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IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, Plaintiff, v. BRYAN SCHWEDER, et al., Defendants.	Case No. 2:11-CR-449-KJM UNITED STATES' POST-HEARING BRIEF Date: February 4, 2015 Time: 9:00 am Judge: Hon. Kimberly J. Mueller

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I. INTRODUCTION

Defendants' motion to dismiss the indictment should be denied. Defendants failed to meet their burden of negating every possible justification for the law. In reality, the evidence at the hearing shows that marijuana's treatment under the Controlled Substances Act easily clears the low bar of the rational basis test: it is rationally related to a legitimate governmental interest in public health and safety. At most, defendants established that there is some dispute among doctors as to whether marijuana is medicine. But proving that there is some disagreement among experts merely proves that they lose—Congress is free to choose from among competing alternatives, so long as there is a rational basis. After five days of testimony and hundreds of exhibits, it is beyond dispute that there is more than the minimum rational basis for marijuana's continued treatment as a controlled substance. In addition, defendants lack standing to challenge marijuana's status as a controlled substance, and the Court lacks jurisdiction over this back-door scheduling challenge.

This brief first addresses the appropriate standard of review, then why the United States prevails on the issue as properly framed, and even as framed by defendants, and then concludes with brief jurisdiction and standing arguments. Regardless of the grounds on which the Court decides, the motion should be denied.

II. ANALYSIS

A. The Proper Standard is Rational Basis.

The proper standard for evaluating defendants' challenge to the Controlled Substances Act is "rational basis." Absent implication of a fundamental right or a "suspect classification, a statute must be upheld so long as it is "rationally related to a legitimate governmental interest." *City of Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432, 440 [105 S.Ct. 3249] (1985); *see also City of New Orleans v. Dukes*, 427 U.S. 297, 303 [96 S.Ct. 2513] (1976) (rational basis is the default standard); *Korab v. Fink*, 748 F.3d 875, 882 (9th Cir. 2014). Under rational basis, the government "has no obligation to produce evidence to sustain the rationality of a statutory classification; rather, the burden is on the one attacking the legislative arrangement to negative every conceivable basis which might support it." *Kahawaiolaa v. Norton*, 386 F.3d 1271, 1280 (9th Cir.2004) (internal quotations and alteration omitted). As another California district judge faced with the same motion recently held, "rational basis review does not warrant engaging in scrutiny of the factual merits of the scientific debate," so "no evidentiary hearing is warranted…." *See United States v. Wilde*, --- F.Supp.3d ----, 2014 WL 6469024, *5 (N.D. Cal. Nov. 18, 2014). In plain terms,

the challenged law must be upheld if the reasoning for it is "debatable," *United States v. Harding*, 971 F.2d 410, 413 (9th Cir. 1992), or even "imaginable." *Nat'l Paint & Coatings Ass'n v. City of Chicago*, 45 F.3d 1124, 1127 (7th Cir. 1995); *see also Nichols v. Dancer*, 657 F.3d 929, 934 (9th Cir. 2011) (Contrasting other standards against "rational basis review, where we uphold government action as long as there is some imaginable legitimate basis for it") (internal quotations omitted).

Defendants have identified no fundamental right that would require a different standard of review. As explained in prior briefing, there is no fundamental right to grow, possess, or distribute, marijuana. (*See* Motion for Reconsideration, Dkt. No. 264, at 6:26-7:6) (*citing Sacramento Nonprofit Collective v. Holder*, 2014 WL 128998, *2 n.1 (9th Cir. Jan. 15, 2014) (*quoting Raich v. Gonzalez*, 500 F.3d 850 (9th Cir. 2007)).[1] Nor does defendants' general liberty interest raise the level of scrutiny. (*See id*., Dkt. No. 264), at 6:8-25) (citing *Chapman v. United States*, 500 U.S. 453, 464-65 (1991)); *see also United States v. Johnson*, 40 F.3d 436, 439 n. 1 (D.C. Cir. 1994) (general liberty interest does not raise the standard from rational basis).

Likewise, defendants have not shown a suspect classification, which requires a showing of intentional discrimination. (*See, e.g.*, Dkt. No. 279 at 16-17) (quoting *United States v. Coleman*, 24 F.3d 37, 39 (9th Cir. 1994) (law with "disproportionately adverse impact upon a racial minority" must be upheld unless "impact can be traced to a discriminatory purpose.") (internal quotation and citation omitted). Prior to the evidentiary hearing, the Court stated "tentatively" that it did "think it's rational basis that applies," reserving the right "to revisit that question" depending on what happened at the hearing. (Tr. of May 21, 2014, at 7:19-8:17). None of the testimony from the multi-day hearing or the exhibits bore on this issue or requires the Court to reconsider its tentative position. Defendants cannot show intentional discrimination or any other suspect classification in the Controlled Substances Act, and thus rational basis applies.

B. Treating Marijuana as a Controlled Substance is Rationally Related to the Legitimate Governmental Interest in Public Health and Safety.

1. The Court May Not Evaluate Whether Marijuana Meets the Statutory Schedule I Factors.

The question before this Court is not whether marijuana can be properly classified as a Schedule I controlled substance, but whether Congress could rationally have concluded that it should be a controlled

[1] The Ninth Circuit has held that 21 U.S.C. § 841(b), the penalty portion of the Controlled Substances Act, does not implicate a fundamental right. *See United States v. Harding*, 971 F.2d 410, 412 (9th Cir. 1992). For rational basis purposes, there is no distinction between § 841(b) and the portion of the Act challenged here.

substance. In an attempt to avoid the jurisdictional bar of 21 U.S.C. § 877, defendants have repeatedly disavowed any challenge to whether marijuana is properly scheduled. (*See, e.g.*, Tr. of March 19, 2014, at 8:23-9:4 ("We are not challenging the Attorney General, the DEA's discretionary decision to classify -- or to keep marijuana classified as Schedule I….")). They are therefore limited to challenging the constitutionality of the statute itself. Under rational basis review, the only question the Court asks is whether the statute is rationally related to a legitimate governmental interest. *City of Cleburne*, 473 U.S. at 440. The Court need not delve into the minutiae of how Congress chose to enact its prohibition on marijuana, but is limited—in a constitutional challenge—to determining whether the *general* approach taken by Congress is rationally related to a permissible legislative end. This extraordinarily lenient test provides "wide latitude" in formulating policy, *id.*, contains a "strong presumption" that the rule is valid, and is particularly deferential where, as here, the challenged rule reflects a process of regulatory "line-drawing." *FCC v. Beach Communications, Inc*., 508 U.S. 307, 315-16 (1993). Congress' line drawing need not be perfect or precise, and Courts must not venture into the precise details of the particular regulatory scheme; rather judicial review is limited to the general object and general means of the statute. *See, e.g.*, *Dandridge v. Williams*, 397 U.S. 471, 485 [90 S.Ct. 1153] (1970) ("A classification having some reasonable basis does not offend against that clause merely because it is not made with mathematical nicety, or because in practice it results in some inequality") (internal quotations omitted); *see also Kimel v. Florida Bd. of Regents*, 528 U.S. 62, 83, 120 S.Ct. 631, 145 L.Ed.2d 522 (2000) ("The rationality commanded by the Equal Protection Clause does not require states to match … distinctions and the legitimate interests they serve with razorlike precision").

In light of defendants' limited constitutional challenge, the Court is limited to evaluating Congress' *general* approach of treating marijuana as a controlled substance to begin with, but leaving it to expert regulators to determine later whether that initial decision should be changed. This statute is well-clear of the minimal rational basis standard. As set forth below, Congress could have barred marijuana production and distribution without further evaluation, leaving any potential change to future legislatures. But it did not go that far. Rather, Congress recognized that the control of narcotics might need to be modified to reflect changes in scientific knowledge and patterns of abuse. Congress thus added a "safety valve" to the Act, permitting the re-scheduling or de-scheduling of any substance, with the input of expert regulatory agencies such as DEA and FDA. *See* 21 U.S.C. § 811(a). Congress also permitted "any interested party" to petition

for a change in scheduling, mandated public input on the process, and provided statutory factors for to guide the process, along with the right of judicial review in the D.C. Circuit. *See* 21 U.S.C. § 811(a), (c)(1)-(8) (listing eight factors Attorney General must consider in classifying a substance, including current pattern of abuse, risk to public health, and scope and significance of abuse).[2] As the Second Circuit recognized decades ago, the allowance for such "periodic review" is a "sensible mechanism for dealing with a field in which factual claims are conflicting and the state of scientific knowledge is still growing…." *United States v. Kiffer*, 477 F.2d 349, 357 (2d Cir. 1972). The Controlled Substances Act's "flexibility and receptivity to the latest scientific information … is the very antithesis of the irrationality [defendants] attribute to Congress." *Id.* Properly framed, the question answers itself. The statute provides for a blanket ban on marijuana production and distribution, but allows for modification of that ban based on developing science and circumstances, with ample opportunity for public input and judicial review. Such petitions have been repeatedly made, rejected, and upheld by the Courts in the intervening 40 years. *See Americans for Safe Access v. Drug Enforcement Admin.*, 706 F.3d 438 (D.C. Cir. 2013). This is as rational a scheme as any legislature has ever adopted.

2. Treating Marijuana as a Controlled Substance Passes Constitutional Muster.

Even if the Court looks beyond the statutory structure and examines the constitutionality of treating marijuana as a controlled substance generally, such treatment is clearly rationally related to a legitimate governmental interest. The Ninth Circuit has so held on numerous occasions over the past four decades, including as recently as January 2014. *See United States v. Rodriquez-Camacho*, 468 F.2d 1220, 1222 (9th Cir. 1972); *see also United States v. Rogers*, 549 F.2d 107, 108 (9th Cir. 1976); *United States v. Miroyan*, 577 F.2d 489, 495 (9th Cir. 1978) (overruled in part on other grounds); *United States v. Oakland Cannabis Buyers' Cooperative*, 259 Fed. Appx. 936, 938 (9th Cir. 2007) ("Miroyan controls the issue and precludes defendants' rational basis argument"); *Sacramento Nonprofit Collective v. Holder*, 2014 WL 128998, *1 (9th Cir. Jan. 15, 2014). The courts in this district agree. *See United States v. Smith*, 2:11-CR-00428-GEB (Dkt. Nos. 78-84 & 109); *United States v. Albright*, 2:11-CR-2266 GEB (Dkt. Nos. 138 & 149); *United States v. Chavez*, 1:07-CR-192 AWI (Dkt. Nos. 168 & 173). Every other Court to have addressed the issue is in accord. *See, e.g.*, *Kiffer*, 477 F.2d at 356-57; *see also United States v. Fogarty*, 692 F.2d 542, 547-8 (8th Cir. 1982); *United States v. Trujillo*, 2014 WL 3728481 (E.D. Wash., July 25, 2014) (21 U.S.C. § 877

[2] This authority has been delegated to the DEA, which makes a recommendation with the aid of the FDA.

deprives district courts of jurisdiction to decide if there is a "rational basis for retaining marijuana on the list of Schedule I drugs"); *United States v. Firestack-Harvey*, 2014 WL 2862831 (E.D. Wa., June 24, 2014); *United States. v. Heying*, 2014 WL 5286155, *4 (D.Minn., Oct. 15, 2014) ("the classification of marijuana is clearly constitutional"); *United States v. Taylor*, (W.D. Mich. Case No. 1:14-CR-67, Sept. 8, 2014) ("plenty of objective medical information (both from the 1970s and today) to provide a rational basis for Congress to place marijuana on Schedule of the CSA, and to leave future changes in scheduling to the DEA….")[3] As another California District Judge held just last month, there is no basis for finding that marijuana's present treatment lacks a rational basis. *See Wilde*, 2014 WL 6469024 at *4-5.

The Supreme Court has recently reinforced this conclusion, and "ha[d] no difficulty concluding that Congress acted rationally" in refusing to exempt seriously ill patients with recommendations for "medical" marijuana because the "class of activities ... was an essential part of the larger regulatory scheme" of the Controlled Substances Act. *Gonzales v. Raich*, 545 U.S. 1, 9, 26-27 [125 S.Ct. 2195] (2005). The Supreme Court has also endorsed the proposition that combatting drug abuse and protecting the public from drugs that may be diverted for improper purposes is not merely a legitimate interest, but a compelling one. *See Treasury Employees v. Von Raab*, 489 U.S. 656, 668 (1989) (drug trafficking "one of the greatest problems affecting the health and welfare of our population" and that "drug abuse is one of the most serious problems confronting our society today"); *see also Employment Div., Oregon Dep't of Human Res. v. Smith*, 494 U.S. 872, 905 (1990) (O'Connor, J., concurring) (the government has a "compelling" and "overriding interest in preventing the physical harm caused by the use of a Schedule I controlled substance"). In brief, every level of the federal courts has held that treating marijuana as a controlled substance is rationally related to a legitimate governmental interest. Given the controlling Circuit precedent, as recently recognized in *Sacramento Nonprofit Collective v. Holder*, 2014 WL 128998 at *1, this Court has no basis to depart from the unbroken, forty-year line of authority on this issue, and should reject defendants' invitation to be the only court to hold that there is no rational basis for marijuana's treatment under the Controlled Substances Act. Any change in marijuana's status must come through an act of Congress or regulatory action.

In addition to the fact that their motion is foreclosed by Circuit precedent, defendants failed to meet their burden of proving that there is no "imaginable" basis for treating marijuana as a controlled

[3] Copies of these decisions were provided to the Court at Dkt. No. 345.

substance. As noted above, the United States "has no obligation to produce evidence to sustain the rationality of a statutory classification," and any "conceivable basis" will suffice. *See Kahawaiolaa*, 386 F.3d at 1280. Based on the testimony of defendants' own experts, there is easily a "conceivable basis" for treating marijuana as a controlled substance.

Marijuana use clearly has negative consequences for many users. Defendants' concede that marijuana has psychoactive properties and induces a state of intoxication while the user is high. (*See, e.g.*, Motion, Dkt. No. 199-1 at 4:27). It is also clear that *smoking* marijuana has adverse health consequences. (*See* Testimony of Dr. Carter, Tr. of October 24, 2014, at 98:22-99:1; *see also* Testimony of Dr. Hart, Tr. of October 27, 2014, at 180:6-181:10; Testimony of Dr. Denney, Tr. of October 27, 2014, at 338:7-12 ("The advice I would give to patients would be to recommend against smoking"); Testimony of Christopher Conrad, Tr. of October 28, 2014, at 558-560 (conceding that the State of California has identified marijuana smoke as a carcinogen, and contains "toxins" and "poisons"). A college-level textbook authored by defendants' own expert, Dr. Carl Hart, admits that marijuana use can cause heart problems, lung problems, and anxiety, can harm the reproductive and immune systems, and that "data from laboratory studies of computer-controlled driving simulators indicates that marijuana produces significant impairments." (Exhibit 314 at 362-364). An article published in the New England Journal of Medicine—cited by experts on both sides—states that marijuana use impacts brain development, (Volkow, et al., Exhibit 13 at 2220), is associated with an "increased risk of anxiety and depression" and "exacerbates … schizophrenia" (*id.* at 2221), negatively effects school performance in adolescents (*see id.*), and results in myriad other harms. The Diagnostic and Statistical Manual of Mental Disorders (DSM-V) recognizes a cannabis use disorder, and Dr. Hart agreed that diagnoses of the disorder had increased in the past 20 years. (*See* Exhibit 1; *see also* Testimony of Dr. Hart, Tr. of October 27, 2014, at 208-10). Dr. Hart testified that 10-15 million Americans try marijuana for the first time each year, and that 20 million Americans use marijuana every month. (*See id.* at 204). He agreed that "9 percent of people who ever try marijuana will at some point meet the criteria for marijuana use disorder." (*Id.* at 204:4-18). In other words, approximately one million *new* people each year will be diagnosed with marijuana abuse disorder during their lives.

Most mainstream physicians agree that marijuana is a dangerous drug. The American Psychiatric Association agrees that there are "serious adverse side effects" of using marijuana (*see* Exhibit 2a at 2), as

does the American Medical Association and the Canadian Medical Association. (*See* Exhibits 3, 18a, and 18b). Long term studies of marijuana users show persistent cognitive decline over the course of their lives. (*See* Exhibit 208; Meier, et al., *Persistent cannabis users show neuropsychological decline from childhood to midlife*). Marijuana use is associated with brain abnormalities in young adults. (*See* Exhibit 209; Gilman, et al., *Cannabis Use Quantitatively Associated with Nucleus Accumbens and Amygdala Abnormalities in Young Adult Recreational Users*). It is associated with psychosis and other mental health problems. (*See* Exhibit 315; Radhakrishnan, et al., *Cannabis, Cannabinoids, and the Association with Psychosis*). Defendants' experts concede that marijuana is the "most widely used illegal substance in the United States," and is the most widely abused substance of any kind after alcohol and tobacco. (Testimony of Dr. Hart, Tr. of October 27, 2014, at 227:17-23). In 2013 alone, more than 29,000 people checked themselves in for marijuana substance abuse treatment just in California, and more than half of them were teenagers. (Exhibit 3a). Given the state of the science, it is clear that treating marijuana as a controlled substance is rationally related to legitimate public health objectives. *See, e.g.*, *Fogarty*, 692 F.2d 542, 548 (Congress has wide latitude to address social problems, and potential for marijuana's abuse and risks to public health show "the rationality of the continued Schedule I classification.") Congress has the authority to protect the public from dangerous drugs and to criminalize the use, production, and distribution of drugs with adverse side effects.

Defendants failed to meet their burden of proving that treating marijuana as a controlled substance is not even debatable. *Carolene Products Co.*, 304 U.S. at 154; *Harding*, 971 F.2d at 413 (rational basis challenge fails unless defendant proves issue "is not even debatable"). Defendants' own expert Dr. Carter agrees that marijuana belongs on the Schedule of Controlled Substances, even if he disagrees as to *where* it belongs on the Schedule. (*See* Testimony of Dr. Greg Carter, Tr. of October 27, 2014, at 4:16-22; *see also* Direct Testimony of Gregory T. Carter, M.D., (Dkt. No. 310) at Exhibit A, p. 5 (stating that "Marijuana Should Be Rescheduled to Schedule II" for various reasons). Further, scientists are continuing to debate marijuana's potential as a medicine in public forums and scientific literature. Not only did qualified scientists (such as Dr. Madras) take opposing positions over the course of the five-day evidentiary hearing, Drs. Hart and Madras debated the matter in Florida on October 27, 2014, and the record contains published debates among doctors and researchers about whether marijuana is medicine or simply a misguided endeavor. (*See, e.g.*, Exhibits 5-6, 9, 205, & 305-306). How marijuana should be treated is not only

debatable, but it is actually being debated. Moreover, defense-expert Dr. Carter admitted that other qualified experts rejected his opinions regarding marijuana as medicine, that he was in the "minority" among qualified people, and that government expert Dr. Madras was qualified and disagreed with him. (Testimony of Dr. Carter, Tr. of October 24, 2014, at 39:8-23). It cannot be irrational to choose the majority scientific opinion.

Congress' decision to treat marijuana as a controlled substance was and remains well within the broad range of permissible legislative choices. Defendants appear to argue that Congress was wrong or incorrectly weighed the evidence. Although they failed to prove even that much, it would be insufficient. Rational basis review does not permit the Court's to "second guess" Congress' conclusions, *Besinga v. United States*, 14 F.3d 1356, 1362 (9th Cir. 1994), but only to enjoin decisions that are totally irrational or without an "imaginable" basis. Congress is not required to be "right," nor does it matter if the basis on which Congress made its decision turns out to be "wrong." All that is required is that Congress could rationally have believed that its action—banning the production and distribution of marijuana—would advance its indisputably legitimate interests in promoting public health and welfare. Because qualified experts disagree, it is not for the Courts to decide the issue and the statute must be upheld.

Nor is there merit to the argument that Congress over-reached by barring all marijuana production and distribution. The Supreme Court held in *Raich* that Congress' authority, once properly invoked, extended to all marijuana regardless of its source. *See United States v. Henry*, 688 F.3d 637, 641 (9th Cir. 2012) ("In *Raich*, for example, the Supreme Court concluded that the Commerce Clause allows Congress to regulate locally cultivated medical marijuana because Congress had a rational basis for concluding that leaving home-consumed marijuana outside federal control would affect price and market conditions.") (internal quotations omitted). The state of scientific knowledge at this time easily justifies Congress' inaction that continues to treat marijuana as a controlled substance. This Court has no warrant to remove that decision from public and democratic debate. It must therefore deny defendants' motion.

3. There is a Rational Basis for Marijuana's Continued Inclusion on Schedule I.

Even assuming that the proper question is whether there is a rational basis for concluding that marijuana meets the statutory factors for a Schedule I controlled substance, defendants' arguments still fail.[4] 21 U.S.C. § 812(b)(1) provides that a substance belongs on Schedule I if:

[4] As set forth further below and in prior briefing, the Court lacks jurisdiction to address a scheduling challenge.

A. The substance has a high potential for abuse;

B. It has no currently accepted medical use in treatment in the United States; and

C. There is a lack of accepted safety for its use under medical supervision.

Given the rational basis standard, it need be only "debatable" or "imaginable" that marijuana meets the standard. The evidence presented before and during the hearing clears this bar by a wide margin. Dr. Madras' written and oral testimony—which opines that each factor is met and provided significant documentary support—is alone sufficient. As noted above, defense expert Dr. Carter agreed that Dr. Madras is qualified to opine on the subject. (Testimony of Dr. Carter, Tr. of October 24, 2014, at 39:8-23). This Court must deny the motion regardless of whether it agrees with Dr. Madras' testimony or finds Hart, Carter, Denney, and Conrad more credible. The existence of a disagreement among experts is more than is required under the rational basis standard, and is dispositive of this motion.

In addition, the testimony of defendants' experts, along with the documentary evidence admitted, also establishes that there is a rational basis for finding that marijuana meets each of the three factors for Schedule I. The Court should therefore deny the motion.

a. Marijuana Has a High Potential for Abuse.

Ample evidence demonstrates that marijuana has a high potential for abuse. In fact, defense-expert Dr. Gregory Carter agreed that marijuana meets this first factor. In his direct testimony, Dr. Carter advocates that marijuana be moved to Schedule II. (Exhibit 301, Attachment A; *see also* Testimony of Dr. Carter, Tr. of October 24, 2014, at 72:1-14). At the evidentiary hearing, Dr. Carter agreed that he was "advocating that marijuana be scheduled as a II because it meets [statutory] factors." (Testimony of Dr. Carter, Tr. of October 24, 2014, at 73:1-10). But the first factor for a Schedule II listing is that the substance has a "high potential for abuse"—the same as Schedule I. *See* 21 U.S.C. § 812(b)(1)(A). The fact that the defense's own expert testified that it meets this factor is conclusive for rational basis purposes.

Indeed all medical experts testifying at the hearing agreed that, more than having the potential for abuse, marijuana is *actually* abused, and frequently so. The DSM-V recognizes a cannabis use disorder, and diagnoses of it have increased in the past 20 years. (*See* Exhibit 1; *see also* Testimony of Dr. Carter, Tr. of October 24, 2014, at 74:1-9; Testimony of Dr. Hart, Tr. of October 27, 2014, at 208-10). Dr. Carter agreed that the "DSM-5 is the authoritative or canonical statement of what mental disorders are currently

recognized," that it was published within the last year, and that even the prior version (DSM-IV) recognized a cannabis abuse disorder. (Tr. of October 24, 2014, at 74:4-14). And, as noted above, Dr. Hart testified that 10-15 million Americans try marijuana for the first time each year, that 20 million use marijuana each month, and that "9 percent of people who ever try marijuana will at some point meet the criteria for marijuana use disorder." (Testimony of Dr. Hart, Tr. of October 27, 2014, at 204). Defense experts agreed that marijuana is the "most widely used illegal substance in the United States," (*id*. at 227:17-23), and more than 29,000 people were treated for marijuana abuse in 2013 in California alone. (Exhibit 3a). With one million *new* people each year abusing marijuana, it is clearly rational to conclude that it has a high potential for abuse.

DEA has repeatedly analyzed this question, with the aid of the Department of Health and Human Services, and concluded that marijuana abuse remains a wide-spread problem. (*See* Exhibit 11, 76 FR 40552, 40553 (July 8, 2011). Among other factors, DEA considers whether the drug is diverted from legitimate channels, whether people are taking the drug on their own initiative without a doctor, and whether people are taking the drug in sufficient amounts to create a hazard to their own health or the health and safety of others. (*Id*.)[5] Given that tens of thousands of Americans are checking themselves in for marijuana abuse treatment each year (Exhibit 3a) and that one million new people each year meet the criteria for marijuana use disorder, it is quite clearly used by enough people in sufficient amounts to create a hazard to their own health or the health and safety of others. Defendants' own experts testified that most marijuana use is not occurring under a doctor's advice. Defense-expert Dr. Denney testified that 90% of patients who came to him for a marijuana recommendation were already smoking marijuana on their own. (Testimony of Dr. Denney, Tr. of Oct. 27, 2014, at 338:9-18, 334:23-335:1). And Drs. Hart and Carter testified that they had no idea how much marijuana use was "medicinal" and how much was simply getting stoned. (Tr. of October 24, 2014, at 103:19-104:22; Tr. of October 27, 2014, at 229:22-230:6).

The defense's attempt to avoid this conclusion by opining that the *consequences* of abuse are minor misses the point. That is a policy judgment to be made by legislators and regulators, not criminal defendants or the marijuana lobby. The evidence establishes that marijuana has a high potential for abuse and is actually highly abused. *A fortiori*, there is a rational basis for reaching that conclusion.

[5] Although defendants have not challenged these factors, they are entitled to significant deference because DEA has "promulgated a rule based on an implicit interpretation of the statute." *NRDC v. U.S. Dept. of Transp.*, 770 F.3d 1260, 1263-64 (9th Cir. 2014) (*quoting Schleining v. Thomas*, 642 F.3d 1242, 1246 (9th Cir. 2011)).

b. Marijuana Has No Currently Accepted Medical Use in the United States.

The evidence presented at the hearing demonstrates that whole-plant marijuana has no currently accepted medical use in the United States, and that the matter is, at a minimum, up for debate. The defense appears to believe that offering testimony of a few doctors who agree with their position is sufficient under rational basis standard, but it is not. Again, so long as there is an "imaginable" basis for determining that whole-plant marijuana has no currently acceptable medical use, rational basis is satisfied. As noted above, defendants' expert not only agreed that there is an ongoing debate about whether whole-plant marijuana has an accepted medical use, he agreed that the majority of qualified experts believe that whole plant marijuana has no accepted medical use at this time. (Testimony of Dr. Carter, Tr. of October 24, 2014, at 39:8-23). And the exhibits demonstrate that the medical literature is rife with debates among doctors and researchers about whether whole-plant marijuana has medicinal value. (*See, e.g.*, Exhibits 5-6, 9, 205, & 305-06).

This is, of course, different from whether any components of the marijuana plant have medicinal value. Some isolated and purified components have received FDA approval as medicine. (Testimony of Dr. Hart, Tr. of October 27, 2014, at 177:12-16). But the question here is whether *whole-plant marijuana* has a currently accepted medical use. In light of the fact that the AMA, APA, and other major health organizations have taken an official position that whole-plant marijuana does not yet have accepted medical value, determining that it does not have a currently accepted medical use is unassailably rational. (*See, e.g.*, Exhibits 2, 2a, 3, and 18). At a minimum, it is clear that physicians and research scientists are divided on the matter. The Constitution thus permits Congress to choose either policy, and this Court is not free to remove the matter from public and democratic debate.

In addition, DEA has adopted five factors for determining whether a drug has a "currently accepted medical use" even though not approved by the FDA.

a. the drug's chemistry is known and reproducible;
b. there are adequate safety studies;
c. there are adequate and well-controlled studies proving efficacy;
d. the drug is accepted by qualified experts; and
e. the scientific evidence is widely available.

76 Fed. Reg. 40552, 40556-60. Failure to meet any *one* of these factors is dispositive. *See* 57 Fed. Reg. 10499, 10504-10506 (1992); *see also Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131, 1135

(D.C. Cir. 1994); *Americans for Safe Access v. DEA*, 706 F.3d 438, 449-450 (D.C. Cir. 2013).

The evidence adduced at the hearing demonstrates that marijuana fails to meet any of these five factors. For example, Dr. Carter agreed that the chemistry of the marijuana plant is complex and that the chemical profile of marijuana is not completely understood. (Tr. of October 24, 2014, at 51:20-52:23). He also agreed that there is "inherent variation" in marijuana plants, and that there is no standard dosing available. (*Id*. at 52:24- 54:9). All experts agreed that there are a variety of methods for ingesting marijuana (smoking the whole plant, vaporizing, edibles, etc.) and that the method would impact both the amount of various chemicals ingested and "how the end user" would "respond to ingestion." (*Id*. at 54:2-5). Though some defense experts attempted to explain this away by claiming that patients regulate their own doses, they conceded that most medicines are not offered in this fashion: "Typically that is not done. It's written on the bottle when you should" take the medicine and how much one should take. (Testimony of Dr. Hart, Tr. of October 27, 2014, at 294:5-9). The bottom line is that there is no standard, "medical" marijuana, and neither doctor nor patient can know how much of the psychoactive substances one is ingesting, nor what other chemicals in what levels are being ingested with it.

It is also clear that there are no FDA-quality studies showing adequate safety and medical efficacy. As was explained at the hearing and in other exhibits, Phase III studies are required to reach this level of assurance. But Dr. Hart and others admitted that there are no Phase III studies for whole plant marijuana. (Testimony of Dr. Hart, Tr. of October 27, 2014, at 285:24-286:1). The safety profile of the drug is particularly poorly understood over the long term, and even Dr. Hart's college-level textbook concedes that it is "difficult to make definitive statements about long-term cognitive effects of marijuana use because of divergent findings and interpretations." (*See* Exhibit 14 at 357; *see also* Testimony of Dr. Hart, Tr. of October 27, 2014, at 188:9-189:18). In other words, defendants' own experts admit that they do not know whether marijuana use is safe over the long term. By definition, there are no "adequate safety studies" and the drug does not have a currently accepted medical use.

Marijuana also fails the fourth factor because the drug is not accepted by qualified experts. Defendants' experts agreed that Dr. Madras is qualified, and she rejects marijuana as medicine. As noted above, the matter is hotly debated among researchers, physicians, and other qualified persons. As DEA and HHS explained in 2011, this "material conflict of opinion among experts precludes a finding that marijuana

has been accepted by qualified experts." 76 Fed. Reg. at 40560. There simply is "not a consensus of medical opinion concerning medical applications of marijuana." *Id*. The fifth factor—that scientific evidence is widely available—is likewise unsatisfied because there is insufficient raw data available. The papers advocating for medical application of whole plant marijuana typically publish only "summarized" findings rather than the "raw data format." *Id*.; *see also* Testimony of Dr. Bertha Madras, Tr. of October 30, 2014, at 801:3-18. As DEA and HHS explained in 2011, this failing deprives the scientific community of the "opportunity for adequate scientific scrutiny of whether the data demonstrate safety or efficacy." *Id*. At the hearing, defendants presented no raw data, nor any evidence showing that such raw data was available.

The bottom line is that the marijuana plant does not have a currently accepted medical use. Its constituents are too variable, its safety and efficacy unknown, experts disagree, and there is little or no raw data. Although failing on any one of the five factors is fatal, marijuana fails them all. There is thus a rational basis for determining that marijuana does not have a currently accepted medical use.

c. There Is A Lack of Accepted Safety for Use of Marijuana under Medical Supervision.

There is lack of accepted safety for use of marijuana under medical supervision. In addition to there being undisputed evidence of a wide variability in marijuana's quality, potency, origin, and safety, there is no dosage control and no oversight. Defendants' lead witness on this point, Dr. Denney, essentially testified that he was operating a marijuana mill. He saw 20-25 patients per day (Tr. of October 27, 2014, at 320), tried to recommend marijuana to every one of them (*id*. at 325:25-326:2), failed to discuss the patient with their treating physician in an astonishing 95% of cases even though it is normal practice for physicians to do so (*id*. at 322:3-9 & 322:22-323:3), and never followed up or even "heard from" 90% of the patients again—at least not until their one-year recommendation required renewing. (*Id*. at 331:6-14 & 332:16-22). In reality, there is no medical supervision. Or as Dr. Denney put it, "It's the Wild West, absolutely." (Tr. of October 29, 2014, at 444:15-19). Combined with the lack of long-term studies in to marijuana's side effects, there is more than a rational basis for concluding that this psychoactive, addictive drug is not accepted as safe for medical use at this time, even with medical supervision.

4. Conclusion

Whole plant marijuana simply does not measure up at this point. Based on the evidence, the only defensible conclusion is that marijuana meets the Schedule I factors. But this is far more than is required to

pass constitutional muster, and there is clearly a rational argument that marijuana has a high potential for abuse, lacks a currently accepted medical use, and that there is a lack of accepted safety for supervision. Because the hearing established that there is both a rational argument and actual evidence to support the continued inclusion of marijuana as a Schedule I controlled substance, there is no justification for removing this issue from the democratic decision-making process.

C. Defendants' "Equal Sovereignty" Arguments Lacks Merit.

Defendants' "equal sovereignty" argument lacks merit, and has been exhaustively briefed. As the Court tentatively held at the May 21 hearing, the "area of law is distinguishable" and regulation of marijuana does not "invoke[] uniquely state concerns." (Tr. of May 21, 2014, at 9-10). Nothing has changed in the intervening seven months. Further, nothing in the statute treats one state differently from another. This argument has been rejected by every court to address it. *See, e.g., Wilde*, 2014 WL 6469024 at 5; *see also Heying*, 2014 WL 5286155 at 5; *United States v. Firestack-Harvey*, 2014 WL 1682863, *1 (E.D. Wash. 2014). The Court should confirm its tentative conclusion and reject the argument.

D. Defendants Lack Standing to Challenge Marijuana's Continued Inclusion on Schedule I.

Defendants lack standing to challenge marijuana's status as a Schedule I controlled substance because their criminal liability and sentences do not depend on marijuana's placement on Schedule I. They are charged with violating 21 U.S.C. § 841(a), which makes it "unlawful for any person knowingly or intentionally … manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance." Their sentences are controlled by 21 U.S.C. § 841(b)(1)(A)(vii), which sets the penalty for a violation involving "1,000 or more marihuana plants regardless of weight…" Marijuana's placement on Schedule I is not an element of the crime or a factor in the sentence.[6] The matter has been previously briefed (*see* Dkt. No. 279 at 1-3) and will not be repeated at length here. It is sufficient to say that regardless of whether marijuana belongs on Schedule I, defendants will go to jail for the same crime, 21 U.S.C. § 841(a), for the same amount of time. *See* 21 U.S.C. § 841(b) (providing statutory sentences for marijuana violations). Defendants' own expert agreed that marijuana meets the criteria for inclusion on some part of the schedule of controlled substances. (*See, e.g.*, Testimony of Dr. Carter, Tr. of October 24, 2014, at

[6] Defendants are also charged with conspiracy under 21 U.S.C. § 846, which does not refer to scheduling. Any reference in the indictment to Schedule I is mere surplusage, and marijuana's continued inclusion on Schedule I is immaterial to defendants' criminal liability or their sentencing.

34:11-22) (advocating for Schedule II placement); *see also* Exhibit 301, Attachment A). For these defendants then, marijuana's placement on Schedule I is academic, and they lack standing to challenge it.

This is a serious issue that goes to this Court's authority to consider the substance of the matter, and it may not be avoided. Article III's "case-or-controversy requirement bars federal courts from deciding questions that cannot affect the rights of litigants in the case before them." *Natural Resources Defense Council v. Jewell*, 749 F.3d 776, 781-82 (9th Cir. 2014) (internal quotations omitted). As the Ninth Circuit has held, "issues of constitutional standing are jurisdictional, they must be addressed whenever raised." *Pershing Park Villas Homeowners Ass'n v. United Pacific Ins. Co.*, 219 F.3d 895, 899 (9th Cir. 2000). In fact, the Ninth Circuit has twice rejected challenges to the rationality of marijuana's scheduling on standing grounds. *See United States v. Osburn*, 175 Fed. Appx 789, 790 (9th Cir. 2006) (unpublished) ("Because a rescheduling of marijuana would not have affected defendants' criminal liability, defendants lack standing to bring an equal protection challenge to the indictment."); *United States v. McWilliams*, 138 F. App'x 1, 2 (9th Cir. 2005) (unpublished) ("Changing marijuana's classification would not, therefore, provide grounds to invalidate his indictment, so McWilliams does not have standing to challenge that classification.") Another court addressing held that "a criminal defendant who has not sought authorization from the Attorney General prior to manufacturing or distributing a Schedule I controlled substance lacks standing to challenge a drug's classification in Schedule I." *United States v. Tat*, 2014 WL 1646943, at *4 (W.D. Penn. April 24, 2014).

There is no concrete "case or controversy" under Article III, and this Court has no power to proceed. Regardless of how it would decide on the merits, it must address the standing issue, and should reject defendants' motion because marijuana's "continued inclusion" on Schedule I does not change the bottom line for these defendants.

E. Exclusive Jurisdiction over Scheduling Challenges Is Vested in the D.C. Circuit.

The United States has previously briefed the issue of subject matter jurisdiction, and will not repeat those arguments here. (*See, e.g.*, Dkt. No. 279). As these issues are jurisdictional, the Court must address them. *See Sea-Land Service, Inc. v. Lozen Intern., LLC.*, 285 F.3d 808, 814 (9th Cir. 2002). Both defendants' papers and the hearing openly challenged the Scheduling of marijuana despite repeated assurances that they were not challenging doing so. (*See* Tr. of March 19, 2014, at 8:23-9:4; *see also* Motion, Dkt. No. 199-1, at 12:23-24 ("Cannabis Does Not Meet the Requirements for Inclusion as a

Schedule I Controlled Substance."); *see also id*. at 30:5-7 ("marijuana does not fit the criteria of a Schedule I controlled substance.") The entire hearing focused on the three-factor statutory test for Schedule I, and defense experts organized their testimony around these Schedule I factors. (*See, e.g.*, Exhibits 201 and 301). The Ninth Circuit has held that scheduling challenges are squarely barred by § 877, which deprives this Court of subject matter jurisdiction over the question. *United States v. Forrester* 616 F.3d 929, 936 (9th Cir. 2010) (*citing United States v. Carlson*, 87 F.3d 440 (11th Cir. 1996)). Neither § 877 nor *Forrester* may be avoided by re-framing the question in constitutional terms. First, the Ninth Circuit has explained that parties may not craft constitutional claims "either as a means of relitigating the merits of the previous administrative proceedings, or as a way of evading entirely established administrative procedures." *Latif v. Holder*, 686 F.3d 1122, 1128 (9th Cir. 2012). It is perfectly permissible for Congress to vest jurisdiction in a single court, even if that deprives criminal defendants of making a collateral constitutional challenge later. *United States v. Szabo*, 760 F.3d 997, 1005 (9th Cir. 2014) (citing in *Yakus v. United States*, 321 U.S. 414, 444-46 [64 S.Ct. 660] (1944)). The Court should therefore hold that it lacks jurisdiction to entertain defendants' *sub rosa* scheduling challenge, and deny the motion.

Nothing in *Raich*, including its footnote 37, confers jurisdiction on this Court. *Raich* did not involve a scheduling challenge, but a challenge to Congress' authority to regulate home-grown marijuana under the Commerce Clause. *Raich*, 545 U.S. at 5. If anything, footnote 37 states that the Court is not reaching the issue of marijuana's medical utility because it was immaterial. *See id*. at 27 n.37. Moreover, the Supreme Court and the Ninth Circuit have cautioned against giving "precedential effect" to any such "drive-by jurisdictional rulings." *Kwai Fun Wong v. Beebe*, 732 F.3d 1030, 1045 (9th Cir. 2013) (en banc) (internal quotations omitted). Nothing in *Raich* changes the clear command of § 877 that scheduling challenges are vested exclusively in the D.C. Circuit, and may not be made in any way in any other forum.

III. CONCLUSION

For these reasons, the Court should deny the motion to dismiss the indictment.

Respectfully Submitted,

DATED: December 31, 2014

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