a petition to reclassify marijuana. *Green,* 222 F. Supp. 3d at 273-74 (noting that "it was doubtful whether an administrative remedy actually existed"); *see also Kiffer,* 477 F.2d at 351-52. The D.C. Circuit later rejected that position. *See Nat'l Org. for Reform of Marijuana Laws (NORML) v. Ingersoll,* 497 F.2d 654 (D.C. Cir. 1974); *see also Nat'l Org. for Reform of Marijuana Laws (NORML) v. DEA,* 559 F.2d 735 (D.C. Cir. 1977).

Kiffer is also distinguishable on a more fundamental ground: The Court held that imposing the exhaustion requirement would also be unduly burdensome to *criminal defendants* challenging their convictions. *See Kiffer,* 477 F.2d at 353 ("Second, even assuming the existence of a viable administrative remedy, application of the exhaustion doctrine to criminal cases is generally not favored because of 'the severe burden' it imposes on defendants." (quoting *McKart v. United States,* 395 U.S. 185,197 (1969))). Those concerns are less forceful in the civil context, especially given that the DEA no longer takes the position that it is categorically barred by a treaty from considering reclassification petitions.[2]

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[2] Plaintiffs also claim that the administrative review process is futile because the relevant executive officials are biased against their cause and will not faithfully consider the relevant medical

Even if the Court were to reach the merits of plaintiffs' rational basis claim, I would be bound by precedent to reject it.[3] The Second Circuit has already resolved this question in *United States v. Kiffer,* 477 F.2d at 355-57, which upheld the constitutionality of the CSA. Every other court to consider this issue has held similarly.[4] Even without the benefit of precedent,

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evidence. *See* FAC, ECF 23, at ¶¶ 357-70. But this claim is undercut by the statutory scheme, which specifically requires these officials to defer to HHS on scientific and medical questions. *See* 21 U.S.C. § 811(b).

[3] Plaintiffs rely heavily on *United States v. Pickard,* 100 F. Supp. 3d 981, 996 (E.D. Cal. 2015), for the proposition that the CSA is not "insulated from constitutional review by Congressional delegation of authority to an agency to consider an administrative petition." But as explained above, by raising this challenge based on the factors set out in 21 U.S.C. § 812(b)(1), plaintiffs' claim is properly understood as a collateral attack on the administrative determination not to reclassify marijuana. To the extent that plaintiffs attempt to raise a typical rational basis claim based on whether Congress had *any* conceivable basis to classify marijuana in Schedule I, which would not be the subject of an administrative proceeding, such a claim is barred by precedent.

[4] *See, e.g., Sacramento Nonprofit Collective v. Holder,* 552 F. App'x 680, 683 (9th Cir. 2014) (rejecting rational basis challenge to the CSA); *Am. for Safe Access,* 706 F.3d at 449 (upholding the DEA's decision not to reclassify marijuana in a different schedule under the more stringent "substantial evidence" standard); *United States v. Oakland Cannabis Buyers' Co-op,* 259 F. App'x 936, 938 (9th Cir. 2007); *United States v. White Plume,* 447 F.3d 1067, 1075 (8th Cir. 2006) (holding that the CSA's enforcement against industrial hemp production was rationally related to a legitimate government purpose); *United States v. Greene,* 892 F.2d 453, 455 (6th Cir. 1989); *United States v. Fry,* 787 F.2d 903, 905 (4th Cir. 1986); *United States v. Fogarty,* 692 F.2d 542, 547 (8th Cir. 1982); *United States v. Middleton,* 690 F.2d 820, 823 (11th Cir. 1982).

it is clear that Congress had a rational basis for classifying marijuana in Schedule I, and executive officials in different administrations have consistently retained its placement there.[5] For instance, the DEA's most recent denial of a petition to reclassify marijuana listed a number of public health and safety justifications for keeping marijuana in Schedule I. *See* Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 81 Fed. Reg. 53,767 (Aug. 12, 2016). The reasons offered by the DEA included marijuana's "various psychoactive effects," *id.* at 53,774, its potential to cause a "decrease in IQ and general neuropsychological performance" for adolescents who consume it, *id.,* and its potential effect on prenatal development, *id.* at 53,775. Even if marijuana has current medical uses, I cannot say that Congress acted irrationally in placing marijuana in Schedule I.

In sum, the Second Circuit has already determined that Congress had a rational basis to classify marijuana as a Schedule I drug, *see United States v. Kiffer,* 477 F.2d at 355-57, and any constitutional rigidity is overcome by granting the Attorney General, through a designated agent, the authority to

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[5] Under the rational basis test, "a statutory classification that neither proceeds along suspect lines nor infringes fundamental constitutional rights must be upheld against equal protection challenge if there is any reasonably conceivable state of facts that could provide a rational basis for the classification." *F. C. C. v. Beach Commc'ns, Inc.,* 508 U.S. 307, 313 (1993). "On rational-basis review, a classification in a statute . . . comes to [the court] bearing a strong presumption of validity . . . and those attacking the rationality of the legislative classification have the burden 'to negative every conceivable basis which might support it.'" *Id.* at 314-15 (quoting *Lehnhausen v. Lake Shore Auto Parts Co,* 410 U.S. 356, 364 (1973)).

reclassify a drug according to the evidence before it and based on the criteria outlined in 21 U.S.C. § 812(b)(1). There can be no complaint of constitutional error when such a process is designed to provide a safety valve of this kind.[6] The argument is made that Attorney General's refusal, through the DEA, to quickly resolve reclassification petitions creates sloth. But that sloth, if presented in the appropriate case, can be overcome through a mandamus proceeding in the appropriate Court of Appeals. Judicial economy is not served through a collateral proceeding of this kind that seeks to undercut the regulatory machinery on the Executive Branch and the process of judicial review in the Court of Appeals.

I emphasize that this decision is not on the merits of plaintiffs' claim. Plaintiffs' amended complaint, which I must accept as true for the purpose of this motion, claims that the use of medical marijuana has, quite literally, saved their lives. One plaintiff in this case, Alexis Borten, suffers from intractable epilepsy, a severe seizure disorder that once caused her to experience multiple seizures every day. After years of

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[6] As the Second Circuit explained in *Kiffer*:

> The provisions of the Act allowing periodic review of the control and classification of allegedly dangerous substances create a sensible mechanism for dealing with a field in which factual claims are conflicting and the state of scientific knowledge is still growing. The question whether a substance belongs in one schedule rather than another clearly calls for fine distinctions, but the statutory procedure at least offers the means for producing a thorough factual record upon which to base an informed judgment.

Kiffer, 477 F.2d at 357.

searching for viable treatment options, Alexis began using medical marijuana. Since then, she has gone nearly three years without a single seizure. Jagger Cotte, another plaintiff in the case, suffers from a rare, congenital disease known as Leigh's disease, which kills approximately 95% of those afflicted before they reach the age of four. After turning to medical marijuana, Jagger's life has been extended by two years and his pain has become manageable. I highlight plaintiffs' experience to emphasize that this decision should not be understood as a factual finding that marijuana lacks any medical use in the United States, for the authority to make that determination is vested in the administrative process. In light of the decision of the Second Circuit, *see United States v. Kiffer,* 477 F.2d at 355-57, and the several decisions of the D.C. Circuit, *see, e.g., Am. for Safe Access,* 706 F.3d at 449, I am required to dismiss plaintiffs' rational basis claim.

B. Standing and Plaintiffs' Equal Protection Claim

The Cannabis Cultural Association, Inc. ("CCA"), a nonprofit entity dedicated to advancing the business footprint of marginalized groups in the cannabis industry, alleges that the CSA violates the Equal Protection Clause because it was passed with racial animus. *See* FAC, ECF 23, ¶¶ 406-21. Defendants claim that the CCA lacks standing to maintain this claim and, alternatively, that the CCA has failed to state an Equal Protection claim. I hold that the CCA lacks standing to maintain its Equal Protection claim because plaintiffs have failed to demonstrate that a favorable decision is likely to redress plaintiffs' alleged injuries.

To satisfy the "irreducible constitutional minimum of standing," a "plaintiff must have (1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins,* 136 S. Ct. 1540, 1547 (2016), *as revised* (May 24, 2016) (internal quotation marks omitted) (quoting *Lujan v. Defs. of Wildlife,* 504 U.S. 555, 560 (1992)). Specifically, "[t]o establish injury in fact, a plaintiff must show that he or she suffered 'an invasion of a legally protected interest' that is 'concrete and particularized' and 'actual or imminent, not conjectural or hypothetical.'" *Id.* at 1548 (quoting *Lujan,* 504 U.S. at 560). "The plaintiff, as the party invoking federal jurisdiction, bears the burden of establishing these elements." *Id.* at 1547.

Plaintiffs do not claim that the CCA has standing to sue on its own behalf, but rather is suing on behalf of its members. In general,

> an association has standing to bring suit on behalf of its members when: (a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization's purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit.

Centro de la Comunidad Hispana de Locust Valley v. Town of Oyster Bay, 868 F.3d 104, 123 (2d Cir. 2017) (internal quotation marks omitted) (quoting *Hunt v. Washington Apple Advert. Comm'n,* 432 U.S. 333, 343 (1977)).

In opposing this motion, plaintiffs submitted three affidavits from members of the CCA: Kordell Nesbitt, Leo Bridgewater, and Thomas Motley. *See* Declaration of Michael S. Hiller, ECF 43, Ex. 12-14. Kordell Nesbitt, the first affiant, is an African American male and a member of the CCA. *See* Declaration of Michael S. Hiller, ECF 43, Ex. 12, ¶¶ 1. Mr. Nesbitt was charged in 2013 with participating in a marijuana conspiracy, and he pled guilty in 2014. *See id.* at ¶¶ 2-3. He claims that he continues to face collateral consequences as a result of his conviction, including difficulty finding employment. *See id.* at ¶¶ 7-9. Leo Bridgewater, the second affiant, is a veteran of the U.S. Army who previously served as a telecommunications specialist. *See* Declaration of Michael S. Hiller, ECF 43, Ex. 13, ¶¶ 1-2. Mr. Bridgewater began using medical cannabis in 2015 and claims that, as a result, he cannot renew the government security clearance necessary to work as a private military contractor. *See id.* at ¶¶ 7-9.[7] Finally, Thomas Motley, like Mr. Nesbitt, is an African-American male who was indicted and pled guilty to violating federal law by participating in a conspiracy to distribute and cultivate marijuana. *See* Declaration of Michael S. Hiller, ECF 43, Ex. 14, ¶¶ 1-3. Mr. Motley also states that although he would like to participate in a minority-owned business loan or grant, he believes that his prior felony conviction would make him ineligible to do so. *See id.* at ¶¶ 5-6.

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[7] Although Mr. Nesbitt and Mr. Motley claim that they are African-American, Mr. Bridgewater's affidavit does not disclose his ethnicity. This technicality does not affect the Court's reasoning.

Although the affidavits demonstrate that members of the CCA have suffered an injury-in-fact,[8] the pleadings fail to demonstrate that "it is likely that a favorable ruling will redress" those injuries. *Massachusetts v. E.P.A.,* 549 U.S. 497, 517 (2007). Plaintiffs' FAC seeks "a permanent injunction . . . restraining Defendants from enforcing the CSA as it pertains to Cannabis." FAC, ECF 23, at 97. But plaintiffs have not shown that, were they to receive a favorable ruling that marijuana cannot be treated as a Schedule I drug, their prior convictions would be undone.[9] Nor have plaintiffs shown, for instance, that those within the government in charge of security clearance determinations would no longer include marijuana in a urine test if plaintiffs are successful in

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[8] Defendants are correct that *City of Los Angeles v. Lyons,* 461 U.S. 95, 105 (1983) forecloses plaintiffs' claims that they have standing based on a fear of future arrest. *See* Plaintiffs' Memorandum of Law in Opposition, ECF 44, at 56. However, each of the individuals who submitted an affidavit suffers from a forward-looking injury-in-fact that is concrete, particularized, and imminent. For instance, Mr. Nesbitt claims, with documentation from a potential employer, that his prior conviction has harmed his ability to obtain future employment. As described above, other affiants have similar claims that are sufficient to demonstrate an injury-in-fact.

[9] The Supreme Court recently held for the first time that a guilty plea, standing alone, does not bar a criminal defendant from challenging the constitutionality of the statute of his conviction on direct appeal *Class v. United States,* No. 16-424, 2018 WL 987347, at *8 (U.S. Feb. 21, 2018). But the challenge here is even more attenuated, for plaintiffs are not challenging their underlying convictions, either on direct appeal or in habeas proceedings. Plaintiffs have presented no basis, even a speculative one, explaining how a favorable decision in this case would redress their alleged injuries.

having marijuana reclassified to a different drug schedule. Although one could imagine how plaintiffs might connect these dots, plaintiffs bear the burden of pleading each element of standing, and their various submissions have failed to do so. *Spokeo,* 136 S. Ct. at 1547.

Alternatively, even if plaintiffs had standing, I hold that plaintiffs fail to state a claim under Rule 12(b)(6). To survive a motion to dismiss an Equal Protection claim, plaintiffs must plausibly plead that "the decision-maker . . . selected or reaffirmed a particular course of action at least in part 'because of,' not merely 'in spite of,' its adverse effects upon an identifiable group." *Pers. Adm'r of Massachusetts v. Feeney,* 442 U.S. 256, 279 (1979); *see also Washington v. Davis,* 426 U.S. 229, 239 (1976) (holding that a law violates the equal protection clause if passed with discriminatory purpose). If a plaintiff plausibly pleads such a claim, a law is then subject to strict constitutional scrutiny, which holds that "such classifications are constitutional only if they are narrowly tailored measures that further compelling governmental interests." *Adarand Constructors, Inc. v. Pena,* 515 U.S. 200, 227 (1995).

Plaintiffs' racial animus claim is based on a patchwork of statements by former Nixon Administration officials, many of which were made after the passage of the CSA. *See* FAC, ECF 23, at ¶¶ 235-52. Even taking these allegations as true, plaintiffs have failed to demonstrate that the relevant decision-maker—Congress—passed the CSA and placed marijuana in Schedule I in order to intentionally discriminate against African Americans. *See Feeney,* 442 U.S. at 279 (recognizing that the relevant "decision-maker" in the case was the "state legislature"); *United*

States v. Then, 56 F.3d 464, 466 (2d Cir. 1995) (considering, in the context of the sentencing disparity between powder cocaine and crack cocaine, whether "Congress" acted "with discriminatory intent in adopting the sentencing ratio at issue"). Plaintiffs have cited no authority for the proposition that various statements by Executive Branch officials, such as those at issue here, which are untethered from the Congressional process, can support an Equal Protection claim premised on racial animus. Therefore, even if plaintiffs could demonstrate standing, I would still hold that plaintiffs failed to state a claim.

C. Remaining Constitutional Claims

Plaintiffs advance a number of additional constitutional challenges to the placement of marijuana in Schedule I under the CSA, independent of plaintiffs' rational basis challenge based on medical evidence, largely in order to subject the CSA to heightened constitutional scrutiny. Because plaintiffs have failed to state a claim under any constitutional theory, all of plaintiffs' remaining claims are also dismissed.

Plaintiffs first claim that the GSA's regulation of marijuana violates the Commerce Clause. There is no need to belabor this point. The Supreme Court has held, in no uncertain terms, that "intrastate manufacture and possession of marijuana for medical purposes," even if legal under state law, does not exceed Congress's authority under the Commerce Clause.

Raich, 545 U.S. at 15. I am bound to apply this precedent and plaintiffs' claim under the Commerce Clause is therefore dismissed.[10]

Plaintiffs also appear to assert a fundamental right to use medical marijuana, which is then used to prop up plaintiffs' remaining causes of action. Plaintiffs frame their claim as "the right of Plaintiffs to exercise personal autonomy and to preserve their health and lives." *See* Plaintiffs' Memorandum of Law in Opposition, ECF 44, at 68. No such fundamental right exists. Every court to consider the specific, carefully framed right at issue here has held that there is no substantive due process right to use medical marijuana. The Ninth Circuit, on remand from the Supreme Court's decision in *Raich I,* analyzed this question in detail, holding that "federal law does not recognize a fundamental right to use medical marijuana prescribed by a licensed physician to alleviate excruciating pain and human suffering." *Raich v. Gonzales,* 500 F.3d 850, 866 (9th Cir. 2007). Other

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[10] Apart from simply attempting to relitigate the issues firmly decided in *Raich,* plaintiffs argue that "the classification of cannabis as a Schedule I drug under the CSA is void under the doctrine of *desuetude.*" Plaintiffs' Memorandum of Law in Opposition, ECF 44, at 92. Plaintiffs' argument borders on frivolous. "Desuetude is the `obscure doctrine by which a legislative enactment is judicially abrogated following a long period of non-enforcement.'" *United States v. Morrison,* 596 F. Supp. 2d 661, 702 (E.D.N.Y. 2009) (quoting Note, *Desuetude,* 119 Harv. L. Rev. 2209, 2209 (2006)). First of all, this civil law doctrine is not applicable in federal courts. *See D C. v. John R Thompson Co.,* 346 U.S. 100, 113-14 (1953) ("The failure of the executive branch to enforce a law does not result in its modification or repeal."). And even if this doctrine were viable, plaintiffs have not shown that the federal government has entirely abandoned application of the CSA as applied to marijuana.

courts have reached the same conclusion. *See, e.g., United States v. Washington,* 887 F. Supp. 2d 1077, 1102 (D. Mont. 2012), *adhered to on reconsideration,* No. CR 11-61-M-DLC, 2012 WL 4602838 (D. Mont. Oct. 2, 2012) (rejecting a fundamental right to use medical marijuana and applying rational basis review); *Elansari v. United States,* No. CV 3:15-1461, 2016 WL 4386145, at *3 (M.D. Pa. Aug. 17, 2016) (noting "that 'no court to date has held that citizens have a constitutionally fundamental right to use medical marijuana' (quoting *United States v. Wilde,* 74 F. Supp. 3d 1092, 1095 (N.D. Ca. 2014))).[11] Accordingly, plaintiffs' substantive Due Process claim is dismissed.

Plaintiffs also raise an ill-defined right to travel claim. The thrust of this claim appears to be that because plaintiffs are more likely to be arrested for possession of medical marijuana if they travel by airplane or enter federal buildings (where they might be subject to search), the CSA unconstitutionally infringes on their right to travel. *Saenz v. Roe,* 526 U.S. 489, 500 (1999) (defining one element of the right to travel as "protect[ing] the right of a citizen of one State to enter and to leave another State"). This claim fails for substantially the same reasons already discussed above, for no fundamental right to use medical marijuana exists.

As a general matter, the right to travel has been understood primarily as a restriction on state-created

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[11] Plaintiffs largely rely on *Cruzan v. Director, Missouri Department of Health,* 497 U.S. 261, 278 (1990) for the proposition that "a competent person has a constitutionally protected liberty interest in refusing unwanted medical treatment." But *Cruzan* speaks only to one's right to refuse medical treatment, not a positive right to obtain any particular medical treatment.

obstructions to interstate travel, not as a bar on federal regulatory schemes. *See, e.g., Minnesota Senior Fed'n, Metro. Region v. United States,* 273 F.3d 805, 810 (8th Cir. 2001) (noting that "the Court's other modern cases . . . have applied the federal constitutional right to travel to *state* legislation that had a negative impact on travel between the various states," rather than to a *"federal* statutory regime because it allegedly deters interstate travel"). The CSA is facially neutral as to travel—it does not impose any bar on plaintiffs' movement from state to state. *See Five Borough Bicycle Club v. City of New York,* 483 F. Supp. 2d 351, 362 (S.D.N.Y. 2007), *aff'd,* 308 F. App'x 511 (2d Cir. 2009) ("A statute implicates the constitutional right to travel when it actually deters such travel, or when impedance of travel is its primary objective, or when it uses any classification which serves to penalize the exercise of that right" (internal quotation marks omitted) (quoting *Soto—Lopez v. N.Y.C. Civil Serv. Comm'n,* 755 F.2d 266, 278 (2d Cir. 1985))).

Instead, the CSA makes possession and distribution of certain controlled substances, including marijuana, illegal, regardless of one's movement between states. Properly understood, plaintiffs' complaint is simply that they are deterred from travel because they fear that they are more likely to be arrested for marijuana possession at airport security checkpoints. Such an interpretation of the right to travel, if adopted, would invalidate any number of bans on controlled substances or firearms simply because the enforcement of these facially neutral laws might have some conceivable, tangential impact on travel. Plaintiffs have identified no authority for such

an expansive interpretation of the right to travel, and the Court has not found any. A suggestion has been made that the CSA presents plaintiffs with a Hobson's choice between their fundamental right to use medical marijuana and a right to travel. But as explained above, no such fundamental right to use medical marijuana exists. Plaintiffs' right to travel claim is therefore dismissed.

For substantially the same reasons, plaintiffs' First Amendment claim also fails. The core of plaintiffs' claim stems from the fact that Alexis Bortell has previously been invited to speak with members of Congress in Washington, D.C. about ongoing efforts to decriminalize medical marijuana, but cannot do so because she cannot fly on an airplane or enter federal buildings without risking arrest and prosecution for marijuana possession under the CSA. But the First Amendment protects freedom of speech, first and foremost. To be sure, the Supreme Court has extended constitutional protection to certain kinds of expressive conduct, but only such conduct that is "sufficiently imbued with elements of communication to fall within the scope of the First and Fourteenth Amendments." *Spence v. Washington,* 418 U.S. 405, 409 (1974); *see also United States v. O'Brien,* 391 U.S. 367, 376 (1968) ("We cannot accept the view that an apparently limitless variety of conduct can be labeled 'speech' whenever the person engaging in the conduct intends thereby to express an idea."). Accordingly, the First Amendment's protections have been extended "only to conduct that is inherently expressive," *see Rumsfeld v. Forum for Acad. & Institutional Rights, Inc.,* 547 U.S. 47, 66 (2006), such as burning the American flag, *see Texas v. Johnson,* 491 U.S. 397, 406 (1989), or

conducting a sit-in to protest racial segregation, *see Brown v. Louisiana,* 383 U.S. 131 (1966).

The CSA is not targeted at speech, nor does it directly implicate speech in any way. Laws of this kind, which are directed as "commerce or conduct," are not implicated by the First Amendment simply because they impose "incidental burdens on speech." *Sorrell v. IMS Health Inc.,* 564 U.S. 552, 567 (2011); *see also id.* ("[R]estrictions on protected expression are distinct from restrictions on economic activity or, more generally, on non-expressive conduct."). As the Supreme Court has explained, "every civil and criminal remedy imposes some conceivable burden on First Amendment protected activities," but such laws do not automatically warrant First Amendment protection. *Arcara v. Cloud Books, Inc.,* 478 U.S. 697, 706 (1986). Put differently, "the First Amendment is not implicated by the enforcement o' laws, like the CSA, which are "directed at imposing sanctions on non-expressive activity." *Id.* at 707. Were plaintiffs correct, any law regulating possession of illegal substances, firearms, or any number of other things would be subject to First Amendment scrutiny simply because those who possess such items risk arrest by carrying them onto federal property. And as explained above, because there is no fundamental right to use medical marijuana, plaintiffs do not face a Hobson's choice with respect to the exercise of their constitutional rights.

For the reasons stated herein, defendants' motion to dismiss the complaint is granted. Plaintiffs have already amended their complaint once, and I find that further amendments would be futile. *Ruffolo v. Oppenheimer & Co.,* 987 F.2d 129, 131 (2d Cir. 1993).

The clerk is instructed to terminate the motion (ECF 36), mark the case as closed, and tax costs as appropriate.

SO ORDERED.

/s/ Alvin K. Hellerstein
United States District Judge

Dated: February 26, 2018,
New York, New York

CONSTITUTIONAL AND STATUTORY PROVISIONS

UNITED STATES CONSTITUTIONAL PROVISIONS

Amendment I

Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances.

Amendment V

No person shall be held to answer for a capital, or otherwise infamous crime, unless on a presentment or indictment of a grand jury, except in cases arising in the land or naval forces, or in the militia, when in actual service in time of war or public danger; nor shall any person be subject for the same offense to be twice put in jeopardy of life or limb; nor shall be compelled in any criminal case to be a witness against himself, nor be deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use, without just compensation.

STATUTES

Controlled Substances Act
21 U.S.C., Title 21, Chapter 13, Sec. 811

§ 811. Authority and Criteria for Classification of Substances

(a) Rules and Regulations of Attorney General; Hearing

The Attorney General shall apply the provisions of this subchapter to the controlled substances listed in the schedules established by section 812 of this title and to any other drug or other substance added to such schedules under this subchapter. Except as provided in subsections (d) and (e) of this section, the Attorney General may by rule—

(1) add to such a schedule or transfer between such schedules any drug or other substance if he—

(A) finds that such drug or other substance has a potential for abuse, and

(B) makes with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of this title for the schedule in which such drug is to be placed; or

(2) remove any drug or other substance from the schedules if he finds that the drug or other substance does not meet the requirements for inclusion in any schedule.

Rules of the Attorney General under this subsection shall be made on the record after opportunity for a hearing pursuant to the rulemaking procedures

prescribed by subchapter II of chapter 5 of title 5. Proceedings for the issuance, amendment, or repeal of such rules may be initiated by the Attorney General (1) on his own motion, (2) at the request of the Secretary, or (3) on the petition of any interested party.

(b) Evaluation of Drugs and Other Substances

The Attorney General shall, before initiating proceedings under subsection (a) of this section to control a drug or other substance or to remove a drug or other substance entirely from the schedules, and after gathering the necessary data, request from the Secretary a scientific and medical evaluation, and his recommendations, as to whether such drug or other substance should be so controlled or removed as a controlled substance. In making such evaluation and recommendations, the Secretary shall consider the factors listed in paragraphs (2), (3), (6), (7), and (8) of subsection (c) of this section and any scientific or medical considerations involved in paragraphs (1), (4), and (5) of such subsection. The recommendations of the Secretary shall include recommendations with respect to the appropriate schedule, if any, under which such drug or other substance should be listed. The evaluation and the recommendations of the Secretary shall be made in writing and submitted to the Attorney General within a reasonable time. The recommendations of the Secretary to the Attorney General shall be binding on the Attorney General as to such scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance. If the Attorney General determines that these facts and all other relevant data constitute substantial evidence of potential for

abuse such as to warrant control or substantial evidence that the drug or other substance should be removed entirely from the schedules, he shall initiate proceedings for control or removal, as the case may be, under subsection (a) of this section.

(c) Factors Determinative of Control or Removal from Schedules

In making any finding under subsection (a) of this section or under subsection (b) of section 812 of this title, the Attorney General shall consider the following factors with respect to each drug or other substance proposed to be controlled or removed from the schedules:

(1) Its actual or relative potential for abuse.

(2) Scientific evidence of its pharmacological effect, if known.

(3) The state of current scientific knowledge regarding the drug or other substance.

(4) Its history and current pattern of abuse.

(5) The scope, duration, and significance of abuse.

(6) What, if any, risk there is to the public health.

(7) Its psychic or physiological dependence liability.

(8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.

(d) International Treaties, Conventions, and Protocols Requiring Control; Procedures Respecting Changes in Drug Schedules of Convention on Psychotropic Substances

(1) If control is required by United States obligations under international treaties, conventions, or protocols in effect on October 27, 1970, the Attorney General shall issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings required by subsection (a) of this section or section 812(b) of this title and without regard to the procedures prescribed by subsections (a) and (b) of this section.

(2)

(A) Whenever the Secretary of State receives notification from the Secretary-General of the United Nations that information has been transmitted by or to the World Health Organization, pursuant to article 2 of the Convention on Psychotropic Substances, which may justify adding a drug or other substance to one of the schedules of the Convention, transferring a drug or substance from one schedule to another, or deleting it from the schedules, the Secretary of State shall immediately transmit the notice to the Secretary of Health and Human Services who shall publish it in the Federal Register and provide opportunity to interested persons to submit to him comments respecting the scientific and medical evaluations which he is to prepare respecting such drug or substance. The Secretary of Health and Human Services shall prepare for transmission through the Secretary of State to the World Health

Organization such medical and scientific evaluations as may be appropriate regarding the possible action that could be proposed by the World Health Organization respecting the drug or substance with respect to which a notice was transmitted under this subparagraph.

(B) Whenever the Secretary of State receives information that the Commission on Narcotic Drugs of the United Nations proposes to decide whether to add a drug or other substance to one of the schedules of the Convention, transfer a drug or substance from one schedule to another, or delete it from the schedules, the Secretary of State shall transmit timely notice to the Secretary of Health and Human Services of such information who shall publish a summary of such information in the Federal Register and provide opportunity to interested persons to submit to him comments respecting the recommendation which he is to furnish, pursuant to this subparagraph, respecting such proposal. The Secretary of Health and Human Services shall evaluate the proposal and furnish a recommendation to the Secretary of State which shall be binding on the representative of the United States in discussions and negotiations relating to the proposal.

(3) When the United States receives notification of a scheduling decision pursuant to article 2 of the Convention on Psychotropic Substances that a drug or other substance has been added or transferred to a schedule specified in the notification or receives notification (referred to in this subsection as a "schedule notice") that existing legal controls applicable under this subchapter to a drug or substance and the controls

required by the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] do not meet the requirements of the schedule of the Convention in which such drug or substance has been placed, the Secretary of Health and Human Services after consultation with the Attorney General, shall first determine whether existing legal controls under this subchapter applicable to the drug or substance and the controls required by the Federal Food, Drug, and Cosmetic Act, meet the requirements of the schedule specified in the notification or schedule notice and shall take the following action:

(A) If such requirements are met by such existing controls but the Secretary of Health and Human Services nonetheless believes that more stringent controls should be applied to the drug or substance, the Secretary shall recommend to the Attorney General that he initiate proceedings for scheduling the drug or substance, pursuant to subsections (a) and (b) of this section, to apply to such controls.

(B) If such requirements are not met by such existing controls and the Secretary of Health and Human Services concurs in the scheduling decision or schedule notice transmitted by the notification, the Secretary shall recommend to the Attorney General that he initiate proceedings for scheduling the drug or substance under the appropriate schedule pursuant to subsections (a) and (b) of this section.

(C) If such requirements are not met by such existing controls and the Secretary of Health and Human Services does not concur in the scheduling decision or schedule notice transmitted by the notification, the Secretary shall—

(i) if he deems that additional controls are necessary to protect the public health and safety, recommend to the Attorney General that he initiate proceedings for scheduling the drug or substance pursuant to subsections (a) and (b) of this section, to apply such additional controls;

(ii) request the Secretary of State to transmit a notice of qualified acceptance, within the period specified in the Convention, pursuant to paragraph 7 of article 2 of the Convention, to the Secretary-General of the United Nations;

(iii) request the Secretary of State to transmit a notice of qualified acceptance as prescribed in clause (ii) and request the Secretary of State to ask for a review by the Economic and Social Council of the United Nations, in accordance with paragraph 8 of article 2 of the Convention, of the scheduling decision; or

(iv) in the case of a schedule notice, request the Secretary of State to take appropriate action under the Convention to initiate proceedings to remove the drug or substance from the schedules under the Convention or to transfer the drug or substance to a schedule under the Convention different from the one specified in the schedule notice.

(4)

(A) If the Attorney General determines, after consultation with the Secretary of Health and Human Services, that proceedings initiated under

recommendations made under paragraph[1] (B) or (C)(i) of paragraph (3) will not be completed within the time period required by paragraph 7 of article 2 of the Convention, the Attorney General, after consultation with the Secretary and after providing interested persons opportunity to submit comments respecting the requirements of the temporary order to be issued under this sentence, shall issue a temporary order controlling the drug or substance under schedule IV or V, whichever is most appropriate to carry out the minimum United States obligations under paragraph 7 of article 2 of the Convention. As a part of such order, the Attorney General shall, after consultation with the Secretary, except such drug or substance from the application of any provision of part C of this subchapter which he finds is not required to carry out the United States obligations under paragraph 7 of article 2 of the Convention. In the case of proceedings initiated under subparagraph (B) of paragraph (3), the Attorney General, concurrently with the issuance of such order, shall request the Secretary of State to transmit a notice of qualified acceptance to the Secretary-General of the United Nations pursuant to paragraph 7 of article 2 of the Convention. A temporary order issued under this subparagraph controlling a drug or other substance subject to proceedings initiated under subsections (a) and (b) of this section shall expire upon the effective date of the application to the drug or substance of the controls resulting from such proceedings.

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[1] So in original. Probably should be "subparagraph".

(B) After a notice of qualified acceptance of a scheduling decision with respect to a drug or other substance is transmitted to the Secretary-General of the United Nations in accordance with clause (ii) or (iii) of paragraph (3)(C) or after a request has been made under clause (iv) of such paragraph with respect to a drug or substance described in a schedule notice, the Attorney General, after consultation with the Secretary of Health and Human Services and after providing interested persons opportunity to submit comments respecting the requirements of the order to be issued under this sentence, shall issue an order controlling the drug or substance under schedule IV or V, whichever is most appropriate to carry out the minimum United States obligations under paragraph 7 of article 2 of the Convention in the case of a drug or substance for which a notice of qualified acceptance was transmitted or whichever the Attorney General determines is appropriate in the case of a drug or substance described in a schedule notice. As a part of such order, the Attorney General shall, after consultation with the Secretary, except such drug or substance from the application of any provision of part C of this subchapter which he finds is not required to carry out the United States obligations under paragraph 7 of article 2 of the Convention. If, as a result of a review under paragraph 8 of article 2 of the Convention of the scheduling decision with respect to which a notice of qualified acceptance was transmitted in accordance with clause (ii) or (iii) of paragraph (3)(C)—

(i) the decision is reversed, and

(ii) the drug or substance subject to such decision is not required to be controlled under schedule IV or V to carry out the minimum United States obligations under paragraph 7 of article 2 of the Convention,

the order issued under this subparagraph with respect to such drug or substance shall expire upon receipt by the United States of the review decision. If, as a result of action taken pursuant to action initiated under a request transmitted under clause (iv) of paragraph (3)(C), the drug or substance with respect to which such action was taken is not required to be controlled under schedule IV or V, the order issued under this paragraph with respect to such drug or substance shall expire upon receipt by the United States of a notice of the action taken with respect to such drug or substance under the Convention.

(C) An order issued under subparagraph (A) or (B) may be issued without regard to the findings required by subsection (a) of this section or by section 812(b) of this title and without regard to the procedures prescribed by subsection (a) or (b) of this section.

(5) Nothing in the amendments made by the Psychotropic Substances Act of 1978 or the regulations or orders promulgated thereunder shall be construed to preclude requests by the Secretary of Health and Human Services or the Attorney General through the Secretary of State, pursuant to article 2 or other applicable provisions of the Convention, for review of

scheduling decisions under such Convention, based on new or additional information.

(e) Immediate Precursors

The Attorney General may, without regard to the findings required by subsection (a) of this section or section 812(b) of this title and without regard to the procedures prescribed by subsections (a) and (b) of this section, place an immediate precursor in the same schedule in which the controlled substance of which it is an immediate precursor is placed or in any other schedule with a higher numerical designation. If the Attorney General designates a substance as an immediate precursor and places it in a schedule, other substances shall not be placed in a schedule solely because they are its precursors.

(f) Abuse Potential

If, at the time a new-drug application is submitted to the Secretary for any drug having a stimulant, depressant, or hallucinogenic effect on the central nervous system, it appears that such drug has an abuse potential, such information shall be forwarded by the Secretary to the Attorney General.

(g) Exclusion of Non-Narcotic Substances Sold Over the Counter Without a Prescription; Dextromethorphan; Exemption of Substances Lacking Abuse Potential

(1) The Attorney General shall by regulation exclude any non-narcotic drug which contains a controlled substance from the application of this subchapter and subchapter II of this chapter if such drug may, under the Federal Food, Drug, and Cosmetic

Act [21 U.S.C. 301 et seq.], be lawfully sold over the counter without a prescription.

(2) Dextromethorphan shall not be deemed to be included in any schedule by reason of enactment of this subchapter unless controlled after October 27, 1970 pursuant to the foregoing provisions of this section.

(3) The Attorney General may, by regulation, exempt any compound, mixture, or preparation containing a controlled substance from the application of all or any part of this subchapter if he finds such compound, mixture, or preparation meets the requirements of one of the following categories:

(A) A mixture, or preparation containing a nonnarcotic controlled substance, which mixture or preparation is approved for prescription use, and which contains one or more other active ingredients which are not listed in any schedule and which are included therein in such combinations, quantity, proportion, or concentration as to vitiate the potential for abuse.

(B) A compound, mixture, or preparation which contains any controlled substance, which is not for administration to a human being or animal, and which is packaged in such form or concentration, or with adulterants or denaturants, so that as packaged it does not present any significant potential for abuse.

(C) Upon the recommendation of the Secretary of Health and Human Services, a compound, mixture, or preparation which contains any anabolic steroid, which is intended for administration to a human being or an animal, and which, because of

its concentration, preparation, formulation or delivery system, does not present any significant potential for abuse.

(h) Temporary Scheduling to Avoid Imminent Hazards to Public Safety

(1) If the Attorney General finds that the scheduling of a substance in schedule I on a temporary basis is necessary to avoid an imminent hazard to the public safety, he may, by order and without regard to the requirements of subsection (b) of this section relating to the Secretary of Health and Human Services, schedule such substance in schedule I if the substance is not listed in any other schedule in section 812 of this title or if no exemption or approval is in effect for the substance under section 505 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355]. Such an order may not be issued before the expiration of thirty days from—

(A) the date of the publication by the Attorney General of a notice in the Federal Register of the intention to issue such order and the grounds upon which such order is to be issued, and

(B) the date the Attorney General has transmitted the notice required by paragraph (4).

(2) The scheduling of a substance under this subsection shall expire at the end of 2 years from the date of the issuance of the order scheduling such substance, except that the Attorney General may, during the pendency of proceedings under subsection (a)(1) of this section with respect to the substance, extend the temporary scheduling for up to 1 year.

(3) When issuing an order under paragraph (1), the Attorney General shall be required to consider, with respect to the finding of an imminent hazard to the public safety, only those factors set forth in paragraphs (4), (5), and (6) of subsection (c) of this section, including actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution.

(4) The Attorney General shall transmit notice of an order proposed to be issued under paragraph (1) to the Secretary of Health and Human Services. In issuing an order under paragraph (1), the Attorney General shall take into consideration any comments submitted by the Secretary in response to a notice transmitted pursuant to this paragraph.

(5) An order issued under paragraph (1) with respect to a substance shall be vacated upon the conclusion of a subsequent rulemaking proceeding initiated under subsection (a) of this section with respect to such substance.

(6) An order issued under paragraph (1) is not subject to judicial review.

(i) Temporary and Permanent Scheduling of Recently Emerged Anabolic Steroids

(1) The Attorney General may issue a temporary order adding a drug or other substance to the definition of anabolic steroids if the Attorney General finds that—

(A) the drug or other substance satisfies the criteria for being considered an anabolic steroid under section 802(41) of this title but is not listed

in that section or by regulation of the Attorney General as being an anabolic steroid; and

(B) adding such drug or other substance to the definition of anabolic steroids will assist in preventing abuse or misuse of the drug or other substance.

(2) An order issued under paragraph (1) shall not take effect until 30 days after the date of the publication by the Attorney General of a notice in the Federal Register of the intention to issue such order and the grounds upon which such order is to be issued. The order shall expire not later than 24 months after the date it becomes effective, except that the Attorney General may, during the pendency of proceedings under paragraph (6), extend the temporary scheduling order for up to 6 months.

(3) The Attorney General shall transmit notice of an order proposed to be issued under paragraph (1) to the Secretary of Health and Human Services. In issuing an order under paragraph (1), the Attorney General shall take into consideration any comments submitted by the Secretary in response to a notice transmitted pursuant to this paragraph.

(4) A temporary scheduling order issued under paragraph (1) shall be vacated upon the issuance of a permanent scheduling order under paragraph (6).

(5) An order issued under paragraph (1) is not subject to judicial review.

(6) The Attorney General may, by rule, issue a permanent order adding a drug or other substance to the definition of anabolic steroids if such drug or other substance satisfies the criteria for being considered an

anabolic steroid under section 802(41) of this title. Such rulemaking may be commenced simultaneously with the issuance of the temporary order issued under paragraph (1).

(j) Interim Final Rule; Date of Issuance; Procedure for Final Rule

(1) With respect to a drug referred to in subsection (f), if the Secretary of Health and Human Services recommends that the Attorney General control the drug in schedule II, III, IV, or V pursuant to subsections (a) and (b), the Attorney General shall, not later than 90 days after the date described in paragraph (2), issue an interim final rule controlling the drug in accordance with such subsections and section 812(b) of this title using the procedures described in paragraph (3).

(2) The date described in this paragraph shall be the later of—

(A) the date on which the Attorney General receives the scientific and medical evaluation and the scheduling recommendation from the Secretary of Health and Human Services in accordance with subsection (b); or

(B) the date on which the Attorney General receives notification from the Secretary of Health and Human Services that the Secretary has approved an application under section 505(c), 512, or 571 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(c), 360b, 360ccc] or section 262(a) of title 42, or indexed a drug under section 572 of the Federal Food, Drug, and

Cosmetic Act [21 U.S.C. 360ccc–1], with respect to the drug described in paragraph (1).

(3) A rule issued by the Attorney General under paragraph (1) shall become immediately effective as an interim final rule without requiring the Attorney General to demonstrate good cause therefor. The interim final rule shall give interested persons the opportunity to comment and to request a hearing. After the conclusion of such proceedings, the Attorney General shall issue a final rule in accordance with the scheduling criteria of subsections (b), (c), and (d) of this section and section 812(b) of this title.

(Pub. L. 91–513, title II, §201, Oct. 27, 1970, 84 Stat. 1245; Pub. L. 95–633, title I, §102(a), Nov. 10, 1978, 92 Stat. 3769; Pub. L. 96–88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695; Pub. L. 98–473, title II, §§508, 509(a), Oct. 12, 1984, 98 Stat. 2071, 2072; Pub. L. 108–358, §2(b), Oct. 22, 2004, 118 Stat. 1663; Pub. L. 112–144, title XI, §1153, July 9, 2012, 126 Stat. 1132; Pub. L. 113–260, §2(b), Dec. 18, 2014, 128 Stat. 2930; Pub. L. 114–89, §2(b), Nov. 25, 2015, 129 Stat. 700.)

Controlled Substances Act
21 U.S.C., Title 21, Chapter 13, Sec. 812

§ 812. Schedules of controlled substances

(a) Establishment

There are established five schedules of controlled substances, to be known as schedules I, II, III, IV, and V. Such schedules shall initially consist of the substances listed in this section. The schedules established by this section shall be updated and republished on a semiannual basis during the two-year period beginning one year after October 27, 1970, and shall be updated and republished on an annual basis thereafter.

(b) Placement on schedules; findings required

Except where control is required by United States obligations under an international treaty, convention, or protocol, in effect on October 27, 1970, and except in the case of an immediate precursor, a drug or other substance may not be placed in any schedule unless the findings required for such schedule are made with respect to such drug or other substance. The findings required for each of the schedules are as follows:

(1) Schedule I.—

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has no currently accepted medical use in treatment in the United States.

(C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.

(2) Schedule II.—

(A) The drug or other substance has a high potential for abuse.

(B) 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.

(C) Abuse of the drug or other substances may lead to severe psychological or physical dependence.

(3) Schedule III.—

(A) The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.

(4) Schedule IV.—

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule III.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.

(5) Schedule V.—

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule IV.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV.

(c) Initial schedules of controlled substances

Schedules I, II, III, IV, and V shall, unless and until amended[1] pursuant to section 811 of this title, consist of the following drugs or other substances, by whatever official name, common or usual name, chemical name, or brand name designated:

Schedule I

(a) Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence

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[1] Revised schedules are published in the Code of Federal Regulations, Part 1308 of Title 21, Food and Drugs.

of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

(1) Acetylmethadol.

(2) Allylprodine.

(3) Alphacetylmathadol.[2]

(4) Alphameprodine.

(5) Alphamethadol.

(6) Benzethidine.

(7) Betacetylmethadol.

(8) Betameprodine.

(9) Betamethadol.

(10) Betaprodine.

(11) Clonitazene.

(12) Dextromoramide.

(13) Dextrorphan.

(14) Diampromide.

(15) Diethylthiambutene.

(16) Dimenoxadol.

(17) Dimepheptanol.

(18) Dimethylthiambutene.

(19) Dioxaphetyl butyrate.

(20) Dipipanone.

(21) Ethylmethylthiambutene.

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[2] So in original. Probably should be "Alphacetylmethadol."

(22) Etonitazene.

(23) Etoxeridine.

(24) Furethidine.

(25) Hydroxypethidine.

(26) Ketobemidone.

(27) Levomoramide.

(28) Levophenacylmorphan.

(29) Morpheridine.

(30) Noracymethadol.

(31) Norlevorphanol.

(32) Normethadone.

(33) Norpipanone.

(34) Phenadoxone.

(35) Phenampromide.

(36) Phenomorphan.

(37) Phenoperidine.

(38) Piritramide.

(39) Propheptazine.

(40) Properidine.

(41) Racemoramide.

(42) Trimeperidine.

(b) Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and

salts of isomers is possible within the specific chemical designation:

(1) Acetorphine.

(2) Acetyldihydrocodeine.

(3) Benzylmorphine.

(4) Codeine methylbromide.

(5) Codeine-N-Oxide.

(6) Cyprenorphine.

(7) Desomorphine.

(8) Dihydromorphine.

(9) Etorphine.

(10) Heroin.

(11) Hydromorphinol.

(12) Methyldesorphine.

(13) Methylhydromorphine.

(14) Morphine methylbromide.

(15) Morphine methylsulfonate.

(16) Morphine-N-Oxide.

(17) Myrophine.

(18) Nicocodeine.

(19) Nicomorphine.

(20) Normorphine.

(21) Pholcodine.

(22) Thebacon.

(c) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) 3,4-methylenedioxy amphetamine.

(2) 5-methoxy-3,4-methylenedioxy amphetamine.

(3) 3,4,5-trimethoxy amphetamine.

(4) Bufotenine.

(5) Diethyltryptamine.

(6) Dimethyltryptamine.

(7) 4-methyl-2,5-diamethoxyamphetamine.

(8) Ibogaine.

(9) Lysergic acid diethylamide.

(10) Marihuana.

(11) Mescaline.

(12) Peyote.

(13) N-ethyl-3-piperidyl benzilate.

(14) N-methyl-3-piperidyl benzilate.

(15) Psilocybin.

(16) Psilocyn.

(17) Tetrahydrocannabinols.

(18) 4-methylmethcathinone (Mephedrone).

(19) 3,4-methylenedioxypyrovalerone (MDPV).

(20) 2-(2,5-Dimethoxy-4-ethylphenyl) ethanamine (2C–E).

(21) 2-(2,5-Dimethoxy-4-methylphenyl) ethanamine (2C–D).

(22) 2-(4-Chloro-2,5-dimethoxyphenyl) ethanamine (2C–C).

(23) 2-(4-Iodo-2,5-dimethoxyphenyl) ethanamine (2C–I).

(24) 2-[4-(Ethylthio)-2,5-dimethoxyphenyl] ethanamine (2C–T–2).

(25) 2-[4-(Isopropylthio)-2,5-dimethoxyphenyl] ethanamine (2C–T–4).

(26) 2-(2,5-Dimethoxyphenyl) ethanamine (2C–H).

(27) 2-(2,5-Dimethoxy-4-nitro-phenyl) ethanamine (2C–N).

(28) 2-(2,5-Dimethoxy-4-(n)-propylphenyl) ethanamine (2C–P).

(d)

(1) Unless specifically exempted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of cannabimimetic agents, or which contains their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

(2) In paragraph (1):

(A) The term "cannabimimetic agents" means any substance that is a cannabinoid receptor type

1 (CB1 receptor) agonist as demonstrated by binding studies and functional assays within any of the following structural classes:

(i) 2-(3-hydroxycyclohexyl)phenol with substitution at the 5-position of the phenolic ring by alkyl or alkenyl, whether or not substituted on the cyclohexyl ring to any extent.

(ii) 3-(1-naphthoyl) indole or 3-(1-naphthylmethane) indole by substitution at the nitrogen atom of the indole ring, whether or not further substituted on the indole ring to any extent, whether or not substituted on the naphthoyl or naphthyl ring to any extent.

(iii) 3-(1-naphthoyl)pyrrole by substitution at the nitrogen atom of the pyrrole ring, whether or not further substituted in the pyrrole ring to any extent, whether or not substituted on the naphthoyl ring to any extent.

(iv) 1-(1-naphthylmethylene)indene by substitution of the 3-position of the indene ring, whether or not further substituted in the indene ring to any extent, whether or not substituted on the naphthyl ring to any extent.

(v) 3-phenylacetylindole or 3-benzoylindole by substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent, whether or not substituted on the phenyl ring to any extent.

(B) Such term includes—

(i) 5-(1,1-dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (CP–47,497);

(ii) 5-(1,1-dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP–47,497 C8-homolog);

(iii) 1-pentyl-3-(1-naphthoyl) indole (JWH–018 and AM678);

(iv) 1-butyl-3-(1-naphthoyl) indole (JWH–073);

(v) 1-hexyl-3-(1-naphthoyl) indole (JWH–019);

(vi) 1-[2-(4-morpholinyl) ethyl]-3-(1-naphthoyl) indole (JWH–200);

(vii) 1-pentyl-3-(2-methoxyphenylacetyl) indole (JWH–250);

(viii) 1-pentyl-3-[1-(4-methoxynaphthoyl)] indole (JWH–081);

(ix) 1-pentyl-3-(4-methyl-1-naphthoyl)indole (JWH–122);

(x) 1-pentyl-3-(4-chloro-1-naphthoyl) indole (JWH–398);

(xi) 1-(5-fluoropentyl)-3-(1-naphthoyl) indole (AM2201);

(xii) 1-(5-fluoropentyl)-3-(2-iodobenzoyl) indole (AM694);

(xiii) 1-pentyl-3-[(4-methoxy)-benzoyl] indole (SR–19 and RCS–4);

(xiv) 1-cyclohexylethyl-3-(2-methoxyphenylacetyl) indole (SR–18 and RCS–8); and

(xv) 1-pentyl-3-(2-chlorophenylacetyl) indole (JWH–203).

Schedule II

(a) Unless specifically excepted or unless listed in another schedule, any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate.

(2) Any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause (1), except that these substances shall not include the isoquinoline alkaloids of opium.

(3) Opium poppy and poppy straw.

(4) coca[3] leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed; cocaine, its salts, optical and geometric isomers, and salts of isomers; ecgonine, its derivatives, their salts, isomers, and salts of isomers; or any compound, mixture, or preparation which contains any

[3] So in original. Probably should be capitalized.

quantity of any of the substances referred to in this paragraph.

(b) Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

(1) Alphaprodine.

(2) Anileridine.

(3) Bezitramide.

(4) Dihydrocodeine.

(5) Diphenoxylate.

(6) Fentanyl.

(7) Isomethadone.

(8) Levomethorphan.

(9) Levorphanol.

(10) Metazocine.

(11) Methadone.

(12) Methadone-Intermediate, 4-cyano-2-dimethyl-amino-4,4-diphenyl butane.

(13) Moramide-Intermediate, 2-methyl-3-morpho-lino-1, 1-diphenylpropane-carboxylic acid.

(14) Pethidine.

(15) Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine.

(16) Pethidine-Intermediate-B, ethyl-4-phenyl-piperidine-4-carboxylate.

(17) Pethidine-Intermediate-C, 1-methyl-4-phenyl-piperidine-4-carboxylic acid.

(18) Phenazocine.

(19) Piminodine.

(20) Racemethorphan.

(21) Racemorphan.

(c) Unless specifically excepted or unless listed in another schedule, any injectable liquid which contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers.

Schedule III

(a) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:

(1) Amphetamine, its salts, optical isomers, and salts of its optical isomers.

(2) Phenmetrazine and its salts.

(3) Any substance (except an injectable liquid) which contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers.

(4) Methylphenidate.

(b) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system:

(1) Any substance which contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid.

(2) Chorhexadol.

(3) Glutethimide.

(4) Lysergic acid.

(5) Lysergic acid amide.

(6) Methyprylon.

(7) Phencyclidine.

(8) Sulfondiethylmethane.

(9) Sulfonethylmethane.

(10) Sulfonmethane.

(c) Nalorphine.

(d) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, or any salts thereof:

(1) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium.

(2) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, non-narcotic ingredients in recognized therapeutic amounts.

(3) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with a

fourfold or greater quantity of an isoquinoline alkaloid of opium.

(4) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(5) Not more than 1.8 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(6) Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(7) Not more than 500 milligrams of opium per 100 milliliters or per 100 grams, or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(8) Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(e) Anabolic steroids.

Schedule IV

(1) Barbital.

(2) Chloral betaine.

(3) Chloral hydrate.

(4) Ethchlorvynol.

(5) Ethinamate.

(6) Methohexital.

(7) Meprobamate.

(8) Methylphenobarbital.

(9) Paraldehyde.

(10) Petrichloral.

(11) Phenobarbital.

Schedule V

Any compound, mixture, or preparation containing any of the following limited quantities of narcotic drugs, which shall include one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone:

(1) Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams.

(2) Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams.

(3) Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams.

(4) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.

(5) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams.

(Pub. L. 91–513, title II, §202, Oct. 27, 1970, 84 Stat. 1247; Pub. L. 95–633, title I, §103, Nov. 10, 1978, 92 Stat. 3772; Pub. L. 98–473, title II, §§507(c), 509(b), Oct. 12, 1984, 98 Stat. 2071, 2072; Pub. L. 99–570, title I, §1867, Oct. 27, 1986, 100 Stat. 3207–55; Pub. L. 99–646, §84, Nov. 10, 1986, 100 Stat. 3619; Pub. L. 101–647, title XIX, §1902(a), Nov. 29, 1990, 104 Stat. 4851; Pub. L. 112–144, title XI, §1152, July 9, 2012, 126 Stat. 1130.)

Amendments

2012—Subsec. (c). Pub. L. 112–144, §1152(b), added schedule I(c)(18) to (28).

Pub. L. 112–144, §1152(a), added schedule I(d).

1990—Subsec. (c). Pub. L. 101–647 added item (e) at end of schedule III.

1986—Subsec. (c). Pub. L. 99–646 amended schedule II(a)(4) generally. Prior to amendment, schedule II(a)(4) read as follows: "Coca leaves (except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed); cocaine, its salts, optical and geometric isomers, and salts of isomers; and ecgonine, its derivatives, their salts, isomers, and salts of isomers."

Pub. L. 99–570 amended schedule II(a)(4) generally. Prior to amendment, schedule II(a)(4) read as follows: "Coca leaves and any salt, compound, derivative, or preparation of coca leaves (including cocaine and ecgonine and their salts, isomers, derivatives, and salts of isomers and derivatives), and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these

substances, except that the substances shall not include decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine or ecgonine."

1984—Subsec. (c). Pub. L. 98–473, §507(c), in schedule II(a)(4) added applicability to cocaine and ecgonine and their salts, isomers, etc.

Subsec. (d). Pub. L. 98–473, §509(b), struck out subsec. (d) which related to authority of Attorney General to except stimulants or depressants containing active medicinal ingredients.

1978—Subsec. (d)(3). Pub. L. 95–633 added cl. (3).

Effective Date of 1990 Amendment

Amendment by Pub. L. 101–647 effective 90 days after Nov. 29, 1990, see section 1902(d) of Pub. L. 101–647, set out as a note under section 802 of this title.

Effective Date of 1978 Amendment

Amendment by Pub. L. 95–633 effective on date the Convention on Psychotropic Substances enters into force in the United States [July 15, 1980], see section 112 of Pub. L. 95–633, set out as an Effective Date note under section 801a of this title.

Title 21 Chapter 13 Section 841(b)(1)(A)(vii)

(b) Penalties Except as otherwise provided in section 849, 859, 860, or 861 of this title, any person who violates subsection (a) of this section shall be sentenced as follows:

(1)

(A) In the case of a violation of subsection (a) of this section involving—

(vii) 1000 kilograms or more of a mixture or substance containing a detectable amount of marihuana, or 1,000 or more marihuana plants regardless of weight; such person shall be sentenced to a term of imprisonment which may not be less than 10 years or more than life and if death or serious bodily injury results from the use of such substance shall be not less than 20 years or more than life, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18 or $10,000,000 if the defendant is an individual or $50,000,000 if the defendant is other than an individual, or both. If any person commits such a violation after a prior conviction for a serious drug felony or serious violent felony has become final, such person shall be sentenced to a term of imprisonment of not less than 15 years and not more than life imprisonment and if death or serious bodily injury results from the use of such substance shall be sentenced to life imprisonment, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18 or $20,000,000 if the defendant is an individual or $75,000,000 if the defendant is other than an individual, or both. If any person commits a violation of this subparagraph or of section 849, 859, 860, or 861 of this title after 2 or more prior convictions for a serious drug felony or serious violent felony have become final, such person shall be sentenced to a term of imprisonment of

not less than 25 years and fined in accordance with the preceding sentence. Notwithstanding section 3583 of title 18, any sentence under this subparagraph shall, in the absence of such a prior conviction, impose a term of supervised release of at least 5 years in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a term of supervised release of at least 10 years in addition to such term of imprisonment. Notwithstanding any other provision of law, the court shall not place on probation or suspend the sentence of any person sentenced under this subparagraph. No person sentenced under this subparagraph shall be eligible for parole during the term of imprisonment imposed therein.

Title 21 Chapter 13 Section 841(b)(1)(B)(vii)

(B) In the case of a violation of subsection (a) of this section involving—

(vii) 100 kilograms or more of a mixture or substance containing a detectable amount of marihuana, or 100 or more marihuana plants regardless of weight;

such person shall be sentenced to a term of imprisonment which may not be less than 5 years and not more than 40 years and if death or serious bodily injury results from the use of such substance shall be not less than 20 years or more than life, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18 or $5,000,000 if the defendant is an individual or $25,000,000 if the defendant is other than an individual, or both. If any person

commits such a violation after a prior conviction for a serious drug felony or serious violent felony has become final, such person shall be sentenced to a term of imprisonment which may not be less than 10 years and not more than life imprisonment and if death or serious bodily injury results from the use of such substance shall be sentenced to life imprisonment, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18 or $8,000,000 if the defendant is an individual or $50,000,000 if the defendant is other than an individual, or both. Notwithstanding section 3583 of title 18, any sentence imposed under this subparagraph shall, in the absence of such a prior conviction, include a term of supervised release of at least 4 years in addition to such term of imprisonment and shall, if there was such a prior conviction, include a term of supervised release of at least 8 years in addition to such term of imprisonment. Notwithstanding any other provision of law, the court shall not place on probation or suspend the sentence of any person sentenced under this subparagraph. No person sentenced under this subparagraph shall be eligible for parole during the term of imprisonment imposed therein.

21 U.S.C. § 844—Penalties for Simple Possession

(a) Unlawful acts; penalties

It shall be unlawful for any person knowingly or intentionally to possess a controlled substance unless such substance was obtained directly, or pursuant to a valid prescription or order, from a practitioner, while acting in the course of his

professional practice, or except as otherwise authorized by this subchapter or subchapter II of this chapter. It shall be unlawful for any person knowingly or intentionally to possess any list I chemical obtained pursuant to or under authority of a registration issued to that person under section 823 of this title or section 958 of this title if that registration has been revoked or suspended, if that registration has expired, or if the registrant has ceased to do business in the manner contemplated by his registration. It shall be unlawful for any person to knowingly or intentionally purchase at retail during a 30 day period more than 9 grams of ephedrine base, pseudoephedrine base, or phenylpropanolamine base in a scheduled listed chemical product, except that, of such 9 grams, not more than 7.5 grams may be imported by means of shipping through any private or commercial carrier or the Postal Service. Any person who violates this subsection may be sentenced to a term of imprisonment of not more than 1 year, and shall be fined a minimum of $1,000, or both, except that if he commits such offense after a prior conviction under this subchapter or subchapter II of this chapter, or a prior conviction for any drug, narcotic, or chemical offense chargeable under the law of any State, has become final, he shall be sentenced to a term of imprisonment for not less than 15 days but not more than 2 years, and shall be fined a minimum of $2,500, except, further, that if he commits such offense after two or more prior convictions under this subchapter or subchapter II of this chapter, or two or more prior convictions for any drug, narcotic, or chemical offense chargeable under

the law of any State, or a combination of two or more such offenses have become final, he shall be sentenced to a term of imprisonment for not less than 90 days but not more than 3 years, and shall be fined a minimum of $5,000. Notwithstanding any penalty provided in this subsection, any person convicted under this subsection for the possession of flunitrazepam shall be imprisoned for not more than 3 years, shall be fined as otherwise provided in this section, or both. The imposition or execution of a minimum sentence required to be imposed under this subsection shall not be suspended or deferred. Further, upon conviction, a person who violates this subsection shall be fined the reasonable costs of the investigation and prosecution of the offense, including the costs of prosecution of an offense as defined in sections 1918 and 1920 of title 28, except that this sentence shall not apply and a fine under this section need not be imposed if the court determines under the provision of title 18 that the defendant lacks the ability to pay.

(b) Repealed. Pub. L. 98–473, title II, § 219(a), Oct. 12, 1984, 98 Stat. 2027

(c) "Drug, Narcotic, or Chemical Offense" Defined

As used in this section, the term "drug, narcotic, or chemical offense" means any offense which proscribes the possession, distribution, manufacture, cultivation, sale, transfer, or the attempt or conspiracy to possess, distribute, manufacture, cultivate, sell or transfer any substance the possession of which is prohibited under this subchapter.

CONGRESSIONAL RECORD

CONGRESSIONAL RECORD—
HOUSE OF REPRESENTATIVES
JUNE 19, 2019

COMMERCE, JUSTICE, SCIENCE, AND RELATED AGENCIES APPROPRIATIONS ACT, 2020

GENERAL LEAVE

Mrs. LOWEY. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days to revise and extend their remarks and to include extraneous material on H.R. 3055.

The SPEAKER pro tempore. Is there objection to the request of the gentlewoman from New York?

There was no objection.

The SPEAKER pro tempore. Pursuant to House Resolution 445 and rule XVIII, the Chair declares the House in the Committee of the Whole House on the state of the Union for the consideration of the bill, H.R. 3055.

The Chair appoints the gentleman from Oregon (Mr. BLUMENAUER) to preside over the Committee of the Whole.

[…]

SEC. 530.

None of the funds made available by this Act may be used in contravention of section 7606 ("Legitimacy of Industrial Hemp Research") of the Agricultural Act of 2014 (Public Law 113–79) by

the Department of Justice or the Drug Enforcement Administration.

SEC. 531.

None of the funds made available under this Act to the Department of Justice may be used, with respect to any of the States of Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, and Wyoming, or with respect to the District of Columbia, the Commonwealth of the Northern Mariana Islands, Guam, or Puerto Rico, to prevent any of them from implementing their own laws that authorize the use, distribution, possession, or cultivation of medical marijuana.

Rules Committee Print 115–66
Text of the House Amendment to the Senate Amendment to H.R. 1625

[Showing the text of the Consolidated Appropriations Act, 2018.]

SEC. 538.

None of the funds made available under this Act to the Department of Justice may be used, with respect to any of the States of Alabama, Alaska,

Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, and Wyoming, or with respect to the District of Columbia, Guam, or Puerto Rico, to prevent any of them from implementing their own laws that authorize the use, distribution, possession, or cultivation of medical marijuana.

115TH CONGRESS 1ST SESSION
S. 1662 [REPORT NO. 115-139]

Making appropriations for the Departments of Commerce and Justice, Science, and Related Agencies for the fiscal year ending September 30, 2018, and for other purposes.

In the Senate of the United States July 27, 2017

A BILL

Making appropriations for the Departments of Commerce and Justice, Science, and Related Agencies for the fiscal year ending September 30, 2018, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of Anierica in Congress assembled, That the following sums are

appropriated, out of any money in the Treasury not otherwise appropriated, for the Departments of Commerce and Justice, Science, and Related Agencies for the fiscal year ending September 30, 2018, and for other purposes, namely:

SEC. 537.

Of the funds appropriated or otherwise made available in this Act for the National Oceanic and Atmospheric Administration (NOAA), NOAA shall, as part of fisheries science and management activities, obligate funding for the placement of at sea monitors on vessels before obligating funding for observer-related costs associated with standardized bycatch reporting methodology requirements.

MEDICAL MARIJUANA

SEC. 538.

None of the funds made available under this Act to the Department of Justice may be used, with respect to any of the States of Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, and Wyoming, or with respect to the District of Columbia, Guam, or Puerto Rico, to prevent any

such State or jurisdiction from implementing a law that authorizes the use, distribution, possession, or cultivation of medical marijuana.

114TH CONGRESS 1ST SESSION
H. R. 2578 [REPORT NO. 114-66]

June 8, 2015–Received—Read Twice and Referred to the Committee on Appropriations June 16, 2015
Reported with an Amendment

AN ACT

Making appropriations for the Departments of Commerce and Justice, Science, and Related Agencies for the fiscal year ending September 30, 2016, and for other purposes.

SEC. 542.

None of the funds made available in this Act to the Department of Justice may be used, with respect to any of the States of Alabama, Alaska, Arizona, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Iowa, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Oregon, Rhode Island, South Carolina, Tennessee, Texas, Utah, Vermont, Virginia, Washington, and Wisconsin, or with respect to either the District of Columbia or Guam, to prevent any of them from implementing their own laws that

authorize the use, distribution, possession, or cultivation of medical marijuana.

This Act may be cited as the "Commerce, Justice, Science, and Related Agencies Appropriations Act, 2016"

113TH CONGRESS 2D SESSION

H. R. 4660

IN THE SENATE OF THE UNITED STATES

June 2, 2014–Received—June 10, 2014

Read twice and placed on the calendar

AN ACT

Making appropriations for the Departments of Commerce and Justice, Science, and Related Agencies for the fiscal year ending September 30, 2015, and for other purposes.

558.

None of the funds made available in this Act to the Department of Justice may be used, with respect to the States of Alabama, Alaska, Arizona, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Hawaii, Illinois, Iowa, Kentucky, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nevada, New Hampshire, New Jersey, New Mexico, Oregon, Rhode Island, South Carolina, Tennessee, Utah, Vermont, Washington, and Wisconsin, to prevent such States from implementing their own State laws that authorize

the use, distribution, possession, or cultivation of medical marijuana.

TRANSCRIPT OF THE ORAL ARGUMENT IN THE UNITED STATES DISTRICT COURT, SOUTHERN DISTRICT OF NEW YORK (FEBRUARY 14, 2018)

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MARVIN WASHINGTON, ET AL.,

Plaintiffs,

v.

JEFFERSON BEAUREGARD SESSIONS, III, ET AL.,

Defendants.

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17 Civ. 5625 (AKH)

Before: Hon. Alvin K. HELLERSTEIN, District Judge.

(Case called)

THE COURT: The next time we hear that command "all rise" it may be that Aaron Judge has hit his first home run.

This is Marvin Washington and others against Jefferson Beauregard Sessions, III in his official capacity as United States Attorney General and other officials and agencies of the government, 17 Civ. 5625.

Who is going to speak for the plaintiff?

MR. HILLER: Your Honor, Michael Hiller of Hiller, PC. I'll be addressing five causes of action. With the Court's permission we would like Lauren Rudick to argue the commerce clause claim and Joseph Bondy to argue—

THE COURT: We are not going to do that. They can get up and answer to my specific questions, but I'll look to you, Mr. Hiller, to do it all.

MR. HILLER: Very well, your Honor.

THE COURT: Why don't you introduce everyone else on your side.

MR. HILLER: Again, Michael Hiller from Hiller, PC; my partner, Lauren Rudick also of Hiller, PC; Joseph Bondy; David Holland. With the Court's permission I would just like to introduce the plaintiffs who are all represented here today.

THE COURT: Sure.

MR. HILLER: The first gentleman on the aisle is Jose Belen. The two gentlemen next to him are Jake Plowden and Nelson Guerrero from the Cannabis Cultural Association. Marvin Washington. Neil Bridgewater, also of the Cannabis Cultural Association. Dean and Liza Bortell, on behalf of Alexis Bortell. Lastly, Sebastian Cotte on behalf of his son, Jagger Cotte.

THE COURT: Welcome, all.

Defendants.

MR. DOLINGER: Good morning, your Honor, Samuel Dolinger, Assistant United States Attorney, for

the government. With me at counsel table is David S. Jones.

THE COURT: Sorry?

MR. DOLINGER: David Jones.

THE COURT: Is Isodore Dolinger, the Bronx congressman, your grandfather?

MR. DOLINGER: He is not. Nor am I related to Magistrate Judge Dolinger.

THE COURT: Just a coincidence.

MR. DOLINGER: I think that's right, your Honor.

THE COURT: Mr. Dolinger, you are up. It's your motion.

MR. DOLINGER: Thank you.

Your Honor, we are here on defendants' motion to dismiss the amended complaint. The plaintiffs assert a variety of constitutional challenges to the federal regulation of marijuana under the Controlled Substances Act. Courts around the country have considered similar or identical claims and have rejected them.

The Court should do the same here. The briefs in support of our motion are lengthy, and I'm happy to answer any questions the Court has.

THE COURT: I'll have them along the way. Make your argument.

MR. DOLINGER: Thank you, your Honor.

The plaintiffs' principal challenge sounds in due process, and they assert that the regulation of

marijuana on schedule 1 of the CSA violates the rational basis test.

Under rational basis review, a law passed by Congress must only be rationally related to a legitimate government interest. This is the most deferential standard of review. Any conceivable basis will suffice. It need not be a stated basis that Congress made factual findings on or put into a record. A law has a presumption of rationality under this test. In order to state a claim the plaintiffs' complaint must negate every conceivable basis that could support the law, and they haven't done so here.

Among the interests that Congress stated that it was—

THE COURT: What is the relief that plaintiffs seek?

MR. DOLINGER: As I understand it, your Honor, they seek the invalidation of the Controlled Substances Act as relates to marijuana.

THE COURT: That narrow?

MR. DOLINGER: I'm sorry, your Honor?

THE COURT: Is it that narrow?

MR. DOLINGER: I don't know whether they are seeking a broader invalidation of the Controlled Substances Act. It's my understanding.

THE COURT: That's what you just said. Is it a validation of the act insofar as it places marijuana on schedule 1?

MR. DOLINGER: Yes, your Honor.

THE COURT: That's by act of Congress in 1972?

MR. DOLINGER: 1970, your Honor.

At the time of passage Congress stated that its goals were to protect public health and welfare from drug abuse and drug trafficking. In 1998, your Honor, Congress passed a supplemental statement in which it opposed the legalization of marijuana for medical use, citing the prevalence of its use and abuse by children under the age of 18. This is one of the many bases that Congress and others have cited for marijuana on schedule 1, is the potential of its abuse by children and thereby to protect the health of minors. There are also public safety concerns associated with marijuana use, including—

THE COURT: There is another criteria also that's discussed. That is whether there was any medical use. Was there any finding on that by Congress in 19—when was the amendment, 1998?

MR. DOLINGER: In 1998, there was no amendment, your Honor. It was a statement that was attached to appropriations legislation.

THE COURT: What effect is that?

MR. DOLINGER: It states Congress' intent and findings and its opposition to the legalization of medical marijuana.

THE COURT: It's a statement of general policy. It's nothing more than that. I don't know what kind of legal consequence it has.

MR. DOLINGER: Among other things, your Honor, it's one of many legitimate rational bases that Congress could have—

THE COURT: This is 28 years after the law was passed.

MR. DOLINGER: That's right, your Honor. At the time the law was passed Congress had a rational basis for it as well.

THE COURT: Seems to me the only test that's relevant is what was before the Congress in 1970. The escape valve in the law is a forward-seeking law. It created a schedule, set of schedules that would last, and Congress provided that from time to time there would be review.

MR. DOLINGER: That's right, your Honor.

THE COURT: A later event doesn't necessarily invalidate the law.

MR. DOLINGER: I think that's especially true in this case, as you are pointing out.

THE COURT: All I think about is that the 1998 law interfered with the due process set up by the law that would be in Attorney General review.

MR. DOLINGER: Your Honor, the congressional purpose in setting up this administrative review process was to permit the Attorney General and his delegates to assess new scientific and medical information on controlled substances.

THE COURT: Doesn't the 1998 pronouncement in the air by Congress, as it were, interfere with that process by the Attorney General or his delegee?

MR. DOLINGER: No, your Honor. Because Congress isn't the ultimate decider here of federal drug policy.

THE COURT: Congress in 1970 passed a law. Congress acts only through laws.

MR. DOLINGER: That's true, your Honor.

THE COURT: If it's not a law, whatever Congress says doesn't have any legal consequence.

MR. DOLINGER: This was, in fact, passed through an appropriations bill that did have the force of law.

THE COURT: Which bill?

MR. DOLINGER: It was the appropriations legislation for 1999. To your point, your Honor.

THE COURT: Mr. Dolinger, don't go fast. You go faster than I can think.

MR. DOLINGER: Sure, your Honor. My apologies.

THE COURT: Let me stop you there. It's part of an appropriations bill appropriating money for the DEA, is that it?

MR. DOLINGER: I believe it was omnibus general appropriations legislation.

THE COURT: What does that have to do with what happened in 1970 or what the Attorney General is supposed to be considering in 1998 or today?

MR. DOLINGER: The relevance of the bill is it expressed Congress' intent some years—

THE COURT: Fine. It gave money. What's the big deal? How much of that went to Schedule 1?

MR. DOLINGER: That, your Honor, I don't have information about.

THE COURT: Mr. Dolinger, that argument is not getting anywhere.

MR. DOLINGER: Understood, your Honor.

THE COURT: Stick with 1970 and the process after that.

MR. DOLINGER: As of 1970, Congress made a list of rationales for the law, principally among which were these public health and safety concerns.

THE COURT: And it created five schedules.

MR. DOLINGER: That's correct.

THE COURT: Teach me the importance of the schedules.

MR. DOLINGER: And placed marijuana on schedule 1. The schedules are arrayed from 1 through 5 in terms of the amount of control that the law places on each substance.

THE COURT: What's the difference among the different schedules?

MR. DOLINGER: The only schedule that's relevant here is schedule 1, which requires that—

THE COURT: My mind goes beyond what's focused and relevant. What do the other schedules do?

MR. DOLINGER: The other schedules also provide for the control of controlled substances that are known to have some currently accepted medical use.

THE COURT: What would be the consequence, for example, if marijuana was shifted from schedule 1 to schedule 2?

MR. DOLINGER: The consequence would be that it could be recognized to have some accepted medical use if it were shifted.

THE COURT: Would it still be criminal?

MR. DOLINGER: There would be criminal penalties attached to the illegal distribution.

THE COURT: Resulting in custody.

MR. DOLINGER: Yes. Among other substances on schedule 2 are certain opiates and amphetamines.

THE COURT: The scourge that's now going on would be a schedule 2 scourge.

MR. DOLINGER: There are drugs on schedule 2 that are part of the current opioid crisis, your Honor. Yes, that's correct.

THE COURT: What happens if marijuana went to schedule 3? What would be the consequence?

MR. DOLINGER: All of these schedules have potential consequences for illegal distribution and use, your Honor.

THE COURT: Even if it were on schedule 5, the most lenient of the schedules, would there be criminal consequences?

MR. DOLINGER: For illicit use, your Honor, and distribution, that is my understanding, but I would respectfully request to get back to the Court on this.

THE COURT: What's the answer to that question, Mr. Hiller?

MR. HILLER: Not necessarily, your Honor. For example, Robitussin is a schedule 5 drug. That's not an illicit drug. There are other drugs which are prescription.

THE COURT: If you periled Robitussin because of the contents of the cough medicine, it could be illegal, right?

MR. HILLER: Yes, it could.

THE COURT: Even though it's an off-the-shelf drug?

MR. HILLER: That's my understanding, Judge.

THE COURT: Off the record.

(Discussion off the record)

THE COURT: Mr. Hiller, even if it was on schedule 5 there would be circumstances where selling, distributing an item on schedule 5 could be criminal.

MR. HILLER: It could be, yes. There are circumstances.

THE COURT: Thank you, Mr. Hiller.

MR. HILLER: Sure.

MR. DOLINGER: As your Honor pointed out, there is a scheduling process that the DEA follows by delegation from the Attorney General to account for developments in science and medicine—

THE COURT: Let's say I'm a doctor specializing or wanting to specialize in the administration of marijuana for certain medical purposes, and we recognize that there are now medical purposes that can be useful to be treated with marijuana, at least to remedy the problem of pain. How would that doctor go about getting a reclassification?

MR. DOLINGER: Any person can submit a petition to the DEA seeking a rescheduling of a drug and can submit evidence that they assert supports the rescheduling. In making the scheduling decision

the DEA seeks a recommendation from the Secretary of Health and Human Services.

THE COURT: Is there some kind of a trial?

MR. DOLINGER: There is an agency review process that does result in an agency decision. There is an extensive record.

THE COURT: Is a record created?

MR. DOLINGER: A record is created and is subject to review in the courts of appeal.

THE COURT: Can the petitioner bring evidence?

MR. DOLINGER: Yes. The petitioner can submit evidence.

THE COURT: So the petitioner is free to bring in all kinds of evidence supporting his claim that there should be a liberalization of the scheduling of marijuana?

MR. DOLINGER: That's right, your Honor. And that is the forum in which—

THE COURT: Then there is a process and a final determination by the agency.

MR. DOLINGER: Correct, your Honor.

THE COURT: Or under the Administrative Procedure Act, there is a review by the D.C. Court of Appeals.

MR. DOLINGER: There is actually a specific statutory provision under the Controlled Substances Act that provides for review in any of the courts of appeals. But the D.C. circuit has reviewed these rescheduling decisions several times.

THE COURT: As in any administrative agency cases, the petitioner is free to ask the Court of Appeals the jurisdiction where he lives to review the final determination of the agency.

MR. DOLINGER: Yes, a petitioner may.

THE COURT: And then there is ultimate review in the Supreme Court.

MR. DOLINGER: Yes, your Honor.

THE COURT: If the agency doesn't do its duty, a writ of mandamus can be taken out in an appropriate Court of Appeals.

MR. DOLINGER: That's true as well.

THE COURT: It's just like any other situation in any agency?

MR. DOLINGER: Yes, your Honor. With the specific statutory guidelines that the agency must follow in rescheduling decisions.

THE COURT: Like all other administrative agencies, there are legal criteria that must be observed?

MR. DOLINGER: Yes, your Honor.

THE COURT: Indeed there have been such proceedings.

MR. DOLINGER: There have been a number of those proceedings.

THE COURT: Was it part of your argument to tell me about it?

MR. DOLINGER: Yes, your Honor.

THE COURT: Now would be a good time.

MR. DOLINGER: This is addressed in our brief and that is one of the grounds on which we have moved to dismiss. There is this possibility of administrative review that the plaintiffs have not sought to take advantage of here.

THE COURT: They tell me it's futile.

MR. DOLINGER: Yes, your Honor.

THE COURT: Meaning that a lot of people have lost.

MR. DOLINGER: That is correct, your Honor.

THE COURT: Then it takes a long time for the agency to work.

MR. DOLINGER: These petitions have been unsuccessful in the past. But the last two decisions in 2011 and 2016 denying the scheduling of marijuana found that there were not sufficient studies of sufficiently high quality to show the efficacy of marijuana.

THE COURT: Those aren't decisions by the D.C. Court of Appeals.

MR. DOLINGER: Those are decisions by the DEA on the rescheduling petitions. One of those cases—

THE COURT: Affirmed by the District of Columbia Court of Appeals.

MR. DOLINGER: Yes. One of them was affirmed. The other, no review was taken. Or if a review was taken, it was dismissed on jurisdictional grounds.

There was a 2013 D.C. Court of Appeals—

THE COURT: The substantive rule of the D.C. Court of Appeals was established in 2013?

MR. DOLINGER: The D.C. circuit did rule in 2013 and upheld the DEA's refusal to reschedule the drug, as supported by substantial evidence.

THE COURT: And the record that came up in 2013 was dated when?

MR. DOLINGER: That was the 2011 denial, your Honor.

THE COURT: In 2011, six, seven years ago, the DEA, after an administrative hearing and evidence and the like, ruled that marijuana should remain schedule 1?

MR. DOLINGER: Correct, your Honor.

THE COURT: And the petitioner didn't like that rule, so he appealed to the D.C. Court of Appeals that the law says he should, and he lost in D.C. Court of Appeals.

MR. DOLINGER: Yes, your Honor.

THE COURT: Although that rule is not binding on me, it's persuasive, isn't it?

MR. DOLINGER: It's very persuasive, your Honor. Because in coming to that determination the D.C. circuit applied a much more rigorous standard of review than your Honor would apply under a rational basis for a view to the law.

THE COURT: What was the standard review?

MR. DOLINGER: It is an APA type standard, your Honor, substantial evidence.

THE COURT: Whether there is substantial evidence, what is the determination of the agency?

MR. DOLINGER: Supports factual findings which reasonably support the legal conclusion.

THE COURT: And the D.C. Court of Appeals found that there was.

MR. DOLINGER: That's correct, your Honor.

THE COURT: As of 2011.

MR. DOLINGER: Yes. In a decision as of 2013. Among other things, your Honor—

THE COURT: Plaintiff can go back now and say, things have changed since 2011. Here are all these medical uses and here are all these doctors' testimonials about how much it is used and here are my clients, and you have the people who have been helped considerably by it, please change your mind.

MR. DOLINGER: Exactly, your Honor. The administrative review process is the appropriate way to present new evidence to the DEA concerning allegations that there are scientific and medical changes or advancements that could—

THE COURT: What is the doctrine of law that so specifies?

MR. DOLINGER: I'm sorry, your Honor?

THE COURT: What is the doctrine of law that would allow me to dismiss the case, as you want me to do, on the ground that the proper remedy is in the DEA and in the Court of Appeals?

MR. DOLINGER: It's the doctrine of administrative exhaustion, your Honor. Where there is an available and adequate administrative remedy, a court should not first hear a challenge before that

administrative review process has been exhausted. Here, the plaintiffs—

THE COURT: What does available mean? Administrative and available legal remedy?

MR. DOLINGER: It means that the process must provide an opportunity for the relief that the plaintiffs are seeking.

THE COURT: Suppose they just sit on their butts.

MR. DOLINGER: A writ of mandamus, as your Honor stated, can be taken to a Court of Appeals seeking to direct the agency to act if agency action has been unduly delayed.

THE COURT: Plaintiffs say that there was a seven and a half years' delay. Do I remember correctly? How many years, Mr. Hiller?

MR. HILLER: It's nine, your Honor.

THE COURT: Nine years' delay.

MR. DOLINGER: Your Honor, the agency.

THE COURT: Is anyone taking a writ in the D.C. Court of Appeals and say, that's unconscionable?

MR. DOLINGER: I understand there may have been mandamus writs taken in the past in these cases, your Honor. The most two recent rescheduling petitions were pending for a shorter period than that, for, I believe, five to six years, but the agency process is exhaustive. It results in the compilation of a record that is hundreds of pages long.

As I stated, the DEA takes a recommendation from the secretary of HHS who delegates that responsibility to the Food and Drug Administration, which

makes scientific findings that are binding on DEA. That process necessarily takes time and provides for this exhaustive record that is then available to the Court of Appeals for administrative review.

THE COURT: Is there anything now pending before the DEA?

MR. DOLINGER: Not to my understanding, your Honor. There was this petition that was denied in 2016. Any party who is aggrieved by a DEA decision of that type can take the appeal. But, as I stated, no proper appeal was perfected from that 2016 decision.

THE COURT: I think I understand exhaustion. Let's move on to another point, unless I missed something that you want to tell me about.

MR. DOLINGER: No, your Honor. Just that ruling on exhaustion would dispose of all of the claims in this case.

THE COURT: Including the constitutional claims?

MR. DOLINGER: Yes, your Honor. Because what plaintiffs are seeking here is only a challenge to the scheduling of marijuana on schedule 1.

THE COURT: By act of Congress.

MR. DOLINGER: By act of Congress. And if the drug were rescheduled to another schedule, presumably they would be getting all of the relief they are seeking because they do not assert that marijuana cannot be scheduled on any of the other schedules. Actually, the Second Circuit ruled on that point.

THE COURT: In *Kiffer*.

MR. DOLINGER: In *Kiffer*. That's right, your Honor.

THE COURT: What year was *Kiffer*?

MR. DOLINGER: 1973. The case was cited with approval in 2013 in *U.S. v. Canori*, also a Second Circuit case, but held as—

THE COURT: Spell that last name.

MR. DOLINGER: C-a-n-o-r-i. Cited in our brief, your Honor.

THE COURT: Why do you expose the fact that I don't remember it?

MR. DOLINGER: Just for reference, your Honor.

THE COURT: What year was *Canori*?

MR. DOLINGER: 2013.

THE COURT: It was a summary disposition, summary order?

MR. DOLINGER: I know it was an opinion, I believe, by Judge Cabranes.

THE COURT: You have two precedents that say that the district court in the Southern District of New York and other parts governed by the Second Circuit cannot take up the proposition that the act is unconstitutional.

MR. DOLINGER: *Kiffer* did hold that the scheduling of marijuana as scheduled by Congress in 1970 was constitutionally rational and *Canori*—

THE COURT: It affirmed the conviction for violation of the narcotics laws in the distribution of marijuana, right?

MR. DOLINGER: It did not reopen the question. Yes, your Honor.

THE COURT: And the defense argument was that the law is unconstitutional, right?

MR. DOLINGER: Yes.

THE COURT: And the Court held that it is constitutional?

MR. DOLINGER: Yes.

THE COURT: Is that preclusive?

MR. DOLINGER: Your Honor, these cases remain binding on this court, yes.

THE COURT: Meaning it's preclusive?

MR. DOLINGER: Yes.

THE COURT: Meaning I have no discretion.

MR. DOLINGER: That's the government's position, your Honor.

THE COURT: Meaning if I rule for the plaintiff I would be reversed.

MR. DOLINGER: Your Honor, that is our position, yes.

THE COURT: More than your position. That's the ruling by the Second Circuit.

MR. DOLINGER: That's right, your Honor. That is the rule of the circuit and of the Supreme Court, that the lower courts do not have the discretion to disobey the binding precedents.

THE COURT: I once failed to follow a Second Circuit precedent. I had found a Supreme Court precedent that although not directly on point, I thought was persuasive. And so I followed the Supreme Court and my case went to the Supreme Court and the

Second Circuit was reversed. And in the remand the Second Circuit chastised me for not following Second Circuit precedence. I suppose I could do that now and get chastised again.

Why do you applaud a judge that's going to be chastised?

MR. DOLINGER: Your Honor, it is the rule that even if there were some interceding precedent from the Supreme Court, if it is not directly on point and if it does not reverse that Second Circuit case, the Second Circuit case does remain binding on this Court.

THE COURT: Seems to me that I'm bound by *Kiffer* and *Canori*.

MR. DOLINGER: We agree, your Honor.

THE COURT: What else do you want to tell me that's bad news for the plaintiff?

MR. DOLINGER: Most of the other claims, your Honor, have also been rejected.

First, I'll deal with the commerce clause claim. That one was not rejected only by the Second Circuit, but also by the Supreme Court itself in *Gonzalez v. Raich*.

THE COURT: What's the argument?

MR. DOLINGER: The plaintiffs' argument, as I understand it, is, if there is solely intrastate distribution or use of marijuana, that is not a proper subject for a federal regulation under the commerce clause.

THE COURT: What's the case? Ogden v. something or other established in 1938.

MR. DOLINGER: *Wickard v. Filburn* is the precedent that the Supreme Court ultimately relied on in *Raich* to hold that economic effects of a law can be aggregated—

THE COURT: Where does the distribution in a particular state, since it's quite likely that the drug can come from a different state, or be distributed from a different state, interstate commerce exists and there is jurisdiction on the part of Congress to act. It's like in a Hobbs Act. If someone sells fruits and vegetables in a bodega and is held up, the guy holding him up is subject to enhanced penalties because he is violating the Hobbs Act. Even though there is an argument that the transaction is purely local, the bodega operates on a particular street corner, their argument doesn't prevail because of interstate.

MR. DOLINGER: That's right, your Honor. The effect on interstate commerce can be minimal.

THE COURT: You are teaching me that the commerce argument is not a valid argument.

MR. DOLINGER: It is foreclosed.

THE COURT: What else would you like to teach me?

I'm sorry that I'm disturbing your set argument. You probably prepared for two days and two nights on a sequence of argument and here the judge is interrupting every minute.

MR. DOLINGER: We welcome your questions, your Honor.

THE COURT: You do not.

MR. DOLINGER: There are implications in the plaintiffs' papers concerning a fundamental right either to use marijuana or to access the medication of one's choice. Those arguments have also been rejected by all of the courts that have considered them.

The applicable test for whether there is a fundamental right comes from a Supreme Court case from the late 1990s, *Washington v. Glucksberg*. It holds that a fundamental right exists only if it is deeply rooted in the nation's history and traditions and is implicit in the concept of overt liberty.

All of the cases that have considered whether there is either a specific right to marijuana under the fundamental rights jurisprudence or, more generally, to access medications of one's choice, if they are not approved under the regulatory regime—

THE COURT: By implication, that's the rule of *Kiffer*.

MR. DOLINGER: Your Honor, *Kiffer* did not specifically address fundamental—

THE COURT: I said by implication.

MR. DOLINGER: That's right, your Honor.

THE COURT: If it were a fundamental right to distribute marijuana, *Kiffer* would not have been—

MR. DOLINGER: That's right, your Honor. And the Court there did hold that there is no fundamental right to distribute marijuana. It did not address whether there is a fundamental right to use. But subsequent cases have addressed that point and have concluded that there isn't.

THE COURT: What else would you like to teach me?

MR. DOLINGER: Your Honor—

THE COURT: I think you have hit on all of the high points.

MR. DOLINGER: Also, if you have further questions. We are happy to rest on our brief.

THE COURT: Anything else in your brief that you want to draw to my attention? Your brief is very long.

MR. DOLINGER: Yes. The briefing is lengthy, your Honor.

THE COURT: I read these at night, so my attention span is very limited, even during the olympics.

MR. DOLINGER: Very briefly, your Honor, there are claims concerning the constitutional right to travel in the First Amendment.

THE COURT: Those are fundamental rights.

MR. DOLINGER: Those are fundamental rights. But the Controlled Substances Act regulates only possession of substances. It does not speak to travel. It does not speak to expression. So under the governing precedence there, too, there is no constitutional claim.

THE COURT: If I wanted to hold up a bodega in New Jersey, I couldn't claim that I'm not allowed to travel to New Jersey. My fundamental right to travel is violated. I wouldn't be able to argue that.

MR. DOLINGER: That's right, your Honor.

THE COURT: If it's legitimately a crime, your right to travel for purposes of having the drug for distribution trumps the fundamental right.

MR. DOLINGER: Correct, your Honor.

THE COURT: However, if you just possessed the marijuana to use it medicinally, without intending to distribute it, it's a federal crime.

MR. DOLINGER: Federal law does prohibit marijuana and makes it contraband for all purposes as a general matter.

THE COURT: But the law is it's possession with intent to distribute.

MR. DOLINGER: Distribution is treated differently than simple possession, your Honor, but both are illegal.

THE COURT: Simple possession is a misdemeanor?

MR. DOLINGER: That, your Honor, I would also have to provide you something further on.

MR. BONDY: Yes, your Honor, it's a misdemeanor.

MR. DOLINGER: Unless the Court has any questions.

THE COURT: I never had in 19 years a case of simple possession. I've had cases of distribution.

MR. DOLINGER: I understand that it is—

THE COURT: If someone is using marijuana or carries it, even for medicinal purposes, that person is exposed to being arrested and tried for a misdemeanor.

MR. DOLINGER: It is regulated by the Controlled Substances Act, yes, your Honor.

THE COURT: It depends on whether that Controlled Substances Act is legal. If it's illegal, the travel is violated. If it's not legal, then you can't travel with it.

MR. DOLINGER: These claims do rely on their being some other infirmity in the law. They cannot stand on their own. That's right.

THE COURT: Thank you.

MR. DOLINGER: Thank you.

THE COURT: Mr. Hiller, you want to make a speech or you want to answer questions?

MR. HILLER: I think I want to start where your Honor asked your questions so I can address them directly, and maybe I'll get into the speech and maybe I won't.

First, with respect to the petitioning process, Mr. Dolinger argues that the petitioning process constitutes a full defense to this action. As far as I know, that argument that Mr. Dolinger has made has been made twice and it's been rejected twice.

The first instance was *Kiffer,* actually was the argument in *Kiffer,* was that the defendant had no right—

THE COURT: That was a criminal case, Mr. Hiller. The Second Circuit couldn't duck that. An exhaustion would not play a role there because they had to rule on the validity of a conviction. What would be the consequence if they didn't rule?

MR. HILLER: That wasn't the reason that they gave, your Honor. What they said was, in order to get

to the threshold point of arguing that it's unconstitutional, the government came forward and said, you can't argue that because there is a petitioning process and the judge said no. I am going to allow the argument. So even though it was a criminal case, your Honor, I don't think it's distinguishable on that basis.

I would also point out that in *U.S. v. Pickard*, which is one of the lead cases cited by the government, the very argument that Mr. Dolinger made was rejected by the court in *U.S. v. Pickard*. If I could put my hand on the case, I could actually direct you to the exact page.

Here we are. The citation is 100 F.Supp. 3rd 981 and it's on page 996. And what the Court said was: A provision conferring jurisdiction to entertain such a constitutional challenge is not required to be included in the CSA itself, nor is the statute insulated from constitutional review by congressional delegation of authority to an agency to consider an administrative petition. The government has not pointed to any clear and convincing evidence that Congress intended to preclude review of constitutional claims regarding the CSA. On that basis, the Court entertained the constitutional claims. I would respectfully submit—

THE COURT: What happened?

MR. DOLINGER: In that.

MR. HILLER: In that particular case, because the defendant bears the burden of proving his affirmative defense by a preponderance of the evidence

on a motion to dismiss, he wasn't able to meet that standard.

But I would emphasize to this Court that the standard in this case—

THE COURT: It's also a criminal case, right?

MR. HILLER: It's also a criminal case, your Honor. But it's cited by the defendants. If the defendants are going to take the position that *Pickard* defeats our case—

THE COURT: You are talking too fast. I can't think that fast.

MR. HILLER: Most of the cases upon which the defendants rely in this matter are criminal defense cases and this is one of them.

THE COURT: If I had a criminal case involving distribution and a motion to dismiss were made, I couldn't say that I'm not entertaining that because you have to go through an administrative process that will take years. I have to address it, as *Pickard* did. I don't think there is an option in the criminal case. You have to deal with it directly.

MR. HILLER: There is a three-part test to determine whether or not administrative remedies are futile, your Honor. Even assuming that this Court were not inclined to follow *Pickard* or *Kiffer* on this point, we would respectfully submit that the three-part test favors denial of the defendants' motion with respect to the administrative review process.

THE COURT: What are those three parts?

MR. HILLER: We have to meet just one of them. First, resort to the administrative remedy would cause undue prejudice to a subsequent assertion of a court action due to, for example, an unreasonable or indefinite time frame for administrative action. The second is, if there is any doubt that the agency is empowered to grant relief, such as, for example, if the agency lacks the institutional—

THE COURT: Can you slow up, please.

MR. HILLER: There is a doubt as to whether the agency was empowered to grant effective relief such as when an agency lacks institutional competence to determine the constitutionality of a statute.

THE COURT: That doesn't apply.

MR. HILLER: Third, the administrative body is shown to be biased or otherwise had predetermined the issue before it.

I would submit, your Honor, at a minimum, the first and the third fall squarely in our corner, and I would say the second one does as well. If I may just focus on the first.

The allegations in the complaint, which, as your Honor is well aware, have to be assumed true for purposes of this motion, are that the petitioning process is a futile one. It takes nine years on average.

THE COURT: Only if the argument is plausible.

MR. HILLER: Yes, your Honor. But I would respectfully submit it's not only plausible—

THE COURT: What is the remedy, if there is an administrative delay?

MR. HILLER: Historically what's happened is that petitioners have filed motions for writs of mandamus to require, for example, the DEA to render a decision.

Mr. Holland, who is a co-counsel of ours, he was one of the attorneys on the Americans for Safe Access case, was required to file a motion for a writ of mandamus to require the DEA just to render a decision. It took six years for the DEA just to render a decision before the administrative process continued.

THE COURT: What happened on his writ?

MR. HILLER: I'm sorry?

THE COURT: What happened on the petition for a mandamus?

MR. HILLER: Eventually what happened, as I understand it, was the DEA responds to the writ of mandamus, actually did issue the decision which then proceeded to go forward.

Your Honor, I represent people who need cannabis to live.

Jagger Cotte was diagnosed with Leigh's disease before he turned the age of two and generally if you are diagnosed before the age of two, you die by the age of four. He was admitted to a hospice before his fourth birthday, administered cannabis to treat his pain, and he is seven now.

I represent Alexis Bortell, who was having multiple seizures a day for 14 months and having repeat

hospitalizations to the point where her doctor said that part of the left side of her brain might have to be removed, and even then they weren't sure it would work.

THE COURT: Is there a process for expedited review by an agency when the pleasures of life and the endurance of life are at stake?

MR. HILLER: No, your Honor.

THE COURT: Can't I go to an agency and say, please, agency, my client's life is threatened?

MR. HILLER: Mr. Holland is gesturing to me and my instinct is that the answer is no.

MR. HOLLAND: With regard to Americans with Safe Access, which was also the coalition rescheduled cannabis, a group of scientists, one of the organizations with them was Patients Out of Time, or POT, who are arguing that very thing, that we are suffering immensely without any further action that is expedited in any way. To my knowledge, there has never been a way to expedite—

THE COURT: What happened?

MR. HOLLAND: Ultimately, it was the mandamus action that brought about the determination from the DEA.

THE COURT: Why can't you do that here?

MR. HOLLAND: I'm sorry?

THE COURT: Why can't you do that here?

MR. HOLLAND: It's not clear that our plaintiffs would be alive at that time. I would defer to Mr. Hiller

to answer that question directly. But Alexis Bortell, on any given day that she doesn't have access to that, your Honor, she could pass away.

THE COURT: She has been doing it. No one has bothered her.

MR. HILLER: Your Honor, the real problem with that process-

THE COURT: She has fears to move from her jurisdiction. Colorado is a safe jurisdiction. She moved to Colorado, I think you alleged, because it was the opportunity to get cannabis at the time when Massachusetts didn't allow it.

MR. HILLER: Texas, yes. Your Honor, my client, it's not—

THE COURT: Let's stay with that for a while. I think that's the critical part of your case.

MR. HILLER: Yes, your Honor.

THE COURT: You are really arguing that basic issues of human life are at stake.

MR. HILLER: Yes, your Honor.

THE COURT: Not just an opportunity for recreational use of marijuana, but the opportunity to enjoy life itself is threatened without marijuana.

MR. HILLER: Yes, your Honor.

THE COURT: That's circumstance. What would happen if you went to the agency and said, here is my case, I need quick action, I need immediate response? If there was no response, you take out a mandamus to the Court of Appeals.

MR. HILLER: Your Honor, it is my understanding that petitioners have already been placed in that situation and, nonetheless, the decisions don't come.

And the concern that I have, your Honor, quite frankly, is, yes, Alexis Bortell and Jagger Cotte and Jose Belen need their cannabis to live. Alexis Bortell, who has not had a seizure in almost three years, since she started the cannabis, while she is allowed to stay within Colorado, your Honor, I would remind the Court that 28 percent of the United States is federal land. She is excluded between a quarter and a third of American lands from traveling anywhere.

THE COURT: If Congress can legislate, then she can't travel. If it can, she has got to abide by the law.

MR. HILLER: Your Honor, what I would say to that—

THE COURT: It all depends on the legality. I just put to you that a district court is not the appropriate forum to weigh all of the conflicting arguments with regard to items on the schedules. It's not only that there is a medical use, but it has to be weighed. That criteria has to be weighed against other criteria, including the dangers to the community by too-ready availability of the drug. That has been the holdup, I think, in terms of what Congress is feeling.

There is lots of things district judges have to do. When agencies are set up to do the very kind of thing that you want me to do, I think the right thing is to defer to the agency.

MR. HILLER: Your Honor, what I would suggest to your Honor is, and in the greatest deal of respect, is to review the language in *Pickard* that I have referred to you because that language—

THE COURT: It's the same issue as *Kiffer*. *Kiffer* is a case where the Second Circuit took the case, took the argument, and *Pickard* did the same thing, ultimately holding that the argument did not have merit. But they took it.

MR. HILLER: Your Honor, in each instance the courts allowed the defendants to interpose a constitutional challenge and constitutional challenge was deemed not to be precluded by the existence of the petitioning program. The defendants argued there—

THE COURT: The existence of what?

MR. HILLER: Of the petitioning program, of the administrative review process. The very arguments that were made today were made in those two cases. And what the courts—

THE COURT: The court held that because there is a petitioning process, the law is not unconstitutional.

MR. HILLER: No. I'm sorry, your Honor. What the court did in *Pickard* and *Kiffer* was that when the defense came forward with an affirmative defense, arguing that the statute was unconstitutional, the Federal Government said they are precluded from making any constitutional challenge.

THE COURT: And the Court held not, but then they held against the defendant.

MR. HILLER: The Court held that they were not precluded from raising the constitutional claim, that the threshold issue that the defense is raising now—

THE COURT: Mr. Hiller, let me suggest. I understand you are passionate about your case, and you've got a very strong case and a lot of human interest involved. Unless you discipline yourself to slow down, you lose your effectiveness.

MR. HILLER: Thank you, your Honor. I will do my best.

The threshold argument that the defense made today is the same threshold argument that was rejected in *Pickard*.

THE COURT: I take your point. I take your point. I have it. I really understand it. I may not follow it, but I understand it.

The second part of my question, though, is what I'm focused on. When the district courts and the Second Circuit Court of Appeals focused on the issue, they held that the Constitution was not violated by having marijuana on schedule 1.

MR. HILLER: Yes. That goes to the issue of *stare decisis*, which I am prepared to discuss.

THE COURT: Maybe we should get into that. But I'm thinking that in those cases they held that they had to get onto the question and they gave different reasons than I had. But they got onto the question. They held that the defense was not proved. What did they hold?

MR. HILLER: In *Kiffer*, the claimed constitutional right, as Mr. Dolinger pointed out, was the constitutional right to distribute cannabis, which is clearly not implicated by Alexis Bortell, Jagger Cotte or Jose Belen.

THE COURT: Slow.

MR. HILLER: With respect to *Canori, Canori*'s argument was not constitutional. Mr. Dolinger represented to this Court that *Canori* was decided on constitutional grounds but, in fact, the defendant in *Canori* argued that the *Ogden* memorandum had affected a de facto rescheduling of cannabis and, therefore, he could not be charged as having violated a classification of schedule 1.

THE COURT: I don't think he relies on *Canori* for that purpose. I think he relies on *Canori* for favorable citation of *Kiffer*.

Am I right, Mr. Dolinger?

MR. DOLINGER: Yes, your Honor.

MR. HILLER: With respect to *Kiffer*, your Honor—

THE COURT: What about *Pickard*?

MR. HILLER: I'm sorry.

THE COURT: What about *Pickard*? What was the constitutional ruling of *Pickard*.

MR. HILLER: The argument in *Pickard* was different from what we are arguing. The argument in *Pickard* was, the ruling was that the classification was constitutional, but the arguments and claims were different. The arguments we are making

here are not the same. And I would emphasize to the Court—

THE COURT: What were the arguments in *Pickard*?

MR. HILLER: In *Pickard*, there are quite a few of them.

THE COURT: Pick out two, the two you have the most difficulty in answering.

MR. HILLER: I'm sorry?

THE COURT: The two that you have most difficulty in answering. I'll read the case again before I issue my decision. You might as well anticipate that I'll focus on the two questions that you have difficulty in answering.

MR. HILLER: The first argument in *Kiffer* and in *Pickard*—

THE COURT: Here is the answer.

MR. HILLER: No, it's not.

The principal claim in *Pickard* was that science had reached the point where now the scientific community had raised enough questions that cannabis does have a medical application within the meaning of a schedule 1 definition, which is not the same that we are arguing.

THE COURT: It really is.

MR. HILLER: With all due respect, your Honor, it is definitely not. I can assure you that—

THE COURT: Your clients have a medical need for marijuana that it's saving their lives.

MR. HILLER: That's correct.

THE COURT: Isn't that the same argument?

MR. HILLER: Our argument is not that there is this raging scientific debate that has ultimately started to tip in our favor. That is not the argument. Our argument is that the Federal Government knows that cannabis is safe and effective. The reason I would say that—

THE COURT: It doesn't want to act.

MR. HILLER: The Federal Government has a patent right now that was taken out by the Department of Health and Human Services which, according to defendants' brief on page 5, specifically says is binding on the Federal Government.

Now, in that patent application, the United States Government represented that cannabis constitutes a safe and medically effective treatment for Parkinson's disease, HIV-induced dementia, Alzheimer's disease, autoimmune diseases, and also serves as a neuroprotectant to help people with seizure disorders. And those representations cannot be made in bad faith by law under Section 101 of Title 35 of the United States Code. Any representation made in a patent application must be in good faith based upon the invention's utility. So the United States Government has represented—

THE COURT: Your clients are living proof of the medical appropriateness of marijuana. I don't need a patent to tell me that. I have to take the plausible allegations in your complaint as true. How could anyone say that your clients' lives have not been saved by marijuana? How can anyone say that your clients' pain and suffering

has not been alleviated by marijuana? You can't, right?

MR. HILLER: I could not agree with you more, your Honor.

THE COURT: That criteria, does it trump everything else? Suppose the administrative agency would say, yes, yes, Mr. Hiller, you are right. But the dangers I see in marijuana are such, dangers to the community, are such that I feel and I hold that there is no rescheduling. Can it do that?

MR. HILLER: No. Once cannabis does not meet Section 2 of the definition, it cannot be classified as a schedule 1 drug.

Your Honor, in that sense you have made the point for us. There is no real question that cannabis provides safe or medically effective relief to our clients. And the fact of the matter is, in order for cannabis to be schedule 1 drug, in addition to having to have no medical application whatsoever, it also has to be so dangerous it can't even be tested under strict medical supervision and, yet, the United States Government is allowing over 200 million Americans today to have access to cannabis in 30 states across the country.

In addition to that, your Honor, the government itself has its own investigational new drug program and beginning in 1976 has been distributing cannabis to medical patients all over the country for the treatment of their diseases. If cannabis met the requirements of a schedule 1 drug, the Federal Government, under the FDA's regulations, would not have been permitted to include cannabis as a schedule 1 drug.

THE COURT: Judge Wolford in western New York, *United States v. Green*, I think looked at it in the way that is persuasive to me. She said: It is difficult to conclude that marijuana is not currently being used for medical purposes. It is. There would be no rational basis to conclude otherwise. If that were the central question in this case, defendants' argument would have merit, but it is not the central question.

The issue is not whether it is rational for Congress or the DEA to conclude that there is no currently accepted medical use for marijuana. That would be the issue if a claim were brought in a circuit court challenging the DEA's administrative determination.

Rather, a constitutional issue for equal protection purposes is simply whether there is any conceivable basis to support the placement of marijuana in the most stringent schedule under the act.

This is 222 F.Supp. 3d, 275-280.

MR. HILLER: What page were you at, your Honor?

THE COURT: 275-280.

MR. HILLER: Your Honor, I'm familiar with *Green.* I read it. What I would suggest to the Court is that—

THE COURT: Your argument is that *Kiffer* really overrules *Green* or *Green* is not following *Kiffer* because *Kiffer* holds that the district court should retain the issue, and language does not confine it to a criminal court, to a criminal case.

MR. HILLER: Yes, your Honor. I would also point out-

THE COURT: I have your argument. I know the argument. It's a good argument. I'm not saying it's a win argument. It's a good argument.

MR. HILLER: I appreciate it, your Honor.

THE COURT: I don't know if it's a win argument.

That's one of the things I have to decide.

MR. HILLER: May I address one other point on the issue of *stare decisis* before we change the subject?

THE COURT: Of course.

MR. HILLER: I'll try to do it quickly.

THE COURT: Don't do it quickly.

MR. HILLER: I won't say it quickly. I'll just try to do it quickly.

In *United States v. Pickard*, one of the arguments that the Federal Government made is another argument that was made here, specifically that the presence of a prior decision by the Ninth Circuit specifically foreclosed any constitutional challenge because in that case, just like, for example, in *Kiffer*, the Court ruled that the Controlled Substances Act, as it pertains to cannabis' classification as a schedule 1 drug, is constitutional.

So the government argued then, argued today. The name of that case that *Pickard* was referring to *was Miroyan*. And what the Court in *Pickard* ruled was, the decision in *Miroyan* does not foreclose a Court's consideration of future constitutional challenges to the classification of marijuana as a schedule 1 drug. That case does not stand for

the proposition that even if defendants proffer credible evidence raising serious questions regarding the constitutional soundness of marijuana's listing on schedule 1, that district courts cannot entertain a constitutional challenge.

Then the Court in *Pickard* specifically relied on the decision in *Gonzalez v. Raich* for the proposition that it had no choice but to consider the constitutional challenge, notwithstanding defendants' argument.

And what the Court said, and I quote, to read *Miroyan* so broadly as to preclude constitutional challenges to marijuana scheduling under any circumstances would be inconsistent with the Supreme Court's relatively recent observation in *Raich,* specifically that evidence proffered by the defendants regarding the effective medical uses for marijuana, if found credible after trial, would cast serious doubt on the accuracy of the findings that require marijuana to be listed as a schedule 1 drug.

I would also cite for the Court's attention *Jeno v. Commissioner of Patents & Trademarks*, which talks about changes of circumstances warranting a departure from prior decisions. The Court in *Jeno* said: Nor does the doctrine of *stare decisis* apply to the present action. Contrary to the defendants' reasoning, there is a strong possibility that plaintiff can show changed circumstances. *Stare decisis* may not be so mechanically applied so as to ignore changing facts and inequitable results.

And a case that opposing counsel cited, *Gately v. Massachusetts*, held, as *stare decisis* is concerned with rules of law, a decision dependent upon its underlying facts is not necessarily controlling precedent as to a subsequent analysis of the same question on different facts and on a different record, which is exactly what we are saying here.

Although Mr. Dolinger pointed out in his brief that *Gately* is a First Circuit case, *Gately* also cites a Second Circuit decision, *In Re Tug Helen B. Moran, Inc.*, 607 F.2d 1029 (2d Cir. 1979). This is the Second Circuit. We find no merit in the state's attempt to invoke the doctrine of *stare decisis* since the doctrine is not applicable to determinations of fact.

In view of the fact that *stare decisis* is concerned with rules of law, a decision dependent on the facts is not controlling precedent as to a subsequent determination of the same question on different facts and on a different record.

THE COURT: What is the determination of fact? Who determined it?

MR. HILLER: Your Honor would determine the facts. There is no jury in this case because we are asking for equitable relief.

THE COURT: But issue is not a factual issue. It's a motion to dismiss a complaint as a matter of law.

MR. HILLER: I agree.

THE COURT: The issue that the government raises is that since Congress had a rational basis to have the law in 1970 instead of a procedure for change,

the law is constitutional. That's as far as the argument goes.

The question I would pose as a judge hearing it might go a little further. It might say that even though there was a rational basis for the law when it was promulgated, the inability or unwillingness of the agency to act on changing facts indicates that there is some kind of unconstitutionality. I don't know how to complete that argument. I think that is really your argument.

MR. HILLER: It is, your Honor. It's one of them.

THE COURT: The next question is, you asked for a reclassification. What would happen with a reclassification?

MR. HILLER: We are not asking for reclassification, your Honor. We are simply asking for a declaration that the classification of cannabis as a schedule 1 drug under the CSA is unconstitutional.

THE COURT: That would not give you complete relief. There are other schedules that might go into this. The implication of that argument, it should not be schedule 1; it might be schedule something else.

MR. HILLER: Your Honor, it is my understanding—

THE COURT: The relief you are asking is not to remove marijuana from any and all schedules, because that would fit the argument you are making.

MR. HILLER: Our argument, your Honor, is that once this Court finds that the classification, if the Court were to find that the classification violates

the Constitution, it would be the schedule and it would be incumbent upon Congress to pass new legislation to reschedule it to another level.

THE COURT: If I review what your complaint is I have to focus on 1970.

MR. HILLER: Yes.

THE COURT: And I can't focus on 1970 and give you relief. I can only focus on the as-applied attitude that the Attorney General or his delegee has not been keeping current. That's a different argument and I don't know the answer to it.

MR. HILLER: What I would say, your Honor, is that the Court is duty bound to look at 1970, but also look at the changing facts and circumstances that have occurred since 1970.

THE COURT: It's not a basis for a rational basis test for the law passed in 1970.

MR. HILLER: Your Honor, we have cited cases that take a different position on that issue than you have. The cases that we have cited make very clear that changed circumstances can be considered and factored into a rational relation or rational review analysis.

Your Honor, as long as we are talking about 1970, I think it's important not to lose sight of one critical fact about our case, which also must be assumed true for purposes of this motion, and that is, your Honor, that the Controlled Substances Act was enacted not for the purpose of preserving health and lives, but, instead, to suppress political rights of those that Richard Nixon and his administration believed to be hostile to his

administration and, also, to oppress African Americans.

We have four witnesses who have each stated that the Controlled Substances Act, which was passed, your Honor, in 27 days, and written entirely by the Attorney General at the time, John Mitchell, who went to prison afterwards, not related to the—

THE COURT: Mr. Hiller, what's the point? The point is, I'm not involved here in a discussion of the evaluation of the Nixon administration. I'm not here to evaluate the good faith or not of the Attorney General in drafting this law. There are other very important laws that were passed in the twinkling of an eye, including the Securities Exchange Act, the Securities Act of 1933, the law on setting up the courts and the special master after 9/11. Don't argue with me that it came very fast.

Here is the argument I'm interested in. You can't win on these arguments. You may have appeal on those arguments, but you can't win on those arguments.

Schedule 1 requires that a drug must have a high potential for abuse; no currently accepted medical use and treatment in the United States; third, there is a lack of accepted safety for use of the drug or other substance under medical supervision.

You win on two. One, I don't know. If these are three criteria that have to be weighed, a district judge would have a very hard job in weighing medical use against potential for abuse. I think bias and prejudice would be a danger.

The third criteria, lack of accepted safety for use of the drug or other substance under medical supervision, the opioid epidemic has occurred in a prescription drug. Who was there to say that a requirement of a prescription for marijuana will save the community from the danger of the drug?

My point is this. I don't know if these are conjunctive criteria that all have to be satisfied or disjunctive criteria. But my experience with criteria is that they have to be weighed and evaluated. If as a matter of law I'm wrong on that, I would like you to tell me.

MR. HILLER: Your Honor, as a matter of law, you are wrong on that one, I'm sorry. All three have to be met. I don't think the government is going to tell you differently. I don't believe there is any weighing process—

THE COURT: Are you going to tell me differently, Mr. Dolinger?

MR. DOLINGER: No, your Honor. That is true for the DEA. As your Honor cited, *United States v. Green* holds that that's not the proper analysis for a district court.

THE COURT: I'll hear you in a minute. I think Mr. Hiller is drawing to a close.

MR. HILLER: Absolutely, Judge.

I want to point to two more points, if I may.

The first is, I respect that the Court doesn't want to get involved in the inner machinations of the Nixon administration, but I would respectfully urge the Court to review footnote 45 to our brief

on page 47. Because even if the defendants are given the benefit of the doubt and they are entitled to argue their rational and review, even under those circumstances, if there is a basis to infer antipathy or bad faith in the enactment or passage of a statute, then, your Honor, those factors are actually very relevant.

And if it's also true that the rational basis, the so-called rational basis is merely a subterfuge for something more sinister, your Honor, I would respectfully submit that if we could prove those facts, if we could prove that the Nixon administration, or those that were working for it, were involved in a predatory effort to break up protests and infiltrate opposition groups, your Honor, then the Controlled Substances Act doesn't get rationality review.

THE COURT: As a judge I will not get into that. It's a political question. I will not get into it. The law is the law. I'm sworn to enforce the laws. If it's constitutional, I uphold it. Constitutionality will not depend on what may have been in President Nixon's mind at the time or in Attorney General Mitchell's mind at the time, or in all the legislators' minds at the time. This bill passed by votes.

MR. HILLER: It's not my practice—

THE COURT: Passed the house, passed the Senate, signed by the president. It's either constitutional or not and I will follow those arguments.

What's the last point?

MR. HILLER: I think I want to make that my last point.

THE COURT: Thank you very much, Mr. Hiller. You raised provocative questions.

MR. HILLER: Thank you.

THE COURT: Mr. Dolinger, last few words. We will wrap up the argument and I will reserve decision.

MR. DOLINGER: Just a few points very briefly, your Honor.

The first on the question of the administrative remedy, it is true that *Kiffer* looked past the administrative remedy and ruled on the constitutional question. That is because it cited two rationales for that. The first was that it was a criminal case, as your Honor pointed out.

THE COURT: Mr. Hiller told me it was not one of the rationales.

MR. DOLINGER: Your Honor, it was, in fact, one of the rationales that it was a pending criminal case.

THE COURT: Was it explicitly a rationale?

MR. DOLINGER: Yes, your Honor. I can get you a page cite, if that would be helpful.

THE COURT: Here is the wording. I think Mr. Dolinger is right. 477, F.2d at 352.

MR. HILLER: Are we talking about *Canori* or *Kiffer*?

THE COURT: *Kiffer*.

MR. HILLER: Let me just pull it out.

THE COURT: Got it?

MR. HILLER: I don't have it yet, your Honor. I'm sorry.

THE COURT: I'll wait for you.

Page 352.

MR. HILLER: I'm sorry?

THE COURT: Page 352. Right at the top. You see where it says second? Second, even assuming the existence of a viable administrative remedy, application of the exhaustion doctrine in criminal cases is generally not favored because of the severe burden it imposes on defendants.

MR. DOLINGER: Thank you, your Honor.

The other rationale cited by the Second Circuit was the position of the head of the Bureau of Narcotics and Dangerous Drugs, which is the predecessor to the DEA as of 1973, which is that he had a concurrent obligation under a drug regulation treaty that also had the force of statute. That position is no longer—

THE COURT: Give me that again. I missed it.

MR. DOLINGER: The head of the Bureau of Narcotics and Dangerous Drugs came to the conclusion at the time that rescheduling marijuana was separately prohibited to him as part of the administrative process by a treaty obligation. The DEA does not take that position and has considered a number of petitions to reschedule marijuana since that time.

THE COURT: None of which has succeeded.

MR. DOLINGER: That's right, your Honor.

THE COURT: Let me ask you this. Go back to these three criteria established by 21 U.S.C. Section 812(b)(1). High potential for abuse, no currently

accepted medical use, lack of accepted safety for use of the drug under medical supervision.

Let's say that only criterion 2 is no longer applicable, but 1 and 3 are. Does that mean it cannot be on schedule 1?

MR. DOLINGER: If the DEA is considering a rescheduling petition, it is a conjunctive test, so all three factors must be met.

THE COURT: What happens if two out of the three are met? Does it hit another schedule?

MR. DOLINGER: It may be rescheduled at that point into schedule 2.

The DEA did conclude—

THE COURT: If that were the case, plaintiff can win on schedule 1, maybe not here, but in the administrative process, only to find it comes onto schedule 2 or 3.

MR. DOLINGER: That's right, your Honor.

THE COURT: With lesser penalties but nevertheless criminal penalties.

MR. DOLINGER: And among the factors that the DEA considered in making the determination that it has no currently accepted medical use, this is different from the question of whether there could possibly be any medical utility to the drug. Among other things—

THE COURT: You can't argue that. Given the allegation in the complaint that it saved the life and eliminated epileptic seizures, how can you say that? You have to accept these allegations as true. I can't say they are not plausible.

MR. DOLINGER: We do accept them as true for purposes of the motion. The issue is that the agency must also consider whether there are sufficient studies of the drug and sufficient studies of high enough quality to show its effectiveness such that it can be permitted—

THE COURT: It says no currently accepted medical use and treatment in the United States. Judge Wolford has said, and what I understand to be the case, that there is. It may not be universal, but some statements in their legislative findings have found that there is accepted medical use. You can't say what you are arguing. Your argument doesn't hold.

MR. DOLINGER: Your Honor, I understand—

THE COURT: I think the argument is, Mr. Dolinger, if this were an administrative process I might hold, if I were the agency head, that, no, it's not a schedule 1 drug, but it is a schedule 2 or schedule 3 drug. So nobody has argued the schedules. But I look at them because it's judicial notice. Therefore, we will reschedule it. The relief that's sought by the plaintiff to travel and to petition Congress and the like won't be changed in the slightest by that reclassification. What they are fearing now they can fear later. I think that's the critical issue.

Thank you very much. Thank you both sides. Thank you all for attending and being so patient and laughing at my jokes. I'll take this under advisement.

MR. DOLINGER: Thank you, your Honor.

MR. HILLER: Your Honor, may we afforded the opportunity for supplemental briefing?

THE COURT: No, no supplemental briefs.

MR. HILLER: Thank you, your Honor.

AMENDED COMPLAINT (SEPTEMBER 6, 2017)

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MARVIN WASHINGTON, DEAN BORTELL, as Parent of Infant ALEXIS BORTELL, JOSE BELEN, SEBASTIEN COTTE, as Parent of Infant JAGGER COTTE, CANNABIS CULTURAL ASSOCIATION INC.,

Plaintiffs.

v.

WILLIAM PELHAM BARR, in His Official Capacity as United States Attorney General, UNITED STATES DEPARTMENT OF JUSTICE UTTAM DHILLON, in His Official Capacity as the Acting Administrator of the Drug Enforcement Administration, UNITED STATES DRUG ENFORCEMENT ADMINISTRATION, UNITED STATES OF AMERICA,

Defendants.

No. 17 Civ. 5625

PLAINTIFFS MARVIN WASHINGTON, DEAN BORTELL, as Parent/Guardian for Infant ALEXIS BORTELL, JOSE BELEN, SEBASTIEN COTTE, as Parent/Guardian for Infant JAGGER COTTE, and the

CANNABIS CULTURAL ASSOCIATION, INC. (collectively, "Plaintiffs"), as and for their Amended Complaint against defendants ("Defendants"), allege as follows:

PRELIMINARY STATEMENT

1. This action is brought on behalf of two young children, their fathers, an American military veteran, a retired professional football player and a non-profit membership organization, all of whom have suffered harm, and who are continuously threatened with additional harm, by reason of the provisions of the Controlled Substances Act ("CSA"). 21 U.S.C. § 801, *et. seq.* The CSA has wrongfully and unconstitutionally criminalized the cultivation, distribution, sale, and possession of Cannabis (comprised of Cannabis *Sativa,* Cannabis *Indica,* and Cannabis *Ruderalis*), which, historically, has been harvested to produce, among other things, medicine, industrial hemp, and a substance known as tetrahydrocannabinol ("THC").[1]

2. Although not styled as a class action, this lawsuit stands to benefit tens of millions of Americans who require, but are unable to safely obtain (and in far too many instances, unable to obtain at all, safely or not), Cannabis for the treatment of their illnesses, diseases and medical conditions, the successful treatment of which is dependent upon its curative properties.[2] In addition, this lawsuit, if successful,

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[1] Robert Deitch, HEMP-AMERICAN HISTORY REVISITED: THE PLANT WITH A DIVIDED HISTORY 3 (2003); Editors of the Encyclopedia Britannica, *Cannabis,* ENCYCLOPEDIA BRITANNICA, https://www.britannica.com/plantkannabis-plant.

[2] Cannabis, as used in this Complaint, refers to whole-plant Cannabis, with its full spectrum of cannabinoids, including THC,

would aid in the restoration of communities hardest hit and most egregiously stigmatized by the Federal Government's misguided, Crusades-like "War on Drugs."

3. As shown below, despite the relatively recent and inappropriate stigmatization of Cannabis in the United States as a supposed "gateway drug" used primarily used by "hippies" and minorities, there is a long and rich history, dating back thousands of years, of people from virtually every part of the world using Cannabis for medical, industrial, spiritual, and recreational purposes.[3] Indeed, those who have cultivated, encouraged the cultivation of, and/or used Cannabis include, *inter cilia*, George Washington, Thomas Jefferson, John Adams, James Madison, James Monroe, John F. Kennedy, Jimmy Carter, Bill Clinton, and Barack Obama—an assortment of the most intelligent and accomplished statesmen in American history.

4. As further shown below, the criminalization of Cannabis—a drug that has never killed anyone—arose out of the enactment of legislation underwritten by illegal racial and ethnic animus, and implemented and enforced at the federal level by those who choose

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which is separately mis-classified as a Schedule I drug. 21 C.F.R 1308(d)(31).

[3] Deitch, *supra* note 1 at 1; *History of Marijuana as Medicine-2900 BC to Present,* PROCON.ORG, http://medicalmarijuana.procon.org/view.timeline.php?timelineID=000026 (last updated Jan. 30, 2017) [hereinafter referred to as "PROCON.ORG"]; Lecia Bushak, *A Brief History of Medical Cannabis: From Ancient Anesthesia to the Modern Dispensary,* MEDICAL DAILY (Jan. 21, 2016), http://www.medicaldaily.com/brief-history-medical-cannabis-ancient-anesthesia-modern-dispensary-370 344 [hereinafter referred to as "MEDICAL DAILY"].

to disregard its scientific properties and benefits, and/or have been motivated by hatred and outright bigotry.[4]

5. The consequences of the Federal Government's misguided War on Drugs have been disastrous. Persons of color are four times as likely as white Americans to be investigated, charged, prosecuted and incarcerated for possession and/or use of Cannabis, even though it is used in approximately equal proportions among the races. In addition, those who are administered medical Cannabis for the treatment of illnesses, disease and other health-related conditions, have been required to forfeit their First, Fifth, Ninth and Fourteenth Amendment Rights, plus their fundamental right to travel.

OVERVIEW OF THE CLAIMS

6. Plaintiffs seek a declaration that the CSA, as it pertains to the classification of Cannabis as a Schedule I drug, is unconstitutional, because it violates the Due Process Clause of the Fifth Amendment, an assortment of protections guaranteed by the First, Ninth and Tenth Amendments, plus the fundamental Right to Travel, the right to Equal Protection, and right to Substantive Due Process. Further, Plaintiffs seek a declaration that Congress, in enacting the CSA

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[4] Notably, although a powerful and vocal minority of public officials have continued their irrational opposition to rescheduling or de-scheduling of Cannabis, the overwhelming majority of Americans desire a change. According to an April 20, 2017 Quinnipiac Poll, nearly 94% of Americans support legalization of medical marijuana. And 60% of Americans support full legalization and decriminalization of Cannabis for all purposes (Exh. 1).

as it pertains to Cannabis, violated the Commerce Clause, extending the breadth of legislative power well beyond the scope contemplated by Article I of the Constitution.[5] The claims are as follows:

7. *First*, as shown below, the CSA as it pertains to Cannabis, violates the Due Process Clause of the Fifth Amendment to the United States Constitution because the CSA is so irrational as a matter of law that it cannot be said to be rationally related to any legitimate government purpose. Cannabis is classified as a Schedule I drug under the CSA, along with such psychotropic drugs as heroin, mescaline and LSD. To have been assigned this Schedule I classification, the Federal Government was required to have determined that Cannabis: (i) has a high potential for abuse; (ii) has absolutely no medical use in treatment; and (iii) cannot be used or tested safely, even under strict medical supervision ("Three Schedule I Requirements"). Significantly, however, as also shown below, the Federal Government does not believe, and upon information and belief, never has believed, that Cannabis meets or ever met the Three Schedule I Requirements.

8. Under Federal Law, it is not enough for a government, in arguing in favor of a statute's constitutionality, merely to manufacture a supposedly "legitimate government interest" to which a law is rationally related for the purpose of responding to a lawsuit; the government must also actually believe its own argument. And, as shown below, the Federal Government, at a minimum, does not, and cannot possibly, believe

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[5] In interposing this particular claim, Plaintiffs explicitly seek the overturn of the Supreme Court's decision in *Gonzalez v. Raich,* 545 U.S. 1 (2005).

that there is no acceptable medical use for Cannabis or that it cannot be used or tested safely under medical supervision. In other words, the Federal Government has recognized that Cannabis does not meet (or come close to meeting) two of the Three Schedule I Requirements. Indeed, the Federal Government has admitted repeatedly in writing, and implemented national policy reflecting, that Cannabis does, in fact, have medical uses and can be used and tested safely under medical supervision. On that basis, the Federal Government has exploited Cannabis economically for more than a decade by securing a medical cannabis patent and entering into license agreements with medical licensees. The Federal Government has also been dispensing medical Cannabis to Americans through a certain Investigational New Drug Program since the late 1970s for the treatment of an assortment of diseases. The notion that the Federal Government genuinely believes that Cannabis has no medical application and is so dangerous that, as with heroin, it cannot be tested even under strict medical supervision, is so absurd that it must be rejected as a matter of law. The Federal Government does not believe in the factual prerequisites underlying its own statute.

9. Because the Federal Government does not believe the factual predicate underlying its own arguments in support of the CSA as it pertains to Cannabis, the CSA is irrational and thus unconstitutional (First Cause of Action).

10. *Second*, as shown below, the CSA as it pertains to Cannabis was enacted and subsequently implemented, not to control the spread of a dangerous drug, but rather to suppress the rights and interests

of those whom the Nixon Administration wrongly regarded as hostile to the interests of the United States—African Americans and protesters of the Vietnam War. In particular, members of the Nixon Administration have confirmed that, when the CSA was enacted, President Nixon regarded those who opposed the Vietnam War as a threat to America's Cold War against Communism. And President Nixon and associates in the Nixon Administration, including and especially, Myles Ambrose (America's First Drug Czar), harbored considerable antipathy towards African Americans.

11. The Nixon Administration recognized that African Americans could not be arrested on racial grounds, and war protesters could not be prosecuted for opposing America's involvement in Vietnam. However, the members of the Nixon Administration decided that Cannabis was the drug of choice for these two groups. Consequently, the Nixon Administration ushered the CSA through Congress and insisted that Cannabis be included on Schedule I so that African Americans and war protesters could be raided, prosecuted and incarcerated without identifying the actual and unconstitutional basis for the government's actions.

12. Unfortunately, the Federal Government has been quite successful in using the CSA to harass, intimidate and incarcerate African Americans in disproportionate numbers over the years, ruining the lives of generations of black men and women and other persons of color. War protesters were similarly subjected to unconstitutional enforcement activity by the Federal Government, resulting in convictions that stained reputations and limited the career options of countless politically active Americans. In so doing, the

Federal Government violated (and continues to violate) the First Amendment and the Equal Protection Clause as implied by the Due Process Clause of the Fifth Amendment to the United States Constitution (Second Cause of Action).

13. *Third*, as shown below, the CSA as it pertains to Cannabis violates the constitutional Right to Travel. As of this writing, 29 States plus Washington, DC and U.S. Territories have legalized the use of Cannabis containing high concentrations of THC for the treatment of scores of illnesses, diseases and conditions. Indeed, more than 62% of Americans currently live in States in which Cannabis with high concentrations of THC may be recommended by physicians for medical treatment.

14. Some patients who live in State-legal medical-Cannabis jurisdictions are, for the moment, able, as a practical matter, to avail themselves of medical Cannabis, notwithstanding the provisions of the CSA, based upon a series of federal initiatives which have created temporary, *de facto* impediments to its enforcement at the federal level. However, those temporary federal initiatives do not have the force of law and, in many instances, explicitly state that they <u>do not</u> provide a legal defense to prosecutions under the CSA.

15. Thus, those who cultivate, distribute, sell, recommend and/or use medical Cannabis in conformity with State-legal medical Cannabis programs remain vulnerable to federal enforcement.

16. Worse, those patients who rely upon medical Cannabis, even in State-legal medical-Cannabis jurisdictions, cannot safely travel by airplane; cannot travel onto federal lands or into federal buildings

(even if those federal lands and buildings are situated within State-legal medical-Cannabis jurisdictions); cannot enter facilities owned by the Federal Government, including military bases; and cannot travel to or through States in which medical Cannabis has not been legalized, without risk of arrest and prosecution. Consequently, the physicians who recommend medical Cannabis, the businesses that manufacture and distribute medical Cannabis, and the patients who need and use it remain at constant risk that they could be arrested, prosecuted and incarcerated by the Federal Government at any time.

17. In the context of the Right to Travel, medical Cannabis patients in particular are subjected to a Hobson's Choice of: (i) using their medication but relinquishing their Right to Travel; (ii) exercising their Right to Travel while carrying their medication with them, thereby risking seizure, arrest, prosecution, conviction and incarceration; or (iii) exercising their Right to Travel but foregoing physician-recommended medical treatment that maintains their health and lives. Engaging in an open violation of the CSA and subjecting themselves to the risk of arrest does not constitute a viable option for Plaintiffs. The alternative of leaving their life-sustaining and life-saving medication behind would threaten those Plaintiffs treating with medical Cannabis (and for whom it constitutes a life-saving and-sustaining medicine) with the loss of their health and lives which, as demonstrated below, would constitute a deprivation of their fundamental rights to Substantive Due Process (Third Cause of Action).

18. *Fourth*, the CSA as it pertains to medical Cannabis violates the Commerce Clause and the

Tenth Amendment to the United States Constitution. While empowered by Article I to regulate interstate and international commerce, Congress does not have the authority to regulate purely intra-state activities which do not have any impact on the national economy. Any use of medical Cannabis that is legalized and regulated entirely within an individual State's borders does not have any appreciable impact on the national economy. And Congress, in enacting the CSA, never believed that the cultivation, distribution and sale of Cannabis, purely at the intra-state level, ever affected or will affect the national economy.

19. Regulation of doctor-patient relationships and the administration of medical advice has been, since ratification of the United States Constitution and subsequent adoption of the Tenth Amendment, consistently interpreted as falling within the exclusive regulatory jurisdiction of the States (not the Federal Government) under the provisions of the Tenth Amendment. By injecting itself into the exclusive regulatory jurisdiction of the States, Congress exceeded its powers under the Commerce Clause and violated principles of federalism and the Tenth Amendment of the United States Constitution (Fourth Cause of Action).

20. *Fifth*, the Schedule I classification as it pertains to Cannabis constitutes a completely and utterly irrational legislative construct and thus violates the Due Process Clause of the Fifth Amendment. Specifically, under the CSA, Schedule I drugs are classified as so dangerous that they generally cannot be tested safely; however, in order to obtain the evidence necessary to persuade the Federal Government that Cannabis is safe enough to be rescheduled or descheduled, it must be tested. By imposing as

precondition to re-classification, the testing of a purportedly un-testable drug, Congress created a legislative Gordian Knot—a statute that functions as a one-way, dead end street.[6]

21. What transforms this poorly-conceived provision into an unconstitutional one is that Cannabis was categorized as a Schedule I drug, not because the evidence presented during the legislative process actually demonstrated that it was dangerous, but rather because certain members of Congress pretextually claimed that the data for classifying Cannabis in the first instance was, at the time, supposedly insufficient. Accordingly, Cannabis was to be tested and then rescheduled, de-scheduled or left under the provisions of Schedule I. In classifying Cannabis as a Schedule I drug in the first instance, however, Congress permanently resigned Cannabis to that designation because in the absence of testing, those seeking to petition to reclassify Cannabis are deprived of the opportunity to collect the very evidence deemed necessary by the Federal Government to reschedule or deschedule it (Fifth Cause of Action).

22. *Sixth*, the CSA, as applied to Plaintiffs Alexis Bortell ("Alexis") and Jagger Cotte ("Jagger"), deprives them of their rights under the First Amendment to free speech and to petition the Federal Government for a redress of grievances. Specifically, Alexis and Jagger cannot travel to the Capitol in Washington, DC to petition the Federal Government to enact

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[6] This is not to suggest that no one has ever obtained permission from the Federal Government to test medical Cannabis; but the vetting process renders the approval process substantially impracticable.

legislation which they regard as beneficial, or to repeal laws which they regard as harmful unless they leave their life-saving and-sustaining Cannabis medication behind—a substantial risk for each of these Plaintiffs. Thus, for example, Alexis and Jagger cannot visit their elected representatives to lobby in favor of repealing the CSA or in favor of the Marijuana Justice Act ("MJA"), which Senator Cory Booker of New Jersey is preparing to introduce during the next legislative session. The availability of other forms of communication from a distance does not, as a matter of law, constitute an effective or appropriate substitute for in-person advocacy under the First Amendment, particularly under the circumstances of this case.

23. Under principles of Substantive Due Process, the right to preserve one's health and life by continuing to treat with life-sustaining and life-saving medication, is deeply-rooted in our Nation's history and traditions, and implicit in the concept of ordered liberty. By requiring Alexis and Jagger to forfeit that fundamental right in order to exercise their First Amendment rights (and vice versa), the CSA imposes an unconstitutional Hobson' s Choice upon the aforementioned Plaintiffs and thus violates the Constitution (Sixth Cause of Action).

24. *Lastly*, the Federal Government cannot maintain its position on the existing record that continued enforcement of the CSA as it pertains to Cannabis is "substantially justified." Accordingly, under the Equal Access to Justice Act (28 U.S.C. § 2412), Plaintiffs are entitled to an award of legal fees and costs.

JURISDICTION AND VENUE

25. This Court has subject matter jurisdiction over this controversy under 5 U.S.C. § 8912, 28 U.S.C. §§ 1331, 1346(a)(2), 2201 and 2202.

26. Venue is proper under 28 U.S.C. §§ 1391(e) and 1402(a)(1).

PLAINTIFFS

Marvin Washington

27. Plaintiff Marvin Washington ("Washington") is, and at all relevant times has been, a citizen, resident and domiciliary of the County of Dallas in the State of Texas.

28. Washington is a graduate of the University of Idaho and is a member of the University's Sports Hall of Fame.

29. From 1989 to 1999, Washington played professional football as a defensive lineman for such National Football League franchises as the New York Jets, San Francisco 49ers and Denver Broncos, winning a Super Bowl with the latter.

30. After his retirement from professional football, Washington entered the business world, working for Kannalife, a Long Island company that has been developing Cannabis-based medications to minimize the damage caused by head injuries and to reduce and ultimately eliminate opioid addiction among professional athletes. Washington is currently working with a Swiss company known as Isidiol that has launched, among other things, a line of products infused with Cannabidiol, also known as CBD, produced

in the European Union, outside the confines of the CSA.[7]

31. Washington would like to expand his business to include whole-plant Cannabis (including THC) products, but is concerned that, even in States in which whole-plant Cannabis is legal for medical and/or recreational use, he may be subject to arrest and prosecution.

32. Washington would like to avail himself of the benefits associated with the Federal Minority Business Enterprise program ("MBE") in connection with whole-plant Cannabis products, but he is ineligible for it solely because such activities would be illegal under the CSA. Were Washington to open a whole-plant Cannabis business and apply for participation in the MBE, he would be admitting to the commission of a felony under Federal Law.

33. According to the Federal Government, CBD falls within the ambit of the classification of Cannabis as a Schedule I drug, unless extracted from industrial hemp or a part of the Cannabis plant exempted from the CSA.

34. Washington is concerned that, although CBD products generally have a low concentration or no concentration of THC, his existing business could be subjected to enforcement under the CSA.

35. Washington is African American.

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[7] CBD, although part of the Cannabis plant, generally has no psychoactive effect. Nonetheless, it is currently the position of the Federal Government that the cultivation and/or sale of CBD is prohibited under the CSA.

Dean Bortell and Alexis Bortell

36. Plaintiff Dean Bortell is, and at all relevant times has been, a citizen of Texas and Colorado, currently residing in Larkspur, Colorado ("Dean").

37. Dean is a former member of the Navy, and is a 100% permanently-disabled veteran of foreign wars ("VFW").

38. As a disabled VFW, his children are entitled to receive certain veteran's benefits ("Veterans' Benefits"), including, *inter alia*, health insurance and the right to use the commissary of any nearby military base.

39. Dean is Alexis's father.

40. Alexis is, and at all relevant times has been, a citizen of Texas and Colorado, currently residing in Larkspur, Colorado.

41. Alexis is an 11-year-old girl, who lives with her parents.

42. At the age of seven, Alexis began experiencing seizures, and was eventually diagnosed with a condition known as "intractable epilepsy."

43. Intractable epilepsy is a seizure disorder in which a patient's seizures cannot be safely controlled with FDA approved medical treatments and procedures.

44. By reason of her intractable epilepsy, Alexis often suffered from multiple seizures per day, and spent most of her school-day afternoons in the nurse's office.

45. Alexis, with the assistance of her family and treatment providers, attempted to treat, control and

cure her intractable epilepsy for years without success. Nothing she tried worked.

46. After two years of doctor visits, tests, urgent trips to the emergency room, and pill after pill, all with their assortment of negative side effects, her family exhausted traditional pharmaceutical options to stop what Alexis referred to as the "seizure monster." At that point, they turned to the last known option available: whole-plant Cannabis containing high concentrations of THC.

47. Whole-plant Cannabis with high THC content provided Alexis immediate relief from her seizures, but it is not legal in Texas, where she resided at the time. Accordingly, Alexis and her family were forced to move from her home State of Texas to seek life-saving treatment in Colorado. There, Alexis was thrust into a very grown-up world and joined a then-largely unknown community of Cannabis patients known as "Medical Marijuana Refugees."

48. Since being on whole-plant medical Cannabis, Alexis has gone more than two years seizure-free, without taking any other medication to control her seizures.

49. Without her use of whole-plant medical Cannabis, Alexis would likely have no quality of life, and instead be resigned to spending her days at home inside or worse, in a hospital bed, as medical caregivers surround her with offers of palliative care which fail to provide any actual palliative relief. In addition, Alexis would be subjected to traditional forms of treatment which, aside from being ineffectual, threaten her with serious and life-altering side effects, including infertility.

50. Alexis co-authored the book, Let's Talk About Medical Cannabis, which was launched on April 20, 2017. In her book, she shares her and her family's experiences as "Medical Marijuana Refugees" and gives readers a perspective into the Cannabis refugee community.

51. Alexis was also named a PACT National Pediatric Ambassador (2015-16), and received the Texas Liberty Award (along with her sister) in 2016.

52. Alexis's drive to help those around her led to her newest project, "Patches of Hope." She and her sister Avery are growing USDA certified organic garden vegetables on their family farm to donate to hungry people in need, including her beloved Medical Marijuana Refugees. Her story and advocacy have been featured in documentaries, newspapers, magazines, TV, and on radio stations worldwide.

53. While thrilled with the success she has experienced in treating her intractable epilepsy and eliminating her daily seizures with medical Cannabis, Alexis would like to move back to Texas, where she would be eligible for free college tuition through Texas's State Department of Education. Alexis is not eligible for free state education in Colorado.

54. In addition, Alexis would like to travel to other States and to federal lands (including, for example, national parks and monuments), but cannot safely do so without fear that: (i) her parents, with whom she would travel, might be prosecuted for possession of Cannabis; or worse (ii) her parents might be subjected to proceedings which would imperil their parental rights.

55. Separate and apart from her desire to travel to other States, national parks and monuments, Alexis would like to visit, and has been invited to speak with, members of Congress at the Capitol, *inter alia*, to lobby in favor of repealing the CSA and in favor of the MJA, which would have the effect of de-scheduling Cannabis.

56. However, Alexis cannot make a trip to the Capitol and visit with her elected representatives and other public officials unless she were to leave her medical Cannabis behind, endangering her life.

57. There is no comparable substitute for the opportunity to visit public officials and engage in in-person advocacy.

58. Insofar as Alexis is a minor, she cannot vote; her ability to influence her elected representatives is limited to efforts by her to advocate in support of beneficial legislation and against-laws she regards as harmful.

59. Alexis would also like to avail herself of the Veterans Benefits for which she is eligible and which she would otherwise receive were it not for her necessary Cannabis use; however, Alexis cannot enter the neighboring military base, where she would be able to avail herself of such Benefits, including, for example, commissary benefits, unless she were to leave her medication behind, risking her health. And, although currently receiving health insurance (another of the Veterans Benefits to which she is entitled) through her father's veteran's benefit plan, Alexis will almost certainly lose her eligibility within the next three years, as she would be required to enter a United States military base to renew her health

insurance card—a trip she cannot safely make without taking her State-legal, but federally-illegal, medication with her. Thus, Alexis and her family are subjected to an unacceptable Hobson's Choice: (A) discontinuing the only medication that has ever eliminated her seizures (thereby resigning herself to living permanently with a dangerous and disabling illness) so that she could return to Texas; or (B) continuing to use her medication but refusing to relinquish her Right to Travel, risking arrest, prosecution and her parents' loss of parental rights; or (C) continuing to use her medication within the State of Colorado but foregoing her rights to: (i) live in Texas; (ii) receive free tuition in Texas; (iii) travel to other States; (iv) use an airplane to travel to any other State; (v) step onto federal lands or into federal buildings; (vi) access military bases; and (vii) receive her father's Veteran's Benefits ("Hobson's Choice").

Jose Belen

60. Plaintiff Jose Belen is a citizen of the State of Florida, with a residence in Seminole County ("Jose").

61. On January 16, 2002, at the age of 19, Jose enlisted in the United States Army.

62. Soon after enlisting in the Army, Jose was deployed to Germany, where he participated in training exercises and awaited further deployment.

63. On March 20, 2003, the United States Military began an invasion of Iraq, under the code-name "Operation Iraqi Freedom."

64. In or around May 2003, Jose and his battalion were deployed to Kuwait.

65. Jose's battalion was then pushed directly into active combat, receiving orders to cross the Iraq-Kuwait border and march on to enter Baghdad.

66. In connection with this mission, Jose then served in Iraq for 14 months, often witnessing brutal armed combat first-hand.

67. During his deployment, Jose came to know many of his fellow soldiers personally, developing strong, emotional bonds.

68. During his deployment, Jose was in grave danger and witnessed the killing of several fellow soldiers, including his best friend and roommate.

69. After he was honorably discharged, Jose moved to Florida.

70. It soon became clear to Jose that he was unable to forget and/or otherwise cope with his memory of the horrors of war that he had lived through in Iraq.

71. Jose developed Post-Traumatic Stress Disorder ("PTSD").

72. PTSD is an ailment which commonly afflicts members of the armed forces who have seen active combat.

73. Because of his PTSD, the Veterans Affairs Administration declared Jose "70% disabled."

74. Jose sought treatment for his PTSD from the medical staff at the Veterans Affairs Administration and other treatment centers.

75. The medical staff at the Veteran Affairs Administration issued Jose prescriptions for different opioid medications.

76. The aforesaid and described prescriptions were ineffective and often further disabling.

77. Jose's PTSD intensified, and became so severe that Jose often contemplated taking his own life.

78. Statistics show that an average of 22 American military veterans commit suicide every day.

79. Upon information and belief, most of these suicides are directly linked to PTSD.

80. Jose subsequently discovered that Cannabis is the only substance which actually reduced his PTSD symptoms.

81. Since he began treating with medical Cannabis, Jose has been able to cope with his PTSD.

82. Jose has disclosed his need for medical Cannabis to his Veterans Administration physicians.

83. Jose's treatment providers at the Veterans Administration informed Jose that they are unable to prescribe medical Cannabis because it is illegal under the CSA.

84. As with Alexis, Jose cannot, while possessing his medical Cannabis: (i) enter a military base; (ii) travel by airplane; (iii) step onto federal lands or into federal buildings; (iv) travel to States where medical Cannabis is illegal and enforced under the CSA; (v) request medical Cannabis from his treating physicians; and/or otherwise (vi) avail himself of the Veterans Benefits for which he is otherwise eligible and to which he is legally entitled. Thus, as with Alexis, Jose is subjected to a similar Hobson's Choice—his life and health, or the exercise of his constitutional rights and the risk of arrest.

85. Separate and apart from his desire to receive Veterans Benefits, Jose would like to visit and speak with members of Congress at the Capitol to lobby in favor of, *inter cilia,* repealing the CSA and in favor of the MJA, which would have the effect of de-scheduling Cannabis.

86. However, Jose cannot make a trip to the Capitol and visit with his elected representatives and other public officials unless he were to leave his medical Cannabis behind.

87. There is no comparable substitute for the opportunity to visit public officials and engage in in-person advocacy.

Sebastien Cotte and Jagger Cotte

88. Sebastien Cate is, and at all relevant times has been, a citizen and domiciliary of the State of Georgia, with a residence in Dekalb County ("Sebastien").

89. Jagger Cotte is, and at all relevant times has been, a citizen and domiciliary of the State of Georgia, with a residence in Dekalb County.

90. Sebastien is Jagger's father.

91. Jagger is a six-year old boy who lives with his parents, including his father, Sebastien.

92. Jagger suffers from a rare, congenital disease known as "Leigh's Disease," which disables and then kills approximately 95% of people afflicted with it (if diagnosed before age 2) by the time that they reach the age of four.

93. Consistent with his diagnosis and prognosis, Jagger, beginning at age one, became a hospice patient,

unable to communicate, walk, masticate food, and/or otherwise handle any activities of daily living.

94. Worse, Jagger began experiencing near-constant pain, shrieking in agony as he tried to get through each day.

95. As Sebastien and his wife prepared for what they expected would be their son's inevitable demise, they turned to Cannabis with high concentrations of THC, in the hope of reducing his pain and prolonging his life.

96. Since he began treating with medical Cannabis with high concentrations of THC, Jagger has stopped screaming in pain, has been able to interact with his parents, and has prolonged his life by more than two years.

97. Cannabis with a THC concentration of greater than 5% is illegal in the State of Georgia.

98. Because his required dosage for effective treatment of his condition requires a THC content greater than 5%, Jagger cannot obtain his medical Cannabis in State.

99. Worse, Georgia has no regulatory protocol for the cultivation, distribution and sale of Cannabis. Thus, assuming that medical Cannabis with a THC content of 5% were sufficient to treat Jagger's condition—and it isn't—obtaining State-legal medical Cannabis in Georgia is impossible, as it is unavailable for purchase in a dispensary or otherwise.

100. At one point, Jagger and his family relocated to Colorado so as to facilitate the administration of his medication; however, maintaining two residences and caring for a dying child full time rendered this

prospect economically infeasible. Consequently, the Cotte family returned to Georgia (by car).

101. As with Alexis and Jose, Jagger cannot travel by airplane, enter onto federal lands or into federal buildings, and/or travel to and/or through States in which medical Cannabis, by reason of the CSA and other legislation, is illegal. Thus, Jagger is resigned to a Hobson's Choice of: (i) relinquishing his constitutional rights because of his treatment with medical Cannabis; or (ii) retaining his constitutional rights but foregoing his medical treatment and subjecting himself to the uncompromisingly painful and ultimately fatal effects of his illness; or (iii) traveling without regard to where Cannabis is legal or illegal and risking his or his father's arrest.

102. Jagger would like to visit with members of Congress at the Capitol and, through his father, lobby in favor of repealing the CSA and in favor of the MJA, which would have the effect of de-scheduling Cannabis.

103. However, Jagger cannot make a trip to the Capitol and visit with his elected representatives and other public officials unless he were to leave his medical Cannabis behind, thereby endangering his life.

104. There is no comparable substitute for the opportunity to visit public officials and engage in in-person advocacy.

105. Insofar as Jagger is a minor, he cannot vote; his ability to influence his elected representatives is limited to efforts by him (through his father) to advocate in support of beneficial legislation and against laws he regards as harmful.

Cannabis Cultural Association, Inc.

106. Cannabis Cultural Association, Inc. ("CCA") is, and at all relevant times has been, a not-for-profit corporation organized and existing under the laws of the State of New York, with a principal headquarters in the City and County of New York.

107. The CCA was founded to provide a voice and forum to assist persons of color to develop a presence in the Cannabis industry—an industry in which they are and, at all relevant times have been, grossly under-represented except when it comes to being arrested.

108. People of color, especially black males, are up to four times as likely to be arrested in connection with Cannabis than white Americans, and make up nearly 70% of the 2.5 million people in prison for drug crimes (even though use among races is virtually equal).

109. Convictions for violations of the CSA and other statutes criminalizing cultivation, distribution and/or use of Cannabis frequently disqualify individuals from participating in State-legal medical Cannabis businesses. By reason of the foregoing, persons of color, who are disproportionately investigated and prosecuted for drug offenses, have been unfairly and inequitably excluded from the Cannabis industry.

110. Members of the CCA include persons of color who have been arrested, prosecuted, convicted and/or incarcerated for violating the CSA as it pertains to Cannabis.

DEFENDANTS

Sessions

111. Defendant Jefferson Beauregard Sessions, III ("Sessions") is, and since on or about February 8, 2017 has been, the Attorney General of the United States.[8]

112. Before his ascension to Attorney General, Sessions, from 1997 until in or about late 2016, served as a United States Senator on behalf of the people of the State of Alabama.

113. Prior to his installation as a United States Senator, Sessions was a United States Attorney for the Southern District of Alabama.

114. While serving as a United States Attorney, Sessions was nominated to serve as a United States District Court Judge; however, his nomination was withdrawn following a series of Senate hearings at which witnesses testified that Sessions had:

- made racially insensitive remarks to African American Assistant U.S. Attorneys;
- spoken favorably of the Ku Klux Klan;
- referred to a white civil rights attorney as "maybe" a "disgrace to his race;"
- repeatedly referred to an African American Assistant U.S. Attorney as "boy" and had instructed the latter to "be careful what you say to white folks;"

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[8] Sessions is sued only in his official capacity as Attorney General.

- remarked that the NAACP and ACLU were "un-American" and "Communist-inspired," and that they were trying to force civil rights "down the throats of people;" and
- complained that he had wished he could decline all civil rights cases.[9]

115. Sessions was never again nominated to sit on the Federal Bench.

116. Upon information and belief, Sessions is, and at all relevant times since 1997 has been, a citizen of Alabama, and a resident of both Alabama and Washington, DC.

117. Sessions, as Attorney General, is authorized to re-schedule, de-schedule and/or decline to re-schedule or de-schedule any drug classified under the provisions of the CSA. 21 U.S.C. § 811.

118. As shown below, Sessions has announced that:

- he was "heartbroken" that former President Obama said that "Cannabis is not as dangerous as alcohol;"
- he believes that Cannabis is "a dangerous drug;"

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[9] Sessions admitted that he had made favorable comments about the Ku Klux Klan, but claimed he was not being serious and later apologized. He claimed not to remember saying that a white civil rights lawyer was "maybe" a "disgrace to his race." As to the comments about the ACLU and NAACP, Sessions claimed to have been referring to the organizations' supposed support for the Sandinistas in Nicaragua. He denied making the other above-referenced statements attributed to him.

- he believes that "good people don't smoke marijuana;" and
- he thought favorably of the Ku Klux Klan, but then changed his view when he learned that its members supposedly smoke "pot."

119. On or about May 1, 2017, Sessions sent correspondence to Congress requesting that funding be provided that could allow the United States Department of Justice ("DOJ") to resume criminal prosecutions of: (i) State-legal medical marijuana patients, (ii) State-legal businesses that provide medical Cannabis to patients, and (iii) physicians who recommend such treatment.[10]

120. On July 19, 2017, Sessions announced his intention to resume civil forfeiture activity, previously discontinued under the Obama Administration, as part of his continued war against those whom Sessions claims are engaged in dangerous, illegal drug activity.[11]

United States Department of Justice

121. Defendant DOJ is, and since in or about 1870 has been, an executive department of the United States, "with the Attorney General as its head."[12]

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[10] As discussed below, Congress had previously enacted legislation that prevents the Attorney General and Department of Justice from using legislative appropriations to prosecute those in State-legal medical Cannabis jurisdictions operating in conformity with State law.

[11] https://www.politico.com/story/2017/07/19/jeff-sessions-drug-war-seizures-240706.

[12] https://wwwjustice.gov/about.

122. According to the mission statement contained on its website, the DOD's purpose is:

> [t]o enforce the law and defend the interests of the United States according to the law; to ensure public safety against threats foreign and domestic; to provide federal leadership in preventing and controlling crime; to seek just punishment for those guilty of unlawful behavior; and to ensure fair and impartial administration of justice for all Americans.[13]

123. To the extent that the DOJ treats medical Cannabis as a dangerous and illegal substance, Plaintiffs and everyone else who may need to use, or who desire to cultivate and/or sell, medical Cannabis are at risk of investigation and prosecution by the DOJ.

Charles "Chuck" Rosenberg and the DEA

124. Defendant Charles "Chuck" Rosenberg ("Rosenberg") is, and since May 2015 has been, the acting head of the defendant Drug Enforcement Administration ("DEA").[14]

125. Defendant DEA is, and since 1973 has been, a Federal agency charged with the responsibility of investigating and, together with the DOJ, enforcing, the CSA, and any other controlled substances laws and regulations of the United States.

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[13] *Id.*

[14] Rosenberg is sued only in his official capacity as Acting Administrator of the DEA.

126. Since at least 2002, the DEA's position has been that enforcement of Federal Laws against medical Cannabis is the responsibility of the DEA.

127. On or about November 10, 2015, Rosenberg publicly announced to CBS News that he believes that "medical marijuana" is a "joke."[15]

United States of America

128. The United States of America is named as a defendant because this action challenges the constitutionality of an Act of Congress. 28 U.S.C. § 2403(A).

STATEMENT OF FACTS

I. Cannabis Has Been Cultivated and Safely Used Throughout World History

10,000 BC until the Birth of Christ

129. Cannabis has been utilized in a multitude of ways by diverse groups of people all over the world for the last 10,000 years.[16]

130. The first documented use of Cannabis took place in the area of modern day Taiwan where hemp cords were identified in pottery found in an ancient village dating back to about 10,000 years ago.[17]

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15 http://www.cbsnews.cominews/dea-chief-says-smoking-marijuana-as-medicine-is-a-joke.

16 *See* Deitch, *supra* note 1 at 1, 7-8; Leslie Iversen, THE SCIENCE OF MARIJUANA 122 (2000);

17 Deitch, *supra* note 1 at 7-8; *10,000-year History of Marijuana Use in the World,* ADVANCED HOLISTIC HEALTH, http://www.

131. In 6,000 B.C., China became the first country known to utilize Cannabis seeds and oil for food and, along with Turkestan, China began cultivating hemp for the purpose of producing textiles in 4,000 B.C.[18]

132. The first documented medical use of Cannabis also occurred in China (in or around 2900 B.C.) when Chinese Emperor Fu Hsi, the father of Chinese civilization, noted that "Ma," the Chinese word for Cannabis, was a "very popular medicine that possessed both yin and yang."[19] Its popularity at that time has been confirmed by the "Pen ts'ao," a Chinese digest of herbal medicines which was first published in or about 2800 B.C.

133. The Pen ts'ao "recommended Cannabis for the treatment of constipation, gout, malaria, rheumatism, and menstrual problems."[20]

134. Hemp in particular was so important in ancient China that the Chinese people referred to their country as the "land of mulberry and hemp."[21]

135. The ancient Egyptians began to use Cannabis as medicine in or about 2000 B.C.[22]

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advancedholistichealth.org/history.html (last visited July 20, 2017) [hereinafter referred to as "ADVANCED HOLISTIC HEALTH"].

18 Advanced Holistic Health, *supra* note 17.

19 Deitch, *supra* note 1 at 9.

20 Iversen, *supra* note 16 at 122.

21 Deitch, *supra* note 1 at 9.

22 Claire Rankin, *Marijuana use in ancient Egypt,* NEWS TARGET (Feb. 26, 2016), https://www.newstarget.com/2016-02-26-marijuana-use-in-ancient-egypt.html; *see also In the Matter of Rescheduling Marijuana,* 86-22 at p. 33 (1988) (in a proceeding

136. The ancient Egyptians used Cannabis at that time to treat sore eyes and cataracts, inflammation, hemorrhoids, menstrual bleeding, and Glaucoma.[23] And while the ancient Chinese were the first people known to use Cannabis as medicine, "it was the ancient Egyptians who first identified cancer as an illness and then treated it with Cannabis."[24]

137. Beginning in 2,000 B.C., the use of Cannabis expanded to suit religious and spiritual purposes as well.[25] Around this time, a sacred Hindu text, *Atharvaveda,* first refers to "Bhang," an intoxicant made from the leaves of the female Cannabis plant, as one of the five sacred plants of India.[26]

138. Bhang was used in ancient India medicinally as an anesthetic and anti-phlegmatic.[27]

139. Bhang was used in ancient India religiously as an offering to the god Shiva.[28]

140. In approximately 1450 B.C., when the events of the Book of Exodus (30:22-23) are alleged to have

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contested by the DEA, the ALJ observed: "Uncontroverted evidence [o]n this record indicates that marijuana was being used therapeutically by mankind 2000 years before the Birth of Christ" (citation omitted).

23 Rankin *supra* note 22; *See also* PROCON.ORG, *supra* note 3.

24 Rankin *supra* note 22.

25 *See* ADVANCED HOLISTIC HEALTH, *supra* note 17.

26 *Id.*; Charukesi Ramadurai, *The Intoxicating Drug of an Indian God,* BBC (March 13, 2017), http://www.bbc.com/travellstory/20170307-the-intoxicating-drug-of-an-indian-god.

27 PROCON.ORG, *supra* note 3.

28 ADVANCED HOLISTIC HEALTH, *supra* note 17.

occurred, Cannabis was purportedly one of the ingredients contained in the Holy anointing oil passed from God to Moses.[29]

141. According to the analyses of a number of well-respected etymologists, linguists, anthropologists, and botanists, the recipe for the Holy anointing oil contained over six pounds of "kaneh-bosem," a Hebrew term these professionals have identified as meaning Cannabis.[30]

142. The use of Cannabis as a medicinal substance continued to spread throughout Asia and Europe for centuries.

143. *The Venidad,* a Persian text dating back to 700 BC, cited Cannabis as being one of the most significant of 10,000 medicinal plants.[31]

144. By 600 B.C. India began using Cannabis to treat leprosy.[32]

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[29] *See* PROCON.ORG, *supra* note 3.

[30] *Id.; See also* Jane Marcus, *Holy Cannabis: The Bible Tells Us So,* Huffington Post, http://www.huffingtonpost.com/jane-marcus-phd/holy-cannabis-the-bible-t_b_4784309.html (last updated Apr. 16, 2014).

[31] Rob Streisfeld, NMD, *The Role of the EndoCannabinoid System & Cannabinoids Linked to Gut Health,* NYANP 13, http://www.nyanp.org/wp-content/uploads/2015/10/Streisfeld_Cannabis-F-NYANP.pdf (last visited May 10, 2017);PROCON.ORG, *Supra* note 3 (*citing* Martin Booth, CANNABIS: A HISTORY (2005)).

[32] PROCON.ORG, *supra* note 3 (*citing* Jonathan Green, CANNABIS (2002)).

145. In 200 B.C. Greece, Cannabis was utilized as a remedy for earaches, edema, and inflammation.[33]

Cultivation and Use of Cannabis from the Birth of Christ Through the Period of Colonial America

146. An important Roman medical text, *De Materia Medica,* was published in 70 A.D.

147. *De Materia Medica* refers to the Cannabis plant as "produc[ing] a juice" that was "used to treat earache[s] and to suppress sexual longing."[34]

148. By 200 A.D., a Chinese physician, Hua T'o, became the first known surgeon to use Cannabis as an anesthetic during surgeries such as "organ grafts, resectioning of intestines, laparotomies (incisions into the loin), and thoracotomies (incisions into the chest)."[35]

149. Ancient civilizations cultivated the Cannabis plant, not merely for medicinal and religious needs, but also to produce industrial hemp for the manufacturing of items such as paper, rope, sails, and linen.

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33 U.S. NATIONAL COMMISSION ON MARIHUANA AND DRUG ABUSE, MARIHUANA, A SIGNAL OF MISUNDERSTANDING, Appendix, Chapter One, Part 1(1972).

34 PROCON.ORG, *supra* note 3 (*citing* Martin Booth, CANNABIS: A HISTORY (2005)).

35 Ernest L. Abel, THE FIRST TWELVE THOUSAND YEARS 9 (1980), https://cannabis-truth.yolasite.com/resources/Abel.%20marihuana%20the%20first%20twelve%20thousand%20years.pdf; Deitch, *supra* note 1 at 10.

150. China was among the first known civilizations to produce paper from hemp.[36]

151. Between 900-1200 A.D., the Arab world, Spain, Italy, England, France, and Germany all began replicating China's hemp-paper manufacturing process.[37]

152. The Venetian Republic, the first known Western European nation to industrialize around the production of hemp and the first European country to experience genuine economic progress emerging from the Dark Ages in the late 10th Century A.D., elevated the art of processing raw hemp into rope, sails and fine linen-like cloth.[38] This reliance upon Cannabis to produce industrial hemp lasted well into the Middle Ages and spread all across Europe.[39]

153. Britain became the "industrial goliath of Western Europe" in large part due to its exploitation of hemp for the manufacture of, among other things, rope and sail-commodities that were essential to its large merchant and naval fleet.[40]

154. In 1533, King Henry VIII imposed a law mandating that farmers grow hemp.[41]

155. Three decades after King Henry VIII' s law mandating the cultivation of hemp, Queen Elizabeth

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36 Abel *supra* note 35 at 6-7.

37 *Id.*

38 Deitch, *supra* note 1 at 11.

39 *Id.*

40 *Id.* at 11-12.

41 *Id.* at 12.

I increased the mandated quota imposed on farmers growing hemp and increased the penalties for failing to meet the quota.[42]

156. Britain's reliance on Cannabis was not limited to its navy-related needs; Britain's economy had also become largely driven by its production of hemp-based domestic goods such as fabrics and cordage.[43]

157. Britain, during the 16th and 17th Centuries, utilized Cannabis for its medicinal properties as well.[44]

The Importance of Cannabis to Colonial America

158. By the 17th Century, Britain began colonizing much of the world, including the Americas in particular.

159. Britain's colonization empire was built, in part, upon its cultivation, distribution and use of hemp; however, Britain began to exhaust its geographic agricultural resources to produce adequate amounts of hemp.[45]

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[42] *Id.*

[43] *Id.* at 14.

[44] Queen Elizabeth I's doctor prescribed Cannabis to her to relieve her menstrual pain. *History of Cannabis,* BBC NEWS, https://news.bbc.co.uld2/hi/programmes/panorama/1632726.stm (last visited May 10, 2017).

[45] Deitch, *supra* note 1 at 12. "The fundamental reason for America's predominately Protestant British heritage is that Britain encouraged its people to colonize America—and they did that primarily because Britain's domestic hemp-based industry, the lifeblood of the economy, desperately needed a stable, reliable, and relatively cheap source of raw hemp." *Id.* at 13.

160. England's need for hemp was so substantial that, in 1611, after its establishment of the Jamestown Colony in the Americas, England gave direct orders to the colonists to grow hemp for the production of rope, sails, and clothing.[46]

161. In 1619, "[t]he Virginia Company, by decree of King James I . . . , ordered every [property-owning] colonist . . . to grow 100 [hemp] plants specifically for export."[47]

162. In 1663, the English Parliament passed legislation, granting rights and privileges of natural-born citizens to "any foreigner who settled in England or Wales and established a hemp-related industry within three years," in order to encourage those fleeing persecution in Europe to seek refuge in England.[48]

163. The value of hemp was so well-recognized in the Americas during the colonial period that it was frequently used as a barter medium, and farmers were permitted to pay part of their taxes using the plant in the colonies of Virginia (1682), Maryland (1683), and Pennsylvania (1706).[49]

164. Britain's colonization of the Americas was intended to provide England with raw materials for

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[46] *Id.* at 14; *Marijuana Timeline,* PBS, http://www.pbs.org/wgbh/pages/frontline/shows/dope/etc/cron.html (last visited May 10, 2017) [hereinafter referred to as "PBS"].

[47] Deitch, *supra* note 1 at 16.

[48] *Id.* at 18.

[49] *Id.* at 19.

its own production of goods.[50] However, a combination of America's first textile and shipbuilding industries created a burgeoning domestic market for local hemp, which led the colonists to retain the vast majority of American raw hemp for their own local production of rope, paper, and cloth, rather than for export to England.[51] These growing American industries, based principally upon hemp, helped pave the way for America's economic independence from England.[52]

The Founding Fathers' Cultivation, Distribution and Sale of Cannabis in All its Variations

165. Among the colonists to benefit economically from the commercial uses of hemp in the Americas were the Founding Fathers—several of whom derived significant portions of their wealth from the production of hemp or hemp-based goods.[53]

166. The men who cultivated and/or used hemp included, *inter alia,* George Washington, Thomas Jefferson, Benjamin Franklin and one of America's richest colonists, Robert "King" Carter.[54]

167. Indeed, "Jefferson received the first United States patent for his invention of a machine that

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50 *Id.* at 20.

51 *Id.*

52 *Id.*

53 *Id.* at 19.

54 *Id.*

would break hemp (that is, start the process of extracting the fibers).[55]

168. Benjamin Franklin, America's leading paper producer, became wealthy from the cultivation of hemp, since that was what paper was made from at that time.[56]

169. Hemp was so widely utilized in the late 1700s that early drafts of the Declaration of Independence and the United States Constitution were written on it;[57] many of the supplies and uniforms needed for the Revolutionary War were made from it;[58] and the first United States flag was made from hemp cloth.[59]

170. In fact, all official American flags were made of hemp until 1937, when Congress enacted the Marijuana Tax Act, discussed *infra*.[60]

171. Colonial America's use of the Cannabis plant was by no means restricted to industrial uses. "[C]olonial Americans were aware of the medicinal properties

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[55] *Id.* Hemp was viewed so favorably by Thomas Jefferson that he was quoted as saying that "[h]emp is of first necessity to the wealth & protection of the country." Robbie Gennett, *On Role Models and their Bongs,* HUFFINGTON POST, http://www.huffingtonpost.com/robbie-gennetion-role-models-and-their_b_164387.html (last updated May 25, 2011).

[56] *Id.* Until 1883, 75-90% of all the paper the world produced was made with hemp fiber. *Id.* at 21.

[57] Deitch, *supra* note 1 at 35; Gennett, *supra* note 55.

[58] Deitch, *supra* note 1 at 35.

[59] *Id.*

[60] *Id.*

of Cannabis. It was one of the few medicines they had, and they used it as commonly as we [in America] use aspirin today."[61]

172. Some of the Founding Fathers also smoked Cannabis (known at that time as "hemp" or "sweet hemp") for both medicinal and recreational purposes.[62]

173. Entries from George Washington's diary reveal that Washington grew hemp at his plantation, Mount Vernon, for approximately 30 years.[63]

174. George Washington specifically grew Cannabis with high THC concentrations—the very substance that today, would subject him to prosecution and incarceration under the CSA.[64]

175. Thomas Jefferson, who was also a hemp farmer, mentioned in his diary that he smoked hemp as a remedy for migraine headaches.[65]

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61 *Id.* at 25.

62 *Id.* at 25-26.

63 *Id.* at 25.

64 *Id.* Washington's diary entries read: "'Sowed hemp [presumably Indian hemp] at muddy hole by swamp' (May 12-13, 1765);" "Began to separate the male from female plants at do [sic]—rather too late' (August 7, 1765);" and "Pulling up the (male) hemp. Was too late for the blossom hemp by three weeks or a month' (August 29, 1766)" which all indicate that he was growing the Cannabis away from the hemp for fiber and that he was trying to grow female plants, which produce high THC content. *Id.* (*citing* Washington's Diary Notes, Library of Congress (Volume 33, page 270)); *see also* George Andrews and Simon Vinkenoog, THE BOOK OF GRASS: AN ANTHOLOGY OF INDIAN HEMP 34 (1967).

65 Deitch, at note 1 *supra* at 25.

176. James Madison stated that sweet hemp "gave him insight to create a new and democratic nation."[66]

177. The notion that Cannabis negatively impairs a user's mental or physical abilities is rendered ludicrous by the fact that the visionaries of our democratic system of government were known to use (and admitted using) Cannabis on a regular basis.[67]

Post-Revolutionary War Use of Cannabis for Non-Medical and Medical Purposes

178. At the conclusion of the Revolutionary War in 1781, the value of industrial hemp plummeted.

179. By 1850, hemp dropped to the third most commonly-grown agricultural crop in America—it had been the first until this time—behind only cotton and tobacco.[68]

180. During the mid-19th Century, due to the introduction of more modern sailing ships, hemp became obsolete for military purposes.[69]

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66 Julian Sonny, *The Presidents Who Admitted to Smoking Weed,* ELITE DAILY (Feb. 18 2013), http://elitedaily.com/news/politics/presidents-admitted-smoking-weed/.

67 Deitch, *supra* note I at 27. Aside from George Washington and Thomas Jefferson, whose Cannabis use is discussed *supra,* other American Presidents known to have smoked cannabis include: James Madison, James Monroe, Andrew Jackson, Zachary Taylor, Franklin Pierce, Abraham Lincoln, John F. Kennedy, Jimmy Carter, George W. Bush, Bill Clinton, and Barack Obama. *Id.* at 26-27; Gennett *supra* note 55; Sonny *supra* note 66; Chris Conrad, HEMP: LIFELINE TO THE FUTURE 192 (1994).

68 Deitch *supra* note 1 at 38.

69 *Id.*

181. At or about the time that hemp became obsolete for military purposes, Cannabis was still a mainstream form of medicine in the West and particularly in the United States.

182. Cannabis was formally introduced into Western medicine in the 1830s by William O'Shaughnessy, a doctor working for the British East India Company.[70]

183. After experimenting with Cannabis on both animals and humans for years, Dr. O'Shaughnessy concluded that Cannabis was an "anti-convulsive remedy of the highest value"[71] and that it was highly effective in treating conditions such as rheumatoid arthritis, spasticity, and pain.[72]

184. Shortly after making the aforementioned and described discoveries, Dr. O'Shaughnessy and a London pharmacist created an extract from Cannabis, later termed "Squire's Extract."

185. Dr. O'Shaughnessy put Squire's Extract on the market as an analgesic.[73]

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70 Martin Booth, CANNABIS: A HISTORY 109-10 (2003); Steve DeAngelo, THE CANNABIS MANIFESTO: A NEW PARADIGM FOR WELLNESS 48 (2015).

71 *Id.*

72 DeAngelo, *supra* note 70 at 48.

73 Booth, *supra* note 70 at 112. Indeed, Squire's Extract and similar medicines became quite popular among physicians who found that the only other pain killer that was equally effective was opium, which unlike Cannabis-based products, they found to be highly addictive and riddled with adverse side effects. *Id.* at 113.

186. After the development of Squire's Extract, Cannabis made its way further into American medicine as "Tilden's Extract."[74]

187. As early as 1840, studies regarding the medical uses of Cannabis appeared in American medical academic publications.[75]

188. By 1850, the widely-distributed *United States Pharmacopoeia*, a highly selective listing of America's most widely taken medicines, listed Cannabis as a treatment for "neuralgia, tetanus, typhus, cholera, rabies, dysentery, alcoholism, and opiate addiction, anthrax, leprosy, incontinence, snake bite, gout, convulsive-inducing conditions, tonsillitis, insanity . . . [ ]excessive menstrual bleeding[ ], and uterine hemorrhaging."[76]

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74 *Id.* at 112-13.

75 DeAngelo, *supra* note 70 at 50.

76 Booth, *supra* note 70 at 113-14; Edward M. Brecher, *et al., The Consumers Union Report on Licit and Illicit Drugs,* CONSUMER REPORTS MAGAZINE (1972), http://www.druglibraty.org/schaffer/Library/studies/cuku54.html#Anchor-35882; PROCON.ORG, *supra* note 3. Interestingly, "pharmaceutical supplies of Cannabis indica were entirely imported from India (and occasionally Madagascar), in accordance with the *Pharmacopoeia,* which specified that it come from flowering tops of the Indian variety." PROCON.ORG, *supra* note 3. However, by 1913, the U.S. Department of Agriculture Bureau of Plant Industry determined that it had succeeded in growing Cannabis of equal quality to the Indian variety. *Id.* Thus, when World War I disrupted America's receipt of foreign supplies, the United States was able to be self-sufficient in the production of Cannabis. *Id.* "By 1918, some 60,000 pounds were being produced annually, all from pharmaceutical farms east of the Mississippi." *Id.*

189. Thereafter, the *Pharmacopoeia* included Cannabis, later known as "Extractum Cannabis" or "Extract of Hemp," as a treatment for additional ailments and conditions.[77]

190. In 1860, the Ohio State Medical Society's Committee on Cannabis Indica found Cannabis to be medically effective for ailments including stomach cramps, coughs, venereal disease, postpartum depression, epilepsy, and asthma.[78]

191. By the latter half of the 19th century, "every pharmaceutical company [in America was] . . . busy manufacturing [C]annabis-based patent cures [including] E.R. Squibb & Sons [which] marketed their own Chlorodyne and Corn Collodium; Parke, Davis, [which] turned out Utroval, Casadein and a veterinary [C]annabis colic cure; Eli Lilly [which] produced Dr[.] Brown's Sedative Tablets, Neurosine and the One Day Cough Cure, a mixture of [C]annabis and balsam which was a main competitor for another

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77 *Id.*; Brecher *supra* 76.

78 Booth, *supra* note 70 at 114; DeAngelo, *supra* note 70 at 50. There is even evidence that suggests that none other than Abraham Lincoln smoked "sweet hemp." According to Huffingtonpost.com, Lincoln is reported to have written, while serving as President of the United States:

> Two of my favorite things are sitting on my front porch smoking a pipe, and smoking a pipe of sweet hemp and playing my Hohner harmonica.

See http://m.huffpost.com/us/entry/164387. There are those who have disputed the authenticity of the evidence underlying this claim, but it is not without significance that the claim has been reported by reputable media sources.

new cough cure released by the German pharmaceutical firm, Bayer."[79]

192. During the latter half of the 19th Century and the beginning of the 20th Century, Cannabis was also commonly used to treat asthma in the United States[80] Specifically, pharmaceutical companies began manufacturing cigarettes containing Cannabis ("Legal Cannabis Cigarettes") for the purpose of treating asthma in both England and the United States.[81]

193. Legal Cannabis Cigarettes were so highly regarded as a remedy for asthma in late 19th Century America that the *Boston Medical and Surgical Journal,* in its 1860 publication, advertised Legal Cannabis Cigarettes, which were manufactured by Grimault & Co., as being able to "promptly" cure or relieve "Asthma, Bronchitis, Loss of Voice, and other infections of the respiratory organs."[82]

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79 Booth, *supra* note 70 at 116.

80 *Viewers' Guide to the Botany of Desire: Based on the book by Michael Pollan,* Chapter 3, p. 7, PBS, https://www-te.pbs.org/thebotanyofdesire/pdf/Botany_of Desire_Viewers_Guide.pdf (last visited June 29, 2017).

81 *Id.* Grimault & Co. manufactured "Indian cigarettes" containing Turkish tobacco and Cannabis, which "were promoted as an asthma and cough treatment which would also dull facial pain and aid insomniacs." *Id.; see also* Iversen *supra* note 16 at 130; Rowan Robinson, THE GREAT BOOK OF HEMP: THE COMPLETE GUIDE TO THE ENVIRONMENTAL, COMMERCIAL, AND MEDICINAL USES OF THE WORLD'S MOST EXTRAORDINARY PLANT 47 (1996).

82 Cupples, Upham & Company, *Medical Journal Advertising Sheet,* 83 B. MED. & SURGICAL J. 260 (1870-1871).

194. Legal Cannabis Cigarettes continued to be widely advertised and recommended for the treatment of asthma in the United States until the Marijuana Tax Act of 1937 ("MTA") was enacted.

195. As discussed in greater depth *infra,* the MTA effectively outlawed Cannabis in all of its forms.[83]

196. Nineteenth Century Americans utilized the plant for social purposes as well.[84] A "Cannabis fad" took place in the mid-1800s among intellectuals, and the open use of hashish (*i.e.,* compressed Cannabis containing a very high THC content) continued into the 20th Century.[85]

The Beginning of Marijuana Regulation and Prohibition in America

197. The Food and Drugs Act ("FDA") was enacted in 1906, requiring the labeling of over-the-counter drugs, including, *inter alia,* Cannabis.[86]

198. When the Mexican Revolution resulted in a wave of Mexican immigrants to America's Southern border States in 1910, articles in the *New York Sun, Boston Daily Globe* and other papers decried the "evils of ganjah smoking" and suggested that some

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[83] DeAngelo, *supra* note 70 at 52.

[84] *See* Brecher *et al. supra* note 76, PBS *supra* note 46; The Associated Press, *As pot goes proper, a history of weed,* NY DAILY NEWS (Dec. 6, 2012), http://www.nydailynews.com/news/nationallpot-proper-history-weed-article-1.1214613.

[85] Brecher, *et al., supra* note 79; PBS *supra* note 46; The Associated Press *supra* note 84.

[86] PBS *supra* note 46; The Associated Press *supra* note 84; PROCON.ORG *supra* note 3.

immigrants used it "to key themselves up to the point of killing."[87]

199. The vast majority of stories urging the public to fear the effects of "marijuana" appeared in newspapers published by William Randolph Hearst, a man who had financial interests in the lumber and paper industries, and therefore, saw the hemp industry as an obstacle to his path to economic success.[88]

200. As a result of the hysteria created by the aforementioned and described horror stories published by pro-paper entrepreneurs, Cannabis-became associated with Mexican immigrants, and because there was tremendous fear and prejudice with respect to these newcomers, Cannabis likewise became vilified across the country.[89]

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87 *Id.*

88 PROCON.ORG *supra* note 3 (*citing* Mitchell Earleywine, PhD, UNDERSTANDING MARIJUANA: A NEW LOOK AT THE SCIENTIFIC EVIDENCE (2005). "William Randolph Hearst was an up-and-coming newspaper tycoon, owning twenty-eight newspapers by the mid-1920s . . . Hearst then dropped the words Cannabis and hemp from his newspapers and began a propaganda campaign against 'marijuana,' (following in Anslinger's footsteps)." *Id* (citation omitted).

89 PBS *supra* note 46. "The prejudices and fears that greeted these peasant immigrants also extended to their traditional means of intoxication: smoking marijuana. Police officers in Texas claimed that marijuana incited violent crimes, aroused a 'lust for blood,' and gave its users 'superhuman strength.' Rumors spread that Mexicans were distributing this 'killer weed' to unsuspecting American schoolchildren. . . . In New Orleans newspaper articles associated the drug with African-Americans, jazz musicians, prostitutes, and underworld whites. The Marijuana Menace,' as sketched by anti-drug campaigners, was personified by inferior races and social deviants." Eric Schlosser,

201. The aforementioned and described xenophobia precipitated anti-Cannabis legislation across America. States across the country began outlawing Cannabis.[90]

202. By 1931, 29 states had outlawed Cannabis.[91]

203. This domino effect was largely triggered by the spread, in the 1890s, of false, racist and bigoted horror stories regarding alleged marijuana-induced violence.[92]

204. The aforementioned and described xenophobia was exacerbated by job losses associated with the Great Depression. During that time, "massive unemployment increased public resentment and fear of Mexican immigrants, escalating public and governmental concern [regarding] the [supposed] problem [associated with] marijuana."[93]

205. Harry J. Anslinger ("Anslinger"), the first U.S. Commissioner of the Federal Bureau of Narcotics, initially doubted the seriousness of the so-called "marijuana"[94] problem, but after the repeal of alcohol

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Reefer Madness, THE ATLANTIC (Aug. 1994), https://www.theatlantic.com/magazine/archive/1994/08/reefer-madness/303476/

90 *See* The Associated Press *supra* note 84; PROCON.ORG *supra* note 3.

91 PBS *supra* note 46.

92 *See* The Associated Press *supra* note 84.

93 PBS *supra* note 46.

94 The term "'[Marijuana' came into popular usage in the U.S. in the early 20th century because anti-cannabis factions wanted to underscore the drug's 'Mexican-ness.' It was meant to play off of anti-immigrant sentiments." Matt Thompson, *The Mysterious*

Prohibition in 1933, he began to push vigorously for the nationwide prohibition of Cannabis, ostensibly to create new work for himself.[95]

206. Anslinger then publicly claimed that the use of "evil weed" led to murder, sex crimes, and mental insanity.[96]

207. Anslinger authored sensational articles falsely associating Cannabis with violence and death, with titles such as "Marijuana: Assassin of Youth."[97]

History of Marijuana', NPR (July 22, 2013), http://www.npr.org/sections/codeswitch/2013/07/14/201981025/the-mysterious-history-of-marijuana.

95 The Associated Press, *supra* note 84; Schlosser, *supra* note 89. "Harry [Anslinger] was aware of the weakness of his new position. A war on narcotics alone-cocaine and heroin, outlawed in 1914 wasn't enough . . . they were used only by a tiny minority, and you couldn't keep an entire department alive on such small crumbs. He needed more." Cydney Adams, *The man behind the marijuana ban for all the wrong reasons,* CBS NEWS (Nov. 17, 2016), http://www.cbsnews.com/news/harry-anslinger-the-man-behind-the-marijuana-ban/.

96 Schlosser, *supra* note 89. Much of his rhetoric was blatantly racist in nature. "He claimed that black people and Latinos were the primary users of marijuana, and it made them forget their place in the fabric of American society. He even went so far as to argue that jazz musicians were creating 'Satanic' music all thanks to the influence of pot . . . [and that] cannabis promotes interracial mixing, interracial relationships." Adams, *supra* note 95.

97 *Id.* In this article, he said: "No one knows, when he places a marijuana cigarette to his lips, whether he will become a philosopher, a joyous reveler in a musical heaven, a mad insensate, a calm philosopher, or a murderer." *The Associated Press, supra* note 84.

208. Anslinger also made a series of racist statements pertaining to African Americans and Cannabis, including, *inter alia:*

(a) "Reefer makes darkies think they're as good as white men;"

(b) "Marihuana influences Negroes to look at white people in the eye, step on white men's shadows, and look at a white women [sic] twice;"

(c) "Colored students at the University of Minnesota partying with (white) female students, smoking [marijuana] and getting their sympathy with stories of racial persecution. Result: pregnancy;"

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

(e) "Marijuana is the most violence causing drug in the history of mankind. Most marijuana smokers are Negroes, Hispanics, Filipinos and entertainers;" and

(f) "The primary reason to outlaw marijuana is its effect on the degenerate races.[98]

209. The hysteria that followed was captured in propaganda films such as "Reefer Madness," which

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98 *AZQuotes.* Harry J. Anslinger Quotes. http://www.azquotes.com/author/23159-Harry_JAnslinger

purported to show young adults turning to violence and becoming insane after smoking marijuana.[99]

210. This Cannabis-related propaganda ultimately resulted in the passage of the MTA.[100]

211. The MTA effectively outlawed Cannabis by requiring physicians and pharmacists to register and report use of the plant, as well as pay an excise tax for authorized medical and industrial uses.[101]

212. The MTA was passed even though members of Congress neither understood the chemical properties of Cannabis, nor had they even read the bill itself.[102]

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99 *Id.*; PBS, *supra* note 46.

100 PBS, *supra* note 46; Thompson, *supra* note 94.

101 *PBS, Supra*, note 46. "The Federal law . . . maintained the right to use marijuana for medicinal purposes but required physicians and pharmacists who prescribed or dispensed marijuana to register with federal authorities and pay an annual tax or license fee . . . After the passage of the Act, prescriptions of marijuana declined . . . " PROCON.ORG *supra* note 3 (*citing* Rosalie Liccardo Pacula, PhD, *State Medical Marijuana Laws: Understanding the Laws and Their Limitations,* JOURNAL OF PUBLIC HEALTH POLICY (2002).

102 The following exchange between members of Congress several days after the MTA's passage provides some insight into this ignorance: "Bertrand Snell of New York, confessed, "I do not know anything about the bill." The Democratic majority leader, Sam Rayburn of Texas, educated him. "It has something to do with something that is called marihuana," Rayburn said. "I believe it is a narcotic of some kind." Jacob Sullum, *Marijuana Prohibition Is Unscientific, Unconstitutional And Unjust,* FORBES (May 14, 2015), https://www.forbes.com/sites/jacobsullum/2015/05/14/marijuana-prohibition-is-unscientific-unconstitutional-and-unjust/#3 d9bbddf6cf0

213. Worse, Congress enacted the MTA despite failing to garner support from the medical community for the notion that marijuana was a dangerous substance.[103]

214. During Congressional hearings regarding the proposed MTA, Dr. William Woodward testified:

> There is nothing in the medicinal use of Cannabis that has any relation to Cannabis addiction. I use the word "Cannabis" in preference to the word "marihuana," because Cannabis is the correct term for describing the plant and its products. The term "marihuana" is a mongrel word that has crept into this country over the Mexican border and has no general meaning, except as it relates to the use of Cannabis preparations for smoking . . . To say, however, as has been proposed here, that the use of the drug should be prevented by a prohibitive tax, loses sight of the fact that future investigation may show that there are substantial medical uses for Cannabis.[104]

215. Despite enactment of the MTA, the United States Department of Agriculture ("DOA") and the

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103 "[The]re was little scientific evidence that supported Anslinger's claims. He contacted 30 scientists . . . and 29 told him cannabis was not a dangerous drug. But it was the theory of the single [so-called] ['lexpert['] who agreed with him that he presented to the public—cannabis was an evil that should be banned—and the press ran with this sensationalized version." Adams, *supra* note 95.

104 William C. Woodward, MD, Statement to the U.S. House of Representatives Committee on Ways and Means (May 4, 1937).

New York Academy of Medicine ("NYAM") both recognized the beneficial uses of Cannabis.[105]

216. In 1942, after America lost its access to Asian fiber supplies during World War II, the DOA released a film entitled "Hemp For Victory" (Exh, 2), which encouraged farmers to grow hemp, praising its uses for production of parachutes and rope to support the war effort.[106]

217. In 1944, NYAM issued the "LaGuardia Report," concluding that, "use of marijuana did not induce violence, insanity or sex crimes, or lead to addiction or other drug use."[107]

218. Despite the lack of evidence that Cannabis is or ever was dangerous, and notwithstanding the DOA's insistence that American fanners continue growing hemp for war supplies, Anslinger continued his anti-Cannabis campaign throughout the 1940s and 1950s.[108]

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105 The Associated Press, *supra* note 84.

106 *Id*,; Gennett *supra* note 55.

107 The LaGuardia Report found that: "The practice of smoking marihuana does not lead to addiction in the medical sense of the word . . . The use of marihuana does not lead to morphine or heroin or cocaine addiction and no effort is made to create a market for these narcotics by stimulating the practice of marijuana smoking . . . Marihuana is not the determining factor in the commission of major crimes . . . The publicity concerning the catastrophic effects of marihuana smoking in New York City is unfounded." PROCON.ORG *supra* note 3 (*citing* LaGuardia Committee Report on Marihuana, THE MARIHUANA PROBLEM IN THE CITY OF NEW YORK (1944)).

108 The Associated Press, *supra* note 84.

219. As heroin addiction in America grew worse during the 1950s, Congress responded by increasing penalties on Cannabis-related offenses,[109] in large measure because of Anslinger's bogus claim that "marijuana" was a "gateway drug" that would eventually lead its users to heroin.[110]

220. The 1960's saw a cultural shift in the way Americans viewed Cannabis. "Use of the drug became widespread among members of the white upper middle class."[111]

221. Reports requested by Presidents Kennedy and Johnson concluded that Cannabis was not a "gateway drug" nor did its use induce violence.[112]

222. In 1969, the United States Supreme Court, in *Leary v. United States,* 395 U.S. 6 (1969) struck down the MTA, ruling that it unconstitutionally violated the Fifth Amendment right against self-incrimination.[113]

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109 Congress included "marijuana" in the Narcotics Control Act of 1956, providing stricter mandatory sentences for marijuana-related offenses. PROCON.ORG *supra* note 3; PBS *supra* note 46. Under the statute, "[a] first-offense marijuana possession carrie[d] a minimum sentence of 2-10 years with a fine of up to $20,000." PROCON.ORG *supra* note 3; PBS *supra* note 34.

110 The Associated Press, *supra* note 84.

111 *Id.*; PBS, *supra* note 46.

112 PBS, *supra* note 46.

113 *Leary v. United States,* 395 U.S. 6 (1969); Yasmin Tayag, *Timothy Leary's Arrest for Marijuana Possession Still Matters 50 Years Later,* INVERSE (Mar. 13, 2016), https://www.inverse.com/artiele/12782-timothy-leary-s-arrest-for-marijuana-possession-still-matters-50-y ears-later.

II. How the Nixon Administration's Bigotry and Hostility toward War Protesters Contributed to Enactment of the CSA

Enactment of the CSA and the Mis-Classification of Cannabis as a Schedule I Drug

223. After the Supreme Court decision in *Leary,* the Nixon Administration urged Congress to enact legislation that would classify drugs under separate schedules according to their medical utility, dangerousness, and addictive potential.[114] Congress heeded the President's request by passing the CSA on October 27, 1970.[115]

224. At the request of the Nixon Administration and upon the temporary recommendation of the Department of Health, Education, and Welfare

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[114] Kevin A. Sabe, *The "Local" Matters: A Brief History of the Tension Between Federal Drug Laws and State and Local Policy,* J. Global drug Pol'y. & Prac. 4 (2006-2010), http://www.globaldrugpolicy.org/IssuesNol%201%20Issue%204/The%20Loca1%20Matters.pdf.

[115] *The Controlled Substances Act,* Pub. L. No. 91-513, 84 Stat. 1242, https://www.gpo.gov/fdsys/pkg/Statute-84/pdf/Statute-84-Pg1236.pdf.

("HEW"),[116] Congress placed "Marihuana"[117] under Schedule I, thereby "subject[ing Cannabis] to the most stringent controls under the bill."[118]

225. While "[t]here is almost total agreement among competent scientists and physicians that marihuana is not a narcotic drug like heroin or morphine . . . [and to] equate its risks with the risks inherent in the use of hard narcotics is neither medically or legally defensible[,]"[119] Congress nonetheless listed Cannabis under the same schedule as opiates and opium derivatives.[120]

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116 It should be noted that HEW recommended that Cannabis remain under Schedule I only "until the completion of certain studies now underway to resolve this issue." H.R. Rep. 91-1444 at 2111 (1970). However, despite HEW's temporary recommendation, President Nixon and his Administration subsequently ignored the CSA-required report (discussed *infra)* which (i) explored the pharmacological effects of Cannabis and (ii) recommended decriminalization of the personal use and possession of Cannabis.

117 "Under the CSA, "The term 'marihuana' means all parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin." Pub. L. No. 91-513, 84 Stat. 1244.

118 H.R. Rep. 91-1444 at 2063 (1970).

119 *Drug Abuse Control Amendment-1970: Hearings Before the Subcomm. on Public Health and We*lfare, 91 Cong. 179 (1970) (Statement of Dr. Stanley F. Yolles).

120 Pub. L. No. 91-513, 84 Stat. 1248-49.

226. The placement of Cannabis under Schedule I was intended by Congress to be temporary and subject to further research.[121]

227. The aforementioned and described "further research" was to be conducted by the National Commission on Marihuana and Drug Abuse—a commission established by the CSA for the purpose of studying, *inter alia,* Cannabis's pharmacological makeup and the relationship (if any) of its use to the use of other drugs (Shafer Commission, defined hereafter).[122]

228. Upon completion of its research, the Shafer Commission was required under the CSA to submit a comprehensive report to the President and to Congress within one year after it received funding to conduct its research.[123]

229. The aforementioned and described report was to consist of the Shafer Commission's findings as well as its recommendations and proposals for legislation and administrative actions with respect to Cannabis.[124]

230. President Nixon thereafter appointed Raymond Shafer (the former "law and order" Governor of Pennsylvania) to Chair the National Commission

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121 *See* H.R. Rep. 91-1444 at 2111 (1970); COMMON SENSE FOR DRUG POLICY, NIXON TAPES SHOW ROOTS OF MARIJUANA PROHIBITION: MISINFORMATION, CULTURE WARS AND PREJUDICE 1 (2002) [hereinafter "CSDP"].

122 Pub. L. No. 91-513, 84 Stat. 1281.

123 *Id.*

124 *Id.*

on Marihuana and Drug Abuse which consisted of Shafer and 12 other individuals, including four medical doctors and four members of Congress ("Shafer Commission").[125]

The Shafer Commission, Created Pursuant to the CSA, Recommends De-Scheduling Cannabis for Personal Use

231. The Shafer Commission conducted "more than 50 projects, ranging from a study of the effects of marihuana on man to a field survey of enforcement of the marihuana laws in six metropolitan jurisdictions."[126]

232. Among the Shafer Commission's findings were

(a) "No significant physical, biochemical, or mental abnormalities could be attributed solely to . . . marihuana smoking."[127]

(b) "No verification is found of a causal relationship between marihuana use and subsequent heroin use."[128]

(c) "[T]he weight of the evidence is that marihuana does not cause violent or aggressive behavior, if anything, marihuana

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125 NATIONAL COMMISSION ON MARIHUANA AND DRUG ABUSE, MARIHUANA: A SIGNAL OF MISUNDERSTANDING, at iv (1972).

126 *Id.* at 2.

127 *Id.* at 61.

128 *Id.* at 88.

serves to inhibit the expression of such behavior."[129]

(d) "Neither the marihuana user nor the drug itself can be said to constitute a danger to public safety."[130]

(e) "Most users, young and old, demonstrate an average or above-average degree of social functioning, academic achievement, and job performance."[131]

(f) "Marihuana's relative potential for harm to the vast majority of individual users and its actual impact on society does not justify a social policy designed to seek out and firmly punish those who use it."[132]

(g) Despite the media's portrayal of Vietnam War protesters as being violent while high on Cannabis, the vast majority of those protesters were peaceful and the few who were violent were not under the influence of Cannabis.[133]

(h) "The actual and potential harm of use of the drug is not great enough to justify intrusion by the criminal law into private behavior, a

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129 *Id.* at 73.

130 *Id.* at 61.

131 *Id.* at 96.

132 *Id.* at 130.

133 *Id.* at 99-100.

step which our society takes only with the greatest reluctance."[134]

(i) "[A]ll policy-makers have a responsibility to consider our constitutional heritage when framing public policy . . . we are necessarily influenced by the high place traditionally occupied by the value of privacy in our constitutional scheme. Accordingly, we believe that government must show a compelling reason to justify invasion of the home in order to prevent personal use of marihuana. We find little in marihuana's effects or in its social impact to support such a determination."[135]

233. The Shafer Commission recommended that possession of Cannabis for personal use be decriminalized on both the State and Federal levels.[136]

234. The Nixon Administration rejected the findings and recommendations by the Shafer Commission.

235. The Nixon Administration refused to accept the findings and recommendations by the Shafer Commission because they were not consistent with: (i) the preordained outcome Nixon demanded; and (ii) the Administration's agenda with respect to Cannabis, which was focused on racism and suppression of political and civil rights.

236. John Ehrlichman, who served as the Nixon Administration's Domestic Policy Chief and was one

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134 *Id.* at 140.

135 *Id.* at 142.

136 *Id.* at 151.

of the President's closest political advisors, confirmed that the enactment and enforcement of the CSA criminalizing Cannabis was directed toward political suppression and racial discrimination. In this regard, Mr. Ehrlichman said:

> You want to know what this was really all about? The Nixon campaign in 1968, and the Nixon White House after that, had two enemies: the antiwar left and black people. You understand what I'm saying? 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.

N.Y. *Daily News,* A. Edelman, *Nixon Aide: "War on Drugs" was tool to target "black people"* (March 23, 2016) (Exh. 3); *see also* Harper's Magazine, D. Baum, *Legalize it All: How to Win the War on Drugs* (April 2016) (Exh. 4) ("Nixon's invention of the war on drugs as a political tool was cynical . . . ").

237. Thus, the findings and recommendations of the Shafer Commission were irrelevant to Congress and the Nixon Administration, insofar as the purpose of the CSA was never to "protect" people from the supposed "scourge" of Cannabis use, but rather to harass, intimidate, prosecute and ultimately incarcerate those whom members of the Nixon Administration irrationally regarded as enemies.

238. The irrationality of the Nixon Administration's support for enactment of the CSA and rejection of the Shafer Commission's findings and recommendations is further revealed by tape recordings made by the former President of his Oval Office conversations.

239. Although ostensibly established for the purpose of properly educating lawmakers about Cannabis with respect to the issue of scheduling or decriminalization,[137] the Shafer Commission was resigned by the Nixon Administration to the status of a bureaucratic, kangaroo court.

240. Nixon repeatedly made clear that the real purpose of the Shafer Commission was to justify what he had already decided to do with respect to Cannabis, ultimately linking support for its decriminalization to Jews, whom Nixon irrationally claimed were mostly psychiatrists:

> NIXON: Now, this is one thing I want. I want a Goddamn strong statement on marijuana. Can I get that out of this sonofabitching, uh Domestic Council?
>
> HALDERMAN: Sure.
>
> NIXON: I mean, one on marijuana that just tears the ass out of them. I see another thing in the news summary this morning about it. You know, it's a funny thing—every one of the bastards that are out for legalizing marijuana is Jewish. What the Christ is the matter with the Jews, Bob? What's the matter with them? I suppose it's because

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137 H.R. Rep. 91-1444 at 2111 (1970); CSDP, *supra* note 121 at 1.

> most of them are psychiatrists, you know . . . .[138]

241. In September 1971, before his Commission's report was issued, Raymond Shafer visited the White House to speak with Nixon about a morale problem he was experiencing on the Commission—specifically, that the members of the Shafer Commission were concerned that it was "put together by a President to merely tow the party line . . . "[139]

242. In response, Nixon made absolutely clear that he did not care what the Shafer Commission's conclusions were.[140]

243. During Shafer's meeting with Nixon, the latter proceeded to direct the Shafer Commission to ignore the obvious differences between Cannabis, and heroin and other dangerous, addictive drugs:

> NIXON: I think there's a need to come out with a report that is totally, uh, uh, oblivious to some obvious, uh, differences between marijuana and other drugs, other dangerous drugs, there are differences.[141]

244. When Shafer tried to assure Nixon that the Commission would not go "off half-cocked," ostensibly promising to conclude that Cannabis should remain a Schedule I drug, along with drugs that actually were

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138 Tape Recording, May 26, 1971 (Conversation 505-4).

139 Tape Recording, September 9, 1971 (Oval Office Conversation No. 568-4).

140 *Id.*

141 *Id.*

(and are) dangerous, Nixon responded tersely, "Keep your Commission in line!"[142]

245. Nixon threatened Shafer with public recriminations, asserting that conclusions contrary to Nixon's demands "would make your Commission just look as bad as hell."[143]

246. Nixon's threats were not limited to Shafer and his Commission. When Nixon became aware that Bertram Brown, then-director of the National Institute of Mental Health, called for decriminalization of Cannabis, Nixon responded:

> Now, did you see this statement by [Bertram] Brown, the National Institute of Mental Health, this morning? Uh, he should be out. I mean today, today. If he's a presidential appointee, [what we should] do is fire the son of bitch and I mean today! Get the son of a bitch out of here.[144]

247. In that same conversation, Nixon also tied protesters to use of Cannabis:

> . . . these, uh, radical demonstrators that were here the last, . . . two weeks ago. They're all on drugs. Oh yeah, horrible, it's just a—when, I say "all," virtually all. And uh, uh, just raising hell.[145]

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142 *Id.*

143 *Id.*

144 Tape Recording, May 18, 1971 (Oval Office Conversation No. 500-17).

145 *Id.*

248. The so-called "radical demonstrators" to whom Nixon was referring were those opposed to the Vietnam War, which, at the time, deeply divided the Country.

249. When the Shafer Commission issued its findings and recommendations, which controverted the Nixon Administration's preordained conclusions and agenda against African Americans and war protesters, Nixon responded, predictably:

> Um, I met with Mr. Shafer, uh, I've read the report, uh, eh, it is a report that deserves consideration and will receive it. However, as to one aspect of the report I am in disagreement. I was before I read it, and reading it did not change my mind. Uh, I, uh, oppose the legalization of marijuana, and that includes the sale, its possession and its use.[146]

250. If incarceration of antiwar protestors and African Americans constitutes the measure of the War on Drugs' success, the Nixon Administration's efforts must be characterized as "successful." According to the *New York Daily News,* "by 1973, about 300,000 people were arrested under the law [the CSA]—the majority of whom were African American" (Exh. 3).

251. The Nixon Administration's anti-Cannabis policies thus were manifested in two distinct, but related, efforts—to usher the CSA through Congress and then to use the law as a tool to incarcerate, harass

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146 March 24, 1972 Press Conference (Oval Office Conversation No. 693-01).

and undermine those whom members of the Nixon Administration considered hostile to their interests.

252. Those who opposed Nixon's agendas were cast aside, vilified or ignored. The Shafer Commission's conclusions which conflicted with Nixon's plans were treated similarly.

III. The Evidence Confirms That, Despite the Language of the CSA and Nixon's Enforcement of It, the Federal Government Does Not and Has Never Believed That Cannabis Meets the Requirements of a Schedule I Drug

253. Under the CSA, drugs are classified by five Schedules, with Schedule I drugs identified as the most dangerous to human life, and Schedule V drugs regarded as the most benign.

254. Cannabis is classified as a Schedule I drug under the CSA.[147]

255. To meet the requirements of a Schedule I drug under the CSA, the following elements must all be met:

1. the drug has a high potential for abuse;
2. the drug has "no currently accepted medical use in the United States;" and
3. there is a lack of accepted safety for use of the drug even under medical supervision.[148]

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147 21 C.F.R. 1308.11(d)(23) and (31) (wrongly listed as a hallucinogenic drug, along with heroin, mescaline and LSD).

148 Pub. L. No. 91-513, 84 Stat. 1247.

(the Three Schedule I Requirements, previously defined).

256. The Federal Government does not genuinely believe that Cannabis meets the Three Schedule I Requirements.

257. The Federal Government cannot genuinely believe that Cannabis meets the Three Schedule I Requirements.

258. Upon information and belief, the Federal Government has never believed that Cannabis meets the Three Schedule I Requirements.

The Federal Government Has Authorized Dispensing Medical Cannabis to Patients for More than 30 Years

259. In or about 1978, the United States began subsidizing a program pursuant to which medical patients were provided with Cannabis, directly or indirectly, by the Federal Government.

260. The aforesaid and described program, which exists to this day, is known as the Investigational New Drug Program ("IND Program").

261. The first patient to receive Cannabis under the auspices of the IND Program was Robert Randall.

262. Upon information and belief, Mr. Randall used medical Cannabis provided under the auspices of the IND Program to treat his Glaucoma.

263. Thereafter, at least 12 other individuals participated in the IND Program and received Cannabis for treatment of an assortment of diseases and conditions.

264. Upon information and belief, the Federal Government, as of the date of this filing, continues to sponsor and/or provide medical Cannabis to patients pursuant to the IND Program.

265. Upon information and belief, the number of patients currently receiving medical Cannabis through the IND Program is eight.

266. Pursuant to the IND Program, the Federal Government has authorized the University of Mississippi to harvest acres and acres of Cannabis.

267. Upon information and belief, the acres of land harvested by University of Mississippi produce 50,000 to 60,000 Cannabis cigarettes per year.

268. Upon information and belief, none of the patients who have participated in the IND Program have suffered any serious side effects from their Cannabis treatments.

269. Upon information and belief, none of the patients who have participated in the IND Program have suffered any harm from their Cannabis treatments.

270. Upon information and belief, no Federal Agencies have ever collected any scientific data from the IND Program reflecting serious adverse impacts caused by Cannabis.

271. Upon information and belief, the Federal Government does not have any information suggesting that any of the patients who have participated in the IND Program have ever suffered any harm or serious side effects from their Cannabis treatments.

272. The Missoula Chronic Clinical Cannabis Use Study evaluated the long-term effects of heavy Cannabis use by four patients in the IND Program ("Missoula Study").

273. The Missoula Study demonstrated clinical effectiveness in these patients in treating Glaucoma, chronic musculoskeletal pain, spasm and nausea, and spasticity of multiple sclerosis.

274. All four patients who were the subject of the Missoula Study were stable with respect to their chronic conditions.

275. Upon information and belief, none of the four patients who were the subject of the Missoula Study suffered any serious side effects from their Cannabis treatments.

276. Upon information and belief, none of the four patients who were the subject of the Missoula Study suffered any harm from their Cannabis treatments.

277. Upon information and belief, the Federal Government does not have any information suggesting that any of the four patients who were the subject of the Missoula Study suffered any harm or serious side effects from their Cannabis treatments.

278. Upon information and belief, all four patients who were the subject of the Missoula Study were taking fewer standard pharmaceuticals than before they began treatment with medical Cannabis.[149]

279. The Missoula Study is one of thousands of studies which have confirmed that Cannabis provides

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149 http://—cannabis-med.org/jcant/russochronic_use.pdf.

measurable health benefits while resulting in minimal or no negative side effects.

United States Administrative Law Judge, Francis L. Young, Concludes That Cannabis Safely Provides Medical Benefits to Patients with an Assortment of Illnesses Without Serious Side Effects

280. In 1988, Administrative Law Judge Francis Young, *In the Matter of Marijuana Rescheduling,* DEA Docket No. 86-22, issued a determination arising from a petition by the National Organization for the Reform of Marijuana Laws ("NORML") to reschedule Cannabis ("ALJ Decision") (Exh. 5).

281. In determining whether to recommend rescheduling Cannabis under the CSA, Judge Young focused on two issues—(i) whether Cannabis "has a currently accepted medical use in treatment in the United States, or a currently accepted medical use with severe restrictions;" and (ii) "whether there is a lack of accepted safety for use of the marijuana plant, even under medical supervision" (*Id.* at 6).

282. The two issues analyzed by Judge Young focus on the latter two of the Three Schedule I Requirements necessary under the CSA to classify a drug as a "Schedule I" substance (*Id.* at 8; *see also* Pub. L. No. 91-513, 84 Stat. 1247).

283. If a drug has no medically-accepted use and cannot be safely used or tested even under medical supervision, it may qualify as a Schedule I drug; if the drug does not meet either of these Schedule I Requirements, it cannot be classified as a Schedule I drug (*Id.*).

248. In resolving these issues, Judge Young made a series of "findings of fact" (ALJ Decision at 10-26, 35-38, 40-54, 56-64, Exh. 5)

285. The aforesaid and described findings of fact by Judge Young were "uncontroverted" by the parties (ALJ Decision at 10, 54, 56, Exh. 5).

286. One of the aforesaid and described parties to the proceeding over which Judge Young presided was defendant DEA (ALJ Decision at 10).

287. Judge Young thereafter devoted the next 15 pages of the ALJ Decision to evidence adduced during the hearing process, confirming that Cannabis constitutes a recognized, well-accepted and superior method of treatment of cancer patients suffering from nausea, emesis and wasting (*Id.* at 10-25).

288. As part of his analysis, Judge Young cited to studies, patient histories, State legislative findings and other evidence of the medical efficacy of Cannabis (*Id.* at 10-26).

289. The DEA did not attempt to dispute the facts upon which the aforesaid analysis by Judge Young was based (*Id.* at 26).

290. Judge Young concluded, based upon "overwhelming" evidence, that:

> marijuana has a currently accepted medical use in treatment in the United States for nausea and vomiting resulting from chemotheraphy treatments in some cancer patients. To conclude otherwise, on this record, would be unreasonable, arbitrary and capricious (*Id.* at 34).

291. Judge Young proceeded to analyze the record with respect to the use of medical Cannabis for the treatment of multiple sclerosis, spasticity and hyperparathyroidism (*Id.* at 40-54).

292. After reviewing the extensive record, Judge Young concluded:

> [Marijuana has a currently accepted medical use in treatment in the United States for spasticity resulting from multiple sclerosis and other causes. It would be unreasonable, arbitrary and capricious to find otherwise (*Id.* at 54).

293. The DEA did not attempt to dispute the facts comprising the "extensive record" upon which Judge Young relied in reaching the aforesaid and described conclusion pertaining to the medical efficacy of Cannabis for the treatment of spasticity resulting from multiple sclerosis and other causes.

294. Judge Young similarly concluded that medical Cannabis provides therapeutic benefits to those suffering from hyperparathyroidism (*Id.* at 54-55).

295. The DEA did not attempt to dispute the facts comprising the "extensive record" upon which Judge Young relied in reaching the aforesaid and described conclusion pertaining to the medical efficacy of Cannabis for the treatment of hyperparathyroidism.

296. After concluding that Cannabis does, in fact, have currently-accepted medical uses, Judge Young turned to the issue of whether it may be used or tested safely under medical supervision—the third of the Three Schedule I Requirements (*Id.* at 56).

297. After reviewing the uncontroverted evidence, Judge Young ruled in a series of enumerated paragraphs that, not only is Cannabis not dangerous; it is extraordinarily safe. In this regard, Judge Young ruled:

> 4. Nearly all medicines have toxic, potentially lethal effects. But marijuana is not such a substance. There is no record in the extensive medical literature describing a proven, documented cannabis-induced fatality.
>
> 5. This is a remarkable statement. First, the record on marijuana encompasses 5,000 years of human experience. Second, marijuana is now used daily by enormous numbers of people throughout the world. Estimates suggest that from 20 million to 50 million Americans routinely, albeit illegally, smoke marijuana without the benefit of direct medical supervision. Yet, despite this long history of use and the extraordinarily high numbers of social smokers, there are simply no credible medical reports to suggest that consuming marijuana has caused a single death.
>
> 6. By contrast, aspirin, a commonly-used, over-the-counter medicine, causes hundreds of deaths each year.

Id. at 56-57 (emphasis added).

298. Judge Young found that, to induce a lethal response to Cannabis, the patient would be required to consume approximately 1,500 pounds of marijuana within 15 minutes—an amount and time frame which,

as a practical matter, are completely unrealistic (*Id.* at 57).

299. Judge Young thereafter concluded that:

> In strict medical terms, marijuana is far safer than many foods we commonly consume (*Id.* at 58) (emphasis added).

300. If these findings were not sufficiently damning to the CSA's mis-classification of Cannabis as a Schedule I drug, Judge Young made it even more clear when he wrote:

> Marijuana, in its natural form, is one of the safest therapeutically active substances known to man. By any measure of rational analysis, marijuana can be safely used within a supervised routine of medical care.

Id. at 58-59 (emphasis added).

301. Judge Young thereafter recommended that Cannabis be removed from Schedule I of the CSA (*Id.* at 66).

302. The DEA did not accept Judge Young's findings or recommendation.

303. The ALJ's Decision was issued years before 29 States and the District of Columbia legalized Cannabis for medical use; before eight States plus the District of Columbia legalized Cannabis for recreational use; before two U.S. Territories approved the use of whole-plant Cannabis.

States Begin to Legalize Cannabis

304. In 1996, California became the first State to legalize Cannabis for medical use.

305. Oregon, Alaska and Washington (State) followed soon thereafter and also legalized Cannabis for medical use.

306. Today, the following States have legalized Cannabis for medical and/or recreational use:

- California
- Oregon
- Alaska
- Washington (State)
- Maine
- Hawaii
- Colorado
- Nevada
- Montana
- Vermont
- New Mexico
- Michigan
- New Jersey
- Arizona
- Massachusetts
- New York
- Maryland
- Minnesota
- Florida
- Delaware

- Ohio
- Pennsylvania
- Illinois
- North Dakota
- Arkansas
- Connecticut
- New Hampshire
- Rhode Island
- West Virginia

307. In addition to the States, the following territories, protectorates and other areas under United States jurisdiction have legalized Cannabis for medical and/or recreational uses:

- Washington, DC[150]
- Puerto Rico
- Guam

308. The method of legalization of Cannabis by States and other areas within Federal jurisdiction has

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150 Although initially barring Washington, DC from implementing a medical Cannabis program in or about 1998, Congress took no action to prevent enactment of a medical legalization program in our Nation's Capitol in 2011. Thus, Washington, DC was able to institute a medical Cannabis program in 2011. Thereafter, in 2014, Washington, DC approved a decriminalization program for Cannabis. Although subjected to a mandatory 30-day review period to be undertaken by Congress under the District of Columbia Home Rule Act, Congress took no action. Thus, although afforded the opportunity to stop implementation of Washington, DC's decriminalization program, Congress decided not to do so.

varied from State constitutional amendment, to legislative enactment, to voters' referenda.

309. Today, more than 62% of Americans live within a jurisdiction in which Cannabis is legal to consume for medical and/or other purposes.

310. California, the world's sixth largest economy, has legalized Cannabis for recreational purposes as well.

311. State-legal Cannabis has been available to millions of Americans for decades.

312. Cannabis has been available illegally (*i.e.*, on the "black market") to millions of Americans for approximately 100 years.

313. Upon information and belief, no credible medical report has confirmed a single fatality in the United States from the consumption of Cannabis.

314. By contrast, the following "legal" substances have caused the following number of deaths in the United States on an annual basis:

(a) tobacco-480,000 deaths per year;[151]

(b) alcohol—88,000 deaths per year;[152]

(c) pharmaceutical opioid analgesics—18,893 per year;[153]

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151 https://www.cdc.gov/tobacco/data_statistics/fact_sheets/health_effects/tobacco_related_mortality/index.html

152 https://www.niaaa.nih.gov/alcohol-health/overview-alcohol-consumption/alcohol-facts-and-statistics

153 hitps://www.edc.gov/nchs/data/factsheets/factsheet_drug_poisoning.pdf.

(d) acetaminophen—1,500 deaths from 2001 to 2010.[154]

The Federal Government Admits and Obtains a Medical Patent Based Upon its Assertion That Cannabis Provides Medical Benefits

315. In or about 1999, the United States Government filed a patent application, entitled:

CANNABINOIDS AS ANTI-OXIDANTS AND NEUROPROTECTANTS

See Exh. 6 ("U.S. Cannabis Patent") (capitalization and underscoring in original).

316. In the U.S. Cannabis Patent application ("U.S. Cannabis Patent Application"), the Federal Government made representations to the United States Patent and Trademark Office ("USPTO") relative to the effects of Cannabis on the human body (*Id.)*.

317. In the U.S. Cannabis Patent Application, the Federal Government represented to the USPTO that Cannabis provides medical benefit to, and thus has medical uses for, patients suffering with an assortment of diseases and conditions. In this regard, the Federal Government asserted that:

> Cannabinoids have been found to have antioxidant properties, unrelated to NMDA receptor antagonism. This new found property makes cannabinoids useful in the treatment

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154 http://wwwhuffingtonpost.com.2013/09/24/tylenol-overdose_n_3976991.html. This does not include the 78,000 Americans who are rushed to emergency rooms annually, or the 33,000 hospitalizations in the United States each year, all due to ingestion of acetaminophen. *Id.*

> and prophylaxis of wide variety of oxidation associated diseases, such as ischemic, age-related, inflammatory and autoimmune diseases. The cannabinoids are found to have particular application as neuroprotectants, for example, in limiting neurological damage following ischemic insults, such as stroke and trauma, or in the treatment of neurodegenerative diseases, such as Alzheimer's Disease, Parkinson's Disease, and HIV Dementia (*Id.* at Abstract).

318. In support of its U.S. Cannabis Patent Application, the Federal Government cited a series of studies and academic papers, which, the Federal Government represents, support its conclusion that Cannabis does, in fact, provide medical benefits, including conditions which are listed and which are not listed on the U.S. Cannabis Patent Application (*Id.*).

319. The U.S. Cannabis Patent Application directly and unmistakably controverts the Federal Government's continued classification of Cannabis as a Schedule I drug, which, it is emphasized, requires a finding that it lacks any medical use.

320. Simply put—the Federal Government cannot maintain, on its U.S. Cannabis Patent Application, that Cannabis does, in fact, have curative properties that provide medical benefits to patients suffering from an assortment of diseases while also simultaneously "finding" that Cannabis has no medical application

whatsoever for purposes of application and enforcement of the CSA.[155]

The Justice Department Issues Guidelines for Prosecution of Medical Cannabis Patients (2009)

321. As State-legal Cannabis legislation and other approvals of medical Cannabis continued to pass throughout the United States, the Federal Government was confronted with a problem—under the CSA, the cultivation, harvesting, extraction, distribution, sale and/or use of Cannabis was (and is) illegal; however, States were granting their citizens permission to cultivate, distribute, sell, and/or use Cannabis for medical purposes.

322. On or about October 19, 2009, defendant DOJ, while professing the importance of enforcing the CSA as it pertains to Cannabis, acknowledged the existence of State laws authorizing the use of "medical marijuana," and directed that United States Attorneys:

> should not focus federal resources in your States on individuals whose actions are in clear and unambiguous compliance with existing State laws providing for the medical use of marijuana. For example, prosecution of individuals with cancer or other serious illnesses who use marijuana as part of a recommended treatment regimen consistent with applicable State law, or those caregivers in clear and unambiguous compliance with

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155 Because the U.S. Cannabis Patent was granted by the USPTO, the Federal Government is estopped from contesting the assertions contained in its Application.

> existing state law who provide such individuals with marijuana, is unlikely to be an efficient use of limited federal resources.

See October 19, 2009 Memorandum by Deputy Attorney General of the United States, David W. Ogden ("Ogden Memorandum"), Exh. 7.

323. Thus, notwithstanding the provisions of the CSA, prohibiting cultivation, distribution, sale, possession and/or use of Cannabis, as a drug so dangerous that it cannot be tested under strict medical supervision, the DOJ expressly discouraged United States Attorneys from using federal resources to prosecute violations of the CSA by users of Cannabis for medical purposes in State-legal jurisdictions.

The Justice Department Adopts the Cole Memorandum

324. On or about August 29, 2013, defendant DOJ promulgated what has come to be known as the "Cole Memorandum" (Exh. 8).

325. Under the Cole Memorandum, the DOJ, consistent with the Ogden Memorandum, officially recognized that patients using State-legal-medical Cannabis, in accordance with the laws of the States in which they reside, and businesses cultivating and/or selling State-legal Cannabis for medical purposes, are not appropriate targets for federal investigation, prosecution and incarceration (*Id. at* 3).

326. The net effect of the Cole Memorandum was to inform medical-Cannabis businesses operating in accordance with the laws of the States in which such businesses operate, and patients who use medical Cannabis in accordance with the laws of the States in which such patients reside, that they would not be

prosecuted, provided that such Cannabis businesses and medical Cannabis patients did not engage in conduct which encroached upon eight (8) specific federal priorities, identified in the Cole Memorandum as follows:

1. Preventing the distribution of marijuana to minors;
2. Preventing revenue from the sale of marijuana from going to criminal enterprises, gangs, and cartels;
3. Preventing the diversion of marijuana from States where it is legal under State law in some form to other States;
4. Preventing State-authorized marijuana activity from being used as a cover or pretext for the trafficking of other illegal drugs or other illegal activity;
5. Preventing violence and the use of firearms in the cultivation and distribution of marijuana;
6. Preventing drugged driving and the exacerbation of other adverse public health consequences allegedly associated with marijuana use;
7. Preventing the growing of marijuana on public lands and the supposed attendant public safety and environmental dangers posed by marijuana production on public lands; and
8. Preventing marijuana possession or use on federal property.

See Cole Memorandum, Exh. 8.

The Treasury Department Provides Federal Authorization to Banks to Transact with Cannabis Businesses

327. On February 14, 2014, the Financial Crimes Enforcement Network ("FinCEN") issued a Memorandum providing guidance to clarify Bank Secrecy Act ("BSA") expectations for financial institutions seeking to provide services to marijuana-related businesses ("FinCen Guidance") (Exh. 9 at 1).

328. FinCEN issued the FinCEN Guidance "in light of recent state initiatives to legalize certain marijuana-related activity and related guidance by the DOJ [*i.e.*, the Cole Memorandum] concerning marijuana-related enforcement priorities" (*Id.*).

329. In essence, the FinCEN Guidance was the Treasury Department' s own version of the Cole Memorandum, except that the FinCEN Guidance was sent to private actors (banks and other financial institutions), informing them how it is that they can transact with Cannabis businesses—businesses that are technically illegal under the CSA.

330. FinCEN provides guidance and advice to banks and other financial institutions concerning how they can engage in conduct which is illegal under the CSA, as well as under 18 U.S.C. § 1956 (laundering of monetary instruments).

331. By the FinCEN Guidance, the Treasury Department provided, *inter alia,* the following instructions on how to transact with Cannabis businesses:

> The Financial Crimes Enforcement Network [ ] is issuing guidance to clarify Bank Secrecy Act ("BSA") expectations for financial

> institutions seeking to provide services to marijuana-related businesses. FinCEN is issuing this guidance in light of recent state initiatives to legalize certain marijuana-related activity and related guidance by the U.S. Department of Justice ("DOJ") concerning marijuana-related enforcement priorities. This FinCEN guidance clarifies how financial institutions can provide services to marijuana-related businesses consistent with their BSA obligations, and aligns the information provided by financial institutions in BSA reports with federal and state law enforcement priorities. This FinCEN guidance should enhance the availability of financial services for, and the financial transparency of, marijuana-related businesses.

See FinCEN Guidance at 1 (Exh. 9) (emphasis added).

332. Under the provisions of the FinCEN Guidance, the Federal Government provided authorization to banks and other financial institutions to transact with Cannabis businesses.

333. Under the provisions of the FinCEN Guidance, the Treasury Department directed that financial institutions, prior to engaging in transactions with medical Cannabis businesses, undertake due diligence to ascertain whether the latter are operating in conformity with the provisions of the Cole Memorandum (*Id.*).

334. The Ogden Memorandum, Cole Memorandum and FinCEN Guidance each state, in form and substance, that the CSA has not been superseded and

remains in effect; however, each aforesaid Memorandum/Guidance makes equally clear that the United States Government should not interfere with State-legal medical-Cannabis businesses, and should not otherwise enforce the CSA as against such businesses or the patients who use the products cultivated and dispensed by such businesses, provided that all such businesses and patients act in conformity with the laws of the States in which such businesses operate and in which such patients reside.

335. The 2009 Ogden Memorandum, 2013 Cole Memorandum and 2014 FinCEN Guidance cannot be reconciled with the Federal Government's classification of Cannabis as a Schedule I drug that is so dangerous that it has no medical purpose and cannot be tested even under strict medical supervision.

The United States Surgeon General Acknowledges Medical Benefits of Cannabis Use/The DEA Removes a Series of False Statements Concerning Cannabis from its Website

336. On or about February 4, 2015, the then-United States Surgeon General, Dr. Vivek Murthy, appeared on CBS This Morning, a nationally-televised daily talk show.

337. While on CBS This Morning, the U.S. Surgeon General publicly acknowledged that Cannabis can safely provide bonafide medical benefits to patients ("Surgeon General's Acknowledgment").

338. The DEA, earlier this year, removed from its website: all references to Cannabis as a supposed "gateway drug;" as a drug that causes "permanent

brain damage;" and as a drug that leads to psychosis ("DEA's Website Revision").

339. The DEA's Website Revision is consistent with the Surgeon General's Acknowledgment.

340. Prior to the DEA' s Website Revision, a petition was filed on behalf of Americans for Safe Access, alleging that the DEA's website contained false information ("ASA Petition") (Exh. 10).

341. The ASA Petition was filed under the Information Quality Act ("IQA") (*Id.*).

342. Under the IQA, Federal Agencies are required to devise guidelines to ensure the "quality, objectivity, utility, and integrity of information" they disseminate.[156]

343. These requirements are designed to ensure that, *inter alia,* the information contained on the websites maintained by Federal Agencies is accurate.

344. Upon information and belief, it was in response to the ASA Petition, asserting that the information contained on the DEA website was inaccurate, that the DEA effected its Website Revision. In other words, the DEA, rather than litigating the inaccuracy of the information contained on its website, changed that information and effected its Website Revision in recognition that the language asserting that Cannabis is a supposed "gateway drug" that causes psychosis and permanent brain damage was and is false.[157]

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156 44 U.S.C. § 3516, Statutory and Historical Notes.

157 The FDA also removed all references to Cannabis as a supposed "gateway drug" on its website.

Congress Precludes the DOJ from Using Legislative Appropriations to Prosecute State-Legal Cannabis Cultivation, Distribution, Sale and Use

345. In December 2014, Congress enacted a rider to an omnibus appropriations bill, funding the Federal Government through September 30, 2015 ("2014 Funding Rider").

346. Under the 2014 Funding Rider, Congress expressly prohibited the DOJ from using the appropriations provided thereby to prosecute the use, distribution, possession or cultivation of medical Cannabis in States where such activities are legal.

347. The 2014 Funding Rider includes the following language:

> None of the funds made available in this Act to the Department of Justice may be used, with respect to the States of Alabama, Alaska, Arizona, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Hawaii, Illinois, Iowa, Kentucky, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nevada, New Hampshire, New Jersey, New Mexico, Oregon, Rhode Island, South Carolina, Tennessee, Utah, Vermont, Washington, and Wisconsin, to prevent such States from implementing their own State laws that authorize the use, distribution, possession, or cultivation of medical marijuana.

See Consolidated and Further Continuing Appropriations Act, 2015, Pub. L. No. 113-235, § 538, 128 Stat. 2130, 2217 (2014).

348. The States referenced in the 2014 Funding Rider are those that, as of the date of the 2014 Funding Rider, had established State-legal medical Cannabis programs.

349. Various short-term measures extended the 2014 Funding Rider through December 22, 2015.

350. On December 18, 2015, Congress enacted a new appropriations act, which appropriated funds through the fiscal year ending September 30, 2016, and included essentially the same rider as the 2014 Funding Rider. Consolidated Appropriations Act, 2016, Pub. L. No. 114-113, § 542, 129 Stat. 2242, 2332-33 (2015) (adding Guam and Puerto Rico and changing "prevent such States from implementing their own State laws" to "prevent any of them from implementing their own laws").

351. In 2017, Congress enacted another rider, updating the 2014 Funding Rider to include the States that added medical-Cannabis programs over the preceding three years, and again restricting the use of Congressional appropriations to prosecute only those violations of the CSA in which the defendants cultivate, distribute, and/or sell Cannabis in a manner that violates State-legal medical marijuana programs ("2017 Funding Rider"). In this regard, the 2017 Funding Rider states:

> None of the funds made available in this Act to the Department of Justice may be used, with respect to any of the States of Alabama, Alaska, Arkansas, Arizona, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Iowa, Kentucky, Louisiana, Maine, Maryland, Massachusetts,

> Michigan, Minnesota, Mississippi, Missouri, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, and Wyoming, or with respect to the District of Columbia, Guam, or Puerto Rico, to prevent any of them from implementing their own laws that authorize the use, distribution, possession, or cultivation of medical marijuana.

See Consolidated Appropriations Act, 2017, Pub. L. No. 115-31, § 537 (2017).

IV. Summary of the Allegations and Evidence That the Federal Government Does Not and Cannot Believe That Cannabis Meets the Three Schedule I Requirements

352. The net effect of the foregoing allegations and evidence confirms beyond serious question that the Federal Government does not and cannot believe that Cannabis: (i) has no medical use, and (ii) cannot be used or tested even under strict medical supervision. Indeed, it bears emphasis that Cannabis:

- has been widely used as a legal medication for more than 10,000 years, including by the Founding Fathers of this Country;
- was legal until the end of Prohibition threatened to leave Anslinger without any responsibilities;
- was found by the Shafer Commission to be safe enough to decriminalize for personal use;

- has been dispensed by the Federal Government to participants in the IND Program for more than 30 years without evidence of harm to any of the patients;
- was found by ALT Young to be the safest drug available in the world, based upon evidence that the DEA never attempted to contest;
- has been used continuously as part of State-legal programs for medical purposes throughout the United States, beginning in 1996;
- has been available to millions of Americans on a daily basis for decades without a single fatality—a record that neither coffee nor aspirin can claim;
- is the subject of the successful U.S. Cannabis Patent Application, in which the Federal Government admitted (indeed, bragged) that Cannabis provides safe, medical benefits to patients suffering from an assortment of illnesses, diseases and conditions;
- was identified by the U.S. Surgeon General as having medical benefits-a conclusion that has been separately reached by doctors, scientists, and academics during the course of conducting thousands of studies and tests;
- cannot be the subject of a federal criminal prosecution under the CSA unless cultivated, distributed, sold or used in violation of State law; and
- is the subject of established federal policy which recognizes the medical benefits of Cannabis.

353. Indeed, the notion that the Federal Government persists in classifying Cannabis as a Schedule I drug, while ignoring the undeniable addictive and lethal chemical properties of nicotine and tar, and alcohol, which kill millions of Americans every year, renders this misclassification of Cannabis utterly irrational and absurd.

V. The Petitioning Process Is Illusory and Futile

Prior Petitions to Re-Schedule and/or De-Schedule Cannabis

354. Under the CSA, members of the public are afforded the supposed opportunity to file petitions to request that medications and drugs be re-scheduled and/or de-scheduled. 21 U.S.C. § 811 and 21 C.F.R. § 1308.

355. The legal mechanism available to the public to file petitions to change the classification of drugs and medications previously scheduled under the auspices of the CSA is illusory. Petitions filed with the DEA and/or any other Federal agency linger for years, often decades, without any substantive action.

356. The following chart of petitions filed with the DEA, reflects the futility of the petitioning process:

Requested Action	Transfer any injectable liquid containing Pentazocine (opioid derivative) from Schedule V to Schedule III
Type of Petitioner(s)	7 Individuals

Date Filed	10/5/1971
Date Decided	1/10/1979
Delay	8 years
Outcome	Denied

Requested Action	Remove Cannabis from Schedule I or transfer to Schedule V
Type of Petitioner(s)	NORML, Cannabis Corporation of America (CCA); Alliance for Cannabis Therapeutics (ACT); Individuals
Date Filed	5/18/72
Date Decided	3/26/92
Delay	20 years
Outcome	Denied
Requested Action	Transfer Cannabis from Schedule I to Schedule II
Type of Petitioner(s)	Individual
Date Filed	9/6/92
Date Decided	5/16/94
Delay	N/A

Outcome	DEA declined to accept the filing of the petition

Requested Action	Transfer Marinol from Schedule II to Schedule III
Type of Petitioner(s)	UNIMED Pharmaceutica Is Inc. (manufacturer of Marinol)
Date Filed	2/3/95
Date Decided	7/2/99
Delay	4 years
Outcome	Granted

Requested Action	Remove Cannabis from Schedule I
Type of Petitioner(s)	Individual; High Times Magazine
Date Filed	7/10/95
Date Decided	3/20/01
Delay	5.5 years
Outcome	Denied

Requested Action	Remove Cannabis containing 1 % or less of THC Schedule I

	when used for Industrial Hemp
Type of Petitioner(s)	Individual
Date Filed	3/23/98
Date Decided	12/19/00
Delay	2.5 years
Outcome	Denied

Requested Action	Transfer Hydrocodone combination products (i.e., products mixing Hydrocodone with other drugs) from Schedule III to Schedule II
Type of Petitioner(s)	Physician
Date Filed	Jan 99
Date Decided	8/22/14
Delay	15.5 years
Outcome	Granted

Requested Action	Transfer Cannabis to Schedule III, IV, or V
Type of Petitioner(s)	The Coalition for Rescheduling Cannabis
Date Filed	10/9/02

Date Decided	6/21/11
Delay	8.75 years
Outcome	Denied

Requested Action	Remove Cannabis from Schedule I
Type of Petitioner(s)	Individual
Date Filed	May 12, 2008
Date Decided	Dec 19, 2008
Delay	N/A
Outcome	DEA declined to accept the filing of the petition

Requested Action	Transfer Cannabis to any Schedule other than Schedule I
Type of Petitioner(s)	Individual
Date Filed	12/17/09
Date Decided	7/19/16
Delay	6.45 years
Outcome	Denied

Requested Action	Transfer Cannabis to Schedule II
Type of Petitioner(s)	Governors Chafee & Gregoire
Date Filed	11/30/11
Date Decided	7/19/16
Delay	5.45 years
Outcome	Denied

Requested Action	Remove Industrial Hemp plants (i.e., Cannabis sativa L. plants with a THC concentration of not more than three tenths of one percent) from Schedule I
Type of Petitioner(s)	Hemp Industries Association ("HIA") & the Kentucky Hemp Industry Council
Date Filed	6/1/16
Date Decided	Pending
Delay	N/A
Outcome	Pending

The Petition Process for Changes in the Classification of Cannabis is Futile, Rife with Delays, Subject to Systemic and Institutional Bias and Otherwise Constitutes a Hollow Remedy

357. Excluding the petitions which are either still pending or were never decided at all (because they were rejected based upon standing or other grounds), the average delay from filing a petition to reschedule a drug under the CSA to the date of the petition's resolution is approximately nine (9) years.

358. Persons seeking to re-classify a Schedule I drug or medication based upon an urgent medical need, including and especially, Alexis and Jagger, are resigned to waiting until ostensibly the drug would no longer serve any useful purpose, because the illness, disease and/or condition has resolved or the patient has died.

359. The petitioning process is a hollow remedy.

360. Worse than the entrenched, systemic delays imposed by the Federal Government is the institutional bias of government officials which all but assures denial of applications pertaining to Cannabis.

361. As referenced *supra*, in November 2015, defendant Rosenberg of the defendant DEA, which is responsible for responding to petitions to reclassify drugs under the CSA, publicly asserted that medical Cannabis is "a joke"—essentially pre-judging any petition to re-schedule or de-schedule Cannabis.

362. As reported by Politico, defendant Sessions, "[a]s a U.S. Attorney in Alabama in the 1980s, [ ] said he thought the KKK 'were [sic] OK until I found out they smoked pot.'"

363. On December 5, 2016, Politico reported that, in April 2016, defendant Sessions disclosed that he believes that: "Good people don't smoke marijuana."

364. As the Attorney General of the United States, defendant Sessions would have the opportunity to reclassify Cannabis; however, as with defendant Rosenberg, defendant Sessions has pre-judged the issue.

365. Upon information and belief, Rosenberg did not review any medical or scientific studies prior to asserting, in or about November 2015, that medical Cannabis is a joke.

366. Upon information and belief, Sessions did not review any medical or scientific studies prior to issuing his statement in the 1980s, in which he said that he thought the KKK "were [sic] OK until I found out they smoked pot."

367. Upon information and belief, Sessions did not review any medical or scientific studies prior to issuing his statement on or about December 5, 2016 that "Good people don't smoke marijuana."

368. Upon information and belief, defendants Sessions and Rosenberg, in condemning medical Cannabis and those who recommend and/or use it, were not speaking from experience or an in-depth medical or scientific understanding of the chemical properties of Cannabis and its impact on the body's metabolic systems and processes; nor were their assertions the product of an analysis concerning whether medical Cannabis has been accepted by the medical community. Rather, the opinions of defendants Sessions and Rosenberg are based upon political (not scientific) distinctions made by a diminishing minority

of vocal public officials who, without conducting any scientific review or analysis, assume that any conduct associated with Cannabis is necessarily dangerous and otherwise bad based upon unconstitutional criteria.

369. The unconscionable delays in processing petitions, coupled with the institutional bias at the DOJ and DEA against re-classifying Cannabis, renders the petitioning process illusory and futile. In short, the Federal Government does not provide real "due process" to those aggrieved by the misclassification of Cannabis under the CSA. This lawsuit is the only mechanism by which patients in need of medical Cannabis can lawfully and without risk of prosecution safely obtain and use it.

370. Even assuming *arguendo* that the petitioning process were not futile—and it is—it would not provide a meaningful remedy for Plaintiffs insofar as the petition process: (i) cannot resolve the substantial constitutional issues which Defendants have repeatedly declined to address in a manner consistent with the provisions of the United States Constitution; and (ii) cannot provide Plaintiffs with a genuine opportunity for adequate relief (specifically, a declaration that the CSA, as it pertains to Cannabis, is unconstitutional), insofar as the relief requested herein is beyond the authority of Defendants DEA, DOJ, Sessions and/or Rosenberg.

FIRST CAUSE OF ACTION
(on behalf of all Plaintiffs)

371. Plaintiffs repeat and reallege each and every allegation of the preceding ¶¶ 1-370, as if set forth fully herein.

372. Under the Due Process Clause of the Fifth Amendment, no person may be "deprived of life, liberty or property without due process of law" ("Due Process Clause").

373. Under well-established constitutional jurisprudence, laws which are not rationally related to a legitimate interest of the Federal Government violate the Due Process Clause.

374. The CSA classifies drugs into five scheduled categories—Schedule I, Schedule II, Schedule HI, Schedule IV, and Schedule V.[158]

375. Cannabis has been classified as a Schedule I drug, along with, among others, heroin, mescaline, and LSD. As such, under the CSA as it pertains to Cannabis, the cultivation, distribution, prescription, sale, and/or use of Cannabis constitutes a violation of Federal Law, subjecting those accused of such a crime to prosecution and incarceration.

376. The stated basis for enactment and implementation of the CSA as it pertains to Cannabis was that the drug meets the Three Schedule I Requirements, *i.e.*:

1. the drug has a high potential for abuse;
2. the drug has "no currently accepted medical use in the United States;" and
3. there is a lack of accepted safety for use of the drug even under medical supervision.[159]

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158 Pub. L. No. 91-513, 84 Stat. 1247.

159 *Id.*

377. In view of the facts and evidence set forth above and summarized below, the Federal Government does not believe that Cannabis meets the aforementioned Three Schedule I Requirements.

378. Cannabis has been cultivated and used as a medication for thousands of years.

379. Cannabis was cultivated and used as a medication in Colonial America and in post-Colonial America, including by the Framers of our Constitution.

380. Cannabis was cultivated and used throughout the 19th Century, during which it was one of America's three leading crops for cultivation.

381. Cannabis was listed in prominent pharmacological publications throughout the second half of the 19th Century and the beginning of the 20th Century as a medication that treats dozens of diseases and conditions.

382. The Shafer Commission confirmed that Cannabis is not dangerous and should be decriminalized for personal use.

383. Since in or about 1978, the Federal Government has been continuously dispensing and/or authorizing the dispensing of Cannabis to between at least 8 to 13 patients for the treatment of an assortment of diseases, illnesses and medical conditions.

384. In 1988, ALJ Francis Young, after a review of the uncontroverted medical evidence, concluded that Cannabis provides medical benefits to patients, none of whom have been endangered by it (Exh. 5).

385. Beginning in 1996, States throughout the Country have instituted medical and recreational Cannabis programs without federal intervention.

386. Today, more than 62% of the American public resides in States in which whole-plant Cannabis is legal for medical and/or recreational purposes; thus, millions of Americans have the opportunity to use Cannabis on a daily basis.

387. Upon information and belief, there have never been any documented deaths in the United States due to the consumption of Cannabis.

388. Since 2009, the DOJ has consistently directed its U.S. Attorneys to refrain from prosecuting patients, physicians-and businesses involved in the use, cultivation and/or sale of Cannabis if the same is consistent with State-legal medical-Cannabis programs (Exhs. 8 and 9).

389. Since 2014, the Treasury Department has authorized banking and other financial institutions to engage in transactions with Cannabis businesses that act in conformity with State-legal medical-Cannabis programs (Exh. 9).

390. For the last three years, Congress has defunded the DEA and DOJ from prosecuting individuals and businesses engaging in conduct that is consistent with State-legal medical-Cannabis programs.

391. In or about 2002, the United States Government repeatedly asserted in its U.S. Cannabis Patent Application that, based upon a series of scientific studies, Cannabis has accepted medical uses for the treatment of brain diseases and disorders (Exh. 6).

392. After obtaining a U.S. Cannabis Patent, the Federal Government executed license agreements to private businesses to engage in medical Cannabis cultivation and extraction.

393. While the Federal Government may conceivably argue that the initial and continued classification of Cannabis as a Schedule I drug is necessary because of its alleged high potential for abuse, supposed lack of medical use, and purported risks of potential harm to those who use it even under medical supervision, the foregoing history confirms that the United States Government does not believe the story it is telling.

394. Based upon the foregoing, the Federal Government, not only does not believe that Cannabis meets the Three Schedule I Requirements of the CSA, but further, upon information and belief, no rational person could reasonably believe that it meets such Requirements.

395. There is no credible evidence that Cannabis has a high potential for abuse.

396. There is no credible evidence that Cannabis lacks any medical benefit; to the contrary, the overwhelming weight of evidence confirms that Cannabis has, for millennia, from Ancient Chinese and Egyptian societies, to our Founding Fathers, to modern-day America, provided substantial medical benefits to the patients who have been treated with medical Cannabis.

397. There is no credible evidence that Cannabis poses a serious risk of harm when used under medical supervision; to the contrary, the overwhelming weight of evidence confirms that, although virtually all

medications have some toxic, potentially lethal effects, "marijuana is not such a substance" (ALJ Decision at 56, Exh. 5). And no one in the United States has ever died from using Cannabis (*Id.*).[160]

398. Because Cannabis does not meet the criteria required for classification of a Schedule I drug and is, in fact, safe for use, and because the Federal Government is fully aware of the foregoing but nonetheless insists upon continuing the misclassification of Cannabis as a Schedule I drug, the CSA and its implementation is irrational, arbitrary, capricious and is not rationally related to any legitimate government interest.

399. The only credible explanation for the enactment of the CSA and its subsequent and continuing enforcement by the Federal Government lies in the politically-repressive, xenophobic and racial animus described by John Ehrlichman and other members of the Nixon Administration—an animus proscribed by the Constitution of the United States.

400. As set forth above, the petitioning process for drug scheduling does not constitute "due process" within the meaning of the Fifth Amendment to the Constitution, insofar as the petition process: (i) is rife with unconstitutional delays that render review impracticable for the Plaintiffs {and most medical Cannabis patients); (ii) is rife with institutional bias, by which a vocal minority of public officials refuse to consider the overwhelming weight of medical evidence establishing that Cannabis provides safe medical benefits; (iii) cannot resolve the substantial constitutional issues which Defendants have repeatedly declined to

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160 This allegation does not include reference to those who may have used black-market synthetic Cannabis.

address in a manner consistent with the provisions of the United States Constitution; and (iv) cannot provide Plaintiffs with a genuine opportunity for adequate relief, insofar as the relief requested requires correcting an Act of Congress which is beyond the authority of Defendants DEA, DOJ, Sessions and/or Rosenberg.

401. Alexis, Jose, and Jagger need medical Cannabis for the treatment of their diseases and conditions, but cannot safely use it without risking their freedom or other rights to which they are legally and constitutionally entitled. Washington desires to open a Cannabis business through the use of the MBE Program, but cannot do so, as he would be ineligible to receive such benefits and would be risking potential incarceration were he to file the required paperwork for MBE benefits. The CCA seeks, on behalf of its membership, termination of disproportionate enforcement of the CSA as it pertains to Cannabis against persons of color. Defendants maintain, notwithstanding the overwhelming weight of the evidence in the record (including statements made by the Federal Government itself that Cannabis has curative properties and is safe), that Cannabis is somehow an addictive, dangerous and lethal drug on par with heroin, mescaline and LSD without any medical benefits whatsoever and thus must remain illegal and continue to be enforced in the manner practiced today.

402. Meanwhile, substances that undeniably provide no medical benefit whatsoever, are highly addictive and cause hundreds of thousands of deaths per year, including for example, tobacco, remain widely available and un-scheduled under the CSA.

403. An actual case in controversy exists between Plaintiffs and Defendants, by which Plaintiffs need and/or desire to use and/or engage in business transactions involving Cannabis, whereas Defendants falsely and unconstitutionally maintain that possession and use of Cannabis is lethally dangerous and thus must remain illegal.

404. By reason of the foregoing, Plaintiffs are entitled to issuance of an order and judgment: (i) declaring that the CSA, as it pertains to Cannabis, is irrational, arbitrary, capricious and not rationally related to any legitimate governmental interest, and thus unconstitutional; and (ii) permanently enjoining Defendants from enforcing the CSA.

405. Plaintiffs have no remedy at law.

SECOND CAUSE OF ACTION
(on behalf of the CCA Only)

406. Plaintiffs repeat and reallege each and every allegation of the preceding ¶¶ 1-405, as if set forth fully herein.

407. The United States Supreme Court has consistently held that discrimination may be so unjustifiable as to constitute a violation of the Due Process Clause of the Fifth Amendment.[161]

408. The mis-classification of Cannabis as a Schedule I drug under the CSA was effectuated in an environment tainted by racial discrimination and

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161 *Davis v. Passman,* 442 U.S. 228, 234-35 (1979); *Weinberger v. Wiesenfeld,* 420 U.S. 636, 638 n. 2 (1975); *Cruz v. Hauck,* 404 U.S. 59, 62 n. 10 (1971); *Bolling v. Sharpe,* 347 U.S. 497, 499 (1954).

animus, hostile to the interests of African Americans and other persons of color.

409. The CSA, as it pertains to Cannabis, was implemented in an environment tainted by racial discrimination and animus, hostile to the interests of African Americans and other persons of color.

410. The CSA, as it pertains to Cannabis, has been enforced in a mariner reflective of racial discrimination and animus, hostile to the interests of African Americans and other persons of color.

411. Although Cannabis is consumed and used equally by African Americans and White Americans, African Americans are disproportionately the subject of investigations, prosecutions, convictions and incarcerations under the CSA.

412. Upon information and belief, the racial animus underwriting the mis-classification of Cannabis as a Schedule I drug under the CSA continues to this day, resulting in convictions and the incarceration of African Americans and other persons of color in disproportionate numbers.

413. The misclassification of Cannabis as a Schedule I drug under the CSA was also intended to suppress the First Amendment rights and interests of those protesting the Vietnam War, including such rights as freedom of speech and the right to petition the government for a redress of grievances.

414. Upon information and belief, the Federal Government tactically enforced the CSA against war protesters and persons of color insofar as members of the Nixon Administration irrationally believed such persons to be enemies of America's war on communism.

415. In enacting and disproportionately enforcing the CSA against persons of color, the Federal Government violated, and continues to violate, the Due Process Clause of the Fifth Amendment and the requirements of Equal Protection.

416. In enacting and disproportionately enforcing the CSA against those protesting the Vietnam War, the Federal Government violated, and continues to violate, the First Amendment, the Due Process Clause of the Fifth Amendment and the requirements of Equal Protection.

417. The Federal Government lacks a compelling interest in the enactment of a statute that discriminates against persons of color, and violates and has violated the First and Fifth Amendment rights of members of the CCA, and their rights to Equal Protection,

418. Upon information and belief, even assuming *arguendo* that the Federal Government were to have a compelling interest in enacting and enforcing the CSA in the manner herein described, the CSA is not narrowly tailored to satisfy and achieve that compelling interest (whatever it might be).

419. An actual case in controversy exists between Plaintiff CCA on the one hand, and Defendants on the other, by which the CCA maintains that the CSA was enacted on the basis of racism and political suppression of the rights guaranteed under the First Amendment, and enforced in a manner that is so discriminatory as to rise to the level of a violation of Due Process and Equal Protection, whereas Defendants irrationally and unconstitutionally maintain that the CSA constitutes a valid exercise of federal power.

420. By reason of the foregoing, the CCA is entitled to issuance of an order and judgment: (i) declaring that the CSA, as it pertains to Cannabis, violates the rights of its members under the First and Fifth Amendments to the United States Constitution and under principles of Equal Protection.

421. CCA has no remedy at law.

THIRD CAUSE OF ACTION
(on behalf of all Plaintiffs except Washington)

422. Plaintiffs repeat and reallege each and every allegation of the preceding ¶¶ 1-421, as if set forth fully herein.

423. Freedom to travel throughout the United States, including between and among States of the Union, has long been recognized as a basic right under the Constitution.[162]

424. Alexis requires medical Cannabis to preserve and sustain her life, but cannot travel with medical Cannabis without risking prosecution, incarceration, and/or the loss of other liberty rights and interests.

425. Dean cannot travel without his wife, who, as Alexis's caregiver, cannot leave Alexis alone; thus, Dean cannot safely travel either.

426. Jagger requires medical Cannabis to live without excruciating pain and to avoid death, but cannot travel with medical Cannabis without risking prosecution, incarceration, and/or the loss of other liberty rights and interests.

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162 *See*, *e.g., Williams v. Fears*, 179 U.S. 270, 274 (1900).

427. Sebastien is required to travel in order to obtain the medical Cannabis Jagger requires to eliminate his pain and continue to live; however, if Sebastien were to travel by plane, or on land across State lines or on a federal highway, he would be threatened with seizure of Jagger' s medicine, arrest, prosecution, incarceration, loss of his parental rights and/or other consequences attendant with a conviction for a felony under the CSA.

428. Plaintiffs Alexis and Jagger desire to travel to the Capitol in Washington, DC to meet with their elected representatives and other public officials to advocate in favor of enacting the MJA and repealing the CSA, or otherwise de-scheduling Cannabis; however, they cannot exercise their fundamental right to travel to the Capitol, as such travel would threaten them with seizure of lifesaving medicine, arrest, prosecution, incarceration, and other consequences attendant with a conviction for a felony under the CSA. Plaintiff Jose desires to travel without leaving his medication behind, but cannot do so because, under the CSA, any air travel or travel to a State where Cannabis is legal but does not exercise reciprocity (or does not otherwise permit his possession and use within the State) would expose him to seizure of his medicine, arrest, prosecution, incarceration, and other consequences attendant with a conviction for a felony under the CSA.

429. Alexis and Jagger are unconstitutionally required to choose between depriving themselves of their fundamental right to continue treating with life-sustaining and life-saving medications to preserve their lives, and depriving themselves of the opportunity to: (i) travel to other States; (ii) use an airplane to

travel to any other State; (iii) step onto federal lands or into federal buildings; (iv) access military bases; and/or (v) receive certain federal benefits. Jose is unconstitutionally required to choose between depriving himself of his fundamental right to continue treating with his life-sustaining medication and depriving himself of the opportunity to: (i) travel to other States; (ii) use an airplane to travel to any other State; (iii) step onto federal lands or into federal buildings; (iv) access military bases; and/or (v) receive certain federal benefits.

430. Certain members of the CCA desire to travel between and among the States with their medical Cannabis, but cannot do so without risk of investigation, prosecution, conviction and incarceration under the CSA, which is disproportionately enforced against persons of color.

431. Defendants maintain that, notwithstanding the overwhelming weight of the evidence in the record (including statements made by the Federal Government itself that Cannabis has curative properties and is safe), Cannabis is supposedly an addictive, dangerous and lethal drug on a par with heroin, mescaline and LSD, and without any medical benefits whatsoever and thus the CSA must be enforced.

432. An actual case in controversy exists between Plaintiffs Alexis, Dean, Jose, Sebastien, Jagger and the CCA on the one hand, and Defendants on the other, by which such Plaintiffs require the use of Cannabis and desire to travel, whereas Defendants irrationally and unconstitutionally maintain that such conduct is lethally dangerous and thus must remain illegal.

433. By reason of the foregoing, the aforesaid Plaintiffs are entitled to issuance of an order and judgment: (i) declaring that the CSA, as it pertains to Cannabis, violates their constitutional Right to Travel; and (ii) permanently enjoining Defendants from enforcing the CSA.

434. Plaintiffs have no remedy at law.

FOURTH CAUSE OF ACTION
(on behalf of all Plaintiffs)

435. Plaintiffs repeat and reallege each and every allegation of the preceding 1-434, as if set forth fully herein.

436. The framework of the United States Constitution created a government of limited and enumerated powers.

437. Under Article I, § 8, cl. 3 of the United States Constitution, Congress has the limited power:

> To regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes.[163]

Hereinafter, the "Commerce Clause."

438. The Commerce Clause does not include a general power to regulate intra-State commerce.

439. The United States Constitution does not include a federal police power.

440. Under the Tenth Amendment to the United States Constitution:

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163 U.S. Const. art. I, § 8, cl. 3.

> The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.[164]

441. Congress is not empowered and/or otherwise authorized to legislate as to matters of intra-State commerce that have no appreciable impact on interstate commerce or commerce with foreign nations and/or with Native American Tribes. Such commerce is reserved to the States and the people who live there.

442. Historically, the regulation of the doctor-patient relationship and decisions pertaining to dispensing medications have been reserved to the States under the Tenth Amendment.

443. The Constitution does not empower Congress to regulate doctor-patient relationships.

444. The CSA, proscribing and criminalizing the use of Cannabis, was not enacted for the purpose of regulating interstate commerce; Congress enacted the CSA based upon a series of irrational and discriminatory motives that cannot be justified or even explained when considered against an incontrovertible record that includes evidence that the United States Government has acknowledged in its U.S. Cannabis Patent Application that Cannabis is an effective treatment for, *inter alia,* Parkinson's Disease and Alzheimer's.

445. By legislating subject matter outside its constitutional delegation of enumerated powers, and encroaching upon the powers expressly reserved to the States, Congress engaged in an unauthorized and

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164 U.S. Const. amend. X.

thus unconstitutional exercise of power that violates well-recognized principles of federalism.

446. Even assuming arguendo that distribution and/or sale of Cannabis that occurs on an entirely intrastate level could be deemed to have an appreciable impact on interstate commerce—and, respectfully, it cannot—individual use of Cannabis cannot rationally be claimed to have an effect on the national economy. Thus, it is alleged in the alternative that, even assuming that Congress were to have the power to regulate purely intrastate economic activity that has no relationship with interstate commerce, Congress lacks the power to regulate use as a purely intrastate, non-economic activity.

447. An actual case in controversy exists between Plaintiffs and Defendants, by which Defendants maintain that use of Cannabis is lethally dangerous and thus must remain illegal, whereas Plaintiffs maintain that the CSA, as it pertains to Cannabis, constitutes an unconstitutional exercise of power not authorized by the Constitution.

448. By reason of the foregoing, Plaintiffs are entitled to issuance of an order and judgment: (i) declaring that the CSA, as it pertains to Cannabis, constitutes an unauthorized exercise of power by Congress, rendering the CSA, as it pertains to Cannabis, unconstitutional; and (ii) permanently enjoining Defendants from enforcing the CSA.

449. Plaintiffs have no remedy at law.

FIFTH CAUSE OF ACTION
(on behalf of all Plaintiffs)

450. Plaintiffs repeat and reallege each and every allegation of the preceding ¶¶ 1-449, as if set forth fully herein.

451. Under the provisions of the CSA, de-scheduling or rescheduling a drug such as Cannabis must be supported by medical and/or scientific evidence—such as, for example, the evidence cited in the U.S. Cannabis Patent Application.

452. To acquire and accumulate such medical and/or scientific evidence, studies and tests must be conducted; however, because Cannabis has been classified as a Schedule I drug, it cannot legally be tested unless special permission has been obtained from the Federal Government.[165]

453. Upon information and belief, in the 47 years since the CSA was enacted, the Federal Government has granted only one application to conduct scientific and/or medical testing of Cannabis.

454. The Federal Government has thus created a legislative construct which, by design, is completely dysfunctional. The CSA requires testing and studies to reclassify Cannabis, but prevents such tests and studies from being conducted because Cannabis is supposedly so dangerous that it cannot be tested—except that the stated basis for classifying Cannabis as a Schedule I drug was that Cannabis supposedly had not yet been tested.

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165 Pub. L. No. 91-513, 84 Stat. 1255.

455. After creating the Shafer Commission to conduct such tests and studies, the Federal Government, led by the biased and unstable Nixon Administration, promptly rejected its findings.

456. By creating a process that, by its terms, necessarily requires all petitions for de-scheduling or rescheduling to be denied—and, as regards Cannabis, that is exactly what has occurred with respect to every petition—Congress enacted an irrational, arbitrary and capricious law.

457. Simply put—if, by its terms, the CSA created a petition process to allow aggrieved individuals to file futile challenges to the classification of Schedule I drugs, then the procedure serves no lawful purpose and is thus unconstitutionally irrational and violates the Due Process Clause of the Fifth Amendment.

458. An actual case in controversy exists between Plaintiffs and Defendants, by which Plaintiffs need and/or desire to use, prescribe and/or engage in business transactions involving Cannabis, whereas Defendants falsely and unconstitutionally maintain that cultivation, distribution, possession and use of Cannabis is lethally dangerous and thus must remain illegal.

459. By reason of the foregoing, Plaintiffs are entitled to issuance of an order and judgment: (i) declaring that the CSA, as it pertains to Cannabis, constitutes an unauthorized exercise of power by Congress, rendering the CSA, as it pertains to Cannabis, unconstitutional; and (ii) permanently enjoining Defendants from enforcing the CSA as it pertains to Cannabis.

460. Plaintiffs have no remedy at law.

SIXTH CAUSE OF ACTION
(on behalf of all Plaintiffs except Washington and Jose)

461. Plaintiffs repeat and reallege each and every allegation of the preceding ¶¶ 1-460, as if set forth fully herein.

462. The First Amendment to the Constitution of the United States confirms that:

> Congress shall make no law . . . abridging the freedom of speech . . . or the right of the people to . . . petition the Government for a redress of grievances.

U.S. Const. amend. I.

463. The protections afforded by the First Amendment include, *inter alia,* the right to meet with public officials into advocate in favor or against governmental action.

464. In order for Alexis, Jagger, and certain members of the CCA who treat with medical Cannabis to meet with public officials at-the Capitol, they would be required to leave their medical Cannabis behind—otherwise, under the CSA, their medicine could be seized and they (and/or, in the case of Alexis and Jagger, their parents) could be detained, arrested, prosecuted and/or incarcerated.

465. If Alexis's or Jagger's parents were to be detained, arrested, prosecuted and/or incarcerated, their parental rights could be terminated, depriving Alexis and Jagger of the opportunity to be raised by one or more of their biological parents.

466. The CSA, as applied to Alexis, Jagger, and certain members of the CCA, violates their First Amendment rights to free speech and the opportunity to petition the Government for a redress of grievances by requiring them, as a condition of their entry into the Capitol (or any federal Senate or House office building), to risk their health and their lives in order to engage in in-person advocacy with their elected representatives and other federal public officials.

467. Under the provisions of the Ninth Amendment and Substantive Due Process, Alexis, Jagger, and certain members of the CCA have a fundamental right to continue treating with a medication that, for years, has provided life-saving and-sustaining treatment of their conditions. This fundamental right to life and to preserve one's right to life is deeply rooted in this Nation's history and traditions and is implicit in the concept of ordered liberty.

468. An actual case in controversy exists between Plaintiffs Alexis, Jagger, and certain members of the CCA on the one hand, and Defendants on the other, by which such Plaintiffs need to treat with medical Cannabis while maintaining their constitutional rights to free speech and to petition the federal government for a redress of grievances through in-person advocacy, whereas Defendants unconstitutionally maintain that the CSA must be enforceable on federal lands and in federal buildings, thereby precluding such in-person advocacy. Alternatively, the Federal Government may maintain that the-aforesaid Plaintiffs may travel to Washington, DC to engage in in-person advocacy, but without their life-saving and-sustaining medication—a prospect which threatens each of the aforesaid Plaintiffs with the loss of their lives and health.

469. The Federal Government cannot require persons to sacrifice one fundamental right in order to exercise another.

470. By reason of the foregoing, Plaintiffs are entitled to issuance of an order and judgment: (i) declaring that the CSA, as applied to Alexis, Jagger, and the CCA, constitutes a violation of their First Amendment guarantees of free speech and the right to petition the Federal Government for a redress of grievances, rendering the CSA, as applied to the aforesaid Plaintiffs, unconstitutional; (ii) declaring that the CSA, as applied to Alexis, Jagger, and members of the CCA, constitutes a denial of Substantive Due Process and/or fundamental rights guaranteed by the Ninth Amendment; and (iii) permanently enjoining Defendants from enforcing the CSA as it pertains to Cannabis, as against the aforesaid Plaintiffs.

471. Plaintiffs have no remedy at law.

SEVENTH CAUSE OF ACTION
(on behalf of all Plaintiffs)

472. Plaintiffs repeat and reallege each and every allegation of the preceding ¶¶ 1-471, as if set forth fully herein.

473. The Federal Government cannot maintain its position on the existing record that continued enforcement of the CSA as it pertains to Cannabis is "substantially justified."

474. By reason of the foregoing, Plaintiffs are entitled to reasonable legal fees and costs pursuant to the Equal Access to Justice Act, 28 U.S.C. § 2412.

WHEREFORE, for the reasons stated, Plaintiffs demand judgment, over and against Defendants, declaring that the CSA as it pertains to the cultivation, distribution, marketing, sale, prescription and use of Cannabis, is unconstitutional under the Due Process Clause of the Fifth Amendment, the Free Speech and Right to Petition Clauses of the First Amendment, the Equal Protection Clause of the Fourteenth Amendment (as implied through the Due Process Clause of the Fifth Amendment), the Right to Travel, Substantive Due Process, fundamental rights secured under the Ninth Amendment, and the Commerce Clause, together with: (i) a permanent injunction (and associated temporary relief if so required), restraining Defendants from enforcing the CSA as it pertains to Cannabis; (ii) reasonable legal fees and costs pursuant to the Equal Access to Justice Act, 28 U.S.C. § 2412; and (iii) any and all other and further relief this Court deems just and proper.

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By: /s/ Michael S. Hiller
Michael S. Hiller (MH 9871)
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166 Admission pending.

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By: /s/ Joseph A. Bondy
Joseph A. Bondy

Dated: September 6, 2017
New York, New York

LETTER FROM PETITIONERS' COUNSEL MICHAEL S. HILLER TO THE CLERK OF COURT OF THE SECOND CIRCUIT COURT OF APPEALS (SEPTEMBER 10, 2019)

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Catherine O'Hagan Wolfe, Clerk of Court
United States Court of Appeals for the Second Circuit
Thurgood Marshall U.S. Courthouse
40 Foley Square
New York, New York 10007

Re: *Washington, et al. v. Barr, et al.*, Docket No. 18-859-cv (2d. Cir.)

Dear Madam Clerk:

We represent plaintiffs Marvin Washington, Dean Bortell (as parent of infant Alexis Bortell), Jose Belen, Sebastien Cotte (as parent of infant Jagger Cotte), and the Cannabis Cultural Association (collectively, "Plaintiffs") in the above-referenced action (the "Action") against defendants William Barr (in his capacity as U.S. Attorney General), the U.S. Department of Justice, Uttam Dhillon (in his capacity as Acting Administrator of the U.S. Drug Enforcement Administration), the U.S. Drug Enforcement Administration ("DEA"), and the United States of America (collectively, "Defendants"). We submit this letter in response to the Court's request for an update

with respect to the status of a certain petition which this Court authorized Plaintiffs to file, by December 31, 2019, with the DEA ("DEA Petition"), relative to the misclassification of cannabis under the Controlled Substances Act ("CSA").

As discussed below, Plaintiffs have not yet filed the DEA Petition because, in the course of its preparation, we learned that the DEA, through which the Attorney General typically decides whether to re-schedule and de-schedule substances under the CSA, has already taken the position that cannabis cannot be de-scheduled; rather, according to the DEA, the Attorney General can only re-schedule cannabis and only under Schedule II of the CSA. Such an outcome would: (i) be inconsistent with prevailing medical evidence; and, more importantly (ii) comprise relief—re-classification under Schedule II—that Plaintiffs have never requested and do not seek. Accordingly, it is Plaintiffs' intention to file a motion for an extension of time within which to file the DEA Petition to December 31, 2020, and to commence a new action against the DEA and Attorney General for declaratory relief, confirming that the DEA is mistaken with respect to the Attorney General's powers under the CSA. As reflected below, this would allow Plaintiffs to obtain the relief that, according to the Court, would be equivalent to what Plaintiffs' requested in the Action. As further reflected below, re-classification of cannabis under Schedule II would actually constitute a substantial step backward in the fight to legalize and de-stigmatize medical cannabis.

Background

By the Action, Plaintiffs requested, *inter alia:* (i) a declaratory judgment that the classification of cannabis as a Schedule 1 drug under the CSA is unconstitutional; and (ii) "a permanent injunction (and associated temporary relief if so required), restraining Defendants from enforcing the CSA as it pertains to Cannabis" (Amended Complaint, Second Circuit Dkt. No. 39, pp. 96-97). Plaintiffs never requested that cannabis be re-classified under the CSA, much less as a Schedule II substance. *See* Memorandum of Law, dated December 1, 2017, SDNY Dkt. Nos. 44-46, p. 106) ("Plaintiffs bring this action challenging the constitutionality of the CSA; they are not asking for the Court to reschedule Cannabis or to compel the DEA to do so") (emphasis added). Had the constitutional claims recited in the Amended Complaint been accepted and sustained by the District Court and/or this Court, and the injunction granted, cannabis would have been de-scheduled on a *de facto* basis, particularly insofar as unconstitutional acts of Congress are void *ab initio*, and Plaintiffs requested a permanent injunction to restrain enforcement of the CSA as it pertains to cannabis.[1]

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[1] *Bond v. U.S.*, 564 U.S. 211 (2011); *see also Medical Center Pharmacy v. Mukasey*, 536 F.3d 383 (5th Cir. 2008) ("If that act of amendment is invalid—for instance, because its unconstitutional portions cannot be severed—the act is void *ab initio*, and it is as though Congress had not acted at all"); *U.S v. Morgan*, 230 F.3d 1067 (8th Cir. 2000) ("Congress exceeded its proper authority in enacting [the law]; the law is [thus] unconstitutional, void *ab initio*"); *Mester Mfg. Co. v. I.N.S.*, 879 F.2d 561 (9th Cir. 1989) ("A law passed in violation of the Constitution is null and void *ab initio*").

Before the District Court and on appeal, we argued that a DEA Petition would be futile because, *inter alia*, "administrative review would not afford Plaintiffs the relief that they seek—a declaratory judgment and injunction, restraining the Federal Government from enforcing the CSA as it pertains to Cannabis" (App. Br. at 5, Second Circuit Dkt. No. 37). We interposed the same argument before the District Court. This Court, nonetheless, ruled that Plaintiffs are required to seek a re-scheduling or de-scheduling of cannabis by filing the DEA Petition. In this regard, the Court explained its rationale as follows:

> the gravamen of [Plaintiffs'] argument is that marijuana should not be classified as a Schedule I substance under the CSA. Were a court to agree, the remedy would be to re-schedule or deschedule cannabis. It cannot be seriously argued that this remedy is not available through the administrative process.

See Decision, dated May 30, 2019 at 18-19 ("Decision") (Second Circuit Dkt. No. 101) (emphasis added).

As discussed below, a review of a prior DEA decision denying a petition to re-schedule or de-schedule cannabis confirms that the specific remedies sought by Plaintiffs—the de-scheduling of cannabis and an injunction against enforcement of the CSA as it pertains to that substance—is, in fact, not available based upon the DEA's current position on the issue.

Discussion

In 2016, the DEA denied a petition to initiate rulemaking proceedings to re-schedule cannabis ("Previous DEA Determination"). *See* 21 CFR Chapter

II and Part 1301, Fed. Register, Vol. 156, 53688, Aug, 12, 2016.[2] In the Previous DEA Determination, in a section entitled "Preliminary Note Regarding Treaty Obligations," the DEA advanced the position that, due to United States' obligations under international drug control treaties, cannot be de-scheduled under the CSA. *Id.* at 53688. According to the DEA, under the Single Convention on Narcotic Drugs, 1961 ("Single Convention"), of which the United States is a party, the United States is "obligated to maintain various control provisions related to the drugs that are covered by the treaty," which includes cannabis. In this regard, the DEA wrote that:

> the DEA Administrator is obligated under [the CSA] to control marijuana in the schedule that he deems most appropriate to carry out the U.S. obligations under the Single Convention. It has been established in prior marijuana rescheduling proceedings that placement of marijuana in either schedule I or schedule II of the CSA is "necessary as well as sufficient to satisfy our international obligations" under the Single Convention. *NORML v. DEA*, 559 F.2d 735, 751 (D.C. Cir. 1977). As the United States Court of Appeals for the DC Circuit has stated, "several requirements imposed by the Single Convention would not be met if cannabis and cannabis resin were placed in CSA schedule III, IV, or V." *Id.* Therefore, in

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[2] The Previous DEA Determination states that "marijuana" refers to "cannabis."

> accordance with [the CSA], DEA must place marijuana in either schedule I or schedule II.

Id. at 53688-89.

Based upon the Previous DEA Determination, the DEA, at least currently, would not entertain a petition to de-schedule cannabis, but rather would consider only whether to re-classify cannabis under Schedule II. And, if cannabis were re-classified to Schedule II, Plaintiffs would be saddled with an outcome that, not only would be inconsistent with their prayer for relief, but worse, would exacerbate their situations. Currently, although illegal under federal Law, medical cannabis is available to Plaintiffs and other patients across the United States (in varying degrees) pursuant to 34 state-legal programs. While such programs contain deficiencies and limit cannabis patients in terms of their ability to exercise their constitutional rights, *inter alia*, to travel, free speech and federal benefits and entitlements, such patients can nonetheless, in most instances, travel to an instate dispensary and purchase their medications. And, because the Federal Government has attached funding riders to appropriations legislation annually since 2014, the DEA and Justice Department are prohibited from using federal monies to enforce the CSA as it pertains to cannabis in those states that have implemented medical-cannabis programs. *See* Consolidated and Further Continuing Appropriations Act, 2015, Pub. L. No. 113-235, § 538, 128 Stat. 2130, 2217 (2014); Consolidated Appropriations Act, 2016, Pub. L. No. 114-113, § 542, 129 Stat. 2242, 2332-33 (2015); Consolidated Appropriations Act, 2017, Pub. L. No. 115-31, § 537 (2017); Consolidated Appropriations Act, 2018, Pub. L. No. 115-141, § 538, 132 Stat.

445 (2018). Thus, while far from perfect-indeed, cannabis patients are required to forfeit their constitutional rights in order to obtain the medication to sustain their health and lives-the current state of the law permits Plaintiffs some level of access to medical cannabis in state-legal jurisdictions. If, however, cannabis were to be re-classified under Schedule II, overly-burdensome regulation would resume under federal law, creating substantial increases in the cost of cultivating, extracting, packaging and distributing cannabis, and resulting in built-in increases in cost.[3] Pharmaceutical companies would be able to exploit their vast and superior resources to navigate the regulatory process, monopolizing the cannabis market, and allowing them to charge exorbitant prices for medication that is currently otherwise available to patients at a fraction of the cost. Indeed, the Court need look no further than the pricing for Epidiolex—a cannabis medication approved by the FDA for the treatment of epilepsy in children and classified as a Schedule V drug under the CSA.[4] Currently, pharmaceutical companies charge in excess of $32,000

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[3] *Rescheduling Marijuana in the U.S. Could Backfire*, S. Williams, *Motley Fool.com*, 5/27/2018. https://www.fool.com/investing/2018/05/27/rescheduling-marijuana-in-the-us-could-backfire.aspx

[4] 21 C.F.R. § 1308.15(f). *See also* The United States Department of Justice, FDA-Approved Drug Epidiolex Placed in Schedule V of Controlled Substances Act, Office of Public Affairs (Sept. 27, 2018), https://www.justice.gov/opa/pr/fda-approved-drug-epidiolex-placed-schedule-v-controlled-substances-act ("Epidiolex, the newly approved medication by the Food & Drug Administration (FDA), is being placed in schedule V of the Controlled Substances Act").

per annum for regular administrations of Epidiolex.[5] By contrast, the cannabis medication upon which Plaintiff Alexis Bortell relies daily to treat her epilepsy and otherwise maintain her health and life is less than $5,800 per year-84% less than the cost of Epidiolex. Re-classifying cannabis under another CSA Schedule would constitute merely an invitation to big pharmaceutical companies to fleece a new population of patients, many of whom are currently able to obtain their medical cannabis at a fraction of the cost. Thus, Plaintiffs, not only never requested that the Court re-classify cannabis under Schedule II, but further, would resist any such effort in its entirety. Plaintiffs were seeking a ruling under the constitution that would effectively de-schedule cannabis.[6]

The Decision herein completely controverts the Previous DEA Determination. In particular, this Court interpreted the DC Circuit's decision in *NORML v. DEA* (upon which the DEA previously relied) as holding that "foreign treaty commitments have *not* divested the Attorney General of the power to re-or de-

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[5] Peter Loftus, *New Marijuana-Based Epilepsy Treatment to Cost $32,500 a Year*, THE WALL STREET JOURNAL (Aug. 8, 2018), https://www.wsj.com/articles/new-marijuana-based-epilepsy-treatment-to-cost-32-500-a-year-1533761758 ("GW Pharmaceuticals PLC said it plans to charge about $32,500 per patient annually in the U.S. for its new treatment for rare forms of epilepsy, the first prescription drug derived from the marijuana plant").

[6] The recent concerns over lung damage caused by "vaping" appear to pertain to black-market products that exist outside any regulatory environment—a problem which would be cataclysmically worsened were cannabis to be rendered unaffordable to those who treat with state-legal cannabis daily in regulated state-legal markets.

schedule marijuana" (Decision at 21) *(citing NORML v. DEA*, 559 F.2d 735). Because the Previous DEA Determination and DEA' s interpretation of the ruling in *NORML v. DEA* are inconsistent with this Court's Decision herein, Plaintiffs should be entitled to declaratory relief—specifically, a ruling that the DEA and Attorney General do, in fact, have the power to de-schedule cannabis. To obtain such a result, however, we need to interpose another *pro Bono* action on behalf of Plaintiffs. And because the declaratory judgment action would likely require at least six to nine months to complete, Plaintiffs need an extension of time within which to file their DEA Petition.

Plaintiffs intend to file the motion to extend their time to file the DEA Petition within thirty (30) days. Alternatively, the Court could endorse this correspondence to grant the extension without the necessity of a motion.

Respectfully submitted

/s/ Michael S. Hiller

MSH: me

c: Benjamin H. Torrance, Esq.
Samuel Dolinger, Esq.

UNITED STATES PATENT: CANNABINOIDS AS ANTIOXIDANTS AND NEUROPROTECTANTS (OCTOBER 7, 2003)

United States Patent
Hampson et al.
Patent No.: US 6,630,507 B1
Date of Patent: Oct. 7, 2003

CANNABINOIDS AS ANTIOXIDANTS AND NEUROPROTECTANTS

Inventors: Aldan J. Hampson, Irvine, CA (US); Julius Axelrod, Rockville, MD (US); Maurizio Grimaldi, Bethesda, MD (US)

Assignee: The United States of America as represented by the Department of Health and Human Services, Washington, DC (US)

Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

Appl. No.: 09/674,028

PCT Filed: Apr. 21, 1999

PCT No.: PCT/US99/08769

§ 371(c)(l),

(2), (4) Date: Feb 2, 2001

PCT Pub. No.: WO99/53917

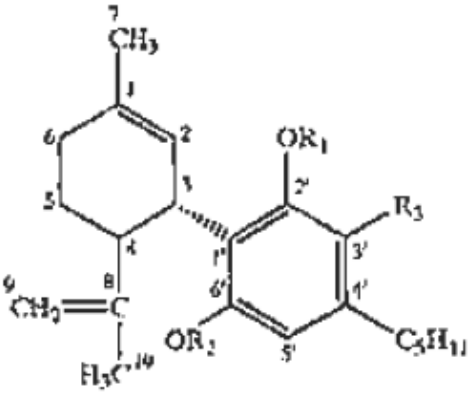
PCT Pub. Date: Oct. 28, 1999

Related U.S. Application Data

Provisional application No. 60/082,589, filed on Apr. 21, 1998, and provisional application No. 60/095, 993, filed on Aug, 10, 1998.

ABSTRACT

Cannabinoids have been found to have antioxidant properties, unrelated to NMDA receptor antagonism. This new found property makes cannabinoids useful in the treatment and prophylaxis of wide variety of oxidation associated diseases, such as ischemic, age-related, inflammatory and autoimmune diseases. The cannabinoids are found to have particular application as neuroprotectants, for example in limiting neurological damage following ischemic insults, such as stroke and trauma, or in the treatment of neurodegenerative diseases, such as Alzheimer's disease, Parkinson's disease and HIV dementia. Nonpsychoactive cannabinoids, such as cannabidoil, are particularly advantageous to use because they avoid toxicity that is uncounted with psychoactive cannabinoids at high doses useful in the method of the present invention. A particular disclosed class of cannabinoids useful as neuroprotective, antioxidants is formula (I) wherein the R group is independently selected from the group consisting of H, CH_3, and $COCH_3$.



26 Claims, 7 Drawing Sheets

FIG. 1

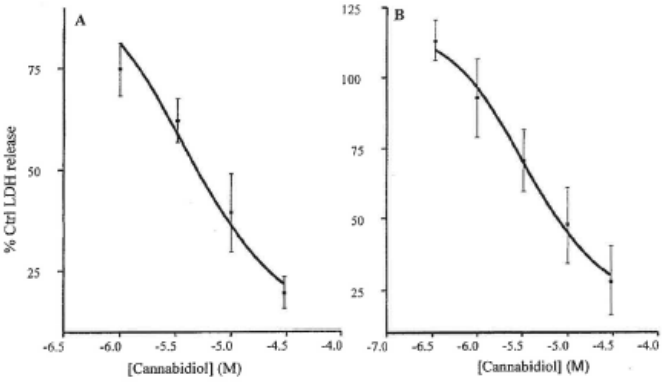


FIG. 2

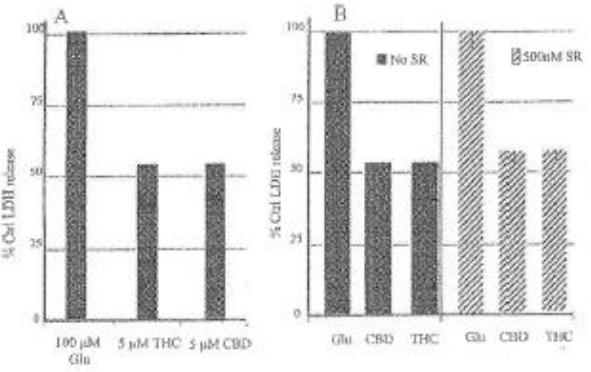


FIG. 3

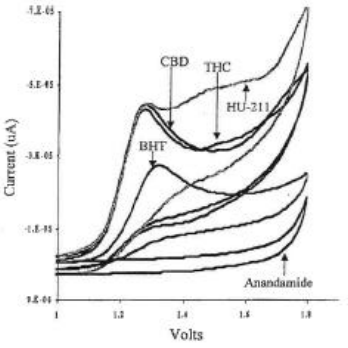


FIG. 4

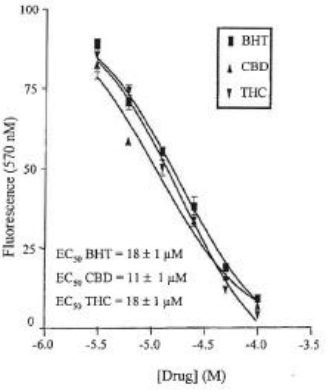


FIG. 5

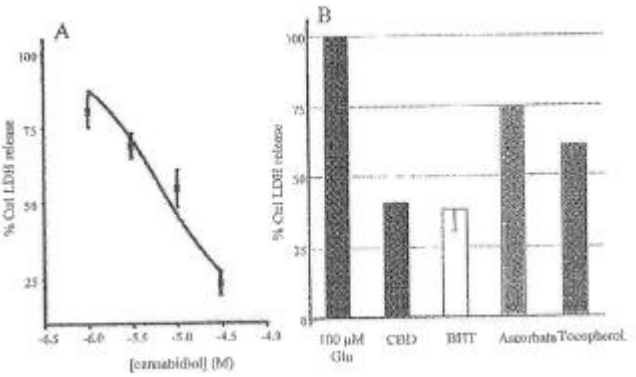

A
% Ctrl LDH release
[cannabidiol] (M)
B
% Ctrl LDH release
100 µM Glu
CBD
BHT
Ascorbate
Tocopherol

FIG. 6

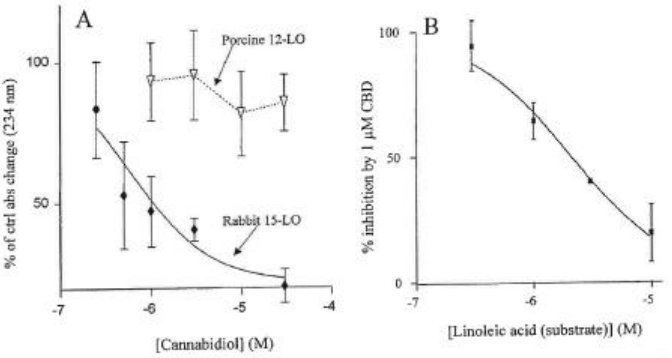

A
Porcine 12-LO
Rabbit 15-LO
% of ctrl abs change (234 nm)
[Cannabidiol] (M)
B
% inhibition by 1 µM CBD
[Linoleic acid (substrate)] (M)

FIG. 7

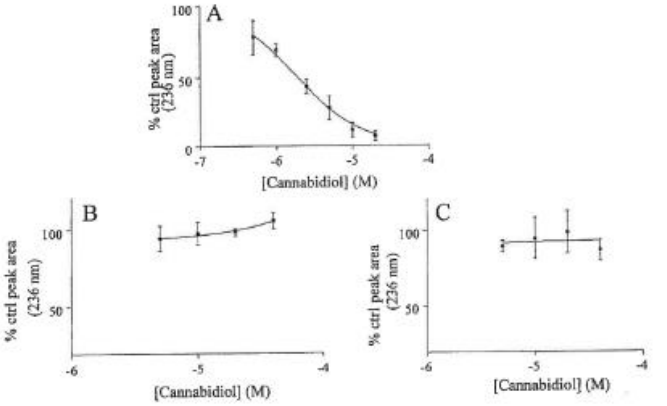
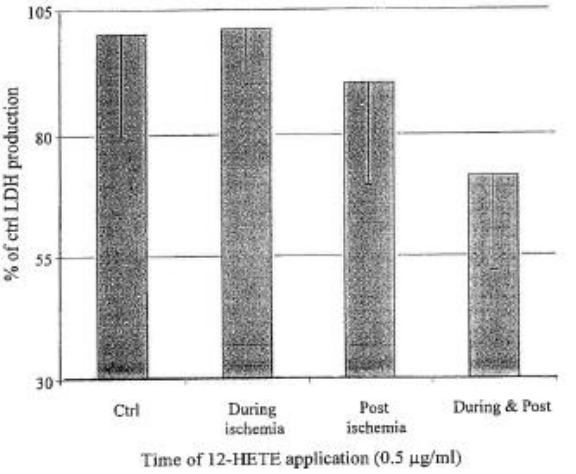

A
B
C
100
50
0
-7
-6
-5
-4
% ctrl peak area (236 nm)
[Cannabidiol] (M)

FIG. 8


105
80
55
30
% of ctrl LDH production
Ctrl
During ischemia
Post ischemia
During & Post
Time of 12-HETE application (0.5 µg/ml)

GUIDANCE MEMORANDUM FROM THE UNITED STATES DEPARTMENT OF TREASURY (FINCEN GUIDANCE) (FEBRUARY 14, 2014)

DEPARTMENT OF THE TREASURY
FINANCIAL CRIMES ENFORCEMENT NETWORK
GUIDANCE

FIN-2014-G001

Subject: BSA Expectations Regarding Marijuana-Related Businesses

The Financial Crimes Enforcement Network ("FinCEN") is issuing guidance to clarify Bank Secrecy Act ("BSA") expectations for financial institutions seeking to provide services to marijuana-related businesses. FinCEN is issuing this guidance in light of recent state initiatives to legalize certain marijuana-related activity and related guidance by the U.S. Department of Justice ("DOJ") concerning marijuana-related enforcement priorities. This FinCEN guidance clarifies how financial institutions can provide services to marijuana-related businesses consistent with their BSA obligations, and aligns the information provided by financial institutions in BSA reports with federal and state law enforcement priorities. This FinCEN guidance should enhance the availability of financial services for, and the financial transparency of, marijuana-related businesses.

Marijuana Laws and Law Enforcement Priorities

The Controlled Substances Act ("CSA") makes it illegal under federal law to manufacture, distribute,

or dispense marijuana.[1] Many states impose and enforce similar prohibitions. Notwithstanding the federal ban, as of the date of this guidance, 20 states and the District of Columbia have legalized certain marijuana-related activity. In light of these developments, U.S. Department of Justice Deputy Attorney General James M. Cole issued a memorandum (the "Cole Memo") to all United States Attorneys providing updated guidance to federal prosecutors concerning marijuana enforcement under the CSA.[2] The Cole Memo guidance applies to all of DOJ's federal enforcement activity, including civil enforcement and criminal investigations and prosecutions, concerning marijuana in all states.

The Cole Memo reiterates Congress's determination that marijuana is a dangerous drug and that the illegal distribution and sale of marijuana is a serious crime that provides a significant source of revenue to large-scale criminal enterprises, gangs, and cartels. The Cole Memo notes that DOJ is committed to enforcement of the CSA consistent with those determinations. It also notes that DOJ is committed to using its investigative and prosecutorial resources to address the most significant threats in the most effective, consistent, and rational way. In furtherance of those objectives, the Cole Memo provides guidance to DOJ

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[1] Controlled Substances Act, 21 U.S.C. § 801, *et seq.*

[2] James M. Cole, Deputy Attorney General, U.S. Department of Justice, Memorandum for All United States Attorneys: Guidance Regarding Marijuana Enforcement (August 29, 2013), available at http://www.justice.gov/iso/opa/resources/3052013829132756857467.pdf.

attorneys and law enforcement to focus their enforcement resources on persons or organizations whose conduct interferes with any one or more of the following important priorities (the "Cole Memo priorities"):[3]

- Preventing the distribution of marijuana to minors;
- Preventing revenue from the sale of marijuana from going to criminal enterprises, gangs, and cartels;
- Preventing the diversion of marijuana from states where it is legal under state law in some form to other states;
- Preventing state-authorized marijuana activity from being used as a cover or pretext for the trafficking of other illegal drugs or other illegal activity;
- Preventing violence and the use of firearms in the cultivation and distribution of marijuana;
- Preventing drugged driving and the exacerbation of other adverse public health consequences associated with marijuana use;
- Preventing the growing of marijuana on public lands and the attendant public safety and environmental dangers posed by marijuana production on public lands; and
- Preventing marijuana possession or use on federal property.

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[3] The Cole Memo notes that these enforcement priorities are listed in general terms; each encompasses a variety of conduct that may merit civil or criminal enforcement of the CSA.

Concurrently with this FinCEN guidance, Deputy Attorney General Cole is issuing supplemental guidance directing that prosecutors also consider these enforcement priorities with respect to federal money laundering, unlicensed money transmitter, and BSA offenses predicated on marijuana-related violations of the CSA.[4]

Providing Financial Services to Marijuana-Related Businesses

This FinCEN guidance clarifies how financial institutions can provide services to marijuana-related businesses consistent with their BSA obligations. In general, the decision to open, close, or refuse any particular account or relationship should be made by each financial institution based on a number of factors specific to that institution. These factors may include its particular business objectives, an evaluation of the risks associated with offering a particular product or service, and its capacity to manage those risks effectively. Thorough customer due diligence is a critical aspect of making this assessment.

In assessing the risk of providing services to a marijuana-related business, a financial institution should conduct customer due diligence that includes: (i) verifying with the appropriate state authorities whether the business is duly licensed and registered; (ii) reviewing the license application (and related documentation) submitted by the business for obtaining

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[4] James M. Cole, Deputy Attorney General, U.S. Department of Justice, *Memorandum for All United States Attorneys: Guidance Regarding Marijuana Related Financial Crimes* (February 14, 2014).

a state license to operate its marijuana-related business; (iii) requesting from state licensing and enforcement authorities available information about the business and related parties; (iv) developing an understanding of the normal and expected activity for the business, including the types of products to be sold and the type of customers to be served (e.g., medical versus recreational customers); (v) ongoing monitoring of publicly available sources for adverse information about the business and related patties; (vi) ongoing monitoring for suspicious activity, including for any of the red flags described in this guidance; and (vii) refreshing information obtained as part of customer due diligence on a periodic basis and commensurate with the risk. With respect to information regarding state licensure obtained in connection with such customer due diligence, a financial institution may reasonably rely on the accuracy of information provided by state licensing authorities, where states make such information available.

As part of its customer due diligence, a financial institution should consider whether a marijuana-related business implicates one of the Cole Memo priorities or violates state law. This is a particularly important factor for a financial institution to consider when assessing the risk of providing financial services to a marijuana-related business. Considering this factor also enables the financial institution to provide information in BSA reports pertinent to law enforcement's priorities. A financial institution that decides to provide financial services to a marijuana-related business would be required to file suspicious activity reports ("SARs") as described below.

Filing Suspicious Activity Reports on Marijuana-Related Businesses

The obligation to file a SAR is unaffected by any state law that legalizes marijuana-related activity. A financial institution is required to file a SAR if, consistent with FinCEN regulations, the financial institution knows, suspects, or has reason to suspect that a transaction conducted or attempted by, at, or through the financial institution: (i) involves funds derived from illegal activity or is an attempt to disguise funds derived from illegal activity; (ii) is designed to evade regulations promulgated under the BSA, or (iii) lacks a business or apparent lawful purpose.[5] Because federal law prohibits the distribution and sale of marijuana, financial transactions involving a marijuana-related business would generally involve funds derived from illegal activity. Therefore, a financial institution is required to file a SAR on activity involving a marijuana-related business (including those duly licensed under state law), in accordance with this guidance and FinCEN's suspicious activity reporting requirements and related thresholds.

One of the BSA's purposes is to require financial institutions to file reports that are highly useful in criminal investigations and proceedings. The guidance below furthers this objective by assisting financial

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[5] *See, e.g.*, 31 CFR § 1020.320. Financial institutions shall file with FinCEN, to the extent and in the manner required, a report of any suspicious transaction relevant to a possible violation of law or regulation. A financial institution may also file with FinCEN a SAR with respect to any suspicious transaction that it believes is relevant to the possible violation of any law or regulation but whose reporting is not required by FinCEN regulations.

institutions in determining how to file a SAR that facilitates law enforcement's access to information pertinent to a priority.

"Marijuana Limited" SAR Filings

A financial institution providing financial services to a marijuana-related business that it reasonably believes, based on its customer due diligence, does not implicate one of the Cole Memo priorities or violate state law should file a "Marijuana Limited" SAR. The content of this SAR should be limited to the following information: (i) identifying information of the subject and related parties; (ii) addresses of the subject and related parties; (iii) the fact that the filing institution is filing the SAR solely because the subject is engaged in a marijuana-related business; and (iv) the fact that no additional suspicious activity has been identified. Financial institutions should use the term "MARIJUANA LIMITED" in the narrative section.

A financial institution should follow FinCEN's existing guidance on the timing of filing continuing activity reports for the same activity initially reported on a "Marijuana Limited" SAR.[6] The continuing activity report may contain the same limited content as the initial SAR, plus details about the amount of deposits, withdrawals, and transfers in the account since the last SAR. However, if, in the course of conducting customer due diligence (including ongoing monitoring for red flags), the financial institution

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6 Frequently Asked Questions Regarding the FinCEN Suspicious Activity Report (Question #16), available at: http://fincen.gov/whatsnew/html/sar_faqs.html (providing guidance on the filing timeframe for submitting a continuing activity report).

detects changes in activity that potentially implicate one of the Cole Memo priorities or violate state law, the financial institution should file a "Marijuana Priority" SAR.

"Marijuana Priority" SAR Filings

A financial institution filing a SAR on a marijuana-related business that it reasonably believes, based on its customer due diligence, implicates one of the Cole Memo priorities or violates state law should file a "Marijuana Priority" SAR. The content of this SAR should include comprehensive detail in accordance with existing regulations and guidance. Details particularly relevant to law enforcement in this context include: (i) identifying information of the subject and related parties; (ii) addresses of the subject and related parties; (iii) details regarding the enforcement priorities the financial institution believes have been implicated; and (iv) dates, amounts, and other relevant details of financial transactions involved in the suspicious activity. Financial institutions should use the term "MARIJUANA PRIORITY" in the narrative section to help law enforcement distinguish these SARs.[7]

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[7] FinCEN recognizes that a financial institution filing a SAR on a marijuana-related business may not always be well-positioned to determine whether the business implicates one of the Cole Memo priorities or violates state law, and thus which terms would be most appropriate to include (i.e., "Marijuana Limited" or "Marijuana Priority"). For example, a financial institution could be providing services to another domestic financial institution that, in turn, provides financial services to a marijuana-related business. Similarly, a financial institution could be providing services to a non-financial customer that provides goods or services to a marijuana-related business (e.g., a commercial landlord that leases property to a marijuana-related business).

"Marijuana Termination" SAR Filings

If a financial institution deems it necessary to terminate a relationship with a marijuana-related business in order to maintain an effective anti-money laundering compliance program, it should file a SAR and note in the narrative the basis for the termination. Financial institutions should use the term "MARIJUANA TERMINATION" in the narrative section. To the extent the financial institution becomes aware that the marijuana-related business seeks to move to a second financial institution, FinCEN urges the first institution to use Section 314(b) voluntary information sharing (if it qualifies) to alert the second financial institution of potential illegal activity. *See Section 314(b) Fact Sheet* for more information.[8]

Red Flags to Distinguish Priority SARs

The following red flags indicate that a marijuana-related business may be engaged in activity that implicates one of the Cole Memo priorities or violates state law. These red flags indicate only possible signs of such activity, and also do not constitute an exhaustive

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In such circumstances where services are being provided indirectly, the financial institution may file SARs based on existing regulations and guidance without distinguishing between "'Marijuana Limited" and "Marijuana Priority." Whether the financial institution decides to provide indirect services to a marijuana-related business is a risk-based decision that depends on a number of factors specific to that institution and the relevant circumstances. In making this decision, the institution should consider the Cole Memo priorities, to the extent applicable.

8 Information Sharing Between Financial Institutions: Section 314(b) Fact Sheet, available at: http://fincen.gov/statutes_regs/patriot/pdf/314bfactsheet.pdf.

list. It is thus important to view any red flag(s) in the context of other indicators and facts, such as the financial institution's knowledge about the underlying parties obtained through its customer due diligence. Further, the presence of any of these red flags in a given transaction or business arrangement may indicate a need for additional due diligence, which could include seeking information from other involved financial institutions under Section 314(b). These red flags are based primarily upon schemes and typologies described in SARs or identified by our law enforcement and regulatory partners, and may be updated in future guidance.

- A customer appears to be using a state-licensed marijuana-related business as a front or pretext to launder money derived from other criminal activity (*i.e.*, not related to marijuana) or derived from marijuana-related activity not permitted under state law. Relevant indicia could include:
    - The business receives substantially more

    revenue than may reasonably be expected given the relevant limitations imposed by the state in which it operates.
    - The business receives substantially more revenue than its local competitors or than might be expected given the population demographics.
    - The business is depositing more cash than is commensurate with the amount of marijuana-related revenue it is reporting for federal and state tax purposes.
    - The business is unable to demonstrate that its revenue is derived exclusively from the sale of

marijuana in compliance with state law, as opposed to revenue derived from (i) the sale of other illicit drugs, (ii) the sale of marijuana not in compliance with state law, or (iii) other illegal activity.

- The business makes cash deposits or withdrawals over a short period of time that are excessive relative to local competitors or the expected activity of the business.
- Deposits apparently structured to avoid Currency Transaction Report ("CTR") requirements.
- Rapid movement of funds, such as cash deposits followed by immediate cash withdrawals.
- Deposits by third parties with no apparent connection to the accountholder.
- Excessive commingling of funds with the personal account of the business's owner(s) or manager(s), or with accounts of seemingly unrelated businesses.
- Individuals conducting transactions for the business appear to be acting on behalf of other, undisclosed patties of interest.
- Financial statements provided by the business to the financial institution are inconsistent with actual account activity.
- A surge in activity by third parties offering goods or services to marijuana-related businesses, such as equipment suppliers or shipping servicers.
- The business is unable to produce satisfactory documentation or evidence to demonstrate

that it is duly licensed and operating consistently with state law.

- The business is unable to demonstrate the legitimate source of significant outside investments.
- A customer seeks to conceal or disguise involvement in marijuana-related business activity. For example, the customer may be using a business with a non-descript name (e.g., a "consulting," "holding," or "management" company) that purports to engage in commercial activity unrelated to marijuana, but is depositing cash that smells like marijuana.
- Review of publicly available sources and databases about the business, its owner(s), manager(s), or other related parties, reveal negative information, such as a criminal record, involvement in the illegal purchase or sale of drugs, violence, or other potential connections to illicit activity.
- The business, its owner(s), manager(s), or other related parties are, or have been, subject to an enforcement action by the state or local authorities responsible for administering or enforcing marijuana-related laws or regulations.
- A marijuana-related business engages in international or interstate activity, including by receiving cash deposits from locations outside the state in which the business operates, making or receiving frequent or large interstate transfers, or otherwise transacting with persons or entities located in different states or countries.
- The owner(s) or manager(s) of a marijuana-related business reside outside the state in which the business is located.

- A marijuana-related business is located on federal property or the marijuana sold by the business was grown on federal property.
- A marijuana-related business's proximity to a school is not compliant with state law.
- A marijuana-related business purporting to be a "non-profit" is engaged in commercial activity inconsistent with that classification, or is making excessive payments to its manager(s) or employee(s).

Currency Transaction Reports and Form 8300's

Financial institutions and other persons subject to FinCEN's regulations must report currency transactions in connection with marijuana-related businesses the same as they would in any other context, consistent with existing regulations and with the same thresholds that apply. For example, banks and money services businesses would need to file CTRs on the receipt or withdrawal by any person of more than $10,000 in cash per day. Similarly, any person or entity engaged in a non-financial trade or business would need to report transactions in which they receive more than $10,000 in cash and other monetary instruments for the purchase of goods or services on FinCEN Form 8300 (Report of Cash Payments Over $10,000 Received in a Trade or Business). A business engaged in marijuana-related activity may not be treated as a non-listed business under 31 C.F.R. § 1020. 315(e)(8), and therefore, is not eligible for consideration for an exemption with respect to a bank's CTR obligations under 31 C.F.R. § 1020.315(b)(6).

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FinCEN's enforcement priorities in connection with this guidance will focus on matters of systemic or significant failures, and not isolated lapses in technical compliance. Financial institutions with questions about this guidance are encouraged to contact FinCEN's Resource Center at (800) 767-2825, where industry questions can be addressed and monitored for the purpose of providing any necessary additional guidance.

JUSTICE DEPT PRESS RELEASE: "JUSTICE DEPARTMENT ISSUES MEMO ON MARIJUANA ENFORCEMENT" (JANUARY 4, 2018)

Department of Justice
Office of Public Affairs

The Department of Justice today issued a memo on federal marijuana enforcement policy announcing a return to the rule of law and the rescission of previous guidance documents. Since the passage of the Controlled Substances Act (CSA) in 1970, Congress has generally prohibited the cultivation, distribution, and possession of marijuana.

In the memorandum, Attorney General Jeff Sessions directs all U.S. Attorneys to enforce the laws enacted by Congress and to follow well-established principles when pursuing prosecutions related to marijuana activities. This return to the rule of law is also a return of trust and local control to federal prosecutors who know where and how to deploy Justice Department resources most effectively to reduce violent crime, stem the tide of the drug crisis, and dismantle criminal gangs.

"It is the mission of the Department of Justice to enforce the laws of the United States, and the previous issuance of guidance undermines the rule of law and the ability of our local, state, tribal, and federal law enforcement partners to carry out this mission," said Attorney General Jeff Sessions. "Therefore, today's memo on federal marijuana enforcement simply directs all U.S. Attorneys to use previously established prosecutorial principles that provide them

all the necessary tools to disrupt criminal organizations, tackle the growing drug crisis, and thwart violent crime across our country."

PRESS RELEASE BY SENATOR CORY GARDNER (R-CO) (APRIL 13, 2018)

GARDNER PROTECTS COLORADO'S LEGAL MARIJUANA INDUSTRY
Receives Commitment from President Trump to Support Legislation to Protect States' Rights

354 Russell Senate Office Building,
Washington, DC 20515
(202) 224-5941

Washington, DC—Senator Cory Gardner (R-CO) today released the below statement regarding the current status of the Administration's policy toward legal marijuana.

In response to the Department of Justice's January 4 announcement that Attorney General Jeff Sessions had rescinded the Cole Memorandum, Senator Gardner placed a hold on all DOJ nominees until he received a commitment that Colorado's rights would not be infringed. After positive discussions with DOJ, Gardner lifted some of his holds but kept the rest in place until he received a full commitment that the guidelines of the Cole Memo would be respected.

"Since the campaign, President Trump has consistently supported states' rights to decide for themselves how best to approach marijuana," said Gardner. "Late Wednesday, I received a commitment from the President that the Department of Justice's rescission of the Cole memo will not impact Colorado's legal marijuana industry. Furthermore, President Trump

has assured me that he will support a federalism-based legislative solution to fix this states' rights issue once and for all.

"Because of these commitments, I have informed the Administration that I will be lifting my remaining holds on Department of Justice nominees. My colleagues and I are continuing to work diligently on a bipartisan legislative solution that can pass Congress and head to the President's desk to deliver on his campaign position."

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Cory Gardner is a member of the U.S. Senate serving Colorado. He sits on the Energy & Natural Resources Committee, the Foreign Relations Committee, the Commerce, Science, & Transportation Committee, and the Budget Committee, and is the Chairman of the Subcommittee on East Asia, the Pacific, and International Cybersecurity Policy.

354 Russell Senate Office Building
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ISU MISSOULA STUDY (2002)

CHRONIC CANNABIS USE IN THE COMPASSIONATE INVESTIGATIONAL NEW DRUG PROGRAM: AN EXAMINATION OF BENEFITS AND ADVERSE EFFECTS OF LEGAL CLINICAL CANNABIS

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ABSTRACT. The Missoula Chronic Clinical Cannabis Use Study was proposed to investigate the therapeutic benefits and adverse effects of prolonged use of "medical marijuana" in a cohort of seriously ill patients. Use of cannabis was approved through the Compassionate Investigational New Drug (IND) program of the Food and Drug Administration (FDA). Cannabis is obtained from the National Institute on Drug Abuse (NIDA), and is utilized under the supervision of a study physician. The aim of this study is to examine the overall health status of 4 of the 7 surviving patients in the program. This project provides the first opportunity to scrutinize the long-term effects of cannabis on patients who have used a known dosage of a standardized, heat-sterilized quality-controlled supply of low-grade marijuana for 11 to 27 years.

Results demonstrate clinical effectiveness in these patients in treating glaucoma, chronic musculoskeletal pain, spasm and nausea, and spasticity of multiple sclerosis. All 4 patients are stable with respect to their chronic conditions, and are taking many fewer standard pharmaceuticals than previously.

Mild changes in pulmonary function were observed in 2 patients, while no functionally significant attributable sequelae were noted in any other physiological system examined in the study, which included: MRI scans of the brain, pulmonary function tests, chest X-ray, neuropsy-chological tests, hormone and immunological assays, electroencephalography, P300 testing, history, and neurological clinical examination.

These results would support the provision of clinical cannabis to a greater number of patients in need. We believe that cannabis can be a safe and effective medicine with various suggested improvements in the existing Compassionate IND program. *[Article copies available for a fee from The Haworth Document Delivery Service: 1-800-HAWORTH. E-mail address: <getinfo@haworthpressinc.com> Website: <http://www.HaworthPress.com>*

KEYWORDS. Cannabis, medical marijuana, hashish, investigational new drug, compassionate use, NIDA, FDA, herbal medicine, analgesia, spasticity, chronic pain, glaucoma, multiple sclerosis, epidemiology, history of medicine, drug policy

INTRODUCTION

The Missoula Chronic Clinical Cannabis Use Study was proposed to investigate the therapeutic benefits and adverse effects of prolonged use of "medical marijuana" in a cohort of seriously ill patients approved through the Compassionate Investigational New Drug (IND) program of the Food and Drug Administration (FDA) for legal use of cannabis obtained from the National Institute on Drug Abuse (NIDA), under the supervision of a study physician. The aim

was to examine the overall health status of 8 surviving patients in the program. Four patients were able to take part, while three wished to remain anonymous, and one was too ill to participate. Unfortunately, that person, Robert Randall, succumbed to his condition during the course of the study. Thus, 7 surviving patients in the USA remain in the Compassionate IND program.

Despite the obvious opportunity to generate data on the use of cannabis and its possible sequelae in these patients, neither NIDA, other branches of the National Institutes of Health, nor the FDA has published an analysis of information from this cohort. An examination of the contents of the National Library of Medicine Database (PubMed), and search engines of NIDA employing multiple combinations of key words failed to retrieve a single citation. The Missoula Chronic Cannabis Use Study thus provides a unique and important opportunity to scrutinize the long-term effects of cannabis on patients who have used a known dosage of standardized, heat-sterilized quality-controlled supply of low-grade medical marijuana for 11 to 27 years.

The results are compared to those of past chronic use studies in an effort to gain insight into the benefits and sequelae of this controversial agent in modern health care.

PREVIOUS CHRONIC CANNABIS USE STUDIES

The first systematic modern study of chronic cannabis usage was the *Indian Hemp Drugs Commission Report* at the end of the 19th century (Kaplan 1969; Indian Hemp Drugs Commission 1894). The British government chose not to outlaw cultivation and

commerce of the herb after ascertaining that it had negligible adverse effects on health, even in chronic application.

Similar conclusions were obtained in the "La-Guardia Report" of 1944 (New York, NY), Mayor's committee on marihuana (Wallace, and Cunningham 1944), which was the first to employ clinical and scientific methods of analysis.

Three important systematic epidemiological studies undertaken by research teams in the 1970's exhaustively examined medical issues in chronic cannabis use, but remain obscure due to limited press runs and out-of-print status. The first of these was *Ganja in Jamaica: A Medical Anthropological Study of Chronic Marihuana Use* (Rubin and Comitas 1975). Therapeutic claims for cannabis were mentioned, but the focus of study was on "recreational use." Sixty men were included in a hospital study of various clinical parameters if they had maintained a minimum intake of 3 spliffs a day for a minimum of 10 years. Jamaican ganja "spliffs" formed of unfertilized female flowering tops (sinsemilla) tend to be much larger than an American "joint" of 500-1000 mg. The potency of the cannabis was analyzed with measures in 30 samples ranging from 0.7-10.3% THC, with an average of 2.8%.

In 1977, a detailed study was undertaken in Greece, titled *Hashish: Studies of Long-Term Use* (Stefanis, Dornbush, and Fink 1977). Once again 60 subjects smoking for more than 10 years were selected. Hashish potency was 4-5% THC and was generally mixed with tobacco. Alcoholics were excluded.

In 1980, *Cannabis in Costa Rica: A Study of Chronic Marihuana Use* was published (Carter 1980).

Forty-one subjects smoking for 10 years or more were recruited. Although 10 or more cigarettes per day were smoked, the weight of material was only 2 g with an estimated THC range of 24-70 mg per day. Thirteen samples were assayed with a range of 1.27-3.72%, and average of 2.2% THC. Claims of benefit for cough, asthma, headache, hangovers, anorexia, impotence, depression and malaise were mentioned, but once more, the focus was on social use.

The current study is the first designed to examine clinical benefits and side effects of chronic clinical cannabis usage in which known amounts of quality-controlled material has been employed.

A BRIEF HISTORY OF THE COMPASSIONATE IND

Robert Randall was diagnosed with severe glaucoma at age 24 and was expected to become totally blind long before he turned 30. He soon began a fascinating medical odyssey that has been memorialized in his "personal reflection" co-authored by his wife, Alice O'Leary, titled *Marijuana Rx: The Patients' Fight for Medicinal Pot* (Randall and O'Leary 1998), and other books (Randall 1991a; Randall 1991b). Until the day he died on June 2, 2001 at age 52 of complications of AIDS, Randall retained his vision, and remained a vocal advocate for the benefits of clinical cannabis.

His own journey commenced when he independently discovered that smoking a certain amount of cannabis eliminated the annoying visual haloes produced by his glaucoma. A subsequent arrest in August 1975 for cannabis cultivation led in turn to his dogged pursuit of the right to a legal means to supply his medicine of choice. He subsequently learned of medical support for his treatment (Hepler and Frank

1971). D. Pate has published two more recent reviews (Pate 1999; Pate 2001).

Through painstaking documentation and experimentation, Randall subsequently confirmed the inability of medical science to control his intraocular pressure (IOP) by any legal pharmaceutical means. In contrast, smoked cannabis in large and frequent amounts was successful, where even pure THC was not. As Dr. Hepler observed in their experiments together (Randall and O'Leary 1998, p. 60), " . . . clearly, something other than THC or in addition to THC is helping to lower your pressures. . . . It seems that marijuana works very, very well."

After a great deal of bureaucratic wrangling, Randall obtained his first government supplied cannabis in November 1976, and the legal case against him was subsequently dismissed. The material he received from his study physician was cultivated in a 5-acre plot at the University of Mississippi, mostly from seeds of Mexican origin, and was rolled and packaged at the Research Triangle Institute in North Carolina under the supervision of the National Institute on Drug Abuse (NIDA).

Randall was encouraged to be thankful, but silent, about his treatment. Instead, he chose a different path (Randall and O'Leary 1998, p. 134), "Having won, why go mum? There were souls to save. Better to trust my fellow citizens and shout into the darkness than rely on a devious Government dedicated to a fraudulent prohibition." He chose to make it his mission to seek approval of clinical cannabis for other patients. He developed protocols for glaucoma, multiple sclerosis, chronic pain, and AIDS that he shared with prospective medical marijuana candidates. Randall proved to be a

tireless and persistent researcher, ferreting out hidden facts useful to his cause. Through the Freedom of Information Act (FOIA), he discovered in 1978 that the government's cost of cannabis cultivation and production was 90 cents per ounce (28 g), with 2/3 of this cost attributable to security measures. Thus, the actual cost of production approximated 1 cent per gram (US $0.01/g).

Supply and quality control issues arose frequently, and Randall and other patients experienced delays in receipt of shipments or substitution of weaker strains that required doubling of smoked intake.

The AIDS epidemic and its subsequent involvement in the medical marijuana issue suddenly provided an unlimited supply of available patients for the Compassionate IND program, and Randall assisted them as well. Some succumbed before their supply was approved, or shortly thereafter. By 1991, 34 patients were enrolled in the program according to Randall (Randall and O'Leary 1998), while other sources cite the number as only 15. Facing an onslaught of new applications, the Public Health Service (PHS) in the Bush administration closed the program to new patients in March 1992. A significant number had received medical approval but were never supplied. Randall sought to ascertain who signed the ultimate termination order through the FOIA, but was never successful in this endeavor. At the time of this writing, 7 patients survive in the program.

METHODS

The identities of 6 of 8 of the original Compassionate IND program subjects were known to Patients

Out of Time and were contacted in relation to participating in a study of the clinical parameters cited as concerns with chronic cannabis usage. Four subjects agreed to participate, and 3 traveled to Missoula, MT for testing at Montana Neurobehavioral Specialists, and Saint Patrick Hospital on May 3-4, 2001. One patient was tested to the extent possible in her local area due to physical limitations on travel (Patient Demographics: Table 1). Tests included the following (Tests Performed: Table 2): MRI scans of the brain, pulmonary function tests (spirometry), chest X-ray (P-A and lateral), neuropsychological test battery, hormone and immunological assays (CD4 counts), electroencephalography (EEG), P300 testing (a computerized EEG test of memory), and neurological history and clinical examination.

Past medical records were reviewed insofar as possible and the histories were supplemented with additional information. All patients signed informed consent documents, and the St. Patrick Hospital/ Community Hospital Joint Investigational Review Board (IRB) reviewed the protocol.

RESULTS AND DISCUSSION

Case Histories and Test Data on Four Compassionate IND Program Patients

In the following section case histories, clinical examinations and objective test results are presented.

Patient A

Medical History: This almost 62-year-old female was born with congenital cataracts in Cali, Colombia and spent 13 years of her life there. There was a ques-

tion of possible maternal exposure to malaria or quinine. Over time the patient required a series of 11 surgeries on the right eye and 3 on the left for the cataracts and had resulting problems with glaucoma. Her last surgery was complicated by hemorrhaging, leading to immediate and complete loss of vision OD.

By 1976, the patient's intraocular pressure was out of control with all available drugs, many of which caused significant side effects. At that time she started eating and smoking cannabis to treat the condition. She underwent extensive testing in that regard, measuring pressures to titrate the dosage of cannabis. She initially had personal issues with the concept of smoking. Without cannabis her intraocular pressures may run into the 50's, while with it, values are in the teens to 20's. In 1988, she was arrested for cultivation of 6 cannabis plants. Her ophthalmologist noted (Randall and O'Leary 1998, p. 303), "it's quite clear-cut this is the only thing that will help her." At her trial, she stated in her own defense (Randall and O'Leary 1998, p. 305), "Marijuana saved my sight. I don't think the law has the right to demand blindness from a citizen." She was acquitted on the basis of "medical necessity," but her approval for the Compassionate IND program took 6 months. She had smoked cannabis on her own from black market sources for 12 years previously. MRI scan of the brain.

TABLE 2. TESTS PERFORMED:
CHRONIC CANNABIS IND STUDY

Pulmonary function tests (Spirometry)

Chest X-ray, P-A & lateral (Patients A-C)

Neuropsychological tests

Wechsler Adult Intelligence Scale–
3rd Edition (WAIS-III)

Wechsler Memory Scale–3rd Edition
(WMS-III)

California Verbal Learning Test (CVLT)

Halstead-Reitan Battery

Trail Making Test A & B

Grooved Peg Board

Finger Tapping and Category Subtests

Controlled Oral Word Association Test

Thurstone Word Fluency Test

Category Fluency Test (animal naming)

Wisconsin Card Sorting Test (WCST)

Conner's Continuous Performance Test–
2nd Edition (CPT-II)

Beck Depression Inventory–
2nd Edition (BDI-II).

Endocrine assays

FSH, LH, prolactin, estradiol, estrone, estrogen, testosterone, progesterone

Immunological assays

CBC, CD4 count

Electroencephalography (EEG) (Patients A-C)

P300 testing (Patients A-C)

Neurological examination

At present, she also uses Timoptic . . . (timolol, beta-blocker) eye drops daily in the morning, but has concerns about resulting bronchoconstriction.

She normally uses cannabis 3-4 grams smoked and 3-4 grams orally per day. She feels that the amount that she receives legally from NIDA is insufficient for her medical needs. At times she accepts donations from cannabis buyers' clubs. She admits that the results of these outside cannabis samples on her intraocular pressure are unclear. She has had occasion to go to Amsterdam where intraocular pressures were measured in the teens simply employing cannabis available there. She has used Marinol . . . on an emergency basis, such as on traveling to Canada, in doses of up to 5-10 mg qid. She reports that it lowers intraocular pressure for one day, but within 3-5 days becomes useless for that purpose.

The patient has a history of cigarette smoking as well, 1-2 packs a day. She quit in 1997, but subsequently went on a "binge" of cigarette smoking for 13 months, finally quitting on New Year's Day 2001. She feels that past pulmonary function has been normal.

She also notes lifelong insomnia that is alleviated by eating cannabis. Without such treatment, she feels she would sleep 4 hours, whereas with it she sleeps 6-7. She also feels that the drug produces antidepressant and antianxiety effects for her. She has a history of scoliosis, but notes no symptoms from this and feels that muscle relaxant effects of cannabis have made her quite limber.

The patient had a history of delirium associated with malaria as a child. She had some hardware in her foot from a 1980 surgery after a fall from platform

shoes. She had a hysterectomy for fibroids. The patient was menopausal at age 48 and has had no hormone replacement treatment. There is no known history of specific meningitis, encephalitis, head trauma, seizures, diabetes, or thyroid problems. She is on no medicine save for cannabis and timolol eye drops. There are allergies to penicillin and tetracycline. She completed the equivalent of high school, and is right handed.

Family history is largely negative, although her 2 children had some cataract involvement.

Social history revealed that the patient has worked in the past as a switchboard operator. She is currently disabled due to legal blindness from her condition. She supports herself on Social Security Disability Income (SSDI). She has been an activist with respect to clinical cannabis. The patient drinks alcohol at a rate of about a bottle of wine a week. She had past heavy use of caffeine, but now drinks decaf only. The patient walks for exercise about an hour a day.

Medical Test Results: Objective: Weight: 132 lbs. OFC (Occipitofrontal Circumference): 55.5 cm. BP: 104/62. General: Very pleasant, cooperative 62-year-old female. Head: normocephalic without bruits. ENT: noteworthy as below. Neck: supple. Carotids: full. Cor: S1, S2 without murmur. On auscultation of the chest, there seemed to be a prolonged expiratory phase, but no wheezing. Mental Status: The patient was alert and fully oriented. Fund of knowledge, right-left orientation, praxis and naming skills were normal. She was unable to read a grade 6 paragraph with large type due to visual blurring. When it was read to her, memory of the contents was within normal limits. She performed serial 3's well. She remembered 3 objects

for 5 minutes. On a word list task she named 15 animals in 30 seconds (normal 10-12). Speech and affect were normal.

Cranial Nerves: I: intact to coconut scent. II: acuity had recently been measured. There was no vision OD, 20/200 OS corrected. Visual fields OS intact to confrontation. Optokinetic nystagmus (OKNs) was present in that eye in all fields. The patient is aphakic with an irregular eccentric pupil OS and clouding OD. The disk on the left appeared normal. There was prominent horizontal nystagmus resembling a congenital pattern. External extraocular movements were normal. Remaining cranial nerves V and VII-XII appeared intact in full.

Motor: The patient had normal tone and strength with no drift. Sensation was intact to fine touch, sharp/dull, vibration, position and graphesthesia. Romberg was negative. The patient performed finger-to-nose and heel-to-shin well. Rapid alternating movements of the hands were slightly clumsy and fine finger movements slightly deliberate. Gait including toe and heel were normal with tandem gait normal, but very carefully done. Reflexes were 2-3+, symmetric with downgoing toes.

The patient underwent a battery of tests. On pulmonary function tests (Table 3), a Functional Vital Capacity (FVC) was 103% predicted. Forced Expiratory Volume in 1 second (FEV_1) was 84% of predicted and the FEV_1/FVC ratio was 0.67. This was read as showing a mild obstructive defect based on the above ratio and flow volume curve morphology. No restrictive abnormality was noted. A CBC was wholly within normal limits (Table 4). Absolute lymphocyte count was 4.0, CD4 61.6% and absolute CD4 count 2465, all

within normal limits. A full endocrine battery was performed (Table 5), including FSH, LH, prolactin, estradiol, estrone, estrogen, testosterone, and progesterone, all within normal limits for age and gender.

The patient had a P300 test performed with a latency of 355 milliseconds, within normal limits for a normed population in this laboratory (Figure 1).

The patient had an MRI brain study without contrast. This was read as showing a mild, symmetric, age consistent cerebral atrophy. A small focus of T2 hyperintensity and increased signal was noted on the FLAIR sequence in the mid-pons to the left of midline with no surrounding mass effect or edema. This was felt to be a nonspecific finding representing gliosis most likely from microvascular ischemic change. No corresponding signal abnormality was seen in the same area on a diffusion-weighted sequence.

A chest x-ray showed slight hyperinflation of the lung fields with no other findings.

Patient A was very pleasant and cooperative throughout the neuropsychological assessment and appeared to put forth very good effort. She did have very significant visual deficits and as a result, several instruments were dropped from the battery, including Grooved Peg Board, Picture Arrangement, Symbol Search, and the Faces and Family Pictures Subtests from the Wechsler Memory Scale–3rd Edition (WMS-III). She was able to complete the Trail-Making Test A & B from the Halstead-Reitan Neuropsychological Battery, Spatial Span from the Wechsler Memory Scale–3rd Edition (WMS-III), and the Wechsler Adult Intelligence Scale–3rd Edition (WAIS-III)-Picture Completion, Digit Symbol, and Matrix Reasoning, but

these were not used in interpretation secondary to the very probable interfering effects of her limited sight.

Review of the WAIS-III revealed a Verbal IQ in the upper end of the Average Range (VIQ = 108), and a Performance IQ in the Extremely Low Range, at only the 2nd percentile (PIQ = 69). This latter, however, is secondary to visual deficits as she had extremely low scores on the Digit Symbol and Picture Completion subtests. She obtained an age scaled score of 7 on Block Design; this performance was also adversely impacted by her visual defects to a mild degree.

Assessment of attention and concentration revealed that these abilities are mildly-to-moderately impaired relative to age-matched controls. She demonstrated an abnormally high number of omission errors on the Conner's Continuous Performance Test–2nd Edition (CPT-II) as well as significant variability of reaction time.

Formal assessment of learning and memory revealed that this subject's ability to acquire new verbal material on the WMS-III is within the Average Range relative to age-matched peers. Her Auditory Immediate Index score was in the average range as was her Auditory Delayed Index. She obtained index scores of 97 and 108 on these two indices, respectively. Recognition memory for auditory material was actually in the High Average range, the 75th percentile (Index Score = 110). In contrast she did much more poorly on visual measures secondary to very significant visual defects.

On the California Verbal Learning Test (CVLT), the subject generally performed within normal limits.

Although initial learning trials were two standard deviations below expected limits, her ultimate acquisition at Trial 5 was one standard deviation above normative data sets. Short Delay Free Recall was perfectly normal and long delay recall was only one standard deviation below expected levels. This loss of recalled items from short delay to long delay free recall represented a loss that is approximately 1 standard deviation more than expected. Thus, she appeared to have mild difficulties with initial acquisition of very complex verbal material and also appeared to have minimal-to-mild difficulty retaining it in memory relative to age-matched peers.

Higher-level executive functions appear to be entirely normal in this patient. The Wisconsin Card Sorting Test (WCST) yielded a T-score of 63, while she obtained a T-score of 42 on the Category Test. Thus, she is still within the parameters seen in a normative data set of age and education-matched peers.

This subject's performance on the Thurstone Word Fluency Test was also entirely normal with a T-score of 51. Likewise, on the Controlled Oral Word Association Test, she obtained an overall score placing her at the 78th percentile. She produced 26 items on the Animal Naming Test over a 60-second period. This is within normal limits.

On the Beck Depression Inventory–2nd Edition, she obtained an overall score of 6, arguing against significant depressive symptoms.

In summary, Patient A appears to have mild-to-moderate difficulty with attention and concentration, and minimal-to-mild difficulty with the acquisition

and storage of very complex new verbal material. General learning, however, as measured on the Wechsler Memory Scale–3rd Edition (WMS-III) appears to be within normal limits. Higher-level executive functions and verbal fluency abilities are well within normal limits.

Patient B

Medical History: This 50-year-old white male carries the diagnosis of the nail-patella syndrome, also known as hereditary osteoonychodysplasia, a rare genetic disorder producing hypoplastic nails and kneecaps and renal insufficiency. Information was obtained from the patient, a published affidavit (Randall 1991b), and submitted medical records.

He first smoked cannabis in 1970, but did not become "high." Rather, he felt more relaxed, without his customary muscle spasms and pain. He first actually used clinical cannabis in a different manner. At the time he was mining, and he developed chemical burns in his hands. A Mexican lady gave him a tincture of cannabis flowering tops in grain alcohol to apply. This reduced his hand swelling and burning.

He has been smoking cannabis regularly for medical purposes since about 1974. During a medical crisis in 1985, he suffered a decrease in supply of available cannabis. His recollection is that all the various analgesics he received during this time were ineffective and produced of dangerous side effects including sedation and incapacity.

By 1988, he pursued regular usage of cannabis, about 1/8 of an ounce (3 1/2-4 g/d) a day when available. He initiated inquiries with the FDA to obtain

legal cannabis. Ultimately, with the assistance of Robert Randall, he received approval from the government in March 1990.

He related a history of deformities from birth including missing fingernails, loose finger joints, and small patellae. He was frequently ill as a child, and at age 10, suffered a progression from conjunctivitis to varicella, strep throat and rheumatic fever. He was hospitalized for 6 months, and required another 3 months of bed rest. Subsequently, he underwent four right knee surgeries, reconstructions and rotations, including 3 arthroscopies. He had had a right wrist graft with non-fusion. He had had right elbow surgery and had a "nicked" ulnar nerve. In the late 1960's he developed both hepatitis A and B with prolonged hospitalizations. Despite this, he pursued heavy manual labor in mining, construction, auto bodywork and aircraft repair. He lost all his teeth by age 21. In 1972 he dislocated his knee and had 3 subsequent surgeries. In 1976 he had a wrist fracture with subsequent surgery and later fusion. In 1978 he was hospitalized after a nail wound in his foot failed to heal. In 1983, he injured his back in a fall. Pain continued.

After a 1985 chiropractic session, he became acutely ill with severe back pain. He was given narcotics, and suffered renal failure. He was transferred to a university center. Lithotripsy sessions were followed by transurethral procedures in attempts to clear his nephrolithiasis. Eventually an open procedure was performed for perinephric abscess, but the flank wound failed to heal over the course of a year. Ultimately, it was determined that he was suffering a tubercular nephritis. He took triple therapy with isoniazid (INH), rifampin and pyridoxine regularly for

18 months. Eventually, a massive debridement was necessary, before the flank wound eventually healed. His prolonged convalescence forced him to close his business.

On September 3, 1987, he complained of persistent flank pain and low back discomfort increasing over the preceding 2 years treated with multiple modalities, including TENS unit. He also was using an abdominal binder. Pain radiated to the buttocks and posterior thighs. X-rays of the lumbar spine showed spondylolisthesis grade 1 in the lumbar area with no significant motion of flexion extension views.

On April 8, 1988, the patient was seen for right knee pain after a twisting injury and fall. An effusion developed. X-rays showed a micropatella consistent with nail-patella syndrome, but no evidence of fracture. He was treated conservatively. In October, 1988, chest x-ray showed a diffuse nodular infiltrate unchanged since September 1985.

By June 7, 1989, the patient was in a wheelchair, but was able to ambulate with a cane. Previous x-rays showed bilateral iliac spurs. His chart notes included an FDA consent form in relation to the patient's use of cannabis (Figure 2). On subsequent visits, he had been approved for the Compassionate IND program, and was smoking 10 cannabis cigarettes a day.

On April 1, 1991, some cough was noted attributed to cigarettes. As a baseline, very severe pain was noted in the extremities, but this was reduced to slight to moderate on subsequent visits. By April 17, 1991, the patient was on no medicines except for cannabis. By January 18, 1993, he was said to have only slight

to moderate problems with a cane for support. There were some abdominal spasms.

On the May 14, 1996 visit, he was smoking 10 cannabis cigarettes a day. He used occasional aspirin for increased pain. He had resumed smoking 1/2 to 1 pack of cigarettes a day. Examination was fairly unremarkable save for orthopedic deformities. He was able to walk on his toes and heels. The patient was given 2 more packages of 300 marijuana cigarettes.

On July 16, 1996, the patient was seen for disability examination. It was noted the patient had suffered for many years from lack of strength, mobility and range of motion, and persistent episodes of nausea and muscle spasms. The note indicated, "the marijuana helps the patient function better in the sense that he has increased flexibility, increased strength and range of motion. He has less nausea and less muscle spasm." He needed to shift into different positions at home to get comfortable and could do a sit down type job for an hour or two at most before experiencing spasms, pain and nausea. He had limited backward flexion, and limited right hand strength. He was unable to kneel. He could walk 50 feet before needing to rest, used a cane and sometimes a wheelchair for longer distances. It was felt he could not be a traveling salesman, and any prospective job would require frequent rests. Overall, he was assessed as having a significant functional impairment due to nail-patella syndrome, and was judged unemployable in the short or long term, with little rehabilitation potential.

A May 9, 1997 letter indicates, "continues to smoke about 8-10 marijuana cigarettes per day and still continues to benefit from that medication. He has less

pain, less spasms, he is able to ambulate better. His nausea is improved, he is able to sleep better. He is making some slow deterioration of this disease process." It goes on to say, "I personally do feel that [Patient B] continues to benefit from marijuana and hope that we can continue providing this unfortunate man with marijuana medication."

On May 10, 2000, a letter to FDA noted the patient continued to do well on the therapy, smoking 8-10 cigarettes per day without other medication. He continued to function well using a cane and occasionally a wheelchair when bothered by spasms and nausea.

At present, he utilizes about 7 grams a day or 1/4 ounce of NIDA material that is 3.75% THC, and was processed in April 1999. The patient cleans the cannabis to a minimal degree first, estimating a loss of about 25% of material. He indicates that he has been short on his supply 3 times in 10 years, generally for 1-2 weeks, secondary to lack of supply or paperwork problems. When this occurs he suffers more nausea and muscle spasms and is less active as a consequence. He was never allowed to try Marinol . . . , and points out that he could not afford it in any event.

The patient reports continued problems with pain in the back, hips and legs, also in the upper extremities, right greater than left. When he undergoes spasms the pain rises to a 10 on a 10-point scale and is associated with projectile emesis. His baseline level of pain is 6-7/10. He notes that this pain was never helped by prescription medicines. Morphine sulfate produced a minimal decrement in pain for up to two hours, but caused inebriation. By the third day of application it would become totally ineffective. Without cannabis he feels that he would need very high

doses of narcotics. He previously had dependency issues and took heroin for 2 years in the mid-1960's. Eventually he had become allergic to most pharmaceutical preparations, or had side effects of nausea. The latter continues, particularly in static positions, which without cannabis treatment he rates as a 10/10. In 1985, he was without cannabis for some 30 days and lost 57 pounds when his supply ran out at the same time that he had TB nephritis.

In relation to the spasms, these can occur anywhere in his body. He feels the medicine eliminates them or substantially reduces nocturnal manifestations. Without it he would be "running" at night.

He has no history of diabetes, thyroid problems, meningitis, encephalitis, or head trauma. He may have had seizures associated with fever. The patient has taken rare antibiotics for staph infections of the skin. He feels that he has had lots of reactions to synthetic chemicals of various types, which he considers quite serious. The patient left school at age 14 originally, but attained a GED and had some junior college experience. He is left-handed.

Family history is noteworthy for nail-patella syndrome in mother, niece, two sisters, nephew and daughter. One sister died of the disease at age 44. He has two unaffected children. His affected daughter does not receive legal cannabis. His father died of TB and tumors at age 40.

Social History: He currently smoked cigarettes about 1/2 pack a day, but as high as a pack a day in the past. The patient drinks beer about 1 a month, with little alcohol use in 10 years. The patient last worked full-time in 1985, and part-time in 1990. He is

on SSDI, but does volunteer and activist work. The patient is able to walk very little due to pain, but bikes when he can a short distance (about 4 miles every other day). The patient sleeps from 10 p.m. to 6 a.m., but this is disrupted due to pain or nausea.

Medical Test Results: Weight: 173 lbs. Height: 69 inches (BMI: 25.6). OFC: 60 cm. BP: 122/80. General: Very pleasant, cooperative 50 YOM who appears somewhat wizened. Head: normocephalic without bruits. ENT was noteworthy for edentulous state. Neck: supple. Carotids: full, without bruit. Cor: S1, S2 without murmur. The patient has a large indentation scar in the right flank. Palpation to the spine was unremarkable. Chest auscultation revealed a prolonged expiratory phase without wheezing. Abdominal examination was unremarkable. He had dysplastic nails.

Mental Status: The patient was alert and fully oriented. Fund of knowledge, right-left orientation, praxis and naming skills were normal. He read a grade 6 paragraph well with good recall. Serial 3's were well done. Signature was normal. He remembered 2 of 3 objects after 5 minutes with hesitation, failed the third with hint, but got it with choice of 3. He had a hoarse voice. He named 11 animals in 30 seconds (normal). Affect was normal. Cranial Nerves: I: intact. II: acuity was measured as 20/25 OD, 20/50 OS uncorrected. Fields and OKNs were normal. Fundi were benign. Pupils equally reactive with full EOMs and no nystagmus. Remaining cranial nerves V and VII-XII were unremarkable. On motor examination, the patient had hypotonicity, but decreased bulk. The patient lacked full elbow extension on the right. His strength was generally 4+ secondary to limitations and pain. There was no arm drift. Sensation was intact

to fine touch, vibration, position and graphesthesia, but there was some slight vibratory loss in the feet. Romberg was negative. The patient performed finger-to-nose well. Heel-to-shin required partial assist of the hands. Rapid alternating movements of the hands were very slow on the right secondary to mechanical problems. Fine finger movements were normal. The patient had a stiff, bent gait, but toe gait appeared more normal. On heel gait he favored the left leg. Tandem gait was difficult due to back pain and he wavered some. I was unable to ascertain reflexes at the biceps on the right, but responses elsewhere were 1-2+ with downgoing toes.

The patient underwent the prescribed battery of tests. Pulmonary function tests revealed an FVC of 107% of predicted, FEV_1 of 95% of predicted, and FEV_1/FVC of 0.75. This was interpreted as within normal limits, but with a slightly prolonged forced expiratory time (Table 3). A complete blood count showed some mild polycythemia, probably due to tobacco smoking. An absolute lymphocyte count was 3.4 with CD4 count 68.7% and absolute count of 2324 (Table 4). The patient had a full endocrine battery. Measurement of FSH, LH, prolactin, estradiol, estrone, estrogen, testosterone and progesterone were wholly within normal limits for age and gender (Table 5). An EEG was performed during wakefulness and was within normal limits, but did demonstrate some low voltage fast activity in the beta range, with no focal or epileptiform activity. The patient had a P300 response with a latency of 338 milliseconds, within normal limits for the laboratory (Figure 1). An MRI of the brain without contrast was read as normal. A PA and lateral chest was read as normal.

Patient B was friendly and cooperative and appeared to put forth very good effort on neuropsychological testing. On the WAIS-III, he obtained Verbal and Performance IQ Scores in the Average Range (VIQ = 105 and PIQ = 92). In terms of overall intellectual functioning, he obtained an overall score placing him at the 50th percentile (Full Scale IQ = 100). Assessment of attention and concentration with the CPT-II revealed that these abilities tended toward mildly-to-moderately impaired relative to the normative data set. He made an abnormally high number of omission errors and also demonstrated substantial variability in his reaction time. He also became more variable as time progressed over this 14-minute measure.

On the WMS-III, he obtained Auditory Immediate and Auditory Delayed Index scores of 89 and 86, placing him in the low average range. His Auditory Recognition Delayed Index was in the average range with an index score of 90. Visual Immediate and Visual Delayed abilities were also in the low average range with index scores of 88 on both. Overall, these performances are within normal limits, albeit it in the low average range.

On the CVLT, this patient's initial acquisition of items after the first trial was one standard deviation below expected levels, and his recall after five learning trials was two standard deviations below. Short Delay Free Recall and Long Delay Free Recall were essentially at the same level. Thus, his acquisition of very complex verbal material does appear at least mildly impaired. Interestingly, he does not lose this information from memory after a delay.

Assessment of higher level executive functions yields an overall performance on the WCST at a mildly impaired level relative to age and education matched peers, with a T-score of 38. His overall performance on the Category Test was in the borderline range with a T-score of 40. He also had difficulty following new complex sequences with a T-score of 40 on the Trails A Subtest and a T-score of 32 (mildly-to-moderately impaired) on the Trails B component.

Simple motor testing reveals that Tapping Speed was within normal limits, but he had difficulty with fine motor coordination on the Groove Pegboard Test with his dominant left hand. He obtained a T-score of 36 on this particular measure with his left hand, a T-score of 42 with his right hand.

On the Thurstone Word Fluency Test, he obtained a T-score of 54 and a T-score of 40.2 on the Controlled Oral Word Association Test. Animal naming was within normal limits with a total score of 22.

In summary, Patient B does appear to have a mild-to-moderate impairment of attention and concentration, and his ability to acquire new, complex detailed verbal material also appears to be mildly-to-moderately impaired. There is quite some variability in this regard, however, with performances on the Wechsler Memory Scale–3rd Edition (WMS-III) being generally within normal limits, and his California Verbal Learning Test (CVLT) performance falling approximately 2 standard deviations below expected levels. He had difficulty on motor tasks. His performances may have been adversely affected by peripheral pain as he complained of such during the assessment process. His overall score of 0 on the Beck Depression

Inventory (BDI) argues against significant depressive symptoms.

Patient C

Medical History: This 48-year-old male carries a diagnosis of multiple congenital cartilaginous exostoses, an autosomal dominant disorder. History was obtained from the patient, a published affidavit (Randall 1991b), and submitted progress notes dating from December 5, 1996.

He recalls few medical problems until age 10, when he threw a baseball and his arm became paralyzed for a few hours. Radiographs revealed what was interpreted as an old fracture that had healed with jagged bone fragments. Multiple referrals ensued, and ultimately 250 bony tumors were found throughout his body. He was diagnosed as having multiple congenital cartilaginous exostoses. Each was capable of growth, massive tissue disruption, pain, and malignant transformation. By age 17, he underwent multiple surgical procedures on the left leg, and right wrist. By age 12, constant pain and frequent hemorrhages severely limited his gait along with other basic functions. He required a home tutor by grade 7. By age 14, he required ongoing narcotics for analgesia, escalating to Dilaudid . . . (hydromorphone), and Sopor . . . (methaqualone, now Schedule I in USA) for sleep. He reports resultant fatigue, ennui, and disorientation as side effects.

At age 20, he developed a large bone spur on the right ankle, which recurred dramatically after one surgery. Amputation was recommended, but refused. At age 22, a fist-sized tumor was removed from the pelvis. A medical odyssey ensued, which failed to

identify better therapies and he required massive doses of hydromorphone, methaqualone, and muscle relaxants.

He described himself as a conservative young man who was against drugs, but in college acquiesced to try marijuana. He enjoyed chess, but was normally able to sit for only 5-10 minutes without pain. One day, he smoked cannabis and an hour into a chess match he remained pain-free. After discussion with his doctor, he experimented by smoking it regularly for 6 months. He noted a marked enhancement of his analgesia, and a reduction on his dependence on hydromorphone (taken intravenously for some time), Demerol . . . (meperidine), and hypnotics. Cannabis analgesia exceeded that of any prescription drugs.

He began to investigate possible legal avenues to obtain cannabis, and met Robert Randall in 1978. By 1979, he was spending $3000 annually on therapeutic cannabis through the black market, an unsustainable burden. A Byzantine bureaucratic process ensued over several years, with final FDA approval of his IND application in November 1982. Weekly monitoring sessions including needle electromyography (EMG) were deemed necessary to assess the effects of treatment in his protocol.

Subsequently, he described numerous instances of delayed shipments of cannabis, or exhaustion of supplies of higher potency product. Substitution of 1% THC cannabis required a doubling of dosage to 20 cannabis joints a day.

He was once arrested in Florida despite documentation, handcuffed and jailed overnight, sustaining

an ankle hemorrhage in the process. Only 4 of 7 confiscated joints were ultimately returned. Beyond this, he describes cannabis as much safer than prescribed medicine, and free of serious adverse effects except chest pain with prolonged usage of inferior product.

In 1992, Patient C had occasion to try Marinol . . . during a stockholders meeting in Canada due to his legal proscription from traveling with cannabis. Although he had no side effects on a dose of 10 mg, it was without any benefits, and left his muscles very tight and painful.

Detailed progress notes from the last several years were obtained and will be summarized. December 5, 1996, the patient was using 10-20 mg of baclofen and 10-15 cannabis cigarettes a day. Assessment was of multiple congenital cartilaginous exostoses with hepatitis C, and GE reflux. He was prescribed diazepam 5 mg for spasm. An EKG was read as showing normal sinus rhythm. February 28, 1996, the patient had pulmonary functions with FVC 112% of predicted, FEV_1 of 79% of predicted, read as indicating mild obstruction.

January 24, 1997, he had episodic spasm with pain affecting both arms and legs. It was noted at the time that the patient had a malunion of the right radius. He was down to 2-3 cannabis cigarettes a day, as he had received no supply from NIDA since September 1996, due to logistical problems in seeing his study physician. A transfer of providers was recommended.

September 4, 1997, he remained on baclofen 10 mg p.m., 5 mg a.m. and Prilosec . . . (omeprazole) for epigastric discomfort that had been going on for 7 years,

and cannabis 12 cigarettes a day. September 9, 1997, the patient had a chest x-ray with no findings. September 9, 1997, the patient had laboratory tests done, including a CBC, non-reactive hepatitis A and B tests, and normal thyroid functions. Glucose was low at 24, potassium high at 5.4, SGOT 79 with other parameters negative. September 17, 1997, the patient was said to be doing well smoking 10-12 cannabis cigarettes a day with dramatic decreases in frequency and intensity of flexor spasms. He was also taking baclofen. It was noted that with strong spasms the patient would bruise his skin and sometimes even bleed. His weight was constant, appetite normal. Neurological exam was fairly unremarkable. He was asked to slowly decrease the baclofen to 2.5 mg bid.

May 13, 1998, the patient was said to be doing quite well. In the interim, a liver biopsy demonstrated minimal changes secondary to hepatitis C. Chest x-rays were said to show no changes. The prior December the patient had twisted his left knee with a lot of swelling, and an MRI revealed a minor crack in the tibial head. Pain was under good control with 12 cannabis cigarettes a day with only occasional muscle spasms. Exam was unremarkable. He was said to be doing quite well off of the baclofen and was asked to continue 12 cigarettes of cannabis a day. May 26, 1999, the patient related no difficulty breathing. Weight was constant. There was dull pain in the ankles and some sharp shooting also in the knees. There was minor weakness in the right hand with no other deficits. The remainder of the exam was normal. The patient was felt to be doing well and advised to continue 12 cannabis cigarettes a day. October 6, 1999, the patient was seen in follow up, was on omeprazole,

Vitamin C, and cannabis. The patient had some congestion and mildly productive cough. He was felt to have acute bronchitis and was given cough syrup. January 5, 2000, the patient had pulmonary functions done with an FVC 118% of predicted, FEV_1 82% of predicted. This was felt to indicate borderline obstruction. January 13, 2000, glucose was 126, BUN 26, SGOT 71 with other parameters normal, including CBC. Hepatitis C antibody was reactive with other titers negative. Thyroid functions were normal. An SGPT was 181.

May 4, 2000, the patient was occasionally playing softball and had no complaints of shortness of breath. Again there was mild weakness of the hand with other muscles normal. It was felt that the patient was doing well without aches, pains or spasms on his cannabis.

November 21, 2000, the patient had noticed some increased discomfort following a motor vehicle accident the prior month wherein he was rear-ended and had neck pain. Subsequently, he noted persistent pain in the right thigh. An x-ray was negative. He tried physical therapy, heat and electrical stimulation. He noted more muscle tension with weather change. No neurological changes were observed.

December 28, 2000, the patient was on his omeprazole and cannabis. January 6, 2001, SGOT was 50, SGPT 94 with normal CBC and PSA. A cholesterol total was 221 with LDL 136.

At the time he was examined in Missoula, he noted constant baseline pain of 9-10 on a 10-point scale without cannabis. At rest, with cannabis this fell to a 4/10. He was smoking 9 grams a day of 2.7% THC NIDA cannabis, or 11 ounces every 25 days. At times

he has had to cut back due to an inadequate supply. He would sometimes have to use street cannabis at a cost $110 per quarter ounce (circa $16/g) of an estimated 4-5% THC content. Interestingly, although he found the flavor was an improvement over the government supply, he noted little difference in analgesic effect except, but perhaps greater relaxation effect. Interestingly, even with extensive cannabis use there are only two times he thinks that he ever may have been "high." One time he left his coat somewhere in freezing weather, which is extremely uncharacteristic, and the other he had been without cannabis for a long time and briefly felt euphoric while smoking. However, once he advanced to a second joint, this feeling was gone.

The patient has the most problems with the left arm where pain is a 7-8/10 when there are flare-ups despite medicine. This decreases after he takes rofecoxib (Vioxx . . .) for a week. He experiences pain in both knees, but usually minimal (1-2/10) with his cannabis. He may periodically pull a muscle or hemorrhage, especially in the ribs. He has occasional problems in the wrist.

The patient's sleep remains disrupted rarely attaining 6 hours total. Typically, he is up every 45 to 60 minutes with stiffness and needs to have pillows to position himself. He once got 8 hours of sleep with methaqualone (now illegal in USA), waking only twice.

He feels that his hepatitis C is asymptomatic and was probably due to a transfusion in his teens. Although he did use hydromorphone intravenously for a long period of time, he feels that he pursued a scrupulous aseptic technique. Besides surgeries noted above, he has dental caps due to bruxism, and

tonsillectomy. He has had past hypertension, which he feels was work related. There is no history of diabetes, thyroid problems, meningitis, encephalitis, head trauma or seizures. He uses only omeprazole 30 mg a day regularly in addition to his cannabis. He is allergic to barbiturates. The patient had 3 semesters of college. He is primarily right-handed, somewhat ambidextrous.

Family history is negative for other known involvement, but his father was adopted. His mother has migraine.

Social History: The patient works full time as a stockbroker. He is also a very decorated disabled sailor. He plays softball once a week. He may use a stationary bike about 10 minutes at a time, but this is subject to weather effects. He does not smoke tobacco. The patient drinks about 1.75 liters of Jack Daniels whiskey every 10-14 days, which helps him sleep. He does not drink coffee.

Medical Test Results: Weight: 153 lbs. Height: 5' 4 1/2". General: Very pleasant, cooperative 48-year-old white male who is somewhat obese (BMI: 25.5). Head: normocephalic without bruits. ENT: unremarkable. Neck: supple. Carotids: full, without bruits. Cor: S1, S2 without murmur. The patient had very slight gynecomastia. He has prominent exostoses of the left shoulder, left wrist, right shoulder, and right calf. Auscultation of the chest revealed a prolonged expiratory phase without wheezing. Abdominal palpation was negative.

Mental Status: The patient was alert and fully oriented. He knew the president and had normal right-left orientation, praxis and naming skills. He read a

grade 6 paragraph well with good recall. Serial 3's were done very rapidly. He remembered 3 objects for 5 minutes. He named 15 animals in 30 seconds, which is well above the average of 10-12. Speech and affect were normal.

Cranial Nerves: I: intact. II: fields and OKNs were normal. Fundi were benign. Pupils were equally reactive with full EOMs and no nystagmus. Remaining cranial nerves V and VII-XII were unremarkable. On motor exam, the patient had some limitation due to pain, *but see*med to have good strength throughout except for 4+/5 foot dorsiflexion on the right. There was no drift. Sensation was intact to fine touch, vibration, position and graphesthesia, but there was decrease in sharp/dull discrimination at the top of the right foot secondary to post-operative changes. Romberg was negative. Finger-to-nose and rapid alternating movements of the hands were normal. Heel-to-shin was incomplete on the right, better on the left. Fine finger movements were minimally decreased. On gait testing the patient slightly favored the right leg at the ankle. Toe gait looked better. Heel gait was barely possible due to pain on the right side. Tandem gait was minimally hesitant. Reflexes were 1+, symmetric with downgoing toes.

Medical Test Results: On pulmonary function tests, an FVC was 108% of predicted and FEV_1 67% of predicted. A FEV_1/FVC was 0.51 felt to be indicative of a moderate obstructive defect based on the latter ratio and flow volume curve morphology. No restrictive abnormality was noted (Table 3).

A CBC was wholly within normal limits. An absolute lymphocyte count was 1.8 with CD4 49.1% and CD4 absolute count of 911 (Table 4). An endocrine

battery, including FSH, LH, prolactin, estradiol, estrone, estrogen, testosterone and progesterone, was wholly within normal limits for age and gender (Table 5).

An EEG was performed during wakefulness and early stages of sleep, which was within broad normal limits. There was a good bit of low voltage fast activity in the beta range. No focal nor epileptiform activity was appreciated. A P300 showed a latency of 262 milliseconds felt to be within normal limits for the lab (Figure 1).

An MRI was performed without contrast. There was felt to be no definite abnormality of an acute nature. There were some minor changes in the right parietal area suggestive of a mild degree of gliosis with associated dilated perivascular spaces of doubtful significance. There was a small area of abnormal signal in the right parotid gland overlying the right masseter muscle felt to be probably benign.

A P-A and lateral chest x-ray were performed. This was read as showing a pulmonary nodule in the left upper lobe with minimal airway changes. One examiner (EBR) reviewed those films and felt that the lesion was actually located in a rib. As a result, the patient underwent a CT scan of the chest after returning home. This showed no evidence of mass, lymphadenopathy, or pulmonary nodules. A small amount of pleural calcification was noted. An exostosis was noted in the right anterior 3rd rib, accounting for the false-positive chest x-ray.

On neuropsychological testing, Patient C was pleasant, cooperative, and appeared to put forth very

good effort. His attention was noted to be quite poor at times and many instructions had to be repeated.

On the WAIS-III, he obtained Verbal and Performance IQ Scores in the Average Range with a Verbal IQ of 103 and a Performance IQ of 104. In terms of overall intellectual functioning, he is currently performing at a level equal to or above 58 percent of the general population (Full Scale IQ = 103).

Assessment of attention and concentration with the CPT-II revealed that immediate attentional abilities were within normal limits. His ability to concentrate, however, did appear mildly impaired, as he tended to lose efficiency with the passage of time. Thus, vigilance appeared to be mildly decreased relative to a normative data set.

On the WMS-III, Patient C obtained an Auditory Immediate Index in the Average Range at the 70th percentile. His Auditory Immediate Index was 108. Auditory Delayed Index was also 108, placing him in the Average Range, and his Auditory Recognition Delayed Index was 115, placing him in the High Average Range. The Visual Immediate Index was 115 with a Visual Delayed Index of 122, performances in the High Average and Superior Ranges, respectively.

On the CVLT, this patient's initial acquisition on Trial One was two standard deviations below expected levels and his acquisition of only ten items by Trial 5 was one standard deviation below expected levels. Short Delay Free Recall was also one standard deviation below expected levels but he performed within normal limits if provided cues. His ultimate free recall after a 20-minute delay was also one standard deviation below expected levels. There was not a

substantial loss of information between Long Delay and Short Delay Free Recall trials. Thus, his ability to acquire very complex and detailed new verbal material does appear minimally-to-mildly decreased relative to age matched peers, well below his ability to acquire new thematically organized verbal material, which was in the above average range. Memory, however, appears normal.

Assessment of higher level executive functions yielded a T-score of 45 on the WCST and a T-score of 44 on the Category Test from the Halstead-Reitan Neuropsychological Battery. His ability to follow new complex sequences was entirely within normal limits as indicated by T-scores of 52 and 62 on Trail Making Test A and B, respectively.

Simple motor speed measured by Finger Tapping was within normal limits, bilaterally, as was fine motor coordination measured by the Grooved Pegboard Test.

His performance on the Thurstone Word Fluency Test yielded a T-score of 56, which is entirely within normal limits relative to age and education-matched peers. Likewise, his overall performance on the Controlled Oral Word Association Test yielded a T-score of 52.52, and Animal Naming Fluency also was within normal limits. His overall score on the Beck Depression Inventory-2nd Edition (BDI-II) was 0.

Overall, Patient C appears to have mild difficulty sustaining attention and also minimal-to-mild difficulty with the acquisition of very new, complex verbal material. Overall, however, he appears to be functioning quite well.

Patient D

Medical History: This 45-year-old female carries a diagnosis of multiple sclerosis (MS). The patient was interviewed by telephone (EBR) in lieu of the possibility of contemporaneous examination. The patient feels her first problem may have occurred at age 18 when her vision sequentially went completely black for two months with slow improvement over a subsequent four months. A possible attribution to oral contraception was hypothesized. She was subsequently evaluated at a quaternary referral center and diagnosed as having retro-bulbar neuritis. She was prescribed nicotinic acid. On re-evaluation in 1983, no active disease was noted. On May 29, 1986, best corrected vision was 20/30 OD, 20/25 OS. By May 19, 1988, values fell to 20/200 OD, and 20/70 OS. The patient was formally diagnosed as having MS April 1 of that year with associated bilateral optic neuropathy. She had had symptoms for perhaps 6 months with blurring in both eyes and leg spasms that interfered with walking. The patient had never used cannabis recreationally, and began it only because of her symptoms.

She has been followed in her local area by a psychiatrist and neurologist. Extensive, well-documented notes commencing December 20, 1989 were provided, and will be summarized. When first seen on that date the patient was married for the second time. It was noted that she had been diagnosed with MS about a year and a half previously and had been on diazepam from time-to-time. She was taking 10 mg tid to cope with stress. She had previously tried trazodone and buspirone, had become paralyzed with her MS, and was consequently very frightened of

these medicines. On examination she was felt to be quite anxious and was provisionally diagnosed as having a dysthymic disorder.

On March 20, 1990, she seemed to be suffering from more depression, although she managed to smile. She described difficulty with self-esteem and hopelessness. She had only been taking diazepam intermittently and was rather prescribed Prozac . . . (fluoxetine) 20 mg and Xanax . . . (alprazolam) 0.25 mg up to 3 times a day. She was felt to have recurrent major depression. On subsequent visits the patient had slight adjustments of medicine and was feeling better by May 2, 1990. By August 6, 1990, the patient was having greater difficulties with insomnia. She was given trazodone 50 mg at bedtime on a trial basis. August 24, 1990, the patient was only sleeping until 4 a.m., which was about 2 hours better than without medicine. This was increased to 75 mg.

The patient had heard about some studies of using cannabis in MS as a relaxing agent. She indicated that she had tried this with a good relaxation response. There was a discussion of possible effects on the lungs, and her expected diminished life expectancy because of MS. She was given a prescription for Marinol . . . (dronabinol, synthetic THC) 10 mg to be tried q 4 hours prn to see if this would help with relaxation and nausea. When seen September 5, 1990, she had found that the Marinol . . . had reduced the nausea considerably and had even helped her vision. She continued on fluoxetine.

September 27, 1990, the patient was not sleeping well, possibly due to fluoxetine, and was given a benzodiazepine. October 17, 1990, the patient was seen in follow up and was on Xanax . . . (alprazolam).

It was noted that she had improvement with Marinol . . . , but the patient noted she actually had a better response to smoked cannabis. They began to look into obtaining a legal supply.

December 3, 1990, the patient reported increased depression and was increased to 40 mg a day of fluoxetine. December 5, 1990, the patient had recurrent depression even on the fluoxetine 2 a day and low dose alprazolam. Apparently, her doctor had received notification that he could no longer prescribe Marinol . . . "off label" unless a Schedule I permit for cannabis was being pursued. December 19, 1990, the patient reported nausea, for which some of her remaining Marinol . . . had helped. January 16, 1991, the patient complained of spasticity spells and episodes of nausea. She had run out of Marinol . . . and had no cannabis supply. She indicated she had tried other medications without success and was resistant to try others due to side effects.

February 20, 1991, the patient had purchased illicit cannabis in the interim. April 16, 1991, the patient continued on fluoxetine 20 mg bid. More jerkiness was noted with increased spasticity. She had not smoked cannabis before coming in. It was felt that she would need 6 cannabis cigarettes a day to reduce symptoms. May 10, 1991, she was taking alprazolam about every 2 weeks. She was continuing to have some spasms. She continued to try cannabis illicitly, but had not yet obtained it legally. June 14, 1991, she had lost her driver's license due to visual problems associated with MS. During this interval there were more marital issues. July 2, 1991, it was indicated the patient was legally blind and there were no possible corrective measures. Plans were in place to obtain

legal cannabis for spasticity and nervous problems. It was noted that cannabis seemed to be very effective for her clinically. August 7, 1991, the patient was still without a supply and complained of her legs jerking at night, and increased difficulty walking. The patient requested Marinol . . . , but this could not be prescribed. She was given baclofen 5 mg tid to try.

August 30, 1991, she received her first shipment of NIDA cannabis, seven months after approval of the Compassionate IND. The patient was advised that she should confine her use to government cannabis. She was having problems with her gait, able to walk only with a cane. There were continued vision problems. She complained of left sided weakness. The patient smoked a cannabis cigarette in front of the doctor, which led to her feeling better. It was suggested she try 3 cannabis cigarettes a day. September 3, 1991, the patient reported that the government supply of cannabis did not have the "punch" that street bought material had. Her dose was increased to 5 joints a day. It was indicated that her spasticity responded positively to the dose increase. September 11, 1991, the patient was on 5 NIDA cigarettes a day. This was helping her spasticity. She was unclear as to whether her vision was helped. September 20, 1991, it was felt that 7 cigarettes a day would be necessary. The patient reported increased muscular activity, uncontrollable at times. October 2, 1991, the patient had run out and was noticeably more spastic on examination. Her dose was increased to 10 a day. October 9, 1991, the patient was on 10 cannabis cigarettes a day of the strongest available dosage, which seemed to help her spasticity. She was walking without a cane. It was not felt that her depression was improved.

November 4, 1991, she had been out of her supply for 10 days. Spasticity increased and she complained of pain in the left leg. Increased tone was noted throughout the body. December 5, 1991, apparently a supply came in of lower potency cannabis. December 19, 1991, it was felt she had continued improvement of her spasticity with better gait. February 14, 1992, she was using 1 can of cannabis a month, equal to 300 cigarettes. The patient reported she had not been falling. March 13, 1992, she continued the cannabis at the same rate, plus 40 mg of fluoxetine and no alprazolam. The patient reported she was able to walk, swim better, and do all of her ADL's much easier than she could prior to the cannabis. There was no observable gait disturbance on exam.

April 14, 1992, it was felt that she got a lot of relief from her medicine and that it "probably offers her greater efficacy in her spasticity, also, than Valium would." May 19, 1992, the patient continued to be stable with no exacerbations of her MS and the spasticity under good control. There were concerns about periodontal disease from her dentist. It was thought she might do better with less smoking of a higher potency supply. The patient was also smoking cigarettes and was subsequently advised to avoid tobacco. By July 17, 1992 she continued to respond to cannabis. September 18, 1992, reflexes were equal and not hyperactive. November 16, 1992, there was an increase of depression slowly and insidiously. December 9, 1992, the patient had been off of her treatment for a week and was very shaky. Smoking a joint in front of her doctor caused her to become calm, less shaky and better able to walk. January 19, 1993, she got her first cans of the stronger cannabis, which the

patient felt more effective after smoking one joint. March 22, 1993, she was smoking 6-7 a day. She seemed better after smoking one in the office. April 22, 1993, the patient was smoking 10 cigarettes a day. Smoking produced a decrease in spasticity as observed. There were no adverse effects that were noted in the office. May 24, 1993, the patient was tried on lorazepam. June 24, 1993, the patient was upset with financial issues and was placed on Mellaril . . . (thioridazine). July 22, 1993, when she was examined, no tremor or spasticity was noted. Again cannabis was smoked with no adverse effects noted. August 30, 1993, the patient requested a decrease in her fluoxetine. She felt that spasticity and depression were both helped by the cannabis. September 29, 1993, the patient reported that on a lower fluoxetine dose she was getting tearful. Reflexes were not hyperactive. November 2, 1993, the patient had some paresthesias on the left side, but was maintaining good motor control. December 28, 1993, she was tried on bupropion. January 4, 1994, problems had been noted on bupropion and it was not as effective. She was tried on sertraline. She reported that the cannabis helped her to not think about her MS. She was having fewer spasticity problems.

February 4, 1994, when the patient smoked cannabis in the office, she seemed to be a little more talkative and relax significantly with less spasticity and no adverse effects. February 28, 1994, again significant relief from spasticity was noted upon smoking. March 30, 1994, the patient had some numbness and tingling in the limbs. The patient reported the new material was stronger and had a better effect. May 9, 1994, some increase in emotional

lability was noted. The patient was taken off of sertraline and put on Effexor . . . (venlafaxine). May 25, 1994, she was unable to tolerate the latter and was started back on fluoxetine. August 29, 1994, she continued on fluoxetine and cannabis. Smoking a joint calmed her and limited tremor. September 28, 1994, it was indicated in relation to cannabis "it seems to have a positive effect on her mental status overall." October 31, 1994, the patient was felt to be without signs of depression. She actually lowered her dose on a higher potency material. February 1, 1995, the patient was on diazepam again. February 14, 1995, she was increasingly shaky and tearful. March 29, 1995, she was hardly able to walk due to an exacerbation. May 2, 1995, she still needed support. At the same time the patient was having marital difficulties. August 4, 1995, the patient reported she could see much better with the cannabis. By September 6, 1995, she was walking quite well and was no longer on diazepam, merely the fluoxetine and cannabis. October 4, 1995, she continued to walk well with no problems.

January 17, 1996, an MRI revealed multiple bilateral periventricular and diffuse white matter changes in the cerebrum and cerebellum, but seemingly fewer than on a April 4, 1995 study.

April 19, 1996, the patient had been out of cannabis for a week and was experiencing more spasticity and ambulation difficulties. She was more depressed. May 17, 1996, the patient had been tried on a stimulant. July 10, 1996, the patient reported that cannabis was the only thing that had helped her with her symptoms over the course of her illness.

By September 25, 1996, the patient had been without medicine for a month and had to buy it on the street. She had lost weight and her condition had reportedly decompensated to some degree. The patient reported a 10-pound weight loss. November 13, 1996, the patient was having difficulty sleeping, but did not wish to take trazodone. November 27, 1996, the patient had fallen and had a brief loss of consciousness. December 5, 1996, she had had an episode of spasticity that was the worse she had ever had, starting in the neck and going down her back. January 8, 1997, cannabis came in after a summer drought since September 25. An emergency supply was requested. January 22, 1997, the patient remained concerned about lack of cannabis supply. February 5, 1997, she continued with this concern. February 19, 1997, there was discussion of difficulty the patient had experienced with the authorities in an airport.

April 2, 1997, it was felt the patient continued to get a great deal of relief from smoking 10 joints a day without any adverse effects. July 2, 1997, the patient was observed to become more loquacious and interactive after dosing.

January 29, 1998, the patient was not complaining of spasticity, seeming to have considerable relief with cannabis. Her fluoxetine was lowered to 20 mg a day. March 24, 1998, it was felt that she had a very slow progression of her MS helped by her consumption of cannabis. September 22, 1998, the patient said that the medicine took away her fear of the disease and when she would get a pain she would be able to smoke and take it away.

October 27, 1998, she apparently had been out of her supply for 6 weeks, but had gotten by smoking

only 4 cigarettes a day instead of the usual 10. January 24, 1998, the patient was doing relatively well and was walking with a cane. December 22, 1998, she was having increasing problems. January 26, 1999, the patient indicated that medicine helped her maintain her weight. March 24, 1999, it was observed, "I think her spasticity is being helped with the cannabis." April 23, 1999, she continued to get good relief with 10 cigarettes a day. June 24, 1999, the patient reported some increasing difficulty with walking in the heat and hot weather. July 20, 1999, she was said to have no tremor or spasticity. September 1, 1999, she was having some exacerbation and difficulty walking and limping because her right leg was not working as well. October 20, 1999, the patient reported the only bad side effect would be when she smoked too much she would tend to go to sleep. She discussed alternative treatments for multiple sclerosis with her doctor and they agreed not to pursue them. November 19, 1999, the patient was walking on a wide base felt to be the result of a mild exacerbation. November 24, 1999 neurological examination confirmed greater ataxia. Methylphenidate was prescribed.

December 1, 1999, an MRI of the brain was said to reveal multiple focal white matter changes in bilateral cerebral areas especially in the basal ganglia and in the cerebellar peduncle, compatible with MS.

January 12, 2000, the patient was tried on Ritalin . . . (methylphenidate). She was switched to Remeron . . . (mirtazapine) from fluoxetine. February 22, 2000, the patient reported that her eyes were improved. March 9, 2000, visual acuity was 20/200 OD and 20/80 OS. April 6, 2000, it was felt that she had no declines in function from cannabis use.

June 27, 2000, her cannabis had been late coming in and she had cut from 10 to 6 or 7 cigarettes a day, feeling that that had hurt her physically and that she was not walking as well. January 31, 2001, the patient was a little bit down and labile, but by February 28, 2001, she was not depressed or hyper. April 11, 2001, she was having some trouble walking due to a flare of symptoms, which had been present for a month, but she noted no changes in vision.

When the patient was interviewed by EBR (June 2001), she reported that her vision was currently clear with cannabis. She was able to ambulate without aids, but has to stop after a block or less due to weakness. She swims a few days a week. She feels that there is no nystagmus in her vision and no diplopia. She characterizes her MS as mildly progressive.

The patient indicated that she received the cannabis legally in 1991 and continues to smoke 10 cigarettes a day. She currently receives material of 3.5% THC content that was processed April 1999. Her study physician requests the highest potency material available, which has recently varied between 2.9-3.7% THC. When she uses outside cannabis of higher potency, she feels that she gets twice the relaxation. There is no chronic cough or other difficulties. The patient feels that Marinol . . . at 10 mg was too strong. She used it for 6 months before the cannabis. Customarily she splits each of her supplied cigarettes in two, and manicures it slightly. When she is not on cannabis she has had no withdrawal symptoms, but has had increase in movement problems.

The patient has had a tubal ligation. She continues to menstruate on a regular monthly basis. Her main problems have been depression and some degree

of anxiety. I asked about other diagnoses and she replied that she had "10 personalities and they are all feeling fine!" She denied history of diabetes, thyroid problems, meningitis, encephalitis, head trauma or seizures. The patient remains on fluoxetine 40 mg a day. She is allergic to penicillin. The patient had 1 year of college. She is right handed.

Family history is noteworthy for father having narcolepsy and a sister who is bipolar.

Social History: She had one child by choice. The patient is a retired clothier, and is unable to work at this time. She is currently smoking 1/2 pack of cigarettes a day, previously 1 pack a day, and has smoked since age 20. The patient does not drink at all, has not for 5 years, nor has she ever had a problem with alcohol. She does not drink coffee. She customarily sleeps 8 hours.

Medical Test Results: The patient is 5 feet tall and 97 pounds (BMI: 19). On pulmonary function tests, an FVC was 79% of predicted, and FEV_1 76% of predicted. The FEV_1/FVC was 86 (Table 3). There was felt to be no obstruction based on this ratio or analysis of the F/V curve morphology. Early small airway disease and borderline restrictive disease (*e.g.*, due to MS) were not excluded.

A CBC was wholly within normal limits. An absolute lymphocyte count was 2.3 with CD4 of 58% and CD4 absolute count of 1325 (Table 4). An endocrine battery was performed, with values of FSH, LH, prolactin, estradiol, estrone, estrogen, testosterone and progesterone, all within normal limits for age an gender (pre-menopausal female) (Table 5).

Neuropsychological tests were performed in her home on June 17, 2001. Some confusion was noted throughout the evaluation and significant fatigue over the course of the day was also apparent. She did not have significant difficulty with instructions, however, and effort and cooperation were sufficient to obtain what is believed to be valid data. As a result of significant visual deficits, many visually based tests were omitted and interpretations from those requiring significant visual input were provided in a very cautious manner. For example, this patient required a magnifying glass in order to accomplish the Picture Completion and Trails subtests that very likely had a significant negative impact on her overall performance.

On the WAIS-III, the patient obtained a Verbal IQ of 93. A Performance IQ was not calculated secondary to significant visual deficits that interfered with assessment in this realm. On the WMS-III, the patient performed, on verbal measures, in the Low Average Range. Immediate auditory memory was at the 18th percentile, with an auditory delayed index in the Average Range. Her ability to acquire non-thematically-organized verbal material was in the mildly impaired range relative to age-matched peers, but her retention was actually very good. Also, she did very well on a test measuring her ability to acquire verbal paired associates with a learning slope actually in the above average range, and excellent retention. Her ability to acquire more detailed and non-thematically-organized verbal information was moderately-to-severely impaired relative to age-matched peers. Overall performances on the CVLT

ranged from two to five standard deviations below expected levels. Numerous intrusions during both free and cued recall were noted at levels above and beyond what is generally seen in the normative population. She made eight false-positive errors on recognition testing, which are also an abnormally high number of errors.

Concentration was noted to be markedly impaired in this patient, following the mildly-to-moderately impaired range overall. Assessment of Executive Functions reveals that abstract concept formation and logical analysis abilities were significantly reduced, falling in the moderately impaired range overall. The patient was also noted to be quite perseverative, having difficulty shifting cognitive strategies. In slight contrast, flexibility of thought as measured by the Similarities Subtest from the WAIS-III, was within normal limits. Verbal Fluency was within normal limits relative to age and education-matched peers.

In summary, this patient appears to have decrements in concentration, low average learning, and memory efficiency for new thematic material and verbal paired associates. Her ability to acquire more detailed and non-thematically-organized verbal information is at least moderately impaired. Memory functions, however, appear to be normal in the sense that once she acquires information, she seems to hold it quite effectively. Higher level executive functions are reduced at a moderate level despite a very remarkable psychiatric history. Responses to the BDI-II were well within normal limits.

Patient D thus demonstrates numerous neurocognitive impairments. The general pattern is not particularly uncommon in the context of multiple

sclerosis and significant psychiatric dysfunction. This profile, when combined with the others from the data set do not provide any consistent pattern that one could reasonably ascribe to the therapeutic use of cannabis.

Review of Neuropsychological and Cognitive Data

The scientific study of the effects of chronic cannabis on cognition has remained problematical since such concerns were first raised. Despite intensive effort in this regard, little in the way of "hard findings" or consistent results has emerged. A complete review of alleged problems is beyond the scope of this article, but a few citations are meritorious.

In the Jamaican studies (Rubin and Comitas 1975), 19 neuropsychological tests were administered to chronic cannabis users and controls with no major significant differences between groups. In fact, ganja smokers scored the highest on Wechsler Adult Intelligence Scale (WAIS) Digit Span performance ($p < 0.05$). The authors concluded (p. 119), "in a wide variety of human abilities, there is no evidence that long-term use of cannabis is related to chronic impairment."

In Greece (Kokkevi and Dornbush 1977), no differences were noted between hashish users and age and socio-economically matched controls in total or Performance IQ (PIQ) scores on the WAIS. Controls performed better on three subtests: Comprehension ($p < 0.01$), Similarities ($p < 0.005$), and Digit Symbol Substitution ($p < 0.05$). Control Verbal IQ (VIQ) surpassed that of users ($p < 0.05$). However, these results must be viewed in light of the fact that normal population studies in Greece revealed PIQ:VIQ differences of 7 points. Thus, the authors concluded (p. 46), "These

observations do not provide evidence of deterioration of mental abilities in the hashish users."

In Costa Rica, an extensive battery of neuropsychological measures showed no pathological changes (Carter 1980). It was observed (p. 188), "we failed to uncover significant differences between user and non-user groups–even in those subjects who had consumed cannabis for over eighteen years."

Subsequently follow-up studies were performed on some of this cohort, and certain significant differences were claimed, including learning of word lists and selective and divided attention tasks (Fletcher et al. 1996). However, a detailed critical analysis of those results in *Marijuana Myths, Marijuana Facts* (Zimmer and Morgan 1997) seems to deflate any such claim.

Lyketsos et al. (1999) studied effects of cannabis on cognition in 1318 adults over a period of 12 years. No differences were noted in the degree of decline between heavy, light, and non-users of cannabis on the Mini-Mental State Examination (MMSE). Critics have indicated that the latter represents too crude a tool to measure the issue properly.

In a series of studies in the 1990's summarized in a book, *Cannabis and Cognitive Functioning* (Solowij 1998), Nadia Solowij studied subjects employing cannabis at least twice a week on average for a period of 3 years. After a review of data, the author stated (p. 227), "the weight of the evidence suggests that the long-term use of cannabis does not result in any severe or grossly debilitating impairment of cognitive function." She did note more subtle difficulties in

attention parameters including distraction, loose associations and intrusion errors in memory tasks. In a recent review of cognitive effects of cannabis (Solowij and Grenyer 2001), it was observed (p. 275), "the long term risks for most users are not severe and their effects are relatively subtle. . . . "

Results from the current study seem to indicate similar findings. As part of a Comprehensive Neuropsychological Evaluation, all subjects were administered a battery of instruments including the WAIS-III, the WMS-III, the CVLT, the Trail Making Test A and B, Grooved Peg Board, Finger Tapping, and Category Test, the Controlled Oral Word Association Test, the Thurstone Word Fluency Test, a Category Fluency Test (Animal Naming), the WCST, the CPT-II, and the Beck Depression Inventory–2nd Edition (BDI-II).

Comparing Patients A-D, it appears that all four do have at least mild difficulty with attention and concentration, and verbal acquisition of varying complex new verbal material (as measured on the CVLT), which is at least minimally impaired. Importantly, however, higher-level executive functions generally appear to be within normal limits in two of the subjects.

Difficulties in attention and concentration as well as new complex verbal learning may be directly related, and must be understood in the context of not only these subjects' chronic cannabis use, but also their underlying chronic diseases and clinical syndromes, with attendant fatigue and preoccupation. Interestingly, depressive symptoms are not currently noted at a clinical level in any of the subjects despite

their chronic medical conditions or long-term cannabis use. None displayed evidence of social withdrawal or apathy characteristic of the alleged "a motivational syndrome." Rather, all were animated, engaging in conversation and demonstrating an active involvement with their ongoing care and the current research.

Overall, once more, no significant attributable neuropsychological sequelae are noted due to chronic cannabis usage.

Review of Neuroimaging

In 1971, it was reported that "consistent cannabis smoking" of 3-11 years in ten patients produced evidence for cerebral atrophy employing air encephalography (Campbell et al. 1971), an excruciatingly painful and long abandoned technique. Subsequent study by Kuehnle et al. (1977) employing CT scans on 19 men with long durations of heavy cannabis usage failed to show any changes in the ventricles or subarachnoid spaces. They criticized the prior study for lacking controls on antecedent head trauma or other causes of neurological damage. In the same issue of the *Journal of the American Medical Association*, Co et al. (1977) studied an additional 12 heavy cannabis smokers who displayed no CT abnormalities.

In 1983, an additional 12 subjects who smoked more than 1 g of cannabis daily for 10 years were studied by CT scans of the brain, and only one with concomitant history of alcoholism showed any abnormalities compared to controls (Hannerz and Hindmarsh 1983).

Most recently, Block et al. (2000) employed automated imaging analysis with MRI to examine 18

young heavy users of cannabis. No abnormalities were ascertained. The authors stated (p. 495), "frequent marijuana use does not produce clinically apparent MRI abnormalities or detectable global or regional changes in brain tissue volumes of gray or white matter, or both combined." It was recently noted (Solowij and Grenyer 2001, p. 270), "There is no evidence from human studies of any structural brain damage following prolonged exposure to cannabinoids."

Despite this additional documentation, the claim of brain damage and cerebral atrophy remains a popular myth in prohibitionist rhetoric. Current MRI studies on Patients A-C with a General Electric Sigma LX MR 1.5 Tesla magnet system reveal no clear abnormalities. Patient A had age-compatible atrophy, and Patient C had minor tissue changes of a non-specific nature, commonly seen in middle-aged populations. Patient D has previously demonstrated MRI brain lesions consistent with MS, with possible improvement observed during the period of clinical cannabis usage.

Review of Neurophysiology Tests

In discussing the issue of cannabis and cerebral effects, Homer Reed observed (Reed 1975, pp. 122-123), "The association between many of the EEG measures used to indicate CNS changes and the clinical condition of the patient is approximately zero." That notwithstanding, various researchers have advanced numerous claims of pertinent EEG changes due to cannabis. Cohen (1976) noted differences in computerized EEG measures of delta band power and theta band phase angle (lead/lag) relationship. No mention

was made of the alleged significance of these tests, or of the results of standard EEG.

All the Jamaican subjects had EEG examinations (Rubin and Comitas 1975). As previously noted in other studies, 9 of 30 cannabis smokers had significant low voltage fast activity in the beta range. Although this finding may indicate sedative effects of medication, it is often ascribed to a normal variant. Three of the 30 were said to have unequivocal focal abnormalities, but 4 of 30 controls had similar findings, and another had diffuse abnormalities. Overall, no significant differences were noted between ganja smokers and controls.

Similarly, in Greece (Panayiotopoulos et al. 1977), 8.8% of 46 hashish smokers had abnormal EEGs, while 15% of 40 normal controls were so characterized. The authors stated (p. 62), "We failed to find either an abnormality or an particular EEG change in the resting EEG records of chronic hashish users. . . . "

Current results, performed on a 21-channel Nicolet Voyageur digital EEG system and read by EBR, confirm the presence of low voltage fast activity in Patients A-C, and intermittent sharp waves and rare subtle slowing in the left frontal area in Patient A. Age appropriate atrophy was seen in the same patient on MRI, but she has no history of seizures or CNS insults. There are no corresponding abnormalities on neurological examination. Similar abnormalities are identified on EEGs of 6% of patients, whereas there is only a 0.5% prevalence of seizure disorders in the general population. In essence, no EEG pathology of an attributable nature seems apparent in the study group on the basis of cannabis usage.

With respect to P300 responses, a type of electrophysiological event related potential, even greater caution is necessary. This parameter is offered as an electrophysiological measure of memory, inasmuch as prolongation of its latency occurs with age. The test was popular in the 1980's as an objective test for dementia. Amplitude differences have also been noted in different clinical conditions, but were termed (Spehlmann 1985, p. 370), "of uncertain diagnostic importance because of the great normal variability of the P300 amplitude." Overall, these issues and significant incidence of false positives and false negatives have largely relegated use of this technique to the sidelines as a clinical tool.

Solowij (1998) studied the P300 in chronic cannabis users vs. controls, and noted results felt to be indicative of (p. 150), "inefficient processing of information and impaired selective attention." These consisted of reduced processing negativity to relevant attended stimuli, inappropriately large processing negativity to a source of complex irrelevant stimuli, and reduced P300 amplitude to attended target stimuli to that of controls.

In contrast, Patrick et al. (1995) examined the P300 in psychologically normal chronic cannabis users and controlled the data for age. Results showed no amplitude differences.

More recent studies have shown significant reductions in P300 amplitude in schizophrenia (Martin-Loeches et al. 2001), but also in cigarette smokers (Anokhin et al. 2000), with notable effects according to motivational instructions (Carrillo-de-la-Pena and Cadaveira 2000), and even diurnal variations (Higuchi et al. 2000).

Our study employed a Nicolet Viking 3P 4-channel system with a P300 oddball paradigm. Patients A-C displayed P300 latencies that were well within norms for age-matched controls (Figure 1).

Review of Pulmonary Issues

Pulmonary concerns remain paramount in relation to chronic cannabis smoking. Excellent recent reviews are available (Zimmer and Morgan 1997; Tashkin 2001; Tashkin 2001). In brief, cannabis smoking produces an increase in cough and bronchitis symptoms, but to a lesser degree than in tobacco smokers (Sherrill et al. 1991). Daily cannabis smokers seek medical care for smoking-associated health concerns at a slightly higher rate than non-smokers (Polen et al. 1993). In a large epidemiological study, cannabis use was associated with little statistical association on total mortality in women, and non-AIDS mortality in men (Sidney et al. 1997).

One of the primary associated risks of tobacco smoking is the development of emphysema and lesser declines in bronchial function over time. A careful longitudinal study of chronic smokers has demonstrated a longitudinal decline in the FEV_1 in tobacco smokers, but not heavy cannabis smokers (Tashkin et al. 1997).

Some association of cannabis smoking has been observed to head and neck cancers (Zhang et al. 1999), and pre-cancerous cytological changes have been noted in the lungs in bronchoscopy studies (Fligiel et al. 1988), but to date, no cases of pulmonary carcinoma have been noted in cannabis-only smokers.

In examining the data from chronic cannabis use studies, in Jamaica, a slight downward trend not attaining statistical significance was noted on forced vital capacity (FVC) values (Rubin and Comitas 1975). A similar downward trend was observed on FEV_1 without statistical significance. No differences between cannabis smokers, occasional smokers and non-smokers were observed on FEV_1/FVC ratios. Results of all tests may have been affected by concomitant tobacco usage.

The Greek studies did not closely examine pulmonary function, and although an increase in bronchitis symptoms was noted in hashish smokers over abstainers, the former group also smoked more tobacco. Differences were not statistically significant in any event (Boulougouris, Antypas, and Panayiotopoulos 1977).

In the Costa Rican studies, no spirometry measures were significantly different between cannabis users and non-users. However, statistical trends were, in fact, positive with respect to cannabis usage. Cannabis smokers displayed larger indices of small-airway patency. The authors suggested that in concomitant smoking of tobacco, cannabis seemed to counteract the expected effects of tobacco on small airways. The author stated (Carter 1980, p. 171), "at least it cannot be said of the users that they have suffered an additive of [sic-"or"] synergistic decrement in pulmonary function over that attributable to tobacco alone."

In our Patients A-C, no ultimate chest radiographic changes of significance were noted, despite a false-positive reading of pulmonary nodule in Patient C. It is of particular note that he has had a previous

bronchos-copy procedure with no reported cytological changes.

Observed pulmonary function values in this cohort reveal no clear trends except a slight downward trend in FEV_1 and FEV_1/FVC ratios, and perhaps an increase in FVC (Patients A-C) (Table 3). Concomitant tobacco smoking (Patients A, B, and D) complicates analysis. It is particularly interesting that Patient B, a current concomitant smoker of tobacco displayed the best spirometry values, while those in Patient C, a never-smoker of tobacco were the worst. His underlying connective tissue disease may have played an active role in this finding. His use of the lowest grade cannabis and highest amount per day are the more likely explanation.

Significant questions remain as to the role of low-grade NIDA cannabis as a contributor to the above findings, which will subsequently discussed.

Review of Hematological Studies

No effects on complete blood counts or hemoglobin were observed in the LaGuardia Commission report (New York, NY). Mayor's committee on marihuana (Wallace and Cunningham 1944). In the Jamaican studies, slight increases were observed in hematocrit and hemoglobin readings in cannabis smokers over controls, but results were affected by concomitant tobacco use (Rubin and Comitas 1975). No hematological data was obtained from the Greek studies.

In Costa Rica, a downward trend was observed in hematocrit readings of cannabis smokers, but this was not statistically noteworthy (Carter 1980).

In our studies (Table 4), Patient B, a concomitant tobacco smoker, displayed a mild degree of polycythemia and slightly elevated WBC. No other hematological changes of any type were evident in the other three patients.

Review of Immunological Parameters

Immune system damage remains an area of contention with respect to cannabis usage (Zimmer and Morgan 1997), but one in which there is considerably more heat than light. A closer examination of the available literature may allay concern.

In the chronic use studies in Jamaica, no decrement was observed in cannabis smokers vs. controls in either lymphocyte or neutrophils counts (Rubin and Comitas 1975). Neither were significant changes noted in the data in Costa Rica (Carter 1980). In the 94-Day Cannabis Study, initial acute low values were observed in T cell counts, but these returned to normal over the course of the testing (Cohen 1976).

A closer examination of the pertinent literature raises concerns on theoretical levels to a greater degree than practical ones. Excellent reviews are available (Klein, Friedman, and Specter 1998; Hollister 1992; Cabral 2001; Cabral 2001).

Early reports of inhibition of cell mediated immunity in cannabis smokers (Nahas et al. 1974) were refuted by later studies in which no impairment of lymphocytic response to phytohemagglutinin in hashish smokers was observed (Kaklamani et al. 1978).

A seminal review of the topic was undertaken by Hollister (1992), who stated (p. 159), "evidence of altered immune functions is derived mainly from in vitro tests or ex vivo experiments, which employed doses of cannabinoids far in excess of those that prevail during social use of marijuana." More recently, Klein, Friedman and Specter (1998) have similarly noted (p. 102), "Although cannabinoids modulate immune cell function, it is also clear that these cells are relatively resistant to the drugs in than many effects appear to be relatively small and totally reversible, occur at concentration higher than needed to induce psychoactivity (> 10 μM or > 5 mg/kg), and occur following treatment with nonpsychoactive cannabinoid analogues." They added (p. 102), "The public health risk of smoking marijuana in terms of increased susceptibility to infections, especially opportunistic infections, is still unclear." Finally, despite concerns raised by THC effects on immunity in animals and *in vitro*, Cabral and Dove Pettit (1998) admitted (p. 116), "Definitive data which directly link marijuana use to increased susceptibility to infection in humans currently is unavailable."

A particular public health concern surrounds cannabis effects on HIV/AIDS. Four studies among others may reduce related concern. Kaslow et al. (1989) demonstrated no evidence that cannabis accelerated immunodeficiency parameters in HIV-positive patients. Di Franco et al. (1996) ascertained no acceleration of HIV to full-blown AIDS in cannabis smokers. Whitfield, Bechtel and Starich (1997) observed no deleterious effects of cannabis usage in HIV/AIDS patients, even those with the lowest CD4 counts.

Finally, Abrams et al. (2000) studied the effects of cannabis smoking on HIV positive patients on protease inhibitor drugs in a prospective randomized, partially blinded placebo-controlled trial. No adverse effects on CD4 counts were observed secondary to cannabis.

In our studies of four subjects (Table 4), Patient B had an elevated WBC count, probably attributable to the stress of phlebotomy, but without accompanying disorders of cell count differential. All patients had CD4 counts well within normal limits.

Review of Endocrine Function

Topical reviews of this topic are contained in two recent publications (Murphy 2001; Zimmer and Morgan 1997). As with other physiological systems, much data is based on animal studies, and early claims of deleterious effects on acute endocrine function are not necessarily supported by subsequent investigations or chronic use studies.

One long held claim is the production of gynecomastia in males associated with cannabis use. A case study or 3 cannabis smokers with this malady was reported by Harmon and Aliapoulios (1972). A more thorough investigation a few years later failed to show any differences in cannabis use in affected males between users and controls (Cates and Pope 1977).

Similarly, Kolodny et al. (1974) reported decreased testosterone levels in chronic marijuana smokers, while no differences in testosterone or luteinizing hormone (LH) levels were identified in a 3-week trial of smokers vs. non-smokers (Mendelson et al. 1978).

LH levels in menopausal women showed no significant changes after cannabis usage (Mendelson et al. 1985), but the next year, a similar group noted a 30% suppression of LH in women by smoking a single cannabis cigarette during the luteal phase (Mendelson et al. 1986).

Subsequently, a more in-depth study of both sexes was undertaken to assess multiple hormone effects comparing subjects with different levels of cannabis usage vs. controls (Block, Farinpour, and Schlechte 1991). No significant effects were noted on testosterone, LH, FSH, prolactin or cortisol in young women and men.

Jamaican chronic use studies were confined to examinations of thyroxine and steroid excretion with no significant findings observed due to cannabis use (Rubin and Comitas 1975).

In the 94-Day Cannabis Study, acute drops in testosterone and LH levels were noted after smoking a cannabis cigarette (Cohen 1976). Subsequent drops in testosterone levels were noted after the 5th week of daily usage. LH levels fell after the 4th week and FSH after the 8th week to unspecified degrees.

In Costa Rica, no differences were noted in male testosterone levels between abstainers and cannabis smokers stratified according to amount of use (Carter 1980). Similarly, fertility was unimpaired, with both groups having identical numbers of progeny. The author stated (p. 172), "These findings cast serious doubt on cause-and-effect relationship between marihuana smoking and plasma testosterone level in long-term use."

Zimmer and Morgan (1997) summarized their observations by stating (p. 92), "There is no scientific evidence that marijuana delays adolescent sexual development, has a feminizing effect on males, or a masculinizing effect on females."

The latter statement would seem to be borne out by our findings. While one male subject had a minor degree of gynecomastia associated with obesity, none of the Patients A-D displayed any abnormal values in any endocrine measure (Table 5).

Patient A has two children, Patient B has three, and Patient D had one by choice.

Problems in the Compassionate IND Program

All four patients described varying degrees of logistical difficulties in obtaining their medicine. All have to travel or make special arrangements with their study physician, who is the arbiter of the potency of received material. All described incidents of inadequate supply or provision of inferior quality cannabis. All have had to supplement their supplies of cannabis from illegal black market sources at times.

All have experienced inconveniences or security concerns when traveling. One, Patient C, was arrested, detained, and had some of his medicine permanently confiscated without replacement.

Patients A-C decried the lack of an official identity card that might be readily recognized and accepted by law enforcement and security personnel. Rather, all used combinations of letters and other documents to convey their legal status to interested authorities, often to the accompaniment of much doubt and suspicion. All describe significant worry

and anxiety about their medicine supplies, and whether official promises of continuation of the program will be honored.

A paramount issue affecting the Compassionate IND patients revolves around cannabis quality. It has been well established that recreational cannabis smokers prefer higher potency materials (Herning, Hooker, and Jones 1986; Chait and Burke 1994; Kelly et al. 1997). The same pertains for most clinical cannabis patients.

Chait and Pierri (1989) published a detailed analysis of NIDA marijuana cigarettes that is worthy of review in this context. NIDA marijuana is grown outside, one crop per biennium, harvested from a 5-acre facility at the University of Mississippi. Average yield of "manicured material" is 270 g per plant or 270 g per square foot (letter from NIDA, Steven Gust to Chris Conrad, August 18, 1999). Material is shipped to the Research Triangle Institute in North Carolina where it is chopped and rolled on modified tobacco cigarette machines, then stored partially dehydrated and frozen. Cigarettes average 800-900 g in weight. Material requires rehydration before usage, which the IND patients usually achieve by storage overnight in a refrigerated plastic bag with leaves of lettuce.

As of 1999 (letter, Steven Gust to EBR, June 7, 1999), NIDA had available cannabis cigarettes of 1.8%, 2.8%, 3.0%, and 3.4% THC, and bulk cannabis of up to 5% THC content. Other cannabinoid components were not quantitated. It was further stated that the strongest material was not provided to patients in their cigarette shipments because it was too sticky and would interfere with the rolling machine's functioning

(Personal Communication to EBR, Steven Gust, December 1999).

Static burn rates of NIDA cannabis cigarettes were inversely related to potency (Chait and Pierri 1989), while the number of puffs that could be drawn from each cigarette averaged 8.8. While total particulate matter increased with potency, arguably less smoked material is necessary for medicinal effect. Of more concern, carbon monoxide levels were highest in the lower potency material; that is, CO was inversely proportional to THC content. Finally, test subjects in their study of NIDA cannabis reported (pp. 66-67), "that the marijuana is inferior in sensory qualities (taste, harshness) than the marijuana that they smoke outside the laboratory. Some have stated that it was the worst marijuana they had ever sampled, or that it tasted 'chemically treated.' "

All the study patients criticize the paper employed to roll the cannabis cigarettes as harsh, and tasting poorly. NIDA cannabis cigarettes resemble Pall Mall . . . brand tobacco cigarettes without the logo (Figure 3).

All study patients clean their cannabis and re-roll the material to varying degrees, although at least one former IND patient, now deceased, used the NIDA cigarettes unaltered.

NIDA cannabis is shipped to patients in labeled metal canisters containing 300 cigarettes (Figure 4), and material is frequently two or more years old upon receipt. Even under optimal storage conditions, a certain degree of oxidation of cannabinoids can be expected (Grotenhermen 2001). Most consumers prefer a supply of cured cannabis that is as fresh as possible.

A close inspection of the contents of NIDA-supplied cannabis cigarettes reveals them to be a crude mixture of leaf with abundant stem and seed components (Figures 5-6). The odor is green and herbal in character. The resultant smoke is thick, acrid, and pervasive.

In contrast, a typical sinsemilla "bud" is seedless, covered with visible glandular trichomes (see journal cover), and emits a strong lemony or piney terpenoid scent. The smoke is also less disturbing from a sensory standpoint to most observers.

Whittle, Guy, and Robson (2001) describe in detail the markedly contrasting steps undertaken in a government approved clinical cannabis program in the United Kingdom. Their material is organically grown in soil with no chemical treatment under controlled indoor conditions. All male plants are eliminated, and only unfertilized female flowering tops are harvested for further processing. This material is assayed for cannabinoid and terpenoid content, with controlled ratios through genetic selection of seed strains before extraction. THC yields obtained are routinely 15-20% (Personal Communication, GW Pharmaceuticals, 2000).

Harm reduction techniques in relation to clinical cannabis consumption are well advanced (Russo 2001; Grotenhermen 2001a, 2001b). Particular attention is merited toward vaporization techniques that provide cannabinoid and terpenoid component administration to prospective clinical cannabis patients without pyrolysis (Gieringer 1996a; Gieringer 1996b; Gieringer 2001). Sublingual administration of cannabis extracts is another most promising technique of clinical cannabis administration (Whittle, Guy, and Robson 2001).

Three of the four study subjects have employed Marinol . . . , and found it inadequate or a poor substitute for cannabis in symptomatic relief of their clinical syndromes.

CONCLUSIONS AND RECOMMENDATIONS

1. Cannabis smoking, even of a crude, low-grade product, provides effective symptomatic relief of pain, muscle spasms, and intra-ocular pressure elevations in selected patients failing other modes of treatment.

2. These clinical cannabis patients are able to reduce or eliminate other prescription medicines and their accompanying side effects.

3. Clinical cannabis provides an improved quality of life in these patients.

4. The side effect profile of NIDA cannabis in chronic usage suggests some mild pulmonary risk.

5. No malignant deterioration has been observed.

6. No consistent or attributable neuropsychological or neurological deterioration has been observed.

7. No endocrine, hematological or immunological sequelae have been observed.

8. Improvements in a clinical cannabis program would include a ready and consistent supply of sterilized, potent, organically grown unfertilized female flowering top material, thoroughly cleaned of extraneous inert fibrous matter.

9. It is the authors' opinion that the Compassionate IND program should be reopened and extended to other patients in need of clinical cannabis.

10. Failing that, local, state and federal laws might be amended to provide regulated and monitored clinical cannabis to suitable candidates.

ACKNOWLEDGMENTS

The authors would like to dedicate this study to the loving memory of Robert Randall, the first patient in the Compassionate IND program.

The authors would like to acknowledge the generous financial support of John Gilmore, Preston Parish in memory of W. Erastus Upjohn, the Zimmer Family Foundation, and MAPS (Multidisciplinary Association for Psychedelic Studies).

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IN THE MATTER OF MARIJUANA RESCHEDULING, DEA DKT.NO.: 86-22 (1988) (RELEVANT EXCERPTS)

UNITED STATES DEPARTMENT OF JUSTICE
Drug Enforcement Administration

In The Matter of
MARIJUANA RESCHEDULING PETITION,

No. Docket No. 86-22

OPINION AND RECOMMENDED RULING, FINDINGS OF FACT, CONCLUSIONS OF LAW AND DECISION OF ADMINISTRATIVE LAW JUDGE

I. Introduction

This is a rulemaking pursuant to the Administrative Procedure Act, 5 U.S.C. § 551, *et seq.*, to determine whether the marijuana plant (Cannabis sativa L) considered as a whole may lawfully be transferred from Schedule I to Schedule II of the schedules established by the Controlled Substances Act (the Act), 21 U.S.C. § 801, *et seq.* None of the parties is seeking to "legalize" marijuana generally or for recreational purposes. Placement in Schedule II would mean, essentially, that physicians in the United States would not violate Federal law by prescribing marijuana for their patients for legitimate therapeutic purposes.

It is contrary to Federal law for physicians to do this as long as marijuana remains in Schedule I.

This proceeding had its origins on May 18, 1972 when the National Organization for the Reform of Marijuana Laws (NORML) and two other groups submitted a petition to the Bureau of Narcotics and Dangerous Drugs (BNDD)[1], predecessor

[. . .]

VIII. Accepted Safety for Use Under Medical Supervision

With respect to whether or not there is "a lack of accepted safety for use of [marijuana] under medical supervision", the record shows the following facts to be uncontroverted.

Findings of Fact

1. Richard J. Gralla, M.D., an oncologist and Professor of Medicine who was an Agency witness, accepts that in treating cancer patients oncologists can use the cannabinoids with safety despite their side effects.

2. Andrew T. Weil, M.D., who now practices medicine in Tucson, Arizona and is on the faculity of the College of Medicine, University of Arizona, was a member of the first team of researchers to perform a Federal Government authorized study into the effects of marijuana on human subjects. This team made its study in 1968. These researchers determined that

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[1] The powers and authority granted by the Act to the Attorney General were delegated to the Director of BNOD and subsequently to the Administrator of DEA. 28 C.F.R. § 0.100, *et seq.*

marijuana could be safely used under medical supervision. In the 20 years since then Dr. Weil has seen no information that would cause him to reconsider that conclusion. There is no question in his mind but that marijuana is safe for use under appropriate medical supervision.

3. The most obvious concern when dealing with drug safety is the possibility of lethal effects. Can the drug cause death?

4. Nearly all medicines have toxic, potentially lethal effects. But marijuana is not such a substance. There is no record in the extensive medical literature describing a proven, documented cannabis-induced fatality.

5. This is a remarkable statement. First, the record on marijuana encompasses 5,000 years of human experience. Second, marijuana is now used daily by enormous numbers of people throughout the world. Estimates suggest that from twenty million to fifty million Americans routinely, albeit illegally, smoke marijuana without the benefit of direct medical supervision. Yet, despite this long history of use and the extraordinarily high numbers of social smokers, there are simply no credible medical reports to suggest that consuming marijuana has caused a single death.

6. By contrast aspirin, a commonly used, over-the-counter medicine, causes hundreds of deaths each year.

7. Drugs used in medicine are routinely given what is called an LD-50. The LD-50 rating indicates at what dosage fifty percent of test animals receiving a drug will die as a result of drug induced toxicity. A number of researchers have attempted to determine

marijuana's LD-50 rating in test animals, without success. Simply stated, researchers have been unable to give animals enough marijuana to induce death.

8. At present it is estimated that marijuana's LD-50 is around 1:20,000 or 1:40,000. In layman terms this means that in order to induce death a marijuana smoker would have to consume 20,000 to 40,000 times as much marijuana as is contained in one marijuana cigarette. NIDA-supplied marijuana cigarettes weigh approximately .9 grams. A smoker would theoretically have to consume nearly 1,500 pounds of marijuana within about fifteen minutes to induce a lethal response.

9. In practical terms, marijuana cannot induce a lethal response as a result of drug-related toxicity.

10. Another common medical way to determine drug safety is called the therapeuic ratio. This ratio defines the difference between a therapeutically effective dose and a dose which is capable of inducing adverse effects.

11. A commonly used over-the-counter product like aspirin has a therapeutic ratio of around 1:20. Two aspirins are the recommended dose for adult patients. Twenty times this dose, forty aspirins, may cause a lethal reaction in some patients, and will almost certainly cause gross injury to the digestive system, including extensive internal bleeding.

12. The therapeutic ratio for prescribed drugs is commonly around 1:10 or lower. Valium, a commonly used prescriptive drug, may cause very serious biological damage if patients use ten times the recommended (therapeutic) dose.

13. There are, of course, prescriptive drugs which have much lower therapeutic ratios. Many of the drugs used to treat patients with cancer, glaucoma and multiple sclerosis are highly toxic. The therapeutic ratio of some of the drugs used in antineoplastic therapies, for example, are regarded as extremely toxic poisons with therapeutic ratios that may fall below 1:1.5. These drugs also have very low LD-50 ratios and can result in toxic, even lethal reactions, while being properly employed.

14. By contrast, marijuana's therapeutic ratio, like its LD-50, is impossible to quantify because it is so high.

15. In strict medical terms marijuana is far safer than many foods we commonly consume. For example, eating ten raw potatoes can result in a toxic response. By comparison, it is physically impossible to eat enough marijuana to induce death.

16. Marijuana, in its natural form, is one of the safest therapeutically active substances known to man. By any measure of rational analysis marijuana can be safely used within a supervised routine of medical care.

17. Some of the drugs most widely used in chemotherapy treatment of cancer have adverse effects as follows:

> Ciplatin, one of the most powerful chemotherapeuic agents used on humans-may cause deafness; may lead to life-threatening kidney difficulties and kidney failure; adversely affects the body's immune system, suppressing the patient's ability to fight a host of common infections.

> Nitrogen Mustard, a drug used in therapy for Hodgkins disease-nauseates; so toxic to the skin that, if dropped on the skin, this chemical literally eats it away along with other tissues it contacts; if patient's intravenous lead slips during treatment and this drug gets on or under the skin the patient may suffer serious injury including temporary, and in extreme cases, permanent, loss of use of the arm.
>
> Procarbizine, also used for Hodgkins disease– has known psychogenic, *i.e.*, emotional, effects.
>
> Cytoxin, also known as Cyclophosphanide– suppresses patient's immune system response; results in serious bone marrow depletion; studies indicate this drug may also cause other cancers, including cancers of the bladder.
>
> Adriamycan, has numerous adverse effects; is difficult to employ in long term therapies because it destroys the heart muscle.

While each of these agents has its particular adverse effects, as indicated above, they also cause a number of similar, disturbing adverse effects. Most of these drugs cause hair loss. Studies increasingly indicate all of these drugs may cause other forms of cancer. Death due to kidney, heart or respiratory failure is a very real possibility with all of these agents and the margin for error is minimal. Similarly, there is a danger of overdosing a patient weakened by his cancer. Put simply, there is very great risk associated with the medical . . . .

[. . .]

INVITATION FROM CONGRESSMAN J. LUIS CORREA TO ALEXIS BORTELL (SEPTEMBER 6, 2017)

From: Mendez, Emilio
[mailto:Emilio.Mendez@mail.house.gov]
Sent: Wednesday, September 06, 2017 1:01 PM
To: bortell2@hotmail.com; deanbortell@gmail.com
Cc: Saroff, Laurie
<Laurie.Saroff@mail.house.gov>;
Kermott, Julia
<Julia.Kermott@mail.house.gov>;
Lauren Rudick lrudick@hillerpc.com
Subject: Meeting Invitation

Dear Alexis and Dean:

Congressman Lou Correa is aware that the National Organization for Reform of Marijuana Laws (NORML) has invited you to advocate for marijuana policy reform alongside the organization on Capitol Hill from September 10-12, 2017.

If you are able to participate in the 2017 NORML Conference and Congressional Lobby Day, Congressman Correa would welcome the opportunity to meet with you and your family to discuss your particular experience with medical cannabis. The Congressman believes that it is important that Members of Congress be afforded the opportunity to meet with you to hear your story and receive your perspective.

The Congressman looks forward to meeting with you.

Best,

Emilio Mendez | Legislative Assistant
Office of Congressman J. Luis Correa (CA-46)
1039 Longworth Building | Washington DC 20515
Tel: 202-225-2965

NEW YORK TIMES ARTICLE: "HALDEMAN DIARY SHOWS NIXON WAS WARY OF BLACKS AND JEWS" (MAY 18,1984)

By The Associated Press

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The diaries of H.R. Haldeman, President Richard M. Nixon's chief of staff until the Watergate scandal prompted Mr. Nixon to dismiss him, include references to Mr. Nixon's believing that there was "total Jewish domination of the media" and that "the whole problem is really the blacks."

"The Haldeman Diaries," being published today by G.P. Putnam's Sons, are drawn from audio recordings and Mr. Haldeman's daily diary entries.

In one entry, Mr. Haldeman, referring to the President as "P," said: "P emphasized that you have to face the fact that the whole problem is really the blacks. The key is to devise a system that recognizes this while not appearing to. Pointed out that there has never in history been an adequate black nation, and they are the only race of which this is true. Says Africa

is hopeless. The worst there is Liberia, which we built."

In another segment Mr. Haldeman states: "There was considerable discussion of the terrible problem arising from the total Jewish domination of the media and agreement that this is something that would have to be dealt with."

Mr. Haldeman's entry for Feb. 26, 1970, stated that Mr. Nixon "really raged again against United States Jews" and that the President had ordered his chief of staff "not to let any Jews see him about the Middle East." Mr. Haldeman noted that the outburst was in the presence of the national security adviser, Henry A. Kissinger, who is Jewish. Plot to Impugn Kennedy

In an entry on June 23, 1971, Mr. Haldeman dictated a passage about how to use reports of sexual escapades against Senator Edward M. Kennedy, the Massachusetts Democrat whom Mr. Nixon considered a likely rival for the Presidency in 1972. "We need to take advantage of this opportunity and get him in a compromising situation if we can," Mr. Haldeman said.

Mr. Nixon died last month. Mr. Haldeman died last year.

Mr. Haldeman's recollections also indicate that Mr. Nixon had wanted his predecessor, Lyndon B. Johnson, to persuade Democratic senators to halt their Watergate inquiry and had threatened to reveal that Mr. Johnson bugged the Nixon campaign plane in 1968.

Mr. Haldeman recorded that on June 25, 1972, eight days after the Watergate break-in set in motion the events that eventually led Mr. Nixon to resign, the President was concerned about "the Martha Mitchell problem."

Mrs. Mitchell, the wife of Attorney General John N. Mitchell, Mr. Nixon's campaign manager and mentor, had a habit of calling reporters, especially Helen Thomas, the White House correspondent of United Press International. Martha Mitchell's Telephones

In one entry Mr. Haldeman said Mrs. Mitchell had told Ms. Thomas that if Mr. Mitchell did not get out of politics "she was going to kick him out of the house, but her phones were then pulled out either by her or someone in her room."

After noting that Mrs. Mitchell was demanding that her telephone be reinstalled, Mr. Haldeman said, "She's now threatening that if they don't get her phones in she's going to blow the whole Republican deal, whatever that means."

The next day Mr. Haldeman recorded that it was Mr. Nixon's opinion that "John's got to close her down somehow or lock her up, but he can't just leave her speaking out like this; it's going to create a major national problem."

Later, Mr. Haldeman learned that it had been an agent of the Federal Bureau of Investigation who had pulled out the phone. "She had a monumental tantrum, started throwing things at him, demolishing the room," Mr. Haldeman said. "They locked her in. She busted the window with her hand, cut herself

badly. They had to get a doctor, who had to throw her on the bed and give her a shot in order to subdue her."

Mr. Mitchell resigned as head of the re-election campaign on July 1, saying that he had "to meet the happiness" of his wife and daughter.

Mrs. Mitchell died in 1976, and Mr. Mitchell in 1988.

Asked for comment on the racial statements the Haldeman diaries attributed to Mr. Nixon, the director of the Nixon Library and Birthplace in Yorba Linda, Calif., John H. Taylor, said, "Politics and anti-Semitism are two different things." Mr. Nixon's statements about blacks and Jews "should be viewed strictly in a political context," he said.

"I had the privilege of serving him for 15 years and never heard him make an anti-Semitic statement," Mr. Taylor said.

[. . .]

HARPERS MAGAZINE ARTICLE— "LEGALIZE IT ALL: HOW TO WIN THE WAR ON DRUGS" (APRIL 1, 2016)

By Dan Baum

In 1994, John Ehrlichman, the Watergate co-conspirator, unlocked for me one of the great mysteries of modern American history: How did the United States entangle itself in a policy of drug prohibition that has yielded so much misery and so few good results? Americans have been criminalizing psychoactive substances since San Francisco's anti-opium law of 1875, but it was Ehrlichman's boss, Richard Nixon, who declared the first "war on drugs" and set the country on the wildly punitive and counterproductive path it still pursues. I'd tracked Ehrlichman, who had been Nixon's domestic-policy adviser, to an engineering firm in Atlanta, where he was working on minority recruitment. I barely recognized him. He was much heavier than he'd been at the time of the Watergate scandal two decades earlier, and he wore a mountain-man beard that extended to the middle of his chest.

At the time, I was writing a book about the politics of drug prohibition. I started to ask Ehrlichman a series of earnest, wonky questions that he impatiently waved away. "You want to know what this was really all about?" he asked with the bluntness of a man who, after public disgrace and a stretch in federal prison, had little left to protect. "The Nixon campaign in 1968, and the Nixon White House after that, had two

enemies: the antiwar left and black people. You understand what I'm saying? 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."

I must have looked shocked. Ehrlichman just shrugged. Then he looked at his watch, handed me a signed copy of his steamy spy novel, *The Company*, and led me to the door.

Nixon's invention of the war on drugs as a political tool was cynical, but every president since—Democrat and Republican alike—has found it equally useful for one reason or another. Meanwhile, the growing cost of the drug war is now impossible to ignore: billions of dollars wasted, bloodshed in Latin America and on the streets of our own cities, and millions of lives destroyed by draconian punishment that doesn't end at the prison gate; one of every eight black men has been disenfranchised because of a felony conviction.

As long ago as 1949, H. L. Mencken identified in Americans "the haunting fear that someone, somewhere, may be happy," an astute articulation of our weirdly Puritan need to criminalize people's inclination to adjust how they feel. The desire for altered states of consciousness creates a market, and in suppressing that market we have created a class of genuine bad guys—pushers, gangbangers, smugglers, killers. Addiction is a hideous condition, but it's rare.

Most of what we hate and fear about drugs—the violence, the overdoses, the criminality—derives from prohibition, not drugs. And there will be no victory in this war either; even the Drug Enforcement Administration concedes that the drugs it fights are becoming cheaper and more easily available.

Now, for the first time, we have an opportunity to change course. Experiments in alternatives to harsh prohibition are already under way both in this country and abroad. Twenty-three states, as well as the District of Columbia, allow medical marijuana, and four—Colorado, Washington, Oregon, and Alaska—along with D.C., have legalized pot altogether. Several more states, including Arizona, California, Maine, Massachusetts, and Nevada, will likely vote in November whether to follow suit. Portugal has decriminalized not only marijuana but cocaine and heroin, as well as all other drugs. In Vermont, heroin addicts can avoid jail by committing to state-funded treatment. Canada began a pilot program in Vancouver in 2014 to allow doctors to prescribe pharmaceutical-quality heroin to addicts, Switzerland has a similar program, and the Home Affairs Committee of Britain's House of Commons has recommended that the United Kingdom do likewise. Last July, Chile began a legislative process to legalize both medicinal and recreational marijuana use and allow households to grow as many as six plants. After telling the BBC in December that "if you fight a war for forty years and don't win, you have to sit down and think about other things to do that might be more effective," Colombian president Juan Manuel Santos legalized medical marijuana by decree. In November, the Mexican Supreme Court elevated the debate to a new plane by ruling that the prohibition of

marijuana consumption violated the Mexican Constitution by interfering with "the personal sphere," the "right to dignity," and the right to "personal autonomy." The Supreme Court of Brazil is considering a similar argument.

Depending on how the issue is framed, legalization of all drugs can appeal to conservatives, who are instinctively suspicious of bloated budgets, excess government authority, and intrusions on individual liberty, as well as to liberals, who are horrified at police overreach, the brutalization of Latin America, and the criminalization of entire generations of black men. It will take some courage to move the conversation beyond marijuana to ending all drug prohibitions, but it will take less, I suspect, than most politicians believe. It's already politically permissible to criticize mandatory minimums, mass marijuana-possession arrests, police militarization, and other excesses of the drug war; even former attorney general Eric Holder and Michael Botticelli, the new drug czar—a recovering alcoholic—do so. Few in public life appear eager to defend the status quo.

This month, the General Assembly of the United Nations will be gathering for its first drug conference since 1998. The motto of the 1998 meeting was "A Drug-Free World—We Can Do It!" With all due respect, U.N., how'd that work out for you? Today the U.N. confronts a world in which those who have suffered the most have lost faith in the old strong-arm ideology. That the tide was beginning to turn was evident at the 2012 Summit of the Americas in Cartagena, Colombia, when Latin American leaders for the first time openly discussed—much to the public discomfort of President Obama—whether

legalizing and regulating drugs should be the hemisphere's new approach.

When the General Assembly convenes, it also will have to contend with the startling fact that four states and the capital city of the world's most zealous drug enforcer have fully legalized marijuana. "We're confronted now with the fact that the U.S. cannot enforce domestically what it promotes elsewhere," a member of the U.N.'s International Narcotics Control Board, which monitors international compliance with the conference's directives, told me. Shortly before Oregon, Alaska, and the District of Columbia added themselves to the legal-marijuana list, the State Department's chief drug-control official, William Brownfield, abruptly reversed his stance. Whereas before he had said that the "drug control conventions cannot be changed," in 2014 he admitted that things had changed: "How could I, a representative of the government of the United States of America, be intolerant of a government that permits any experimentation with legalization of marijuana if two of the fifty states of the United States of America have chosen to walk down that road?" Throughout the drug-reform community, jaws dropped.

As the once-unimaginable step of ending the war on drugs shimmers into view, it's time to shift the conversation from why to how. To realize benefits from ending drug prohibition will take more than simply declaring that drugs are legal. The risks are tremendous. Deaths from heroin overdose in the United States rose 500 percent from 2001 to 2014, a staggering increase, and deaths from prescription drugs—which are already legal and regulated—shot up almost 300 percent, proving that where opioids are

concerned, we seem to be inept not only when we prohibit but also when we regulate. A sharp increase in drug dependence or overdoses that followed the legalization of drugs would be a public-health disaster, and it could very well knock the world back into the same counterproductive prohibitionist mind-set from which we appear finally to be emerging. To minimize harm and maximize order, we'll have to design better systems than we have now for licensing, standardizing, inspecting, distributing, and taxing dangerous drugs. A million choices will arise, and we probably won't make any good decisions on the first try. Some things will get better; some things will get worse. But we do have experience on which to draw—from the end of Prohibition, in the 1930s, and from our recent history. Ending drug prohibition is a matter of imagination and management, two things on which Americans justifiably pride themselves. We can do this.

Let's start with a question that is too seldom asked: What exactly *is* our drug problem? It isn't simply drug use. Lots of Americans drink, but relatively few become alcoholics. It's hard to imagine people enjoying a little heroin now and then, or a hit of methamphetamine, without going off the deep end, but they do it all the time. The government's own data, from the Substance Abuse and Mental Health Services Administration, shatters the myth of "instantly addictive" drugs. Although about half of all Americans older than twelve have tried an illegal drug, only 20 percent of those have used one in the past month. In the majority of those monthly-use cases, the drug was cannabis. Only tiny percentages of people who have sampled one of the Big Four—heroin, cocaine, crack, and methamphetamine—have

used that drug in the past month. (For heroin, the number is 8 percent; for cocaine, 4 percent; for crack, 3 percent; for meth, 4 percent.) It isn't even clear that using a drug once a month amounts to having a drug problem. The portion of lifetime alcohol drinkers who become alcoholics is about 8 percent, and we don't think of someone who drinks alcohol monthly as an alcoholic.

In other words, our real drug problem—debilitating addiction—is relatively small. One longtime drug-policy researcher, Peter Reuter of the University of Maryland, puts the number of people addicted to hard drugs at fewer than 4 million, out of a population of 319 million. Addiction is a chronic illness during which relapses or flare-ups can occur, as with diabetes, gout, and high blood pressure. And drug dependence can be as hard on friends and family as it is on the afflicted. But dealing with addiction shouldn't require spending $40 billion a year on enforcement, incarcerating half a million, and quashing the civil liberties of everybody, whether drug user or not.

It's possible, of course, that one reason we have a relatively small number of drug addicts is precisely that the most addictive drugs are illegal. If cocaine were to be legalized, says Mark Kleiman, a professor of public policy at New York University who has been a critic of the war on drugs since the 1970s, there's no evidence indicating that the number of cocaine abusers would be less than the number of alcoholics, or about 17.6 million. Moreover, legalizing cocaine might worsen both cocaine addiction and alcoholism, Kleiman adds. "A limit to alcoholism is you fall asleep. Cocaine fixes that. And a limit to cocaine addiction is you can't sleep. Alcohol fixes that."

Kleiman's prediction of a big increase in post-legalization addiction rates seems intuitively correct. Common sense and decency dictate that any plan for legalizing drugs ought to make provisions for a rise in dependence. Millions of addicts already go untreated in the United States. Although treatment is a bargain—the government estimates that for every dollar spent on drug treatment, seven are saved—treatment and prevention get only 45 percent of the federal drug budget while enforcement and interdiction get 55 percent, and that's not including the stupendous cost of incarcerating drug offenders. Treatment may become more available now that the Affordable Care Act requires many insurers to pay for mental-health services, including drug addiction, at parity with physical illnesses. Training effective treatment providers is time-consuming and expensive, but the billions freed up by the end of enforcement and mass incarceration could be used to help address that need.

It is also not a certainty that legalizing drugs would result in the huge spike in addiction that Kleiman predicts. In fact, some data argue against it. The Netherlands effectively decriminalized marijuana use and possession in 1976, and Australia, the Czech Republic, Italy, Germany, and New York State all followed suit. In none of these jurisdictions did marijuana then become a significant health or public-order problem. But marijuana's easy; it isn't physically addictive. So consider Portugal, which in 2001 took the radical step of decriminalizing not only pot but cocaine, heroin, and the rest of the drug spectrum. Decriminalization in Portugal means that the drugs remain technically prohibited—selling them is a major crime—but the purchase, use, and possession of up to

ten days' supply are administrative offenses. No other country has gone so far, and the results have been astounding. The expected wave of drug tourists never materialized. Teenage use went up shortly before and after decriminalization, but then it settled down, perhaps as the novelty wore off. (Teenagers—particularly eighth graders—are considered harbingers of future societal drug use.)

The lifetime prevalence of adult drug use in Portugal rose slightly, but problem drug use—that is, habitual use of hard drugs—declined after Portugal decriminalized, from 7.6 to 6.8 per 1,000 people. Compare that with nearby Italy, which didn't decriminalize, where the rates rose from 6.0 to 8.6 per 1,000 people over the same time span. Because addicts can now legally obtain sterile syringes in Portugal, decriminalization seems to have cut radically the number of addicts infected with H.I.V., from 907 in 2000 to 267 in 2008, while cases of full-blown AIDS among addicts fell from 506 to 108 during the same period.

The new Portuguese law has also had a striking effect on the size of the country's prison population. The number of inmates serving time for drug offenses fell by more than half, and today they make up only 21 percent of those incarcerated. A similar reduction in the United States would free 260,000 people—the equivalent of letting the entire population of Buffalo out of jail.

When applying the lessons of Portugal to the United States, it's important to note that the Portuguese didn't just throw open access to dangerous drugs without planning for people who couldn't handle them. Portugal poured money into drug treatment,

expanding the number of addicts served by more than 50 percent. It established Commissions for the Dissuasion of Drug Addiction, each of which is composed of three people—often a doctor, a social worker, and an attorney—who are authorized to refer a drug user to treatment and in some cases impose a relatively small fine. Nor did Portugal's decriminalization experiment happen in a vacuum. The country has been increasing its spending on social services since the 1970s, and even instituted a guaranteed minimum income in the late 1990s. The rapid expansion of the welfare state may have contributed to Portugal's well-publicized economic troubles, but it can probably also share credit for the drop in problem drug use.

Decriminalization has been a success in Portugal. Nobody there argues seriously for abandoning the policy, and being identified with the law is good politics: during his successful 2009 reelection campaign, former prime minister José Sócrates boasted of his role in establishing it.

So why doesn't the United States decriminalize? It's an attractive idea: Lay off the innocent users and pitiable addicts; keep going after the really bad guys who import and push the drugs. But decriminalization doesn't do enough. As successful as Portugal's experiment has been, the Lisbon government still has no control over drug purity or dosage, and it doesn't make a dime in tax revenue from the sale of drugs. Organized crime still controls Portugal's supply and distribution, and drug-related violence, corruption, and gunned-up law enforcement continue. For these reasons, the effect of drug decriminalization on crime in Portugal is murky. Some crimes strongly associated

with drug use increased after decriminalization—street robberies went up by 66 percent, auto theft by 15 percent—but others dropped. (Thefts from homes fell by 8 percent, thefts from businesses by 10 percent.) A study by the Portuguese police found an increase in opportunistic crimes and a reduction in premeditated and violent crimes, but it could not conclude that the changes were due to the decriminalization of drugs. Heavy-handed enforcement also requires favoring scare tactics over honest inquiry, experimentation, and data gathering; and scare tactics are no way to deal with substances as dangerous as heroin, cocaine, and methamphetamine.

Portuguese-style decriminalization also wouldn't work in the United States because Portugal is a small country with national laws and a national police force, whereas the United States is a patchwork of jurisdictions—thousands of overlapping law-enforcement agencies and prosecutors at the local, county, state, and federal levels. Philadelphia's city council, for example, voted to decriminalize possession of up to an ounce of marijuana in June 2014, and within a month state police had arrested 140 people for exactly that offense. "State law trumps city ordinances," Police Commissioner Charles Ramsey told the *Philadelphia Inquirer*. And while marijuana may be legal in four states and D.C., under federal law it is still as illegal as heroin or LSD—and even more tightly controlled than cocaine or pharmaceutical opioids. The Obama Administration has decided, for the moment, not to interfere with the states that have legalized marijuana, but times change and so do administrations. We cannot begin to enjoy the benefits of managing drugs as a matter of health and safety,

instead of as a matter of law enforcement, until the drugs are legalized at every level of American jurisprudence, just as alcohol was re-legalized when the United States repealed the Eighteenth Amendment in 1933.

One of the evils that led to Prohibition in the first place was the system of "tied houses"—saloons owned by alcohol producers that marketed their product aggressively. As Prohibition was ending, John D. Rockefeller commissioned a report published as *Toward Liquor Control* that advocated total government control of alcohol distribution. "Only as the profit motive is eliminated is there any hope of controlling the liquor traffic in the interests of a decent society," he said. That never happened, of course. Tied houses were banned, but Seagram, Anheuser-Busch, and other companies became gigantic from the manufacture and sale of alcohol; only eighteen states assumed any direct control over the distribution process.

We've grown used to living with the consequences of legal alcohol, even though alcohol is undeniably costly to the nation in lives and treasure. But few would argue for a return to Prohibition, in part because the liquor industry is so lucrative and so powerful. Binge drinkers—20 percent of the drinking population—consume more than half of the alcohol sold, which means that for all the industry's pious admonitions to "drink responsibly," it depends on people doing the opposite. At the same time, Big Alcohol's clout keeps taxation low. Kleiman, of NYU, estimates alcohol taxes to be about a dime a drink; the societal cost in disease, car wrecks, and violence is about fifteen times that. Neither the binge-dependent economics of alcohol nor the industry's capture of the regulatory process is

something we would want to mimic when legalizing substances such as heroin and crack cocaine. We'll have to do a better job at legalizing drugs than we did at re-legalizing alcohol if we want to hold addiction to a minimum, keep drugs away from children, assure drug purity and consistency of dosage, and limit drugged driving. Last November, Ohio voters rejected marijuana legalization, most observers believe, precisely because the proposed initiative would have allowed only ten companies, all of which sponsored the initiative, to grow and distribute marijuana in the state.

If we can summon the political will, the opportunity to establish a state monopoly on drug distribution, just as Rockefeller urged for alcohol in 1933, is now—before the genie is out of the bottle. Switzerland, Germany, and the Netherlands have successfully made heroin legally available to addicts through networks of government-run dispensaries that are divorced from the profit motive. The advantages of a state monopoly over a free market—even a regulated one—are vast.

In the 1970s, the eighteen states that established government control over alcohol distribution at the end of Prohibition began to water down their systems by feeding their wholesale or retail alcohol businesses, or both, to private industry. Still, in 2013 a team of researchers at the University of Michigan found that even in "weak monopoly" states, consumption of spirits was 12 to 15 percent lower than in states with private liquor stores or grocery stores. In states that retained control over retail sales, alcohol-related traffic fatalities were about 7 to 9 percent lower than in states that did not; crime rates were lower as well.

Just about everybody who thinks seriously about the end of drug prohibition agrees that we'll want to discourage consumption. This goal could be accomplished, at least in part, under a system of regulated, for-profit stores: by setting limits on advertising and promotion (or banning them altogether), by preventing marketing to children, by establishing minimum distances from schools for retail outlets, by nailing down rules about dosage and purity, and by limiting both the number of stores and their hours of operation. In a for-profit system, however, the only way government can influence price—the strongest disincentive to consumption—is by levying a tax, and getting taxes right is no small task. First, on what basis should the tax apply? Federal taxes on alcohol are set according to potency, but keeping up with the THC content of every strain of marijuana would be impossible. Weight? The more potent the drug, the less you need to buy, so taxing by weight might end up promoting stronger drugs over weaker. Price? Post-legalization prices are likely to plummet as the "prohibition premium"—which compensates dealers for the risk of getting caught—disappears, competition sets in, and innovation increases production. To keep prices high enough to discourage use, legislators will have to monitor those prices constantly and risk their jobs by pushing for politically unpopular tax increases.

"It's too hard to adjust taxes quickly enough," said Pat Oglesby, a North Carolina tax lawyer who was chief tax counsel for the Senate Finance Committee from 1988 to 1990 and who now researches marijuana taxes. "Legislatures love lowering taxes. Getting them to raise taxes is like pulling teeth." What's more, if

legislators overdo it and set taxes too high, they'll risk reawakening a black market in untaxed drugs.

A government monopoly on distribution solves the problem by making the setting of prices a matter of administration, not legislation. Government officials, whether at the state or federal level, would have infinite flexibility to adjust the price—daily, if necessary—to minimize use without inspiring a black market. The production of marijuana, cocaine, and heroin could remain in private hands, and the producers could supply the government stores, just as Smirnoff, Coors, and Mondavi provide their products to state liquor stores. If the cost of producing a drug drops because of innovation or competition, the government agency selling that drug to the public would see an increase in revenues. Likewise, it is much easier for the government to set the dosage and purity of products it sells in its own outlets than to police the dosage and purity of products that are spread throughout a free market. And the government could decide on its own to what extent it wants to permit advertising, attractive packaging, and promotions.

Finally, of course, when the government holds a monopoly, the public, not private shareholders, enjoys the profit. The states that retain control over alcohol distribution collect 82 to 90 percent more in revenue than states that license private alcohol sales collect in taxes, depending on whether they control both wholesale and retail. That the government should profit from a product it wants to discourage could be seen as hypocritical, but that's the way things stand now with tobacco, alcohol, and gambling. States generally reduce the moral sting of those profits by earmarking them for education or other popular

causes. In the case of drugs, the profits could go toward treating addicts. The great thing about trying a state monopoly first is that if it doesn't work, it's politically much easier to liberalize to a regulated free market than to go the other way.

But as long as federal law in the United States maintains an absolute prohibition on marijuana, cocaine, and heroin—and stringent restrictions on methamphetamine—it's hard to imagine state drug monopolies on the model of state liquor stores. Even if the international bans on Schedule I drugs were to lift, could our legislators muster the will to legalize them, much less to expand government to distribute them? It's one thing for the chief executive to turn a blind eye to the states' experiments in licensed marijuana commerce; it's another to grind the gears and shift conservative congressional sensibilities.

This is a pity, since a government monopoly would be the least expensive and most flexible way to legalize drugs. It would generate the most revenue and—more important—it would protect public health. Until Congress reschedules marijuana, heroin, and cocaine, and until we get over the idea that government can do nothing right, we're stuck with second best: state-size experiments that ignore the federal ban on marijuana and license private industries. Colorado is the furthest along that path, and its experience is instructive.

Colorado has allowed medical marijuana since 2000 through a system of licensed private dispensaries. The state originally required marijuana businesses to be vertically integrated; dispensaries could sell only what they grew themselves—a replication of the old tied houses. The theory was that it was easier to

regulate businesses from "seed to sale." In November 2012, 55 percent of voters approved Amendment 64 to the Colorado constitution, which legalized recreational marijuana. (The initiative was strategically timed; having marijuana on the ballot helped draw young and progressive voters to the polls to win the state for President Obama.) After the election, Colorado chose a system of licensed businesses over state monopoly; in 2014, it dropped the requirement that recreational dispensaries be vertically integrated—one business can now grow marijuana for another to sell. As soon as Governor John Hickenlooper formalized the results, five weeks after the vote, Coloradans twenty-one years of age and older could legally possess and use marijuana. Stores and commercial cultivators were not allowed to open, though, until January 2014, fourteen months after the vote. The delay was meant to allow the state time to expand the Marijuana Enforcement Division, within the Department of Revenue, to incorporate retail marijuana into its jurisdiction, and to allow the division to write rules concerning signage, advertising, waste disposal, video surveillance, labeling, taxes, and required distances from schools.

Already, legal marijuana in Colorado is following the grim economics of alcohol. Daily smokers make up only 23 percent of the state's pot-smoking population, but they consume 67 percent of the reefer. That may have been true too when marijuana was illegal; maybe the number of daily stoners is neither rising nor falling. We'll never know, because one problem with illegal markets is that you can't track them. But we do know that the legal, for-profit marijuana business in Colorado is already mimicking

the alcohol business in its dependence on heavy users. From a public-health standpoint, that's troubling.

The effect of legalization on crime has been difficult to determine. Overall, crime fell in Denver by almost 2 percent in 2014, the first year of full marijuana legalization. And, strangely, surveys of 40,000 teenagers before and after legalization showed that although fewer now believed marijuana to be harmful—just as the opponents of legalization predicted—*fewer were smoking pot*. Were they lying? Was it a statistical anomaly? Are pot dealers harder to find now that they're competing with legal stores? Or is it possible that marijuana, once legalized, lost its cachet?

Colorado has run into glitches. The fourteen months between the vote and the opening of the stores wasn't enough time to write regulations on such variables as pesticide use in cultivation or dosages in edibles. Nor was there time to write a new training curriculum for police, who found themselves not knowing exactly what to do about the large quantities of marijuana they were encountering. People have been stringing extension cords together to make their own grow rooms—and burning down their homes. They've pumped so much water into pot cultivation that monstrous blooms of black mold have rendered their houses uninhabitable. And Denver has seen a spate of burglaries and robberies at marijuana greenhouses and stores. The law let local jurisdictions decide whether to allow retail pot stores. Only thirty-five counties did so at first, which is partly why the state received only $12 million in new marijuana taxes in the first six months of legal pot sales—about a third of what regulators had anticipated. ("That's changing," said Lewis Koski, the forty-four-year-old

who is the deputy senior director of Colorado's Enforcement Division, in 2014. "Just about every week we have new jurisdictions allowing it.") It may also be that the state set the tax on retail marijuana too high—10 percent on top of the usual sales tax. Some smokers are apparently continuing to buy on the black market, which is often cheaper. (It may be that almost everybody who wanted to buy legal pot already had a medical-marijuana I.D. card; 111,000 Coloradans—more than 2 percent of the population—hold them, and medical pot carries only the regular sales tax.) Still, in 2015, Colorado collected about $135 million in marijuana taxes and fees, almost double what it took in the year before.

Cracking down on unlicensed growing operations and training cops has been relatively easy. What's going to be tougher is keeping big business from overwhelming the exercise and rigging the game. Even with only four states and the District of Columbia having legalized, and only twenty-three states allowing the medical use of marijuana, legitimate production is already a $5.4 billion industry. *Forbes* has published a list of the "8 Hottest Publicly Traded Marijuana Companies." Cannabis stocks include biotech companies, makers of specialized vending machines, and manufacturers of vaporizers that allow inhalation without tar or burning the product. The combined value of marijuana stocks rose by 50 percent in 2013 and by 150 percent in the first three weeks of 2014, before settling down to a still-impressive 38 percent gain for the year. In September 2014, MJardin, a maker of turnkey growing operations, announced that it was considering an initial public offering. Even the *Wall Street Journal* analyzes marijuana as a serious

investment opportunity. These enormous bets are being placed at a time when recreational marijuana is still illegal in forty-six states and under federal law.

The citizens of the U.S. jurisdictions that legalized marijuana may have set in motion more machinery than most of them had imagined. "Without marijuana prohibition, the government can't sustain the drug war," Ira Glasser, who ran the American Civil Liberties Union from 1978 to 2001, told me. "Without marijuana, the use of drugs is negligible, and you can't justify the law-enforcement and prison spending on the other drugs. Their use is vanishingly small. I always thought that if you could cut the marijuana head off the beast, the drug war couldn't be sustained."

Even in my hometown of Boulder, which may be the most pot-friendly city in the United States, "it's not marijuana gone wild," as Jane Brautigam, the city manager, told officials from Colorado and Washington during a public conference call in September 2014. People were, for the most part, "feeling okay about it," she said. Marijuana charges in Colorado were down 80 percent: only 2,000 or so Coloradans were charged for marijuana offenses in 2014, as opposed to nearly 10,000 in 2011. Brautigam has had to shut down a few marijuana businesses for violations, but no more than in other industries. "There was an implication that there would be people smoking all over the place," she said. "That hasn't happened." When I checked in with her office in January, things were still going well, Patrick von Keyserling, the city communications director, told me, in large part because "it's a very well-regulated industry."

To the extent that we in Colorado think about legal marijuana, now that the initial excitement has

worn off, we have a smug sense that we have taken the lead in doing something smart. We are as divided as any place over immigrants, guns, and climate change, but our police don't waste their time chasing down pot smokers anymore. Adults don't have to worry, as they used to, about neighbors smelling reefer smoke wafting from their patios. Even if marijuana tax revenues—which are slated to help public schools—aren't what we'd hoped, our state is making money from something that used to cost it money. Marijuana is *no big deal.* We look at other states that treat it as a public menace and wonder what in the world they're thinking.

Nobody I spoke with in the United States or elsewhere envisioned stores selling heroin, cocaine, or methamphetamine as freely as Colorado stores sell marijuana or as state liquor stores sell vodka. The way most researchers imagine hard-drug distribution, short of a state monopoly, involves some kind of supervision. A network of counselors—not necessarily physicians—would monitor how a drug fits into a person's life. When Kleiman, at NYU, allows himself to imagine legal cocaine, he pictures users setting their own dose. "You can decide whether you want to raise your quota—a bureaucratic process—or see someone about your cocaine problem. This is to give your long-term self a fighting chance against your short-term self."

Eric Sterling, the executive director of the anti-prohibition Criminal Justice Policy Foundation, envisions a similar system. "Someone might say, 'I want cocaine because it stimulates me in my creative work,' or, 'I want cocaine to improve my orgasms.' The response might be, 'Why don't you have enough

energy? Do you exercise?' Or, 'What might be interfering with the current quality of your sex life?' "Those who want to try LSD or other psychedelics, Sterling suggests, might go to licensed "trip leaders," analogous to wilderness guides—people trained, indemnified, and insured to take the uninitiated into potentially dangerous territory.

Of course, it's easy to imagine people who enjoy cocaine, heroin, or psychedelics saying "to hell with all that" and continuing to buy on the black market. But, as Sterling points out, doing so is risky. If someone as rich and well-connected as Philip Seymour Hoffman can die from a heroin shot, nobody is safe. Also, as Sterling notes, "It's a hassle to be an addict. Find a dealer, score, find a place to get off . . . " If a lawful, regulated system is fine-tuned—so that drugs are cheap and trustworthy, the process is not too burdensome, and the taxes on them are not too high—users will likely come to prefer it to the black market. Competition, not violence, will destroy the criminal gangs that control illegal drug distribution. "Ultimately this is all about building the proper cultural context for using drugs," Sterling says, a context in which "the exaggerations and the falsehoods get extinguished."

In 2009, Britain's Transform Drug Policy Foundation put out a 232-page report called "After the War on Drugs: Blueprint for Regulation." The authors suggested issuing licenses for buying and using drugs, with sanctions for those who screw up—much like gun licenses in some U.S. states, or driver's licenses. Users would have their purchases tracked by computer, so rising use would, in theory, be noticed, making inter-

vention possible. Legal vendors would bear partial responsibility for "socially destructive incidents"—the way bartenders can be held responsible for serving an obvious drunk who later has an accident behind the wheel. For pricing, the report suggests prices high enough to "discourage misuse, and sufficiently low to ensure that under-cutting . . . is not profitable for illicit drug suppliers." And although the British group argued for a generally more laissez-faire market than European and Canadian government-run heroin-distribution systems, it embraced a complete ban on any kind of advertising and marketing, and argued instead for plain, pharmaceuticalstyle packaging.

I voted for marijuana legalization even though I hadn't smoked pot in years and wasn't much interested in doing so. Legalization seemed a sensible political and economic measure, and a way to distinguish Colorado as a progressive beacon of the West. But one night in July, I was headed for the Cruiser Ride, Boulder's goofy, costumed weekly bicycle parade, and I thought it might be fun to try it stoned. It was a lightbulb-over-the-head moment. A year ago, I wouldn't have known where to find a joint. Now, I simply pedaled to the Green Room, a marijuana retail store a mile from my house. Although I wear every one of my fifty-nine years on my face, I was carded—in a reception room decorated with portraits of Jerry Garcia and Jimi Hendrix. A bud tender escorted me into the store, where I stood at a counter, separated from the customer next to me by a discreet, bank-teller-like divider. I picked up a card titled EDIBLES EDUCATION: START LOW, GO SLOW and read that if I bought any of the pot-laced artisanal goodies, I should not consume them with alcohol; I should keep

them out of the reach of children; I should start with a single small serving and wait two hours before taking more. "Everybody's metabolism is different," it said. For a new consumer, no more than one to five milligrams of cannabis was recommended; the potency of the buttery candies and cookies was listed on the labels. This was a far cry from the fibrous, foul-tasting pot brownies I used to eat before late-night college screenings of *2001: A Space Odyssey.*

A young bud tender—tattooed and achingly professional—presided over a copious array of marijuana blossoms in large glass apothecary jars. I confess I got a little lost as he discoursed, with Talmudic subtlety, on the differences between Grape Ape, Stardawg, and Bubba Kush. The joint that I bought for $10—fat, expertly rolled, and with a little paper filter—came in a green plastic tube with a police-badge-shaped sticker reading DEPARTMENT OF REVENUE, MARIJUANA. For someone who started buying pot in alleys when Gerald Ford was president, this felt like Elysium.

I wasn't allowed to light up in the store or outside on the street; I had to go home to smoke legally. As instructed, I started low and went slow, taking only one hit. Twenty minutes later, I was stoned in that good way I remembered: I felt perceptive and amused, with none of the sluggishness or paranoia common to the old fifteen-dollar ounces. That single joint I bought is so strong that even though I've taken hits from it half a dozen times since my Cruiser Ride, I still have about a third left, a treat to keep around for the right occasion.

So under legalization I have become a pot smoker again. But I don't drive stoned or need treatment, so

who cares? I drink a beer or a dram of Laphroaig most days too, and I still hit my deadline for this article.

If it is now time to start thinking creatively about legalization, we'd be wise to remember that, like carefully laid military plans, detailed drug-liberalization strategies probably won't survive their first contact with reality. "People are thinking about the utopian endgame, but the transition will be unpredictable," says Sterling, of the Criminal Justice Policy Foundation. "Whatever system of regulation gets set up, there will be people who exploit the edges. But that's true for speeding, for alcohol, for guns." Without a state-run monopoly, there will be more than one type of legal, regulated drug market, he says, and the markets won't solve every conceivable problem. "Nobody thinks our alcohol system is a complete failure because there are after-hours sales, or because people occasionally buy alcohol for minors." Legalizing, and then regulating, drug markets will likely be messy, at least in the short term. Still, in a technocratic, capitalist, and fundamentally free society like the United States, education, counseling, treatment, distribution, regulation, pricing, and taxation all seem to better fit our national skill set than the suppression of immense black markets and the violence and corruption that come with it.

AFFIDAVIT OF ROGER STONE (JUNE 16, 2017)

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MARVIN WASHINGTON; DEAN BORTELL as Parent/Guardian for Infant ALEXIS BORTELL, JOSE BELEN, SEBASTIEN COTTE as Parent/Guardian for Infant JAGGER COTTE, and CANNABIS CULTURAL ASSOCIATION, INC.,

Plaintiffs,

v.

JEFFERSON BEAUREGARD SESSIONS, III, in his official capacity as United States Attorney General; UNITED STATES DEPARTMENT OF JUSTICE; CHARLES "CHUCK" ROSENBERG, in his official capacity as the Acting Director of the Drug Enforcement Agency; UNITED STATES DRUG ENFORCEMENT AGENCY; and the UNITED STATES OF AMERICA,

Defendants.

17 Civ. 5625

State of New York
County of New York)

ROGER STONE, having been duly sworn, deposes and says:

1. I am a former member of the Richard Nixon Presidential Administration. I submit this Affidavit in connection with plaintiffs' Order to Show Cause for a Temporary Restraining Order and Preliminary Injunction. As explained below, I have personal knowledge of the rationales and motivations underlying enactment, administration and enforcement of the Controlled Substances Act ("CSA") by the Nixon Administration.

My Background

2. I am, and for more than 40 years have been, a political consultant and operative, working predominantly with Republican candidates and officials. I began my political career at age 12, working for Barry Goldwater's 1964 Presidential Campaign. Thereafter, while attending George Washington University, I accepted a position with the Committee to Re-Elect President Nixon ("CRP"). My work for CRP provided me with close access to Nixon Administration officials and associates, with whom I interacted regularly.

3. After Richard Nixon was re-elected as President in 1972, 1 was offered and took a position with his Administration's Office of Economic Opportunity, where I continued to work closely with Nixon Administration officials and associates in the creation and administration of policy.

4. In addition to my tenure with the Nixon Administration, I also worked with and/or for other public officials, candidates and campaigns over the years, including, among others: President Ronald Reagan; Senator and Republican Presidential Candidate Robert Dole; Governor Thomas Keane (New Jersey); Congressman Jack Kemp (New York); Senator

Arlen Spector (Pennsylvania); and President Donald J. Trump.

5. I have authored five books: The Man Who Killed Kennedy: The Case Against LBJ (Skyhorse Publishing 2013); Nixon Secrets: The Rise, Fall and Untold Truth About the President, Watergate, and the Pardon (Skyhorse Publishing 2014); The Clinton's War on Women (Skyhorse Publishing 2015); Jeb! and the Bush Crime Family (Skyhorse Publishing 2016); The Making of the President 2016: How Donald Trump Orchestrated a Revolution (Skyhorse Publishing 2017). I also regularly appear as a guest contributor on network and cable news and politically-focused television shows, including, among others, CNN, FoxNews, AB CNews, NB CNews, Meet the Press, Real Time with Bill Maher, and C-Span.

6. In short, I have devoted most of my professional life to politics and public policy, focusing my efforts in support of candidates, causes and policies affiliated with the Republican Party.

The Controlled Substances Act

7. Working with the Nixon Administration afforded me constant contact with Administration officials, both inside and outside the White House. One of the officials with whom I was in regular contact was Myles Ambrose, who, at the time, was involved in President Nixon's "War on Drugs" and eventually became the first "Drug Czar" (Exhibit 23, N.Y. Times Article). I remember that, in the winter of 1971,1 met Mr. Ambrose at "The Exchange," then a popular hangout for politicos in Washington, DC. Over drinks, Mr. Ambrose and I began to discuss the President's agenda. Not surprisingly, he spoke most favorably of

the President's plan to "win" the War on Drugs. In particular, Mr. Ambrose said to me: "We gotta do this drug stuff. We gotta get rid of the 'niggers.'" He proceeded to explain that those associated with the President associated African Americans and hippies protesting the Vietnam War with marijuana, which the President and Mr. Ambrose believed was the drug of choice for these two groups. I remember this conversation well, because it shocked and offended me.

8. I came to learn, and, as is known to history, those associated with the President felt that war protestors and those with whom they associated were a threat to the Nation in its fight against communism. He also had mixed emotions toward African Americans, whom he may have associated with the anti-war left. No legislation could be focused directly at these two groups, as the Administration recognized that such would draw objections based upon, among other things, constitutional grounds. The alternative strategy developed by the Administration was to use the War on Drugs—and, in particular, the efforts to criminalize and prosecute possession and use of cannabis—to marginalize war protestors and African Americans and "get them off the streets." To convert these viewpoints into policy, the President, members of his Administration, and those whom he entrusted to liaise with Congress dedicated themselves to enacting and administering a legislative agenda directed toward prosecuting, in particular, war protestors and African Americans for use of cannabis.

9. The Administration's efforts were successful in enacting the CSA in 1970. Thereafter, the President named Mr. Ambrose to lead the White House Office of

Drug-Abuse Law Enforcement—a precursor to the Drug Enforcement Agency, which then led the Administration's War on Drugs.[1]

10. Again, all of these efforts, as they pertained to criminalizing cannabis, were directed toward suppressing the rights of African Americans and protestors of the Vietnam War, whom the President believed were threatening to undermine America's sense of collective purpose in the Cold War and the battle against communism. My recollection of these events and conversations is consistent with those of others from the Nixon Administration. For example, John Ehrlichman, who served as the Administration's Domestic Policy Chief and was one of the President's closest political advisors, confirmed that the enactment and enforcement of laws criminalizing cannabis were directed toward political suppression and racial discrimination. In this regard, Mr. Ehrlichman said:

> You want to know what this was really all about? The Nixon campaign in 1968, and the Nixon White House after that, had two enemies: the antiwar left and black people. You understand what I'm saying? 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

[1] Ironically, Mr. Ambrose, who was slated to become the first director of the DEA, resigned from the Administration before accepting the post.

> vilify them night after night on the evening news. Did we know we were lying about the drugs? Of course we did.

N.Y. Daily News, A. Edelman, *Nixon Aide: "War on Drugs" was tool to target "black people"* (March 23, 2016) (Exh. 4); *see also* Harper's Magazine, D. Baum, *Legalize it All: How to Win the War on Drugs* (April 2016) (Exh. 5) ("Nixon's invention of the war on drugs as a political tool was cynical . . . ").

11. If incarceration of the antiwar left and African Americans constitutes the measure of the War on Drugs' success, the Administration's efforts must be characterized as "successful." According to the *New York Daily News,* "by 1973, about 300,000 people were arrested under the law—the majority of whom were African American" (Exh. 4).

12. The Administration's anti-carmabis policies thus were manifested in two distinct, but related, efforts—to usher the CSA through Congress and then to use the law as a tool to incarcerate, harass and undermine those whom the President considered hostile to American interests.

13. While there also may well have been those who genuinely believed that marijuana was a dangerous drug on par with heroin, the individuals responsible for making and administering America's drug policy were, in my experience, not among them. The driving force behind the CSA and its administration was to suppress and discriminate. It represents a regrettable and unfortunate period in American history which, I trust, contemporary society will, at some point, endeavor to correct—perhaps now.

For these reasons, I join the plaintiffs' request for a temporary restraining order and preliminary injunction.

/s/ Roger Stone

Sworn before me this 16th day of June, 2017.

/s/ Michael S. Hiller
Notary Public
State of New York
Registration No. 02H16328111
Qualified in Kings County
Commission Expires July 27, 2020

UNITED NATIONS SINGLE CONVENTION ON NARCOTIC DRUGS, 1961, (RELEVANT EXCERPTS)

As amended by the 1972 Protocol Amending the Single Convention on Narcotic Drugs, 1961 including Schedules; Final Acts and Resolutions as agreed by the 1961 United Nations Conference for the Adoption of a Single Convention on Narcotic Drugs and by the 1972 United Nations Conference to Consider Amendments to the Single Convention on Narcotic Drugs, 1961, respectively

FINAL ACT OF THE UNITED NATIONS CONFERENCE FOR THE ADOPTION OF A SINGLE CONVENTION ON NARCOTIC DRUGS

1. The Economic and Social Council of the United Nations, by resolution 689 J (XXVI) of 28 July 1958, decided to convene in accordance with Article 62, paragraph 4, of the Charter of the United Nations, and with the provisions of General Assembly resolution 366 (IV) of 3 December 1949, a plenipotentiary conference for the adoption of a single convention on narcotic drugs to replace by a single instrument the existing multilateral treaties in the field, to reduce the number of international treaty organs exclusively concerned with control of narcotic drugs, and to make provision for the control of the production of raw materials of narcotic drugs.

2. The United Nations Conference for the Adoption of a Single Convention on Narcotic Drugs met at United Nations Headquarters from 24 January to 25 March 1961.

3. The following seventy-three States were represented by representatives at the Conference:

Afghanistan	Iran
Albania	Iraq
Argentina	Israel
Australia	Italy
Bolivia	Japan
Brazil	Jordan
Bulgaria	Korea, Republic of
Burma	Lebanon
Byelorussian Soviet Socialist Republic	Union of Soviet Socialist Republics
Cambodia	United Arab Republic
Canada	United Kingdom of Great Britain and Northern Ireland
Chad	Liberia
Chile	Madagascar
China	Mexico
Congo (Leopoldville)	Monaco
Costa Rica	Morocco
Czechoslovakia	Netherlands
Dahomey	New Zealand
Denmark	Nicaragua
Dominican Republic	Nigeria
Switzerland	Norway
Thailand	Pakistan
Tunisia	Panama
Turkey	Paraguay

Ukrainian Soviet Socialist Republic	Peru
El Salvador	Philippines
Finland	Poland
France	Portugal
Germany, Federal Republic of	Romania
Ghana	Senegal
Greece	Spain
Guatemala	Sweden
Haiti	United States of America
Holy See	Uruguay
Hungary	Venezuela
India	Yugoslavia
Indonesia	

4. The following State was represented by an observer at the Conference:

- Ceylon

5. The following specialized agencies were represented at the Conference:

- Food and Agriculture Organization of the United Nations;
- International Civil Aviation Organization;
- International Labour Organisation;
- World Health Organization.

6. The following international bodies were represented at the Conference:

- Permanent Central Opium Board;

- Drug Supervisory Body.

7. The following non-governmental organizations were also represented at the Conference:

- International Conference of Catholic Charities;
- International Criminal Police Organization;
- International Federation of Women Lawyers.

8. General Safwat, Director of the Permanent Anti-Narcotics Bureau of the League of Arab States, at the invitation of the Conference, also attended in a personal capacity.

9. In accordance with the resolution of the Economic and Social Council referred to in paragraph 1 and with the rules of procedure adopted by the Conference, the observers and the representatives of the above-mentioned organizations and bodies participated in the work of the Conference without the right to vote.

10. The Conference elected Mr. Carl Schurmann (Netherlands) as President, and as Vice-Presidents the representatives of the following States:

Afghanistan	Pakistan
Brazil	Peru
Dahomey	Switzerland
France	Thailand
Hungary	Turkey
India	United Arab Republic

Iran	United Kingdom of Great Britain and Northern Ireland
Japan	Union of Soviet Socialist Republics
Mexico	United States of America
Pakistan	

FINAL ACT OF THE UNITED NATIONS CONFERENCE TO CONSIDER AMENDMENTS TO THE SINGLE CONVENTION ON NARCOTIC DRUGS, 1961

1. The Economic and Social Council of the United Nations, noting that amendments had been proposed to the Single Convention on Narcotic Drugs, 1961, and bearing in mind article 47 of that Convention, decided by its resolution 1577 (L) of 21 May 1971 to call, in accordance with Article 62, paragraph 4, of the Charter of the United Nations a conference of plenipotentiaries to consider all amendments proposed to the Single Convention on Narcotic Drugs, 1961.

2. The United Nations Conference to consider amendments to the Single Convention on Narcotic Drugs, 1961, met at the United Nations Office at Geneva from 6 to 24 March 1972.

3. The following 97 States were represented by representatives at the Conference:

Afghanistan	Poland
Algeria	Ecuador
Argentina	Egypt
Australia	El Salvador
Austria	Federal Republic of

	Germany
Belgium	Finland
Bolivia	France
Brazil	Gabon
Bulgaria	Gambia
Burma	Ghana
Burundi	Greece
Byelorussian Soviet Socialist Republic	Guatemala
Canada	Haiti
Ceylon	Holy See
Chile	Hungary
Colombia	India
Costa Rica	Indonesia
Cuba	Iran
Cyprus	Iraq
Czechoslovakia	Ireland
Dahomey	Israel
Denmark	Italy
Japan	Ivory Coast
Jordan	Jamaica
Kenya	Portugal
Khmer Republic	Republic of Korea
Kuwait	Republic of Viet-Nam
Laos	Saudi Arabia
Lebanon	Senegal
Liberia	Sierra Leone
Libyan Arab	Singapore

Republic	
Liechtenstein	South Africa
Luxembourg	Spain
Madagascar	Sudan
Malawi	Sweden
Mexico	Switzerland
Monaco	Thailand
Mongolian People's Republic	Togo
Morocco	Tunisia
Netherlands	Turkey
New Zealand	Ukrainian Soviet Socialist Republic
Nicaragua	Union of Soviet Socialist Republics
Niger	United Kingdom of Great Britain and Northern Ireland
Nigeria	United States of America
Norway	Uruguay
Pakistan	Venezuela
Panama	Yugoslavia
Peru	Zaire
Philippines	

4. The following States were represented by observers at the Conference:

Cameroon	Malta
Dominican Republic	Romania
Malaysia	

5. The Economic and Social Council, by its resolution 1577 (L), requested the Secretary-General to invite to the Conference the World Health Organization and other interested specialized agencies, the International Narcotics Control Board and the International Criminal Police Organization. The World Health Organization, the International Narcotics Control Board and the International Criminal Police Organization were represented at the Conference.

6. The Conference elected Mr. K. B. Asante (Ghana) as President of the Conference, Mr. D. Nikolie (Yugoslavia) as First Vice-President, and as the other Vice-Presidents the representatives of the following States:

Argentina	France
Egypt	India

SINGLE CONVENTION ON NARCOTIC DRUGS, 1961, AS AMENDED BY THE 1972 PROTOCOL AMENDING THE SINGLE CONVENTION ON NARCOTIC DRUGS, 1961

Preamble

The Parties,

Concerned with the health and welfare of mankind,

Recognizing that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes,

Recognizing that addiction to narcotic drugs constitutes a serious evil for the individual and is fraught with social and economic danger to mankind,

Conscious of their duty to prevent and combat this evil,

Considering that effective measures against abuse of narcotic drugs require co-ordinated and universal action,

Understanding that such universal action calls for international co-operation guided by the same principles and aimed at common objectives,

Acknowledging the competence of the United Nations in the field of narcotics control and desirous that the international organs concerned should be within the framework of that Organization,

Desiring to conclude a generally acceptable international convention replacing existing treaties on narcotic drugs, limiting such drugs to medical and scientific use, and providing for continuous international co-operation and control for the achievement of such aims and objectives,

Hereby agree as follows:[2]

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[2] Note by the Secretariat: The Preamble to the Protocol Amending the Single Convention on Narcotic Drugs, 1961, reads as follows:

"The Parties to the Present Protocol,

ARTICLE 1
Definitions 1

1. Except where otherwise expressly indicated or where the context otherwise requires, the following definitions shall apply throughout the Convention:

(a) "Board" means the International Narcotics Control Board,

(b) "Cannabis" means the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted, by whatever name they may be designated.

(c) "Cannabis plant" means any plant of the genus Cannabis,

(d) "Cannabis resin" means the separated resin, whether crude or purified, obtained from the cannabis plant.

(e) "Coca bush" means the plant of any species of the genus Erythroxylon.

(f) "Coca leaf" means the leaf of the coca bush except a leaf from which all ecgonine, cocaine and any other ecgonine alkaloids have been removed.

"Considering the provisions of the Single Convention on Narcotic Drugs, 1961, done at New York on 30 March 1961 (hereinafter called the Single Convention),

"Desiring to amend the Single Convention,

"Have agreed as follows:"

(g) "Commission" means the Commission on Narcotic Drugs of the Council.

(h) "Council" means the Economic and Social Council of the United Nations.

(i) "Cultivation" means the cultivation of the opium poppy, coca bush or cannabis plant.

(j) "Drug" means any of the substances in Schedules I and II, whether natural or synthetic.

(k) "General Assembly" means the General Assembly of the United Nations.

(l) "Illicit traffic" means cultivation or trafficking in drugs contrary to the provisions of this Convention.

(m) "Import" and "export" mean in their respective connotations the physical transfer of drugs from one State to another State, or from one territory to another territory of the same State.

(n) "Manufacture" means all processes, other than production, by which drugs may be obtained and includes refining as well as the transformation of drugs into other drugs.

(o) "Medicinal opium" means opium which has undergone the processes necessary to adapt it for medicinal use.

(p) "Opium" means the coagulated juice of the opium poppy.

(q) "Opium poppy" means the plant of the species Papaver somniferum L.

(r) "Poppy straw" means all parts (except the seeds) of the opium poppy, after mowing.

(s) "Preparation" means a mixture, solid or liquid, containing a drug.

(t) "Production" means the separation of opium, coca leaves, cannabis and cannabis resin from the plants from which they are obtained.

(u) "Schedule I", "Schedule II", "Schedule III" and "Schedule IV" mean the correspondingly numbered list of drugs or preparations annexed to this Convention, as amended from time to time in accordance with article 3.

(v) "Secretary-General" means the Secretary-General of the United Nations.

(w) "Special stocks" means the amounts of drugs held in a country or territory by the Government of such country or territory for special government purposes and to meet exceptional circumstances; and the expression "special purposes" shall be construed accordingly.

(x) "Stocks" means the amounts of drugs held in a country or territory and intended for:

(i) Consumption in the country or territory for medical and scientific purposes,

(ii) Utilization in the country, or territory for the manufacture of drugs and other substances, or

(iii) Export; but does not include the amounts of drugs held in the country or territory,

(iv) By retail pharmacists or other authorized retail distributors and by institutions or

qualified persons in the duly authorized exercise of therapeutic or scientific functions, or

(v) As "special stocks".

(y) "Territory" means any part of a State which is treated as a separate entity for the application of the system of import certificates and export authorizations provided for in article 31. This definition shall not apply to the term "territory" as used in articles 42 and 46.

2. For the purposes of this Convention a drug shall be regarded as "consumed" when it has been supplied to any person or enterprise for retail distribution, medical use or scientific research; and "consumption" shall be construed accordingly.

ARTICLE 2
Substances Under Control

1. Except as to measures of control which are limited to specified drugs, the drugs in Schedule I are subject to all measures of control applicable to drugs under this Convention and in particular to those prescribed in article 4(c), 19, 20, 21, 29, 30, 31, 32, 33, 34 and 37.

2. The drugs in Schedule II are subject to the same measures of control as drugs in Schedule I with the exception of the measures prescribed in article 30, paragraphs 2 and 5, in respect of the retail trade.

3. Preparations other than those in Schedule III are subject to the same measures of control as the drugs which they contain, but estimates (article 19) and statistics (article 20) distinct from those dealing

with these drugs shall not be required in the case of such preparations, and article 29, paragraph 2(c) and article 30, paragraph 1 (b) (ii) need not apply.

4. Preparations in Schedule III are subject to the same measures of control as preparations containing drugs in Schedule II except that article 31, paragraphs 1 (b) and 3 to 15 and, as regards their acquisition and retail distribution, article 34, paragraph (b), need not apply, and that for the purpose of estimates (article 19) and statistics (article 20) the information required shall be restricted to the quantities of drugs used in the manufacture of such preparations.

5. The drugs in Schedule IV shall also be included in Schedule I and subject to all measures of control applicable to drugs in the latter Schedule, and in addition thereto:

(a) A Party shall adopt any special measures of control which in its opinion are necessary having regard to the particularly dangerous properties of a drug so included; and

(b) A Party shall, if in its opinion the prevailing conditions in its country render it the most appropriate means of protecting the public health and welfare, prohibit the production, manufacture, export and import of, trade in, possession or use of any such drug except for amounts which may be necessary for medical and scientific research only, including clinical trials therewith to be conducted under or subject to the direct supervision and control of the Party.

6. In addition to the measures of control applicable to all drugs in Schedule I, opium is subject to the provisions of article 19, paragraph 1, subparagraph (f), and of articles 21 *bis*, 23 and 24, the coca leaf to those of articles 26 and 27 and cannabis to those of article 28.

7. The opium poppy, the coca bush, the cannabis plant, poppy straw and cannabis leaves are subject to the control measures prescribed in article 19, paragraph 1, subparagraph (e), article 20, paragraph 1, subparagraph (g), article 21 *bis* and in articles 22 to 24; 22, 26 and 27; 22 and 28; 25; and 28, respectively.

8. The Parties shall use their best endeavors to apply to substances which do not fall under this Convention, but which may be used in the illicit manufacture of drugs, such measures of supervision as may be practicable.

9. Parties are not required to apply the provisions of this Convention to drugs which are commonly used in industry for other than medical or scientific purposes, provided that: . . .

[. . .]

. . . furnished to the Board not later than 30 June following the year to which they relate.

(b) The statistical returns in respect to the matters referred to in subparagraph (d) of paragraph 1 shall be prepared quarterly and shall be furnished to the Board within one month after the end of the quarter to which they relate.

3. The Parties are not required to furnish statistical returns respecting special stocks, but shall

furnish separately returns respecting drugs imported into or procured within the country or territory for special purposes, as well as quantities of drugs withdrawn from special stocks to meet the requirements of the civilian population.

ARTICLE 21
Limitation of Manufacture and Importation

1. The total of the quantities of each drug manufactured and imported by any country or territory in any one year shall not exceed the sum of the following:

(a) The quantity consumed, within the limit of the relevant estimate, for medical and scientific purposes;

(b) The quantity used, within the limit of the relevant estimate, for the manufacture of other drugs, of preparations in Schedule III, and of substances not covered by this Convention;

(c) The quantity exported;

(d) The quantity added to the stock for the purpose of bringing that stock up to the level specified in the relevant estimate; and

(e) The quantity acquired within the limit of the relevant estimate for special purposes.

2. From the sum of the quantities specified in paragraph 1 there shall be deducted any quantity that has been seized and released for licit use, as well as any quantity taken from special stocks for the requirements of the civilian population.

3. If the Board finds that the quantity manufactured and imported in any one year exceeds the sum of the quantities specified in paragraph 1, less any deductions required under paragraph 2 of this article, any excess so established and remaining at the end of the year shall, in the following year, be deducted from the quantity to be manufactured or imported and from the total of the estimates as defined in paragraph 2 of article 19.

4.

(a) If it appears from the statistical returns on imports or exports (article 20) that the quantity exported to any country or territory exceeds the total of the estimates for that country or territory, as defined in paragraph 2 of article 19, with the addition of the amounts shown to have been exported, and after deduction of any excess as established in paragraph 3 of this article, the Board may notify this fact to States which, in the opinion of the Board, should be so informed;

(b) On receipt of such a notification, Parties shall not during the year in question authorize any further exports of the drug concerned to that country or territory, except:

(i) In the event of a supplementary estimate being furnished for that country or territory in respect both of any quantity over-imported and of the additional quantity required, or

(ii) In exceptional cases where the export, in the opinion of the Government of the

exporting country, is essential for the treatment of the sick.

ARTICLE 21 *bis*
Limitation of Production of Opium

1. The production of opium by any country or territory shall be organized and controlled in such manner as to ensure that, as far as possible, the quantity produced in any one year shall not exceed the estimate of opium to be produced as established under paragraph 1 (f) of article 19.

2. If the Board fords on the basis of information at its disposal in accordance with the provisions of this Convention that a Party which has submitted an estimate under paragraph 1 (f) of article 19 has not limited opium produced within its borders to licit purposes in accordance with relevant estimates and that a significant amount of opium produced, whether licitly or illicitly, within the borders of such a Party, has been introduced into the illicit traffic, it may, after studying the explanations of the Party concerned, which shall be submitted to it within one month after notification of the finding in question, decide to deduct all, or a portion, of such an amount from the quantity to be produced and from the total of the estimates as defined in paragraph 2 (b) of article 19 for the next year in which such a deduction can be technically accomplished, taking into account the season of the year and contractual commitments to export opium. This decision shall take effect ninety days after the Party concerned is notified thereof.

3. After notifying the Party concerned of the decision it has taken under paragraph 2 above with regard

to a deduction, the Board shall consult with that Party in order to resolve the situation satisfactorily.

4. If the situation is not satisfactorily resolved, the Board may utilize the provisions of article 14 where appropriate.

5. In taking its decision with regard to a deduction under paragraph 2 above, the Board shall take into account not only all relevant circumstances including those giving rise to the illicit traffic problem referred to in paragraph 2 above, but also any relevant new control measures which may have been adopted by the Party.

ARTICLE 22
Special Provision Applicable to Cultivation

1. Whenever the prevailing conditions in the country or a territory of a Party render the prohibition of the cultivation of the opium poppy, the coca bush or the cannabis plant the most suitable measure, in its opinion, for protecting the public health and welfare and preventing the diversion of drugs into the illicit traffic, the Party concerned shall prohibit cultivation.

2. A Party prohibiting cultivation of the opium poppy or the cannabis plant shall take appropriate measures to seize any plants illicitly cultivated and to destroy them, except for small quantities required by the Party for scientific or research purposes.

ARTICLE 23
National Opium Agencies

1. A Party that permits the cultivation of the opium poppy for the production of opium shall establish, if it has not already done so, and maintain, one or

more government agencies (hereafter in this article referred to as the Agency) to carry out the functions required under this article.

2. Each such Party shall apply the following provisions to the cultivation of the opium poppy for the production of opium and to opium;

(a) The Agency shall designate the areas in which, and the plots of land on which, cultivation of the opium poppy for the purpose of producing opium shall be permitted.

(b) Only cultivators licensed by the Agency shall be authorized to engage in such cultivation.

(c) Each license shall specify the extent of the land on which the cultivation is permitted.

(d) All cultivators of the opium poppy shall be required to deliver their total crops of opium to the Agency. The Agency shall purchase and take physical possession of such crops as soon as possible, but not later than four months after the end of the harvest.

(e) The Agency shall, in respect of opium, have the exclusive right of importing, exporting, wholesale trading and maintaining stocks other than those held by manufacturers of opium alkaloids, medicinal opium or opium preparations. Parties need not extend this exclusive right to medicinal opium and opium preparations.

[. . .]

2. The Parties shall so far as possible enforce the uprooting of all coca bushes which grow wild. They shall destroy the coca bushes if illegally cultivated.

ARTICLE 27
Additional Provisions Relating to Coca Leaves

1. The Parties may permit the use of coca leaves for the preparation of a flavouring agent, which shall not contain any alkaloids, and, to the extent necessary for such use, may permit the production, import, export, trade in and possession of such leaves.

2. The Parties shall furnish separately estimates (article 19) and statistical information (article 20) in respect of coca leaves for preparation of the flavouring agent, except to the extent that the same coca leaves are used for the extraction of alkaloids and the flavouring agent, and so explained in the estimates and statistical information.

ARTICLE 28
Control of Cannabis

1. If a Party permits the cultivation of the cannabis plant for the production of cannabis or cannabis resin, it shall apply thereto the system of controls as provided in article 23 respecting the control of the opium poppy.

2. This Convention shall not apply to the cultivation of the cannabis plant exclusively for industrial purposes (fibre and seed) or horticultural purposes.

3. The Parties shall adopt such measures as may be necessary to prevent the misuse of, and illicit traffic in, the leaves of the cannabis plant.

ARTICLE 29
Manufacture

1. The Parties shall require that the manufacture of drugs be under license except where such manufacture is carried out by a State enterprise or State enterprises.

2. The Parties shall:

(a) Control all persons and enterprises carrying on or engaged in the manufacture of drugs;

(b) Control under license the establishments and premises in which such manufacture may take place; and

(c) Require that licensed manufacturers of drugs obtain periodical permits specifying the kinds and amounts of drugs which they shall be entitled to manufacture. A periodical permit, however, need not be required for preparations.

3. The Parties shall prevent the accumulation, in the possession of drug manufacturers, of quantities of drugs and poppy straw in excess of those required for the normal conduct of business, having regard to the prevailing market conditions.

ARTICLE 30
Trade and Distribution

1.

(a) The Parties shall require that the trade in and distribution of drugs be under licence except where such trade or distribution is

carried out by a State enterprise or State enterprises.

(b) The Parties shall:

(i) Control all persons and enterprises carrying on or engaged in the trade in or distribution of drugs;

(ii) Control under license the establishments and premises in which such trade or distribution may take place. The requirement of licensing need not apply to preparations.

(c) The provisions of subparagraphs (a) and (b) relating to licensing need not apply to persons duly authorized to perform and while performing therapeutic or scientific functions.

2. The Parties shall also:

(a) Prevent the accumulation in the possession of traders, distributors, State enterprises or duly authorized persons referred to above, of quantities of drugs and poppy straw in excess of those required for the normal conduct of business, having regard to the prevailing market conditions; and

(b)

(i) Require medical prescriptions for the supply or dispensation of drugs to individuals. This requirement need not apply to such drugs as individuals may

lawfully obtain, use, dispense or administer in connexion with their duly authorized therapeutic functions; and

(ii) If the Parties deem these measures necessary or desirable, require that prescriptions for drugs in Schedule I should be written on officials forms to be issued in the form of counterfoil books by the competent governmental authorities or by authorized professional associations.

3. It is desirable that Parties require that written or printed offers of drugs, advertisements of every kind or descriptive literature relating to drugs and used for commercial purposes, interior wrappings of packages containing drugs, and labels under which drugs are offered for sale indicate the international non-proprietary name communicated by the World Health Organization.

4. If a Party considers such measure necessary or desirable, it shall require that the inner package containing a drug or wrapping thereof shall bear a clearly visible double red band. The exterior wrapping of the package in which such drug is contained shall not bear a double red band.

5. A Party shall require that the label under which a drug is offered for sale show the exact drug content by weight or percentage. This requirement of label information need not apply to a drug dispensed to an individual on medical prescription.

6. The provisions of paragraphs 2 and 5 need not apply to the retail trade in or retail distribution of drugs in Schedule II.

ARTICLE 31
Special Provisions Relating to International Trade

1. The Parties shall not knowingly permit the export of drugs to any country or territory except:

(a) In accordance with the laws and regulations of that country or territory; and

(b) Within the limits of the total of the estimates for that country or territory, as defined in paragraph 2 of article 19, with the addition of the amounts intended to be re-exported.

2. The Parties shall exercise in free ports and zones the same supervision and control as in other parts of their territories, provided, however, that they may apply more drastic measures.

3. The Parties shall:

(a) Control under license the import and export of drugs except where such import or export is carried out by a State enterprise or enterprises;

(b) Control all persons and enterprises carrying on or engaged in such import or export.

4.

(a) Every Party permitting the import or export of drugs shall require a separate import or export authorization to be obtained for each such import or export whether it consists of one or more drugs.

(b) Such authorization shall state the name of the drug, the international non-proprietary name if any, the quantity to be imported or exported, and the name and address of the

importer and exporter, and shall specify the period within which the importation or exportation must be effected.

(c) The export authorization shall also state the number and date of the import certificate (paragraph 5) and the authority by whom it has been issued.

(d) The import authorization may allow an importation in more than one consignment.

5. Before issuing an export authorization the Parties shall require an import certificate, issued by the competent authorities of the importing country or territory and certifying that the importation of the drug or drugs referred to therein, is approved and such certificate shall be produced by the person or establishment applying for the export authorization. The Parties shall follow as closely as may be practicable the form of import certificate approved by the Commission.

6. A copy of the export authorization shall accompany each consignment, and the Government issuing the export authorization shall send a copy to the Government of the importing country or territory.

7.

(a) The Government of the importing country or territory, when the importation has been effected or when the period fixed for the importation has expired, shall return the export authorization, with an endorsement to that effect, to the Government of the exporting country or territory.

(b) The endorsement shall specify the amount actually imported.

(c) If a lesser quantity than that specified in the export authorization is actually exported, the quantity actually exported shall be stated by the competent authorities on the export authorization and on any official copy thereof.

8. Exports of consignments to a post office box, or to a bank to the account of a Party other than the Party named in the export authorization, shall be prohibited.

9. Exports of consignments to a bonded warehouse are prohibited unless the Government of the importing country certifies on the import certificate, produced by the person or establishment applying for the export authorization, that it has approved the importation for the purpose of being placed in a bonded warehouse. In such case the export authorization shall specify that the consignment is exported for such purpose. Each withdrawal from the bonded warehouse shall require a permit from the authorities having jurisdiction over the warehouse and, in the case of a foreign destination shall be treated as if it were a new export within the meaning of this Convention.

10. Consignments of drugs entering or leaving the territory of a Party not accompanied by an export authorization shall be detained by the competent authorities.

11. A Party shall not permit any drugs consigned to another country to pass through its territory, whether or not the consignment is removed from the conveyance in which it is carried, unless a copy of the

export authorization for such consignment is produced to the competent authorities of such Party.

12. The competent authorities of any country or territory through which a consignment of drugs is permitted to pass shall take all due measures to prevent the diversion of the consignment to a destination other than that named in the accompanying copy of the export authorization unless the Government of that country or territory through which the consignment is passing authorizes the diversion. The Government of the country or territory of transit shall treat any requested diversion as if the diversion were an export from the country or territory of transit to the country or territory of new destination. If the diversion is authorized, the provisions of paragraph 7 (a) and (b) shall also apply between the country or territory of transit and the country or territory which originally exported the consignment.

13. No consignment of drugs while in transit, or whilst being stored in a bonded warehouse, may be subjected to any process which would change the nature of the drugs in question. The packing may not be altered without the permission of the competent authorities.

14. The provisions of paragraphs 11 to 13 relating to the passage of drugs through the territory of a Party do not apply where the consignment in question is transported by aircraft which does not land in the country or territory of transit. If the aircraft lands in any such country or territory, those provisions shall be applied so far as circumstances require.

15. The provisions of this article are without prejudice to the provisions of any international

agreements which limit the control which may be exercised by any of the Parties over drugs in transit.

16. Nothing in this article other than paragraphs 1 (a) and 2 need apply in the case of preparations in Schedule III.

ARTICLE 32
Special Provisions Concerning the Carriage of Drugs in First-Aid Kits of Ships or Aircraft Engaged in International Traffic

1. The international carriage by ships or aircraft of such limited amounts of drugs as may be needed during their journey or voyage for first-aid purposes or emergency cases shall not be considered to be import, export or passage through a country within the meaning of this Convention.

2. Appropriate safeguards shall be taken by the country of registry to prevent the improper use of the drugs referred to in paragraph 1 or their diversion for illicit purposes. The Commission, in consultation with the appropriate international organizations, shall recommend such safeguards.

3. Drugs carried by ships or aircraft in accordance with paragraph 1 shall be subject to the laws, regulations, permits and licenses of the country of registry, without prejudice to any rights of the competent local authorities to carry out checks, inspections and other control measures on board ships or aircraft. The administration of such drugs in the case of emergency shall not be considered a violation of the requirements of article 30, paragraph 2 (b).

ARTICLE 33
Possession of Drugs

The Parties shall not permit the possession of drugs except under legal authority.

ARTICLE 34
Measures of Supervision and Inspection

The Parties shall require:

(a) That all persons who obtain licenses as provided in accordance with this Convention, or who have managerial or supervisory positions in a State enterprise established in accordance with this Convention, shall have adequate qualifications for the effective and faithful execution of the provisions of such laws and regulations as are enacted in pursuance thereof; and

(b) That governmental authorities, manufacturers, traders, scientists, scientific institutions and hospitals keep such records as will show the quantities of each drug manufactured and of each individual acquisition and disposal of drugs. Such records shall respectively be preserved for a period of not less than two years. Where counterfoil books (article 30, paragraph 2 (b)) of official prescriptions are used, such books including the counterfoils shall also be kept for a period of not less than two years.

ARTICLE 35
Action Against the Illicit Traffic

Having due regard to their constitutional, legal and administrative systems, the Parties shall:

(a) Make arrangements at the national level for co-ordination of preventive and repressive action against the illicit traffic; to this end they may usefully designate an appropriate agency responsible for such co-ordination;

(b) Assist each other in the campaign against the illicit traffic in narcotic drugs;

(c) Co-operate closely with each other and with the competent international organizations of which they are members with a view to maintaining a co-ordinated campaign against the illicit traffic;

(d) Ensure that international co-operation between the appropriate agencies be conducted in an expeditious manner; and

(e) Ensure that where legal papers are transmitted internationally for the purposes of a prosecution, the transmittal be effected in an expeditious manner to the bodies designated by the Parties; this requirement shall be without prejudice to the right of a Party to require that legal papers be sent to it through the diplomatic channel;

(f) Furnish, if they deem it appropriate, to the Board and the Commission through the Secretary-General, in addition to information required by article 18, information relating to illicit drug activity within their borders,

including information on illicit cultivation, production, manufacture and use of, and on illicit trafficking in, drugs; and

(g) Furnish the information referred to in the preceding paragraph as far as possible in such manner and by such dates as the Board may request; if requested by a Party, the Board may offer its advice to it in furnishing the information and in endeavoring to reduce the illicit drug activity within the borders of that Party.

ARTICLE 36
Penal Provisions

1.

(a) Subject to its constitutional limitations, each Party shall adopt such measures as will ensure that cultivation, production, manufacture, extraction, preparation, possession, offering, offering for sale, distribution, purchase, sale, delivery on any terms whatsoever, brokerage, dispatch, dispatch in transit, transport, importation and exportation of drugs contrary to the provisions of this Convention, and any other action which in the opinion of such Party may be contrary to the provisions of this Convention, shall be punishable offences when committed intentionally, and that serious offences shall be liable to adequate punishment particularly by imprisonment or other penalties of deprivation of liberty.

(b) Notwithstanding the preceding subparagraph, when abusers of drugs have committed such offences, the Parties may provide, either as an alternative to conviction or punishment or in addition to conviction or punishment, that such abusers shall undergo measures of treatment, education, after-care, rehabilitation and social reintegration in conformity with paragraph 1 of article 38.

2. Subject to the constitutional limitations of a Party, its legal system and domestic law,

(a)

(i) Each of the offences enumerated in paragraph 1, if committed in different countries, shall be considered as a distinct offence;

(ii) Intentional participation in, conspiracy to commit and attempts to commit, any of such offences, and preparatory acts and financial operations in connexion with the offences referred to in this article, shall be punishable offences as provided in paragraph 1;

(iii) Foreign convictions for such offences shall be taken into account for the purpose of establishing recidivism; and

(iv) Serious offences heretofore referred to committed either by nationals or by foreigners shall be prosecuted by the Party in whose territory the offence was committed, or by, the Party in whose territory the offender is found if

extradition is not acceptable in conformity with the law of the Party to which application is made, and if such offender has not already been prosecuted and judgement given.

(b)

(i) Each of the offences enumerated in paragraphs 1 and 2 (a) (ii) of this article shall be deemed to be included as an extraditable offence in any extradition treaty existing between Parties. Parties undertake to include such offences as extraditable offences in every extradition treaty to be concluded between them.

(ii) If a Party which makes extradition conditional on the existence of a treaty receives a request for extradition from another Party with which it has no extradition treaty, it may at its option consider this Convention as the legal basis for extradition in respect of the offences enumerated in paragraphs 1 and 2 (a) (ii) of this article. Extradition shall be subject to the other conditions provided by the law of the requested Party.

(iii) Parties which do not make extradition conditional on the existence of a treaty shall recognize the offences enumerated in paragraphs 1 and 2 (a) (ii) of this article as extraditable offences between themselves, subject to the conditions

provided by the law of the requested Party.

(iv) Extradition shall be granted in conformity with the law of the Party to which application is made, and, notwithstanding subparagraphs (b) (i), (ii) and (iii) of this paragraph, the Party shall have the right to refuse to grant the extradition in cases where the competent authorities consider that the offence is not sufficiently serious.

3. The provisions of this article shall be subject to the provisions of the criminal law of the Party concerned on questions of jurisdiction.

4. Nothing contained in this article shall affect the principle that the offences to which it refers shall be defined, prosecuted and punished in conformity with the domestic law of a Party.

ARTICLE 37
Seizure and Confiscation

Any drugs, substances and equipment used in or intended for the commission of any of the offences, referred to in article 36, shall be liable to seizure and confiscation.

[. . .]

Revised Schedules including all amendments made by the Commission on Narcotic Drugs in force as of 31 May 1999*

SCHEDULES

List of Drugs Included in Schedule I

- ACETORPHINE (3-*O*-acetyltetrahydro-7α-(1-hydroxy-1-methylbuty1)-6,14-*endo*-etheno-oripavine)
- ACETYL-ALPHA-METHYLFENTANYL (N-[1-(α-methylphenethyl)-4-piperidyl]acetanilide)
- ACETYLMETHADOL (3-acetoxy-6-dimethylamino-4, 4-diphenylheptane)
- ALFENTANIL (N-[1-[2-(4-ethyl-4,5-dihydro-5-oxo-1*H*-tetrazol-1-yl)ethyl[-4-(methoxymethyl)-4-piperidinyll-*N*-phenylpropanamide)
- ALLYLPRODINE (3-allyl-1-methyl-4-phenyl-4-propionoxypiperidine)
- ALPHACETYLMETHADOL (*alpha*-3-acetoxy-6-dimethylamino-4,4-diphenylheptane)
- ALPHAMEPRODINE (*alpha*-3-ethyl-1-methyl-4-phenyl-4-propionoxypiperidine)
- ALPHAMETHADOL (*alpha*-6-dimethylamino-4, 4-diphenyl-3-heptanol)
- ALPHA-METHYLFENTANYL (*N*-[1-(α-methylphenethyl)-4-piperidyl]propionanilide)
- ALPHA-METHYLTHIOFENTANYL (*N*-[1-[1-methyl-2-(2-thienyl)ethyl]-4-piperidyl] propionanilide)

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* Note by the Secretariat: For the original Schedules *see* E/CONF. 34/24/Add.1.

- ALPHAPRODINE (*alpha*-1,3-dimethyl-4-phenyl-4-propionoxypiperidine)
- ANILERIDINE (1-*para*-aminophenethyl-4-phenylpiperidine-4-carboxylic acid ethyl ester)
- BENZETHIDINE (1-(2-benzyloxyethyl)-4-phenylpiperidine-4-carboxylic acid ethyl ester)
- BENZYLMORPHINE (3-benzylmorphine)
- BETACETYLMETHADOL (*beta*-3-acetoxy-6-dimethylamino-4, 4-diphenylheptane)
- BETA-HYDROXYFENTANYL (*N*-[1-(ß-hydroxyphenethyl)-4-piperidyl]propionanilide)
- BETA-HYDROXY-3-METHYLFENTANYL (*N*-[1-(ß-hydroxyphenethyl)-3-methyl-4-piperidyl]propionanilide)
- BETAMEPRODINE (beta-3-ethyl-1-methyl-4-phenyl-4-propionoxypiperidine)
- BETAMETHADOL (beta-6-dimethylamino-4, 4-diphenyl-3-heptanol)
- BETAPRODINE (*beta*-1, 3-dimethyl-4-phenyl-4-propionoxypiperidine)
- BEZITRAMIDE (1-(3-cyano-3, 3-diphenylpropyl)-4-(2-oxo-3-propionyl-1-benzimidazolinyl)-piperidine)
- CANNABIS and CANNABIS RESIN and EXTRACTS and TINCTURES OF CANNABIS CLONITAZENE (2-*para*-chlorbenzyl-1-diethylaminoethyl-5-nitrobenzimidazole)
- COCA LEAF
- COCAINE (methyl ester of benzoylecgonine)
- CODOXIME (dihydrocodeinone-6-carboxymethyloxime)
- CONCENTRATE OF POPPY STRAW (the material arising when poppy straw has entered into a

process for the concentration of its alkaloids when such material is made available in trade) DESOMORPHINE (dihydrodeoxymorphine)

- DEXTROMORAMIDE ((+)-4-[2-methyl-4-oxo-3, 3diphenyl-4-(1-pyrrolidinyl)butyl]morpholine)
- DIAMPROMIDE (*N*-[2-(methylphenethylamino) propyl]propionanilide)
- DIETHYLTHIAMBUTENE (3-diethylamino-1, 1-di-(2'-thienyl)-1-butene)
- DIFENOXIN (1-(3-cyano-3, 3-diphenylpropyl)-4-phenylisonipecotic acid)
- DIHYDROETORPHINE (7,8-dihydro-7α[1-(*R*)-hydroxy-1-methylbutyl]-6,14-endo-ethano-tetrahydro-otipavine)

List of Drugs included in Schedule IV

- ACETORPHINE (3-*O*-acetyltetrahydro-7α-(1-hydroxy-1-methylbutyl)-6,14-endo-etheno-oripavine)
- ACETYL-ALPHA-METHYLFENTANYL (*N*-[1-(a-methylphenethyl)-4-pipetidyl]acetanilide)
- ALPHA-METHYLFENTANYL (*N*-[1-(α-methylphenethyl)-4-piperidyl]propionanilide)
- ALPHA-METHYLTHIOFENTANYL (*N*-[1-[1-methyl-2-(2-thienypethyl]-4-piperidyl] propionanilide)
- BETA-HYDROXYFENTANYL (*N*-[1-(ß-hydroxyphenethyl)-4-piperidyl]propionanilide)
- BETA-HYDROXY-3-METHYLFENTANYL (*N*-[1-(ß-hydroxyphenethyl)-3-methyl-4-piperidyl]propionanilide)
- CANNABIS and CANNABIS RESIN
- DESOMORPHINE (dihydrodeoxymorphine)

- ETORPHINE (tetrahydro-7α-(1-hydroxy-1-methylbutyl)-6, 14-endo-etheno-oripavine)
- HEROIN (diacetylmorphine)
- KETOBEMIDONE (4-*meta*-hydroxyphenyl-1-methyl-4-propionylpiperidine)
- 3-METHYLFENTANYL (*N*-(3-methyl-1-phenethyl-4-piperidyl)propionanilide); (*cis*-*N*-[3-methyl-1-(2-phenylethyl)-4-piperidyl] propionanilide); (*trans*-*N*-[3-methyl-1-(2-phenylethyl)-4-piperidyl]propionanilide)
- 3-METHYLTHIOFENTANYL (*N*-[3-methyl-1-[2-(2-thienyl)ethyl]-4-pipetidyl]propionanilide)
- MPPP (1-methyl-4-phenyl-4-piperidinol propionate (ester))
- PARA-FLUOROFENTANYL (4'-fluoro-*N*-(1-phenethyl-4-piperidyppropionanilide)
- PEPAP (1-phenethyl-4-phenyl-4-piperidinol acetate (ester))
- THIOFENTANYL (N-[1-[2-(2-thienyl)ethyl]-4-piperidyl]propionanilide); and

The salts of the drugs listed in this Schedule whenever the formation of such salts is possible.