UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA,

Plaintiff,

v.

BRIAN JUSTIN PICKARD, et al.

Defendants.

Case No. 2:11-CR-00449-KJM

AMENDED POST-EVIDENTIARY HEARING BRIEF IN SUPPORT OF MOTION TO DISMISS INDICTMENT AS VIOLATIVE OF THE UNITED STATES CONSTITUTION (AMENDMENT V, AND ARTICLE VI/AMENDMENT X), AND REQUEST FOR EVIDENTIARY HEARING

[Excludable Time: 18 U.S.C. § 3161(h)(1)(D) through disposition]

Date: February 4, 2015
Time: 9:00 a.m.
Judge: Hon. Kimberly J. Mueller

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COMES NOW, Defendant BRIAN JUSTIN PICKARD, by and through counsel, and respectfully submits the following Post-Evidentiary Hearing Brief, intended to incorporate the testimony of witnesses and contents of exhibits into the framework of the constitutional challenges presented in defendant's Motion to Dismiss Indictment. (Doc. 199.)

I. INTRODUCTION

In November, 2013, the defense filed a Motion to Dismiss predicated on the Equal Protection Clause of the Fifth Amendment and the doctrine of Equal Sovereignty of the States. The evidence presented at the evidentiary hearing on this matter, held before this Court on October 21-31, 2014, overwhelmingly established the scientific and medical evidence "casts serious doubt on the accuracy of the findings that require marijuana to be listed in Schedule I," and there exists no rational basis on which such a classification may be justified, as described in Part III, *infra*. Further, since the testimonial evidence was presented, the federal government has taken actions which leave no doubt of the absurdity of this irrational classification, as described in Part IV, *infra*.[1]

II. SCOPE AND PURPOSE OF TESTIMONIAL EVIDENCE

As this Court observed at the initiation of the evidentiary hearing, the United States Supreme Court has anticipated a time when a record may be established which belies the basis on which marijuana has been classified as a Schedule I controlled substance.

> We acknowledge that evidence proffered by respondents in this case 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 in Schedule I. See, *e.g.,* Institute of Medicine, Marijuana and Medicine: Assessing the Science Base 179 (J. Joy, S. Watson, & J. Benson eds. 1999) (recognizing that "[s]cientific data indicate the potential therapeutic value of cannabinoid drugs, primarily THC [Tetrahydrocannabinol] for pain relief, control of nausea and vomiting, and appetite stimulation"); see also Conant v. Walters, 309 F.3d 629, 640-643 (9th Cir. Cal. 2002) (Kozinski, J., concurring) (chronicling medical studies recognizing valid medical uses for marijuana and its derivatives).
>
> Gonzales v. Raich, 545 U.S. 1, 28, *fn* 37 (2005).

The record before this Court not only casts serious doubt on the accuracy of the findings

[1] Most significant is the passage of *Section 538* of the Continuing Appropriations Act, 2015 (*H.R. 83,* Congressional Session 2014-2015) in which the law recognizes "medical marijuana" as a substance worthy of shielding from CSA enforcement.

that require marijuana to be listed in Schedule I, but also, reveals the irrational application of the CSA as it relates to cannabis.

As noted in Defendant's underlying motion, *21 U.S.C. § 812(b)(1)* mandates that "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 [schedule I] are as follows:

> (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]

21 U.S.C. § 812(b)(1), emphasis added.

At the hearing, this Court considered the testimony of seven defense witnesses,[3] and one government witness.[4]

Defendant asserts the evidence failed to support a rational basis for cannabis' continued inclusion in Schedule I, for, as discussed below, even testimony ostensibly presented to establish a conceivable basis for such a classification is "not footed in reality."

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[2] While not stated in the conjunctive, this statute must be interpreted as requiring a finding of each of the three factors, which is the only logical interpretation when considered in light of the criteria for Schedule II, requiring a finding of one of the three Schedule I factors (i.e., "high potential for abuse.)

[3] The defense witnesses include: Gregory T. Carter, M.D., Carl L. Hart, Ph.D., Philip A. Denney, M.D. Christopher Conrad, Jennie Stormes, and Ryan Begin. As the government chose not to cross-examine the latter two witnesses, they did not provide live testimony, but were present during the hearing. It is unclear how this Court will consider the testimony of James J. Nolan, Ph.D., who was testimony was excluded on the grounds that it was not relevant to the issue to be determined through live witnesses (i.e., whether the scientific and medical evidence supports the constitutional challenges raised by the defense motion). The Court indicated Dr. Nolan's testimony would be considered as a proffer. (Doc. 342, p. 3.) Additionally, the Court further indicated that, although the testimonial aspect of the hearing was limited as indicated above, all constitutional issues raised by the defense would be considered in the final order. (Doc. 341, RT 25:21-26:2.)

[4] Bertha K. Madras, Ph.D.

III. APPLICATION OF FACTS AT HEARING TO DEFENDANTS' EQUAL PROTECTION CHALLENGES.

A. Evidence Establishing Cannabis Does Not Meet the *21 U.S.C. § 812(b)(1)* Criteria

1. Defendant Met His Burden To Show Cannabis Does Not Have a High Potential for Abuse.

Abuse liability may be evaluated by examining both the psychological and physiological harm caused by cannabis use. The evidence presented fails to establish that there is a rational basis for finding the potential for abuse of this substance is "high," particularly when compared to other controlled and non-controlled substances.

(a) Psychological: addiction and treatment

The evidence presented on the issue of abuse demonstrates the harm potential of marijuana is far less severe than nicotine, alcohol, and other scheduled, and non-scheduled substances. While all experts testified that there is a potential for cannabis to be abused, Dr. Madras was alone in her contention that this potential was "high." (Madras Decl., ¶ 36-45.) As discussed below, it became apparent during her cross-examination the basis for her opinion is contrary to the facts as presented in the very publications she herself relied upon.

(i) Diagnostic and Statistical Manual of Mental Disorders (DSM-V)

As most expert witnesses relied on, at least in part, the Fifth Edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-V), it is of important evidentiary value and clearly demonstrates the relatively low potential for abuse of cannabis. *See,* Govt. Exh. 119, DSM V, which government witness Bertha K. Madras, Ph.D., described as the manual used throughout the Nation to "assess brain diseases that are not neurological but psychiatric." (RT 645: 16-18.)

Salient sections from the chapter entitled "Substance-Related and Addictive Disorders" (pp. 481-592) establish that diagnostic criteria for Cannabis Use Disorder are far less severe than nearly every other substance use disorder described therein. The diagnostic features of the Cannabis Use Disorder provide: "[i]n cases for which multiple types of substances are used, many times the individual may minimize the symptoms related to cannabis, as the symptoms may be *less severe* or cause *less harm* than those directly related to the use of other substances."

(Gov. Exh 119, DSM V, at p. 511, emphasis added.) In fact, it appears the criteria indicative of Cannabis Use Disorder are most similar to that of Caffeine Use Disorder; however, remarkably, the Functional Consequences of Caffeine Intoxication can be fatal (p. 505); not so for cannabis.[5]

Dr. Madras referenced both the DSM IV and V to support her claim that "marijuana fulfills the criteria of a full spectrum of substance abuse disorder, from abuse (hazardous use, social and interpersonal problems related to use, neglect major roles and responsibilities) to addiction (withdrawal, tolerance, uncontrollable use, repeated unsuccessful attempts to quit, psychological/physical problems related to use, activities given up, craving)." (Madras' Decl. ¶ 36). Critical to the instant analysis, however, the *identical* criteria is utilized for nearly all the use disorders, as demonstrated by a comparison to the criteria indicative of Gambling Disorder and/or even "Unknown Substance Use Disorder."[6] (Gov. Exh 119, Sections 292.9, p 585; 292.9, p. 577.) In addition, the Diagnostic Criteria does not suggest a causal relationship, but rather simply defines behaviors exhibited in those who may suffer from *any* use disorder.

Also of great significance is the distinction for disorders related to medications (pp. 487-490.), as even the manual recognizes "medication-induced mental disorders are seen with prescribed or *over-the-counter medications* that are taken at suggested doses." (*Id*., p. 489, emphasis added). The effects of prescription and over-the-counter drugs described under the

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[5] When asked about the similarities between Caffeine and Cannabis Use Disorders, Dr. Madras stated that they were similar, but the diagnosis criteria listed in the latter includes additional factors such as "cannabis use is continued despite knowledge of having a physical or psychological problem that's likely to be caused, recurrent use of cannabis is physically hazardous situations, important social, occupational or recreational activities are given up, continued use despite having interpersonal problems." (RT 751: 10-20.) Yet, as indicated in the DSM V, at pp. 503-504, the diagnostics for Caffeine Use Disorder do include:"The signs or symptoms in Criteria B cause clinically significant distress or impairment in social, occupational, or other important areas of function," which addresses almost exactly what Dr. Madras claims was left out. Further, the Diagnostic Criteria under the "Other or Unknown Use Disorder" are *identical* to the criteria for Cannabis Use Disorder and, importantly, the fact that the "Other or Unknown" substances includes nonsteroidal anti-inflamatories, and antihistamines (i.e., over-the-counter medications like those Dr. Denney discusses in his direct examination) is of great significance to the instant analysis regarding cannabis' low abuse potential.

[6] It is interesting to note that the criteria for Caffeine Use Disorder are more alarming than that associated with other use disorders such as: restlessness, nervousness, duresis, gastrointestinal disturbance, muscle twitching, rambling flow of though and speech, tachycardia or cardiac arrhythmia, psychomotor agitation, significant distress ore impairment in social occupational, or other important areas of functioning, etc. (p. 503).

heading "Features" are far greater than those articulated in the same section for cannabis:

> Psychotic syndromes may be temporarily experienced in the context of anticholinergic, cardiovascular, and steroid drugs, as well as use of stimulant-like and depressant-like prescription or *over-the-counter drugs*. Temporary but severe mood disturbances can be observed with a wide range of medications, including steroids, antihypertensives, disulfrum, and any prescription or *over-the-counter* depressant or stimulant-like substances. A similar range of medications can be associated with temporary anxiety syndromes, sexual dysfunctions, and conditions of disturbed sleep." (*Id*., at p. 488: emphasis added, compare with pp. 510-512.)

Finally, the manual requires that the legitimate medical use of cannabis be considered before making a cannabis use disorder diagnosis. As Dr. Denney pointed out:

> [W]hether or not cannabis is being used for legitimate medical reasons may also affect diagnosis. When a substance is taken as indicated for a medical condition, symptoms of tolerance and withdrawal will naturally occur, and should not be used as the primary criteria for determining a diagnosis of a substance use disorder. Although medical uses of cannabis remain controversial and equivocal, use for medical circumstances should be considered when a diagnosis is made. (RT 351: 7-12; *see also,* Gov. Exh. 119, DSM V, at p. 511-512.)

(ii) Tolerance and Withdrawal

The DSM V makes clear some tolerance and withdrawal are the expected consequences of *medical* use of cannabis and, of significance, Dr. Denney observed that "acute cannabis intoxication is not the goal for patients, it is the goal for recreational users, and that's the fundamental difference." (RT 351:23-25; 352:1-8.) Indeed, the very fact that cannabis tolerance may be considered detrimental is in large part due to its Schedule I status: as Dr. Hart testified, "if, in fact, marijuana were to become a substance that could be prescribed... [i]t would change how the clinician thinks about tolerance in this way," and would be considered more akin to how morphine tolerance is viewed when used for pain, where tolerance is actually protectant. (RT 271:6-20.)[7]

Be that as it may, Doctors Hart and Denney both testified that withdrawal symptoms for cannabis are mild (RT 272: 2-23 and RT 481-482), and it is clear withdrawal from caffeine is more pronounced than from cannabis. This fact is indisputable, as evidenced in a comparison of the withdrawal criterion for three substances listed in the Substance Abuse section of the DSM 5,

[7] Interestingly, Dr. Denney reported that his patients generally did not increase their doses over time, as discussed in greater detail *infra* in Part III (3). (RT 370:23-371:9; RT 439:19-22; RT 440:21-442:10.)

cocaine, caffeine, and cannabis. (DSM comparison chart, attached hereto as demonstrative evidence only, as Addendum.)

Despite the lengthy discussion regarding tolerance and withdrawal presented in her direct examination (*see*, e.g.,, Madras' Decl. ¶ 39), Dr. Madras agreed tolerance and withdrawal were not significant in her analysis. (RT 743:15-21.)[8] Critically, her testimony was an implicit admission that cannabis is a legitimate medicine.

> Q: So, you would agree that if marijuana or cannabis is being used for legitimate medical reasons, that this would effect the diagnosis?
>
> A: I think the statement is - -
>
> Q: I'm asking if you agree with what I just read.
>
> A: Absolutely. Tolerance and withdrawal should not be used as a primary criteria for determining a diagnosis of substance use disorders. And I stated that a few minutes ago.
>
> Q: And that is if it's being used as legitimate medical purposes, right?
>
> A: Yes. Because many drugs, like opiates, benzodiazepines, will produce tolerance and withdrawal, and many patients use them without addiction. (RT 747:18-748:6.)

(iii) Treatment

In direct testimony, Dr. Madras relied heavily on government publications to support her position the numbers of people diagnosed with Cannabis Use Disorder were expanding at alarming rates. When confronted with these publications, which actually reported: (1) the number of adults diagnosed with this disorder has remained the same for a decade, despite the increase in cannabis use, and (2) also the number of adolescent diagnoses has declined, Dr. Madras attempted to justify her opinion by referencing the number of people seeking treatment for cannabis use disorder, rather than any allegation about the substance itself. (RT 731:5-736:13.) She asserted, in her direct testimony, statistics related to Cannabis Use Disorder, though she was patently unable to identify the source of such statistics. *Id.* On cross examination, Dr. Madras testified that use rates, determined by sheer "number of people" using

[8] Likewise, she indicated that she did not use words such as "addiction" and "dependence" because it implies a "physical dependence which is very difficult to define properly." (RT 743:1-9.)

cannabis, were higher in states where cannabis has been made legal for medical use, and she based this assertion on the National Survey on Drug Use and Health [NSDUH] 2013 Summary of National Findings. (Def. Exh. G-133, Madras Vol. II[9]; RT 731:18-25, 732:1.) She offered this publication as "one of the most reliable surveys that the U.S. has with regard to trends." (RT 732:8-9.) However, the NSDUH data actually reports the number of people diagnosed with Cannabis Use Disorder has not changed in 10 years, from 2002 to 2012. (*See*, Def. Exh. G-133, Madras Vol I..) When confronted with this statistic, Dr. Madras skirted her mistake and shifted her reliance to some purported NSDUH for 2013, a document not produced, claiming the unsubstantiated report (which, if published in 2013, could not feasibly include statistics beyond the data in Def. Exh. G-133, that includes data from 2002 to 2012) indicates that 19 million people use cannabis in this Nation, and 8 million are using it daily. (RT 733:16-20.) While this may or may not be accurate, the critical question here is not how many people are *using* marijuana, but rather whether a high number of them are *abusing* it. If so, such abuse would be reflected in the statistics regarding the number of Cannabis Use Disorder diagnoses, though Dr. Madras' own testimony based on a government study she described as of the utmost reliability, shows that such numbers have remained stable in spite of the purported increase in use.[10]

After finding the NSDUH report unsatisfactory, Dr. Madras referenced the Treatment and Episode Data Set [TEDS] to support her assertion regarding the substances high potential for abuse. Once again, she was confronted with the very source, which reported the number of adolescent marijuana admission for treatment actually *decreased* by 9% in the years 2002 through 2012. (RT 734; Def. Exh. H-40, Armentano Vol. II, TEDS Report.)[11] Thereafter, she

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[9] Defense Exhibits shall hereinafter be cited as "[Exhibit Letter]-[number], [Binder Name]" where several exhibits are numbered within a particular exhibit letter.

[10] It is evident that many people use cannabis as a medicine, and even more may use it much like alcohol. In fact, it could be said that Dr. Madras would agree with this contention, as she has written that alcohol has been shown to destroy neurons, though testifying that cannabis does not. Def. Exh. G, Madras Tab 102, at p. 19; RT 825: 18-826:7; RT 765: 19.)

[11] Dr. Madras acknowledged a report out of Colorado indicating that teen use of cannabis has declined since the state legalized marijuana for recreational use. (RT 731:12-17.) Such a trend is consistent with Dr. Madras' findings regarding the decline in teen use of other legal, but regulated,

attempted to discredit the data provided in both NSDUH and TEDS, the same data upon which she relied on in both her direct and cross examinations, by referencing "other data from Wilson Compton at NIDA showing there has been an increase in his analysis of the data." (RT 736:1-3.) No evidence was produced to support this assertion, because none exists and, in fact, her misreading of the NSDUH and TEDS data should raise questions regarding the accuracy of her representation of some claimed Wilson Compton data that was never clearly identified.

The TEDS Report is also instructive in evaluating the severity of harm experienced by those diagnosed with Cannabis Use Disorder. As Dr. Denney testified (Dr. Madras confirmed), the TEDS report establishes 85% of marijuana admissions received ambulatory care (the least restrictive and intense, described by Dr. Denney as "talk therapy),[12] zero received detoxification services, zero received rehabilitation/residential treatment, and zero received medication-assisted opioid therapy. (RT 739-741.)[13] Further, admissions receiving ambulatory services were more likely to have been referred through the criminal justice system. (Def. Exh. H-40, Armentano Vol. II, p. 40; RT 737-739.)

(b) Physiological: Physical Health and Impairment

Other abuse liabilities include the potential of causing physiological damage. In this regard, Dr. Madras raised the following concerns: (1) cardiovascular effect could lead to heart attack and stroke; (2) marijuana changes the brain, (3) marijuana precipitates schizophrenia, and (4) marijuana has caused greater roadway fatalities. As discussed below, none of these concerns are supported by the evidence, and further, even if true, the claimed effects of cannabis are so mild they could not conceivably support a justification for the current classification of cannabis on Schedule I.

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substances such as alcohol and nicotine. (RT 731.5-9)

[12] RT 492:6-15; 494:2-10.

[13] Dr. Madras tried to explain away the significance of the fact that those seeking treatment for cannabis use disorder do not require residential or detoxification treatment by suggesting that marijuana smokers may not have insurance. (RT 741.)

(i) Mortality and Morbidity

Regarding the acute danger of using marijuana, Dr. Madras agreed there is a biomedical explanation for the fact that nobody dies from marijuana overdose. (RT 625:5-8.) She raised, however, the potential for cannabis to have a cardiovascular effect, stating there is only "some" evidence that large doses or heavy users of marijuana may be "associated" with heart attack or stroke in people with a compromised cardiovascular system. Dr. Madras, however, conceded that even vigorous exercise is known to trigger a heart condition, and can precipitate a heart attack: a medically accepted fact, rather than in unsubstantiated theory unfooted in the realities of modern medicine. (RT 625:5-628:5.)[14]

While Dr. Madras did not testify regarding marijuana-related emergency department visits, the prosecution used Gov. Exh. 13 to question Doctors Carter and Denney about cannabis in the emergency room. It must be made clear, however, that the table referenced in Gov. Exh. 13 at p. 2223 "provides estimates of the number of emergency department visits involving the use of selected illicit drugs (marijuana, cocaine, and heroin) either singularly *or in combination* with other drugs between 2004 and 2011." *Id*, emphasis added. Furthermore, the conclusion drawn from this data was not that cannabis *caused* more visits to the emergency room than the other drugs listed, but rather that "[a]mong these three drugs, only marijuana, used either in *combination with other drugs* or alone, was *associated* with significant increases in the number of visits during this period." *Id*., emphasis added. This evidence utterly fails to support Dr. Madras' highly questionable contention that "3 or 4 million people" have "gone to the ER for marijuana related problems," nor did any other evidence produced by the prosecution support such a notion. (RT 79:4-8.)

As demonstrated by the defense evidence these people are not going to the ER because of marijuana related problems, but rather as the Drug Abuse Warning Network (DAWN) makes

[14] In fact, it could be argued that the use of cannabis has actually saved lives, as Dr. Denney testified to a marked decrease in opioid overdose in those states wherein medical cannabis is permitted. (RT 498:20 - 501:13, "[t]o put a human number on it, this represents about 5,000 lives that have been saved on an annual basis in states that have approved the use of medicine – cannabis as medicine"; *see also,* Def. Exh. H-67 Armentano Vol. II: Bachhuber. 2014. *Medical Cannabis Laws and Opioid Analgesic Overdose Mortality in the United States, 1999-2010.*)

clear, these are instances when marijuana is in any way mentioned during the course of the visit. (Def. Exh. A.) Dr. Denney, who served as an emergency room physician for over a decade, affirmed that he never had a patient arrive at his ER with a marijuana related emergency. In addition to consulting Section 1.8 of the DAWN report (Def. Exh. A), Dr. Denney described how cannabis is documented in the ER, which is simply *any mention* of marijuana in the chart: hence, the term, "marijuana mentions." (RT 477:7-478:8.) Even Dr. Madras described these instances as "emergency department mentions," (RT 801-802)[15], and the Government failed to seek further explanation of Government's Exhibit 13.

(ii) Brain Changes

Dr. Madras put much weight on the studies of brain scans comparing images of those who use cannabis with those who do not. She asserted in her direct testimony, as well as during cross-examination: "marijuana changes the brain." (Madras Decl. ¶ 40; RT 792: 24.) While this evidence does not generally speak to any of the three criteria required for Schedule I classification, it is important to address the accuracy, and meaning, of these studies when determining whether there is a rational basis for the continued complete prohibition of a substance approved for medical use by almost half the States in this Nation.

First, Dr. Madras conceded there have been no longitudinal studies which compare an individual's brain prior to and after using cannabis. (RT 755:1-3.) The only conclusions, therefore, which can be drawn from the limited data is that there is an association between heavy marijuana use and snapshots of the brain at a particular moment in time. Not one study has ever professed there to be a causal effect.

Second, the types of differences between cannabis users and non-users were never associated with any pathology,[16] and there is no evidence that marijuana alters brain structure. (RT 193:11-12.) Dr. Madras initially testified that one study conducted by Dr. Nora Volkow

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[15] *See also*, Madras Decl. ¶ 38, explicitly relying on the TEDS data, which the Government refrained from moving into evidence, and was instead introduced as Def. Exh. H-40 and H-41, Armentano Vol. I.

[16] "Pathological is a diseased state. Something that's diseased." (RT 259:21-24.)

showed heavy marijuana users have deficits in dopamine release, brain change, and in cerebral arterial blood flow which is correlated with lack of positive mood, restlessness, and anxiety," she clarified the study simply found the dopamine release in these marijuana users was blunted. (RT 760:2-761:13.) Although Dr. Madras believed she had not included this study in her bibliography, it appears this reference is located in the Madras Binder at Tab 187 (Def. Exh. H-187, Madras Vol. II). The study predicted only that, in 20 subjects who used marijuana, a challenged dose of methylphenidate (which promotes dopamine release) exhibited a blunted response but, importantly, the results were similar to *those using alcohol, cocaine, and "many other drugs."*[17]

Third, a careful reading of all the studies referenced in Dr. Madras' direct examination established: (1) the findings do not suggest there is a pathological difference between the brains of users and non-users of cannabis; (2) they do not suggest that the observed differences have been a detriment to the users of cannabis, and (3) significantly, as Dr. Hart testified, the observed differences reported in the studies are not consistent, and indeed are simply meaningless. (RT 249-259.)[18]

It can not be too greatly emphasized, there is simply no study which correlates a pathology, or an even moderately serious behavioral outcome with any of the brain scan differences found in the studies presented. In fact, Dr. Madras confirmed the testimony of Dr. Hart (RT 191:5-10) when on re-direct examination she testified that "[e]very single thing we do in life changes our brain, because our brain has to adapt to all incoming sensory input, and also adapt to new conditions. That's part of life." (RT 793:5-7.) When the prosecutor then asked how

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[17] RT 763; *see also,* Def. Exh. G-187, Madras Vol. II: Volkow et at. *Decreased dopamine brain reactivity in marijuana abusers is associated with negative emotionality and addiction severity*. Proc. Natl Acad Sci USA, 2014 Jul 14.

[18] Dr. Hart was particularly critical of the Gilman study (Govt. Exh. 209). He testified, "the use of the term 'abnormality' implies there is some pathology going on . There is no indication that there is any kind of pathology going on in any of these [brain study] participants. So, that kind of language, it's so inappropriate that it – *it is shocking*." (RT 233: 5-16, emphasis added; 235:18-236:1-4; Govt. Exh. 209.) He additionally noted, "[t]he language in this paper is so inappropriate, my undergraduate students would not have published this paper." (RT 232:23-25.) Dr. Hart went on to say, "I use [the Gilman study] as a teaching tool in my seminar with graduate and undergraduate students. *We use this paper... to show how science should not be conducted*." *Id.,* emphasis added.

these changes are different from those she posits are caused by using marijuana her response, while somewhat technical, essentially indicated that the brain has to adapt, and then went on to describe some acute effects of marijuana. (RT794-795.)[19] At no time does she indicate that the differences reported in the various studies are destroying or in any way impacting this adaptive process.[20]

There is no evidence that marijuana is toxic to the brain, as are other controlled and non-controlled substances. Dr. Madras so testified (RT 765-766), and wrote in her own book:

> Some drugs can be toxic to the brain which cocaine, methamphetamine, MDMA (ecstacy), inhalants, and alcohol, shown to destroy neurons (alcohol, inhalants) or axons (amphetamines), disrupt normal blood supply (cocaine), or alter gross brain morphology.
>
> (Def. Exh. G-102, Madras Vol. II: Drug Use and its Consequences, Chapter One, p. 19.)

While not involving brain imaging, Dr. Madras suggested a study conducted in New Zealand supported her opinion that cannabis alters brain functioning when she testified individuals who start using cannabis before the age of 13 lost an average of 8 IQ points by the time they reached their mid-30s.[21] Dr. Hart, however, pointed out this study design was flawed because it is inappropriate to assess cognitive function by scoring participants vertically and consequently inferring a high score is somehow normative, but rather participants's scores must placed within a normative *range:*

> When we do cognitive testing, what we do is we compare it against -- your score against a normative database. And there is a range. And that -- if you fall within the normal range,

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[19] Dr. Madras had to reluctantly admit there is no evidence "at the present time" that cannabis is toxic. (RT 825:13-15.)

[20] She does go on to discuss a study she has been conducting in which she claims the introduction of marijuana during adolescence could influence the final wiring diagram of the dopamine system. (RT 796-797.) On re-cross she admitted she has done no studies on humans, and this one was conducted on rats. (RT 827.) This study is of little, if any import, as the results are not complete, and her own prior research using marijuana established that observations made in studies using cannabis in the rodent population were not reproduced when the same experiments were conducted on monkeys. (See , Def. Exh. G, Madras Tab 120, *Cannabinoid receptor agonist and antagonist effects on motor function in normal and 1-methyl-4-phenylI-1, 2, 5, 6 tetrahydropyridine (MPTP)-treated non-human primates*, in which the researchers, including Dr. Madras found: "Cannabinoid agonists do not induce catalepsy in primates, a *finding that differs from their effects in rodents*." Psychopharmacology (Berl.) 2001 Jun), emphasis added.

[21] *See*, Govt. Exh. 208; Def. Exh. G-119, Madras Vol. II: Meier, et al., *Persistent cannabis users show neuropsychological decline from childhood to midlife*. Proc Natl Acad Sci USA 2012, Oct 2.

> you are functioning as a normal human being, and there is a variability, there is a range. (RT 224:13-17.)

In this (Meier) study, "IQs remained within the normal range of functioning," as to *each and every* participant. (RT 222: 24-3:17-18, 225-226.) [22]

Further, no witness advocated for children to chronically smoke marijuana. Indeed, it is likely that all the witnesses would agree the chronic use of cannabis by these New Zealand adolescents raises serious social and psychological questions about the subjects tested, and must serve to devalue the results of the study. Even the researchers suggested that an alternative explanation for the results was that there was persistent hard-drug and alcohol use among the persistent cannabis users. (Gov. Exh. 208, p. 2661.)

(iii) Schizophrenia

Dr. Madras testified that the evidence of a causal relationship between schizophrenia and marijuana use is increasing. Yet, she failed to identify any study which would lend credibility to this assertion. In fact, most studies question how there could be a causal effect when there is no indication of an increase in schizophrenia diagnoses to correspond with the increase in marijuana use. Further, even Wayne Hall, one of Dr. Madras' own sources, observes:

> Researchers who remain skeptical about a causal explanation often argue that a causal hypothesis is inconsistent with the absence of any increase in the incidence of schizophrenia, as cannabis has increased among young adults. . .

And then concludes:

> It is difficult to decide whether cannabis use has had any effects on psychosis incidence, because even if the relationship were causal, cannabis use would produce a very modest increase in incidence. The detection of any such increase is complicated by changes in diagnostic criteria and psychiatric services for psychosis, the poor quality of administrative data on treated cases of psychosis, and possibly by social improvements (e.g., in antenatal care) that may have reduced incidence of psychosis during the period in which cannabis use increased.
>
> Govt. Exh. 15: Hall, Monograph: *What Research over the past two decades revealed about the adverse effects of recreational cannabis use?* 2014, Society for the Study of Addiction, at p. 8.

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[22] Dr. Hart noted that "[w]e can generalize from this study. Lets take this study. Yes. This study says, even in people who started to smoke marijuana before age 18 regularly, which we all will say that's not a good thing, even in those people, they will still remain normal. Their IQ still remains normal." (RT 226: 11-16.)

Not only do Dr. Madras' own references fail to support a casual relationship between marijuana and schizophrenia, the book for which she served as editor actually questions such an assertion.

> A current theory posits that cannabis use may cause or exacerbate psychosis. In situ radioligand binding and autoradiography revealed an increased density of cannabinoid-1 receptor binding in the dorsolateral prefrontal cortex in schizophrenia, regardless of cannabis ingestion, suggesting that schizophrenia patients have altered endocannabinoid systems. (Govt. Exh. 121, Imaging the Human Brain, p. 32.)

In fact, one of the reviews submitted in Dr. Madras' bibliography suggests that cannabis has been shown to treat many medical conditions, including schizophrenia:

> Cannabis in the twenty-first century is perceived primarily as the most widely used illegal recreational drug, but this relatively recent notoriety obscures its extensive utilization as a medicine throughout the world for several thousand years. (Def. Exh. G, Madras Tab 147, P.J. Robson; *Therapeutic potential of cannabinoid medicines*, p. 24, Drug Testing Analysis (3 July 2013).)

Regarding treatment for schizophrenia, the Robson review found:

> The presence of significant amounts of CBD in street cannabis (an increasingly uncommon phenomenon) has been shown to protect users against both psychotic symptoms and memory impairment. Studies in humans using functional magnetic resonance imaging of the brain have demonstrated that these effects are related to oppositional effects of THC and CBD in key areas of interest for schizophrenia including striatum prefrontal cortex and hippocampus.
>
> Single case reports of the use of CBD in schizophrenia patients have given mixed results, but the only clinical trial conducted to date has been encouraging. Leweke et al. compared the effects of CBD and a standard anti-psychotic (amisulpride) in a double-blind, randomized, parallel group study in 42 schizophrenia patients over a period of 4 weeks. Both treatments produced a marked and equivalent improvement in psychotic symptoms from baseline, and there were significant advantages for CBD in terms of adverse event profile. *Id*., at p. 27.

Further, as Dr. Denney testified, NIDA itself is providing funding to explore the use of cannabis to treat addiction and other medical applications of both THC and CBD. (RT 476:4-477:6; *see,* Def. Exh. 78.)[23]

[23] Also, in the book edited by Dr. Madras, Imaging the Human Brain, the author observes: "Specifically, studies show increased striatal dopamine D2 receptors, increased cortical D1 receptors, and increased presynaptic dopamine turnover in the striatum in individuals at risk [for schizophrenia]." Govt. Exhibit 121, at p. 353. Such a finding considered in light of Dr. Volkow's 2013 paper would suggest that the blunting of dopamine release could have a counter effect to the onset of schizophrenia, and would support the observations made by Dr. Robson, *infra*, in which he suggests CBD may be a treatment for schizophrenia.

(iv) Driving Under the Influence

In her direct testimony, Dr. Madras stated that a "2009 National Highway Traffic Safety Administration (NHTSA) report "showed that more people are driving on weekend nights *under the influence* of marijuana (8.3%) than alcohol (2.2%)." (Madras Decl., ¶ 43.) It is unclear to what report she refers, as it is not listed in her bibliography. NHTSA did, however, publish a report in December of 2009, in which there are no statistics provided, and in fact it states:

> The development of a method of measuring driver impairment due to the use of drugs would greatly enhance the ability of law enforcement to investigate drug-impaired driving cases. *However, there is currently no accurate and reliable way to measure the level or degree of driving impairment associated with the use of drugs*. Def. Exh. H-33, Armentano Vol. I, at p. 8, emphasis added.

It follows that any report prepared by this government agency in 2009 would not have had the statistic to which Dr. Madras references. Further, this report warns:

> As discussed earlier in this report, drug use by drivers does not necessarily imply impairment. For many drug types, drug presence can be detected long after any impairment that might affect driving has passed. For example, *traces of marijuana can be detected in blood samples several weeks after ingestion*. *Id*. at p. 12, emphasis added.

It is clear that most available statistics do not refer to drivers under the influence, but rather to marijuana *positive* drivers, which in effect means they had used marijuana some time within a week or longer before driving.[24]

Dr. Madras also states: "There is a significant increase nationally in traffic fatalities involving drivers that tested positive for marijuana (Brady JE and Li G. *Trends in Alcohol and Other Drugs Detected in Fatally Injured Drivers in the United States, 1999-2010*. Am J Epidemiol. 17: 692-699, 2014) and a large increase in fatalities involving marijuana-positive drivers since marijuana has become more available in states like Colorado. (Salomonsen-Sautel S, et al. *Trends in fatal motor vehicle crashes before and after marijuana commercialization in Colorado*. Drug Alcohol Depend. 2014 Apr 23)." (Madras Decl., ¶ 43.) Again, Dr. Madras gravely twists the findings of these studies to suit her purpose. First, Doctors Brady and Li were very careful to be clear that the study tested for the metabolite of THC, and therefore, were

[24] Def. Exh. H-33, Armentano Vol. I: NHTSA 2009. *Drug-Impaired Driving - Understanding the Problem and Ways to Reduce It. A Report to Congress*

explicit in the fact they were not suggesting these drivers were acutely under the influence of marijuana. (Def. Ex. G-18, Madras Vol. I, p. 6.) The authors recognized that drug use does not mean drug impairment, as marijuana stays in the system for "up to a week." *Id*. Second, these statistics fail to account for the increase in people who would be using cannabis under medical supervision where allowed by state law, as an increase in legal users would naturally increase the number of positive drivers. *Id.*

Indeed, the second study cited by Dr. Madras, the Salomonsen-Sautel paper, examined this very issue. There, it was again emphasized the study was not measuring impaired drivers but those who tested positive for the marijuana metabolite. Researchers found that in 1994 the metabolite for THC was present in 1.1% of fatal car accident victims, and in the beginning of 2009 this number rose to 4.2%, and slightly decreased to 4.1% at the end of 2009. In addition, however, it was found that the number of registered medical cannabis patients went from 0 in 1994 (as there were no states which authorized the use of medical marijuana) to 5, 051 at the beginning of 2009, 11,094 in mid-2009, and 41,039 at the end of 2009. Clearly the percentage increase in the patient populations 4,100% is far greater than the percentage increase in marijuana positive drivers (3%). In fact, despite the large increase in the number of registered patients during the year 2009, there was a slight decrease in the percentage of marijuana positive fatal car accident victims. As the authors recognized, the primary result of this study may simply reflect a general increase in marijuana use during this time period.

It can be argued the most significant paper on this issue is the meta-analysis published in the Journal of Accident Analysis and Prevention by Rune Elvik. (Def. Exh. H-31, Armentano Vol. I.) Dr. Elvik compiled 66 studies and determined the odds ratios of vehicle accidents for various drugs, including cannabis. *Id.* In sum, the odds ratio, adjusted for publication, indicated an accident resulting in fatality or injury caused by the use of cannabis was so low as to be statistically insignificant, as it was less than 1.31% and 1.26%, and was less than for anti-

asthmatics and anti-depressives.[25] *Id.,* at Table 6. While Dr. Madras testified she was aware of this meta-analysis, she would not accept that it was accurate, and testified that the numbers did not coincide with the National Highway Transportation Safety Administration (NHTSA) data, or an unproduced study by Huestis. (RT 778:7-781:3.) When it was pointed out that these other studies involved the testing of the THC metabolite, which remains in the system long after ingestion, she claimed that some cognitive studies have shown cognitive impairment for up to a week. *Id.* This statement is simply one more example of this witness' inability, or even refusal, to accept the realities of the present state of evidence. Indeed, Dr. Madras was questioned about a survey on drugs and human performance issued by the National Survey on Drug Use and Health (NSDUH), which recognized the utter converse of Dr. Madras' testimony, to wit: there is no way to measure impairment by THC concentrates alone:

> It is difficult to establish a relationship between blood or plasma concentration and performance impairing effects. It is inadvisable to try to predict effects based on blood THC concentrations alone, and currently impossible to predict specific effects based on THC-COOH [the metabolite]. (RT 782:1-11.)

Dr. Madras' clearly bias is not surprising given that, in her work with the Office of National Drug Control Policy, she was *statutorily* required to "ensure that no federal funds appropriated to the National Control Policy shall be expended for any study or contract relating to the legalization for a medical use, or any other use, of a substance listed in Schedule I..." *See, 21 U.S.C. §1703(12)(b).* (RT 782.) Also, although she denied it, Dr. Madras is the co-owner of an invention which is a partial agonist to the CB1 receptor, and may have therapeutic benefit in treating cannabis addiction. (RT 783-787; Def. Exh. II.) As such, common sense dictates that Dr. Madras would personally benefit from an increase in findings of Cannabis Use Disorder, a fact Dr. Hart attested would diminish if cannabis was struck from Schedule I. (RT 271:6-20.)

[25] During cross-examination, there was some confusion regarding whether the odds ration for property damage accidents was statistically significant as there was a slight difference between the numbers for the publication adjusted data. Be that as it may, the odds ratios in each of the categories is hardly remarkable, as it is nearly identical to the odds ration for individuals taking Penicillin. (See, Armentano Tab 31, page 262.)

2. Defendant Met His Burden to Show Sufficient Evidence of Accepted Medical Value.

The critical inquiry here involved is not whether there are *any* negative effects of marijuana, but rather whether marijuana has *no* medical benefits. The evidence is overwhelming and irrefutable, cannabis has remarkable medicinal qualities which have been known and applied throughout history. As Dr. Carter testified:

> It's been used by mankind for thousands of years, dating back probably 5,000 years as medicine. And actually, you know, it was available by prescription. That's what a lot of people forget. But doctors, before 1937, there were commercially available cannabis-based medicines. (RT 69:6-10.)

When asked why he and his co-researchers determined that cannabis has medical utility, Dr. Hart forcefully, and with a bit of frustration, stated :

> And the conclusion from that study is from a group of researchers who are -- who would be really reluctant to make such claims, and so that is a -- that's quite a statement. And it is – and the statement is made because, unequivocally, researchers in this area know that marijuana has medical utility. It's almost, no disrespect, but a joke to be arguing whether it does not have medical utility. It's clear. The scientific evidence is overwhelming. (RT 283: 4-23.)

Even Dr. Madras did not disagree, stating, "[t]here are 20,000 papers on marijuana" (RT 777:3) and that "there is tantalizing evidence in the literature that [the components of marijuana] may have therapeutic benefits." (RT 689:6-8.) Whether described as "tantalizing" or "overwhelming," the medical and scientific evidence defeats any notion that cannabis "has no currently accepted medical use in treatment in the United States." *21 U.S.C. § 812(b)(1)(A).* And thus, "casts serious doubt on the accuracy of the findings that require marijuana to be listed in Schedule I." (Raich, *supra*, 545 U.S. at 28, *fn* 37.)

The evidence established that cannabis has therapeutic benefits for treating each of the following medical conditions:

* Wasting syndrome
See, *inter alia,* RT 147: 16-21; 138: 13-18; RT 647: 13-20; Def. Exh. G-1, Madras Vol. I (Abrams, Study); Def. Exh. H-62, Armentano Vol. II (Dr. Hart's HIV study); Def. Exh. G-14, Madras Vol. I (Ben Amar, Review); Govt. 317 (Grant, Review); Govt. 319 (Hazecamp, Review) (nausea/vomiting/appetite); Govt. 321 (Musty, Review).

* Pain
See, *inter alia,* RT 88:8-1; 89: 5-10; RT 89: 18-90:6; RT 92: 12-21; 164:9-12; 278: 22-25; 279 1-15; RT 270:1-5; 271: 13-18; 283:1-24; RT 290: 13-17; RT 336:3-337:25; RT 508: 16-21; 509: 15-18; Def. Exh. G-97 (Lynch): Def. Exh. H-6; Govt. 320 (Rocha,

Review).

* Multiple Sclerosis
See, *inter alia,* RT 89: 5-10; RT 92: 12-21; RT 271: 13-18; 278: 9-21; RT 336:3-337:25; RT 507:16-21; RT 508: 16-21; Def. Exh. H-6; Def. Exh. H-10, Armentano Vol. I (Corey-Bloom Study); Def. Exh. H-6, Armentano Vol. I (Russo, Study); Govt. 319 (Hazecamp, Review).

* Cancer
See, *inter alia,* RT 270:1-5; RT 336:3-337:25; RT 513: 11-17; RT 508: 16-21 (nausea); Govt. 319 (Hazecamp, Review) (nausea/vomiting/appetite).

* Amyotrophic Lateral Sclerosis
See, *inter alia,* RT 82: 15-23; 92: 12-21; Carter Decl. (Doc. 310), ¶ 17-18; Govt. Exh. 309 (Carter, Review).

* Post Traumatic Stress Disorder
See, *inter alia,* RT 167: 13-15; 336:3-337:25; Direct Examination of Sgt. Ryan Begin.

* Dravet's Syndrome
See, *inter alia,* RT 667: 20-668:16; Direct Examination of Jennie Stormes.

* Spasticity/Muscle Relaxation
See, RT 92: 12-21; RT 290: 13-17; RT 508: 16-21; RT 508: 16-21; RT 511: 4-5.

* Crohns Disease
See, inter alia, RT 512: 8-513:5; Exh. F-3, Denney Binder; Def. Exh. H-17, Armentano Vol. 1; Govt. 319 (Hazecamp, Review).

* Glaucoma
See, *inter alia,* RT 508: 16-21; 509:15-18; Def. Exh. H-6; Def. Exh. G-14, Madras Vol. I (Ben Amar, Review); Govt. 319 (Hazecamp, Review).

* Spinal Cord Injuries
See, *inter alia,* Def. Exh. G-14, Madras Vol. I (Ben Amar, Review).

* Parkinson's Disease
See, *inter alia,* RT 404: 510: 1-25.

* Gastioparesis
See, *inter alia,* RT 336:3-337:25.

* Fibromyalgia
See, *inter alia,* RT 89: 5-10; RT 677: 22-678: 2.

* Tourette's Syndrome
See, *inter alia,* RT 336:3-337:25; Def. Exh. G-14, Madras Vol. I (Ben Amar, Review).

* Rheumatoid arthritis and autoimmune diseases
See, *inter alia,* RT 92: 12-21; RT 677: 22-678: 2.

* Neuro-protectant value
See, *inter alia,* RT 92: 12-21; Govt. 309 (Carter, Review).

* Anti-inflammatory

See, *inter alia,* RT 92: 12-21.

* Depression/Anxiety/Mood
See, *inter alia,* RT 283: 7-13;RT 336:3-337:25; RT 647: 13-20.

* Insomnia
See, *inter alia,* RT 283: 7-13; RT 336:3-337:25; RT 647: 13-20.

* Attention deficit/hyperactivity disorder (ADHD)
See, *inter alia,* RT 336:3-337:25.

* Bradykinesia
See, *inter alia,* RT 511: 4-5.

* Schizophrenia
See, *inter alia,* Govt. 319 (Hazecamp, Review), at Table 9.

Dr. Denney also testified to the clear weight of medical and scientific evidence showing cannabis' medical value: Medical conditions for which Dr. Denney recommended cannabis include: chronic pain, cancer, PTSD, peripheral neuropathy associated with Diabetes, ADHD, Tourettes Syndrome, Insomnia, Alcoholism, methamphetamine addiction, depression, anxiety. (RT 336-338.)

A medication which treated *even one* of the above listed medical conditions would be lauded as a scientific breakthrough; in the case of cannabis, however, nothing shy of curing old age would render it worthy of inclusion in the legal pharmacopeia of medicine. In an effort to present a conceivable basis for ignoring the scientific evidence, the Government relies on Dr. Madras, who has never treated even one patient and admits she has "not studied the effects of cannabis on the human system." (RT 620:17-18.)[26] While she has taught medical students, her instruction is limited to "substance abuse and addiction," which includes a single component related to cannabis. (RT 620:18-25.)

Importantly, despite her expressed lack of faith in medical cannabis, 20 of the 199 papers provided in Dr. Madras' own bibliography involve clinical trials involving human subjects

[26] Dr. Madras has participated in just two preclinical studies involving cannabis. (*See*, Madras CV, submitted as Exhibit A to her Declaration (Doc. 324-1); *see also,* Defendant's Motion to Exclude Madras Testimony (Doc. 329), p. 7:21-8:4, explaining Dr. Madras' minimal research experience relating to cannabis.)

examining the therapeutic effects of cannabis.[27] The conclusion of nearly all such studies found that cannabis (whether whole plant, or isolated cannabinoids) had a positive effect on the patients treated. While just one study found marijuana hindered the balance of patients with Multiple Sclerosis, not a single one of these researchers found marijuana was a danger to the subject patients.[28]

Rather than accept the results of the studies she included in her bibliography, when confronted with the positive findings Dr. Madras attempted to discredit the researchers and their papers. For example, she testified that the Abrams study was contradicted in a meta-analysis performed by researcher Mohamed Ben Amar. (RT 641-642.) This is simply inaccurate. The Ben Amar meta-analysis finds:

> Seventy-two controlled studies evaluating the therapeutic effects of cannabinoids were identified. For each clinical trial, the country where the project was held, the number of patients assessed, the type of study comparison done, the products and dosages used, their efficacy and their adverse effects described. Cannabinoids present an interesting therapeutic potential as antiemetics, appetite stimulants in debilitating diseases (cancer and AIDS), analgesics, and treatment for multiple sclerosis, spinal cord injuries, Tourette's syndrom, epilepsy and glaucoma.
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> Govt. Exh. 318. Ben Amar. *Cannabinoids in Medicine: A review of their therapeutic potential*. Journal of Ethno-Pharmacology (2006).

Other studies presented in Dr. Madras' own bibliography in Defense Exhibit G to which she took exception included: (1) Def. Exh. G-62, Post Traumatic Stress Disorder; (2) Def. Exh. G-30, food intake, improving mood, and subjective and objective sleep measures. (RT 647-649), and (3) Def. Exh. G-97, Lynch, chronic non-cancer pain. (RT 675-680.) She did finally agree that the Lynch paper had merit, testifying "for this indication, [chronic non-cancer pain] I think

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[27] These are found in Def. Exh. G, Madras Binders, Vol. I, II. as follows: No. 1, 13, 14, 15, 34, 35, 53, 61, 62, 69, 79, 87, 90, 91,137, 157, 158, 169, 190, 193, 194.

[28] See, Def. Exh. G-61, Madras Vol. I: *Greenberg et al. Short-term effects of smoking marijuana on balance in patients with multiple sclerosis and normal volunteers*. Clin Pharmacol Ther. 1994 Mar;55(3):324-8.

While admitting she chose the 199 papers because they are "pivotal and significant," (RT 630:16-17), she attempted in her live testimony to discredit many of those that she relied on for the statements made in her Direct Examination. For example, she claims there was a high drop out rate in the CMRC clinical trials of "people who were cannabis naive." (RT 635.) As she testified that every study must include the drop out rate (RT 828:22-24), very few of the leading studies upon which she relies pass her own convoluted muster.

that there is - - there is promise." (RT:681:12-13.) In addition, when questioning regarding the results of a study examining the use of smoked cannabis for neuropathic pain in AIDS patients, Dr. Madras very reluctantly testified, "I would say that there is pain reduction, I would agree with that. But that is not the way one defines medicine that gets approved through rigorous, scientific processes."[29] (RT 642:1-11.)[30]

Despite agreeing to cannabis' indisputable therapeutic value in pain management, Dr. Madras continued to objected to using cannabis as medicine, and her rationale can be distilled into four categories: (a) a whole plant can not be a medicine; (b) smoking is an inappropriate method of ingesting a medicine; (c) the psychoactive effect of THC limits its use as medicine, and (d) the FDA has not approved it as a medicine, and should not do so in reliance on the studies which are insufficient in large part because they do not test the substance on naive users.[31] As discussed below, none of these concerns are footed in the realities of the scientific and medical evidence presented.

(a) Whole Plant Medications

As many of the witnesses pointed out, including Dr. Madras, whole plant medications, such as digitalis, have been used to treat numerous medical conditions. Dr. Carter identified the following whole plant medicines: St. John's wort, Valerian root, digitalis-based medicine and other herbal medicines found in health food stores (RT 96:22-97:1), and pointed out that digitalis

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[29] Def. Exh. G-53, Madras Vol. I: Ellis RJ et al. *"Smoked medical cannabis for neuropathic pain in HIV: a randomized crossover clinical trial*." Neuropsychopharmacology. 2009 Feb.

[30] Having conceded "the ability for marijuana to reduce pain in a certain population" (RT 642:18-20), Dr. Madras opined that this fact still did not warrant FDA approval, as it did not prove cannabis was the "best" treatment option. "In some types of pain you need side-by-side comparison with NSAIDS, you need a side-by-side comparison with other types of antipain medications in order to prove that the safety, the benefits outweigh the risks, and that these cannabinoids are the best possible in view of the fact that there are other types of analgesics available on the market." RT:681:18-24. Later she agreed that there was no general FDA requirement to prove the proffered drug is the best, admitting by implication her own "standards" for cannabis exceed even that of the FDA and, consequently, that her position is not evidence-based. (RT 681:12-682:7.)

[31] Of course, Dr. Madras also objects to the use of cannabis as a medicine because of what she views as the abuse potential. As this issue has been fully discussed in Part III(A)(1), *supra*, the defense feels that her position in this regard has been fully recognized and addressed, and therefore, will not be included in the present section dealing with medical benefits.

is a whole plant medicine approved by the FDA. (RT 106.)[32] Further, Dr. Madras' concern regarding the effects of numerous components of the cannabis plant is predicated on nothing but her own imagination. She could point to no study nor scientific basis for concluding that the components of the marijuana plant have some unknown and harmful quality.[33] She did concede, "it is very possible" to isolate each compound in the marijuana plant, and "extremely feasible to isolate each of the cannabinoids and study them individually." (RT 694:18, 21-22.)

Further, as Christopher Conrad testified, not only are the components known and reproducible (RT 586:14-20), the quality and cannabinoid ratio can be, and are being controlled and regulated, as chromatography provides a fairly precise ratio profile of the plant material. (RT 546.) In addition, as Mr. Conrad points out, the very regulation that is impossible so long as cannabis remains in Schedule I would actually eliminate many of the concerns raised by Dr. Madras. For example, the potency may be limited, as is being done in Holland (RT 555:20-23), and contaminants can be addressed through regulation (RT 547:8-9, 18-20, 555:1-2). In fact, the American Herbal Pharmacopoeia, assisted by Mahoud Elsolhy (who also heads the government's NIDA Garden in Mississippi (RT 617-618)), works "to establish that there is a way of meeting the goals and the mission of the American Herbal Pharmacopeia, which is to make sure herbal medicine is safe and efficacious." (RT 617:23-618:1) These protections, can not be universally employed as long as cannabis remains on Schedule I. (RT 571:11-18; 582:17-20.)

Even Dr. Madras admits cannabis has been used by humans for medical and psychoactive

[32] Dr. Madras glibly states in her direct examination, "[a]lthough more than 30% of current therapeutic drugs are plant-derived, no one currently eats or smokes foxglove plants to treat a heart condition, chews cinchona bark to alleviate malaria symptoms, or eats opium poppies to relieve post-surgical pain." (Madras Decl., ¶ 16.) This comment demonstrates her failure to understand the impact the Schedule I classification has on those who depend on cannabis to treat their serious medical conditions. For, if digitalis and morphine were on the same schedule as cannabis, people would indeed be forced to smoke foxglove, chew cinchona bark, or eat opium poppies for their therapeutic value.

[33] It should also be noted that as the Phase III trials are performed only after Phase IIa. and IIb., and as the Phase II trials are designed to ensure the substance is safe for human use (RT 15), it must be presumed that these safety standards have satisfied the researchers since they are presently at the stage for testing for efficacy.

purposes for thousands of years,[34] and therefore its effects on the human body have been observed and studied both in and outside of the clinical trial setting. The situation is unlike other pharmaceuticals for which the impact is unknown until introduced through clinical trials.[35]

(b) Route of Administration

As all witnesses agreed, smoking is not the only method of administering cannabis, and alternatives to smoking are clearly gaining broader use, particularly vaporization. (RT 639:9-15.)[36] When asked, "[i]f you had to rank [the popularity of the routes of administration], most often to least often?," Dr. Denney responded "[p]robably vaporizing is probably most... these days." (RT 199: 2-9; *see also*, RT 436:14-23.)

Dr. Madras opined, however, that studies involving smoked cannabis were of no value to the FDA approval process and would have to be re-performed using a different route of administration. (RT 639.) Again, Dr. Madras is throwing up imaginary hurdles, failing to articulate the basis for this proposition which, if true, would open NIDA up to extreme criticism for wasting taxpayer funds for over 30 years on the IND program wherein *smoked* cannabis is administered, or indeed in any of the numerous studies whereby NIDA manipulated the cannabinoids so that scientists could administer smoked cannabis, which would include each and every one of the *thousands* of smoked cannabis doses administered by Dr. Hart. More importantly, Dr. Madras ignores the vast number of studies in which cannabis or cannabinoids were administered either orally, or using a vaporizer. When asked about vaporization, she first testified that she was aware of only one study which employed the use of a vaporizer (RT:691:25.) When confronted, however, with another Israeli study that evidenced cannabis may

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[34] *See*, Def. Exh. G-102, Madras Vol. II, p.2; RT 624:2-25.

[35] Also, as Dr. Carter testified, scientists know more about the mechanism of action involved with cannabis than for most other medications. (RT 93:5-7.)

[36] While no witness advocated smoking medical cannabis, it should be noted that a study discussed by the experts during the hearing found there was no association between lung cancer and smoking cannabis, and that in fact, there was a lower rate of lung cancer in those patients who smoked both cannabis and tobacco than in tobacco smokers alone. (*See*, Def. Exh. H-44, Armentano Vol. II: Tashkin, et al. *The Effects of Marijuana and Smoking on the Lung*. AnnalsATS, June 2013; see also, Def. Exh. H-45, Armentano Vol. II: Zhang et al. *Cannabis smoking and lung cancer risk: Pooled analysis in the International Lung Cancer Consortium*. Int J Cancer. 2015 Feb 15.

easily be administered via a portable, metered-dose inhaler, she stated: "So, there are others. And I was not familiar with this. Thank you for the correction."[37]

(c) Psychoactive Effect

Dr. Madras' referenced a study by researcher A. Izzo and colleagues which describes the many therapeutic benefits of various cannabinoids in the marijuana plant,[38] and when asked about this study she agreed that it contained: neuroprotective, anti-psychotic, and antibacterial properties.[39] (RT 657-658.) In addition, she recognized the "entourage effect" was indeed helpful in a therapeutic setting. (RT 658:9-12.)[40]

Dr. Madras asserted the conclusion of the Izzo paper was that "the psychoactivity of THC greatly limits [marijuana's] use," but conversely failing to provide any rational explanation for the fact that dranabinol (synthetic THC, the only cannabinoid that produces a psychoactive effect) is actually a Schedule III controlled substance. (RT 658:23-24.) Her lack of knowledge regarding the status of cannabis within the CSA seriously calls into question the basis of her opinion. For instance, her failure to acknowledge that CBD is a Schedule I substance (RT:663, 673), as well as to provide any rational basis for classifying dranabinol (synthetic THC which is chemically identical to natural THC) on Schedule III, while natural THC and CBD remain on Schedule I (RT 660-664), demonstrate that her opinion is not based on the scientific realities.

Additionally, her admission "there is some evidence" Sativex, a combination of THC and CBD extracted from botanical cannabis, is an effective medication, flatly defeats the notion marijuana "has no currently accepted medical use for treatment" as mandated under *Section*

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[37] RT 692:13-14; *see also,* Def. Exh. H-20, Armentano Vol. I: Eisenberg. 2014. *The Pharmacokinetics, Efficacy, Safety, and Ease of a Novel Portable Metered-Dose Cannabis Inhaler in Patients with Chronic Neuropathic Pain.* J Pain Palliat Care Pharmacother. 2014 Sep;28. This study also noted, " [n]o participant withdrew because of tolerability issues."

[38] *See*, Def. Exh. G-81, Madras Vol. I: Izzo AA et al. *Non-psychoactive plant cannabinoids: new therapeutic opportunities from an ancient herb.* Trends in Pharmacol.Sci. 2009, Oct. 30.

[39] The antibacterial properties are important in addressing the concern raised by the prosecution when cross-examining Christopher Conrad. For this antibacterial characteristic protects the user from external contaminants. Thus demonstrating another advantage of the entourage effect.

[40] Although she testified this is not the way marijuana is being dispensed currently (RT 658:11-12), such an observation only lends support to the need to remove marijuana from Schedule I.

812(b)(1)(B). After recognizing, "[t]he components should be evaluated because there is tantalizing evidence in the literature that they may have therapeutic benefit" (RT 689:6-8), Dr. Madras goes on to surmise:

> There is tantalizing good evidence that they do have medical benefit. What is missing in the entire field are studies on the consequences of keeping a person on daily marijuana use, or daily cannabinoids, for extended periods of time. If you can point to me one study like that, I've not been able to find it. (RT 689:19-24.)

When one such study[41] was thereafter pointed out to her, she stated, "And I was unable to identify it. And that is a failing on my part, I admit."[42]

(d) FDA Approval

When asked the basis for her opinion that marijuana does not have a currently accepted medical use, Dr. Madras stated:

> Because, A, it does not fulfill – come close to fulfilling the Food and Drug Administration requirements for a medicine, and that, to me, is critical, because that - - that is my standard, because that is the gold standard for this country and the world. (RT 819:1012.)[43]

Dr. Madras' assertion cannabis has no therapeutic value is based on the fact that the FDA has yet to approve it as a medicine again fails to recognize the realities of this situation, to which all defense experts agreed: the fact that marijuana is a Schedule I controlled substance impinges on the FDA approval process. Even Dr. Madras, however, was forced to agree the current science has produced very promising results.[44]

While the DEA five-part test[45] may be helpful in assessing the medical benefits of

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[41] RT 790:5-6, referring to Def. Exh. F-46, Denny: Russo et al. 2002. *Chronic cannabis use in the Compassionate Investigational New Drug program: An examination of benefits and adverse effects of legal clinical cannabis*. Journal of Cannabis Therapeutics 2: 3-57.

[42] It should also be noted that not all medication are intended for long-term use.

[43] Dr. Madras does not articulate a point "B."

[44] *See, inter alia,* RT 696:12, Dr. Madras: "CBD was promising"; RT 681: 12-13, Dr. Madras: "For this indication, I think that there is -- there is promise."

[45] These include: (1) the drug's chemistry must be known and reproducible; (2) there must be adequate safety studies; (3) there must be adequate and well-controlled studies proving efficacy; (4) the drug must be accepted by qualified experts, and (5) the scientific evidence must be widely available." Alliance for Cannabis Therapeutics v. DEA, 15 F.3d 1131, 1135 (D.C. Cir. 1994); Americans for Safe

cannabis, the intended use of these factors is to determine whether a substance should be *rescheduled* and this Court need not track those elements in a constitutional inquiry. Be that as it may, the defense contends the application of the facts presented at the hearing do support a finding that marijuana satisfies this five-part test. However, as this is *not* an administrative petition to reschedule, these criteria are not essential to the Court's analysis. Relevant in this inquiry, however, is the fact pointed out by the defense witnesses: the DEA must act before the FDA can approve cannabis as a medicine in any form. Thus, Dr. Madras' stated belief that a substance could not be considered a medicine unless and until the FDA says so, is circular and based on politics rather than science.

Accordingly, this Court must consider the executive branch's irrational policy of demanding extensive "Phase III" medical and scientific studies showing cannabis' medical utility prior to even the mere consideration of altering its Schedule I designation as utterly ungrounded in reality, while *at the same time* the very reason such studies are arguably stifled is the proximate cause of the government's own conduct of refusing to release cannabis for experimentation.[46] This fact is supported by the following testimony:

Defense witness Dr. Carl Hart testified to this government-created quandary when

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Access [ASA] v. DEA, 706 F.3d 438, 450-52 (D.C. Cir. 2013)." The DEA recently asserted that the fourth factor, whether "adequate and well controlled studies proving efficacy" is only satisfied by approval by the Food and Drug Administration (FDA) via its New Drug Application (NDA) process, as opposed to the hundreds upon hundreds of "peer reviewed" medical and scientific studies agreeing marijuana is generally accepted by the medical community in the United States as having an accepted medical use to treat and even prevent cancer. Americans for Safe Access [ASA] v. DEA, *supra*, 706 F.3d at 452, cert. denied. However, several courts have held just the opposite on the same issue. In the D.C. Circuit, as well as in the 1st and 11th Circuits, the Justices held that the lack of FDA approval does not negate "the possibility that the substance in question has an accepted medical use. *See* Grinspoon v. DEA, 828 F.2d 881, 890-91 (1st Cir. 1987), holding this "accepted medical use" factor is *not* coextensive with approval by the Food and Drug Administration (FDA), cited approvingly to United States v. Franz, 818 F. Supp. 1478 (11th Cir. 1993) and John Doe, Inc. v. DEA, 484 F.3d 561, 571 (D.C. Cir. 2007), "the absence of FDA marketing approval may not be a reasonable proxy for a lack of currently accepted medical use."

[46] However, even in spite of these government-imposed hurdles, the research on medical cannabis is extensive and comprehensive, under the federal government's own studies, research conducted in the private sector by scientists such as Dr. Hart, and also by research in other nations such as Israel. However, the large-scale, pharmaceutical company-sponsored studies purportedly required cannot and will not occur in the United States while cannabis continues to be in Schedule I, nor while subject to additional regulatory hurdles for medical and scientific research *not required of any other Schedule I substance*.

discussing his invited testimony before the U.S. House of Representatives' Committee on Oversight & Government Reform on June 20, 2014.[47] He stated that at that hearing, witness, Dr. Nora Volkow, the Director of NIDA, admitted her agency has a monopoly on cannabis available for medical use and research, and also that cannabis is the *only* substance subjected to a triple tier application process necessary to obtain its release for medical or scientific study. (RT 240:18-246:11.) The relevant colloquy is as follows:

> Q: As a researcher, are you able to obtain the botanical plant, the botanical cannabis, from any source other than the NIDA?
>
> A. No. The marijuana that is used in our studies is supplied to us from the University of Mississippi, which is the farm -- the NIDA farm, if you will. And so you have to have a NIDA grant in order to get access to that marijuana.
>
> Q. So, you couldn't just go out and buy marijuana, let'ssay, from a dispensary, or something of that nature, and utilize that?
>
> A. No. No. No. That's not -- that wouldn't be appropriate today. That's not allowed.
>
> Q. And why is it not allowed?
>
> A. Why isn't it allowed. That's a good -- it's not allowed because marijuana is a Schedule I drug. That's the major reason it's not allowed.... The marijuana situation is the way it is because there is only one supplier. There is only one possible supplier for marijuana research in the country, and that supplier is at the University of Mississippi. *Id.*

In describing Dr. Volkow' testimony before Congress, Dr. Hart stated:

> [T]here were more steps in order to study marijuana -- one had to accomplish more steps than to study heroin. And Dr. Volkow, I believe, was pointing out, yes, that, indeed, that is true. And she didn't seem to have an answer when [the House member] asked her why is that the case. (RT 245: 8-25. 246: 3-11.)

Defense witness Gregory Carter, M.D., another noted cannabis researcher, testifed that "we know a lot more about how cannabis works than we do about a fair number of prescription medications" (RT 93: 5-7), but he observed:

> [Y]ou couldn't do trials with marijuana. As long as it's in Schedule I, that's the end of the story. I mean not those type of trials. You can do the NIDA sponsored sort of shrunk-down version of those trials. But as I did testify earlier, that's almost comparing apples and oranges. *So we're sort of set up to fail, even though the trials have shown efficacy*. (RT 100: 9-15, emphasis added.)

Defense witness Dr. Phillip Denney testified:

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[47] Def. Exh. E(2), "Mixed Signals Hearing Tapes," for June 20, 2014, subject to Application to Reconsider filed concurrently herewith.

> [T]he classification of marijuana as a Schedule I drug, as well as the continuing controversy as to whether or not cannabis is of medical value, are obstacles to medical progress in this area.[48]

Despite these hurdles, however, the research has surpassed what is generally expected for FDA approval. As Dr. Denney noted:

> If you look at the actual approval history of novel therapeutic agents by the FDA, these are often based on very few studies, with a limited number of patients. I would agree the ideal would be to have large-scale studies but, in actuality, the drugs that are FDA approved are often approved on the basis of very small studies and very limited data. For example, the approval of Marinol, THC, the active ingredient in cannabis, a Schedule III drug, was based on two studies. Two.... So, again, to hold cannabis to a higher standard than the approval of other novel therapeutic agents is not only not fair but is politically charged, I think. (RT 405: 4-17.)

As to this point, the Government witness evidenced blind faith to the non-evidence-based underpinnings for the current Schedule I designation when she controverted each of the other witnesses, and even her own testimony, posting that cannabis' Schedule I designation does not inhibit the same type of Phase III clinical trials she would require in order to testify cannabis has a definite therapeutic value. (RT 689: 1-20.)[49] As enumerated above, the defense experts Doctors Hart, Denney, and Carter, all untrained by the same political "highly skilled media trainer" who trained Dr. Madras,[50] each testified that cannabis' Schedule I designation directly inhibits its release for medical and scientific research. Madras' testimony on this issue, particularly as a witness who readily admits she has *never* studied cannabis on humans, must be given reduced, if

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[48] *See*, RT 517:9-17, where Dr. Denney read a statement into the record made by Dr. Igor Grant, head of the California Center for Cannabis Research, a research center funded by California statute for the specific purpose of coordinating "rigorous scientific studies to assess the safety and efficacy of cannabis and cannabis compounds for treating medical conditions"; *see also,* Def. Exh. F-9, Denney: Grant et al. 2012. *Medical marijuana: Clearing away the smoke*. The Open Neurology Journal 6: 18-25.

[49] Directly contradicting the pervasive theme of Dr. Madras' testimony, and every single one of the other witnesses' testimony, she claims that "[t]here is tantalizing good evidence that [cannabinoids] do have a medical benefit," and that the only thing missing from the field of evidence is the "consequence of keeping a person on daily marijuana use, or daily cannabindoids, for extended periods of time." (RT 689: 15-20.) Not only does such a statement clearly admit that the medical and scientific research does indeed exists as to cannabis, despite its Schedule I designation, but it further admits that both Dr. Madras and the FDA's position to the contrary is based on something *other than* the volumes of medical and scientific research at Dr. Madras' own fingertips.

[50] *See*, Exhibit A to Dr. Madras' Supplemental Declaration (Doc. 366-1), where she wrote a White House "highly skilled media trainer" converted her to a "rapid-fire, passionate, sound-bite delivery system" for the purpose of driving policy and politics during her time as an employee of the executive branch.

any, weight, in the face of the directly contradictory testimony of the other witnesses, particularly Dr. Hart who is one of the few researchers in this Nation tasked with obtaining cannabis from the single source, NIDA, and personally administering thousands of doses to human subjects for rigorous scientific study.

Dr. Madras adhered to the notion that marijuana must be good for all in order to be considered medicinal when she testified the clinical trials evaluating the medical use of cannabis were flawed because the subjects had previously used cannabis, and therefore the FDA would not approve cannabis as a medicine because the trials failed to establish a therapeutic benefit for the general population.

When asked ". . just because somebody used cannabis doesn't mean they're not worthy of treatment." Dr. Madras testified:

> You're absolutely right, except for one thing. If this is a medicine that's to be widely used and accepted, and let's say, approved by the FDA, or rescheduled, it would assume that anybody on this – in this country should have access to it. (RT:638:11-18.)

She also stated:

> If it's a medicine, it should be a medicine that's applicable to the majority of the population who could benefit. (RT 649:18-20.)

When asked why she thought it sufficient to rely on *preclinical* data when testifying regarding the potential *harm* of marijuana, but that randomized double-blinded placebo controlled clinical trials were insufficient when considering the *medical benefits,* she testified:

> Because every person in those randomized controlled trials is an experienced marijuana user, and so distinguishing pain sensations from psychoactive effects of marijuana could be questionable.
>
> And, also, is this generalized to the population as a whole. If only 20 percent of people with HIV/AIDS used marijuana for relief, if only 20% use it for fibromyalgia, if only 20% use it for multiple sclerosis, what about the other 80 percent who have not used it? (RT 769:4-19.)

Dr. Madras conceded, however, the FDA has no requirement that Phase III clinical trials be conducted with naive users (RT:701:7-10), and in fact not a shred of evidence was introduced to support her odd conclusion (which was also notably contrary to the testimony of an actual researcher, Dr. Hart.) (RT 139:14-16, RT 347: 18-22.),

After much discord regarding what would qualify as a "gold standard" Phase III clinical

trial, Dr. Madras concluded there were "more than five, possibly less than ten, maybe a few more, not many more" regarding cannabis at the present time. (RT 703:16-17.) It is, however, apparent that such studies are more than sufficient for FDA approval of other substances, as indicated in the application to the FDA for approval of dranabinol, as Marinol was approved for two separate indications based on one Phase III clinical trial for each indication.[51] Further, as demonstrated by the Downing study, 188 new drugs were approved by the FDA Review between 2005 and 2012, and the median number of clinical trials per indication was just two.[52] Furthermore, 37% were approved after only one clinical trial. *Id.* Again, Dr. Madras' opinion simply do not conform to the evidence.

In conclusion of this section, the evidence adduced at the hearing established that cannabis does indeed have numerous therapeutic applications and also controverted Dr. Madras' adherence to policies *not* grounded in evidence. Importantly, her insistence that no long term studies exist regarding the effect of cannabis in treating various illnesses was challenged when she was asked about the IND program during which patients were treated with medical cannabis for decades with positive health improvements and minimal ill effects. (RT 787-790.) And finally, her position flatly ignores the reality: marijuana has been used for centuries, and is likely the most studied plant in history. As such, the defendant has met his burden as to this factor.

3. Defendant Met His Burden to Show Evidence Cannabis can Be Safely Used Under Medical Supervision.

The evidence clearly established that cannabis can be, and *is* used safely under medical supervision.

First, the federal government has been providing marijuana to the IND patients for 30 years, and has done so without any medical supervision. (RT 504: 18 - 506: 15.)[53] Dr. Denney

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[51] RT 707-708; Def. Exh. H-61, Armentano Vol. II: FDA printout (2004). Marinol (Dranabinol).

[52] Def. Exh. H-77, Armentano Vol. II: Downing. 2014. *Clinical Trial Evidence supporting FDA Approval of Novel Therapeutic Agents, 2005-2012.*

[53] *See also,* Def. Exh. H-6, Armentano Vol. 1, Russo. 2012. *Chronic Cannabis Use in the Compassionate Investigational New Drug Program: An Examination of Benefits and Adverse Effects of Legal Clinical Cannabis*. Journal of Cannabis Therapeutics, Vol. 2(1) 2002; *see also*, Motion to Dismiss,

testified, "[t]he patients that are enrolled in this program are provided cannabis, through NIDA, from the University of Mississippi, which is the only source." *Id.* In 2012, researcher Ethan Russo and his colleagues performed a "detailed examination of the patients who were in this program," ultimately finding the "[r]esults demonstrate clinical effectiveness in these patients in treating glaucoma, chronic musculoskeletal pain, spasm and nausea, and spasticity of multiple sclerosis. All four patients are stable with respect to their chronic conditions, and are taking many fewer standard pharmaceuticals than previously." (RT 507: 7- 24; Def. Exh. H-6, p. 5.) Importantly, neither NIDA nor the FDA, both of whom participated in administering the IND program, did not find it necessary to closely supervise the participants' cannabis use since the program began in November of 1976, *almost four decades*.

Second, the Executive Branch also implicitly admitted that "strong and effective regulatory and enforcement systems" are sufficient to establish that cannabis may be safely used with minimal supervision in its 2013 "Cole Memorandum." (Def. Exh. J.) This is particularly important because the DOJ itself did not mandate supervision, medical or otherwise, as a requisite for the State regulation of cannabis distribution, evidencing again that cannabis simply does not fit this criteria by their own conduct.

Third, the evidence covered numerous studies in which it was established that cannabis may be used safely under medical supervision. (*See*, e.g., "Cannabis Induces a Clinical Response in Patients with Crohn's Disease: A Prospective Placebo-Controlled Study," where the Israeli researchers administered smoked whole-plant cannabis to Crohns's patients, and determined the cannabis "produced significant clinical, steroid-free benefits." (Def. Exh. H-17, Armentano Vol. 1.)[54]

This finding is consistent with Dr. Hart's testimony that cannabis use can be safely supervised, an opinion he based on his experience of "personally, giv[ing] thousands of doses of marijuana under these conditions where we have physicians and nurses and so forth." (RT Doc. 199, p. 26: 8-13.)

[54] RT 409: 12-19; 513: 4 - 514: 24; *see also*, Def. Ex. H-17, Denney Binder.

165:16-166:2; *see also,* Hart Decl., Doc. 313, ¶ 13-21.) It is this personal experience of supervising thousands of humans under the influence of cannabis that gives him a unique qualification to opine that "marijuana can be safely administered under the... supervision of a doctor," unlike Dr. Madras who readily admits she has never supervised a patient. (RT 620:14-18.)

Finally, Dr. Denney's testimony was particularly important on this point, as he was a practicing physician who spent over 10 years focused on medical cannabis treatment. Dr. Denney's supervision was in full compliance with the requirements put forth by the California Medical Board.[55]

While the prosecution insinuated that Dr. Denney's yearly supervision was insufficient because of "the implications of long-term use of marijuana," Dr. Denney testified that he understandably did not feel he needed to supervise his patients as closely as, for instance, a physician recommending opiate use for the following reasons, established throughout his testimony. (RT 390:18-391:10) He noted that physicians supervising cannabis use are in a position unique to this particular substance; unlike those who supervise the use of other Schedule I substances such as opiates, death due to acute cannabis overdose is *physically impossible* due to the manner in which cannabinoids bind to receptors in the body. (RT 501:6-7; 384:21; RT 625:1-13.) The Government's own witness supported Dr. Denney's statement that, "[t]here has never been a recorded overdose death for cannabis, ever." *Id.; see also,* RT 801:20-25, "nobody dies acutely from a marijuana overdose nobody dies acutely from a marijuana overdose, other than the possibility of heart attack, is that there are no cannabinoid receptors in the brainstem that control heart rate and respiration.")

Furthermore, Dr. Denney, who worked as an emergency room physician for over a

[55] The Government solicited testimony designed to make it appear that Dr. Denney was handing out recommendations like Halloween candy. It should, however, be noted that when he agreed to have previously testified that it was his goal to not have to turn any one away, and that he recommend cannabis to 90% of patients who came to him, he was not asked about the context in which that previous testimony was made. RT 325-326 RT 345:24-25. A review of Government's Exhibit 102, clarifies that the Doctor had been explaining his office screening process, and immediately preceding the sentence regarding his "goal," he stated: "so when I have to turn someone away, that means we did not do a good enough screening job and so – We try as a goal not to have to turn anyone away." *Id*., at p. 121:18-21.

decade, and went on to supervise the medical use of cannabis in approximately 12,000 Californians for another decade, was *never* once presented with or made aware of a cannabis overdose in the emergency department. (RT 485:13-25.) Nor can it be ignored that cannabis has been approved for medical use in California for almost two decades, and was subsequently approved for such use in 19 other States, and the District of Colombia. (Motion to Dismiss, Doc. 199, p. 25, *fn. 31*.) With such vast numbers of Americans using cannabis, not one single lethal overdose of marijuana or serious adverse consequence has ever been reported by the supervising physicians in any of these states, nor throughout history. (RT 384: 21; 501:6-7.)

Although the Government attempted to allege cannabis could not be safely used under medical supervision because of issues with standardized dosage, any possible problems involved in dosing is directly related to its Schedule I status that forecloses the large-scale studies purportedly required by the FDA, at least as to this particular substance. (RT 430:12-20; 513:21-514:9, 15-24.) This circular logic: that a Schedule I designation is appropriate because the FDA has not set forth standard dosing guidelines, which is impossible *due to* its Schedule I status, was unquestionably controverted at the evidentiary hearing, as it became clear, "[t]he dose that patients take to provide benefit for their symptoms tends to remain pretty uniform," "because the patients titrate their dose. So, if you get higher quality cannabis, you use less of it. If you have lower quality cannabis, you have to use a little more of it." (RT 437:10-19.) Indeed, the evidence supported that self-titration is common to the administration of most medications, including asthma medicines, anti-inflammatories, and in *each* of the over-the-counter medications discussed in Dr. Denney's written direct examination. (RT 486:12-20; *see also*, Denney Decl., Doc. 312, ¶ 7-18.) Dr. Denney repeatedly noted that self-titration of cannabis is a far lesser problem than that occurs with opiates, for example, as:

> [C]annabis is rarely taken in increasingly larger amounts by patients who is it medicinally... [T]hey determine a dose level that meets their needs, and they typically – that stays very constant for a long time.... [Patients] smoke as much as they need and then they stop. This is what happens. This is how its used. RT 370:23-371:2; RT 440:21-

442:10.[56]

In sum, the evidence is undisputable: cannabis can and has been used safely under medical supervision for decades.

IV. FEDERAL GOVERNMENT ACTIONS TAKEN SINCE THE FILING OF THIS MOTION FURTHER DEMONSTRATING THE IRRATIONALITY OF THE CHALLENGED LAW.

As noted above, in December, 2014, Congress passed their annual appropriations bill for fiscal year 2015, entitled the Consolidated and Further Continuing Appropriations Act, 2015 (*H.R. 83,* Congressional Session 2014-2015), signed into law by the President on December 16, 2014.[57] *Section 538* of this new law contains *Section 538* declares:

> 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.

This statute not only codifies the Administration's State-based enforcement policies shielding medical cannabis distributors from prosecution based upon the State in which they conduct business, but also expressly recognizes the existence of marijuana as medicine.[58]

Of great significance is the fact that the statute uses the words "medical marijuana," without caveat or limitation. This Court must query how it is Congress can justify a finding that marijuana has no medical benefit while demanding that the distribution of medical marijuana be

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[56] *See also,* RT 443:25-444:3, comparing dosing of cannabis with opiates, as "the package insert says for opiates; you know, use great care, use great caution when using this drug until you know how it affects you"; RT 502: 7-11, "patients who use opioids, because of their inherent toxicity and potential for overdose, do require a bit more caution. I think that most physicians who would use opioids keep -- keep track of refills, and so forth"; RT 439:19-22 "this close monitoring of dosage, I think, is – has no bearing on this, because this is a non-toxic drug, it doesn't hurt people."

[57] See, Def. Exh. WW, attached hereto. Also located online at: https://www.congress.gov/amendment/113th-congress/house-amendment/748/actions.

[58] These Administration policies include: U.S. Department of Justice marijuana-related memoranda, issued on August 29, 2013, and February 14, 2014 (Defense Exhibit J and K, respectively), as well as the U.S. Department of the Treasury cannabis-related memorandum issued on February 14, 2014 (Defense Exhibit L.)

protected from federal government interference. This is not only irrational, it is absurd.

Without doubt the passage of *Section 538* runs afoul of the concern raised by the Ninth Circuit Court of Appeal in James v. City of Costa Mesa, 700 F.3d 394 (9th Cir. 2012), where the Court held that there was no disparate treatment between California and Washington D.C., because the federal government applied federal prohibition in both jurisdiction. The Circuit Court noted:

> [T]he unambiguous *federal* prohibitions on medical marijuana use set forth in the CSA continue to apply equally in both jurisdictions, as does the ADA's illegal drug exclusion. There is no unequal treatment, and thus no equal protection violation. *Id.,* at 405, emphasis in original.

It can no longer be said that the federal government applies federal law evenly among local jurisdictions. For *Section 538* of the Continuing Appropriations Act (2015) specifically prohibits federal law from being applied equally in all jurisdictions by cutting off funding for enforcement of marijuana laws in specified states, and the District of Columbia.

Additionally, in a memo released on December 11, 2014, the Department of Justice outlines new policies allowing American Indian tribes to grow and sell marijuana on reservation lands.[59] Also, of note is the fact that in the November 2014 elections, the states of Alaska and Oregon passed laws legalizing cannabis, as did the District of Columbia.

Although *Section 538* is unassailable evidence of disparate enforcement of the CSA as to cannabis, this Court should also consider the testimony of Jennie Stormes and Sergeant Ryan Begin. Most notably, Jennie Stormes testified that she was required to move her family across the country in order to live in Colorado, a state in which she is able to obtain medical cannabis to treat her son's Dravet Syndrome, a rare and debilitating form of epilepsy. (*See*, Supplemental Declaration of Jennie Stormes, Doc. 368-1, ¶ 3-4.) Sgt. Begin, injured in battle defending our Nation, asked, "[a]s I am about to be married and my family and life are in Maine, should I be expected to move half way across the country in order to ensure I receive the medical treatment I earned the right to expect? (*See*, Direct Examination of Sergeant Ryan Begin, Doc. 309, at ¶ 13.)

[59] *See*, Def. Exh. XX, attached hereto.

V. THE GOVERNMENT CONDUCT IMPERMISSIBLY VIOLATES EQUAL SOVEREIGNTY.

The defendant met his burden establishing a disparate state-based enforcement of the CSA as to cannabis. While the Court raised some concern regarding the application of the doctrine of equal sovereignty in areas regulated under Congress' commerce power, such a limitation is not in play here because the challenged legislation is an extraordinary intrusion into an areas of law "the Framers of the Constitution intended the States to keep for themselves," such as the power to regulate elections at issue in Shelby County v. Holder, 570 U.S. ___ , 133 S. Ct. 1612, 2623 - 2624 (2013). Indeed, the *primary* authority for defining the criminal law is vested first in the States, as the Framers declined to grant any police power in the federal government in our system of enumerated powers. *See*, *inter alia*, United States v. Lopez, 514 U.S. 549, 561, *fn* 3 (1995), "[s]tates possess primary authority for defining and enforcing the criminal law."[60] Additionally, it is well settled that the practice of medicine, the regulation of controlled substances, and other laws relating to the health and welfare of citizens are each matters traditionally left to State regulation. *See*, Gonzales v. Oregon, 546 U.S. 243, 270 (2006), "the structure and limitations of federalism... allow the States great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons"; Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996), "[*t]hroughout our history* the several States have exercised their police powers to protect the health and safety of their citizens," emphasis added; Metropolitan Life Ins. Co. v. Massachusetts, 471 U.S. 724, 756 (1985),[61] "[t]he States traditionally have had great latitude under their police powers to legislate as "to the protection of the lives, limbs, health, comfort, and quiet of all persons," relying on the Slaughter-House Cases, 16 Wall. 36, 62 (1873); Hillsborough County v. Automated Medical Laboratories, Inc., 471 U.S. 707, 719 (1985), regulation of health and safety is "primarily, and

[60] Lopez, *supra*, quoting Brecht v. Abrahamson, 507 U.S. 619, 635 (1993). Additionally, that the police power, particularly as to cannabis, rests in the State, is expressly admitted by the Government in its 2013 "Cole Memo," noting "the federal government has traditionally relied on state and local law enforcement agencies to address marijuana activity through their own enforcement." (Defense Exhibit, J, p. 2.)

[61] Overruled in part by statute on unrelated grounds.

historically, a matter of local concern"; Jacobson v. Massachusetts, 197 U.S. 11, 25 (1905), the United States Supreme Court "has distinctly recognized the authority of a State to enact... health laws of every description."[62]

Importantly, the areas of law implicated here represent a far greater imposition into traditional state regulation than the election laws implicated in Shelby County, *supra*, where Congress' power to regulate was *expressly* vested in Congress by the Fifteenth Amendment, which prohibits any abridgement of one's right to vote on account of race, color, or previous condition of servitude and, importantly, delineated to Congress the "power to enforce this article by appropriate legislation." *See, U.S. Const. Amend. XV*; South Carolina v. Katzenbach, 383 U.S. 301, 307 (1966), *generally*. Here, however, the federal power to regulate cannabis was not given by any express grant of authority as in Shelby County, nor was it even initially clear which (if any) authority empowered Congress to regulate intrastate medical cannabis, as that question was not answered until 2005 in Gonzalez v. Raich, 545 U.S. 1 (2005), which was found in the commerce power, filtered further through the Necessary and Proper Clause. *See generally, U.S. Const. Art. I, § 8, cl. 18*; Raich, 545 U.S. at 22.

This distinction is critical to the instant analysis, as authority to regulate voting under the Reconstruction Amendments, such at the 15th Amendment, was enacted for the purpose of *limiting* the State authority to regulate its own elections, whereas the 10th Amendment was purposed to limit federal overreach. *See*, Gregory v. Ashcroft, 501 U.S. 452, 468 (1991), citing City of Rome v. United States, 446 U.S. 156, 179 (1980).[63] The Ashcroft Court noted that federalism concerns are *reduced,* rather than heightened, in legislation enacted to carry out the Reconstruction Amendments, whereas the commerce power is unquestionably limited by *U.S.*

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[62] "The historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 203 (1947). In the case of the Controlled Substance Act, Congress manifested an intent *not* to preempt State drug laws by way of *21 U.S.C. § 903*, which states: "[n]o provision of this title shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State."

[63] Superceded by statute, as noted in Northwest Austin Mun. Util. Dist. No. One v. Holder, 557 U.S. 193, 209 (2009).

Amend. X, the very authority under which the instant Equal Sovereignty challenge arises:

> The principles of federalism that constrain Congress' exercise of its Commerce Clause powers are attenuated when Congress acts pursuant to its powers to enforce the Civil War Amendments. This is because those Amendments were specifically designed as an expansion of federal power and an intrusion on state sovereignty.

Id., internal quotations omitted; *see also,* City of Rome, 446 U.S. at 179-80, "[w]e agree with the court below that... principles of federalism *that might otherwise* be an obstacle to congressional authority are necessarily overridden by the power to enforce the Civil War Amendments," emphasis added.

As such, the policing power and authority to regulate medicine, health and welfare areas the Framers intended the States keep for themselves and the federal intrusion into such matters indeed constitutes a *greater* imposition into those "sensitive areas of state and local policymaking" than was the regulation at issue in Shelby County, enacted pursuant to its express authority to *limit* the States. Thus, the disparate intrusion here is properly considered a more extraordinary exercise of federal power, and this Court may enforce the doctrine of equality of the States upon which the structure of this Nation is founded.

VI. APPLICABLE LEVEL OF SCRUTINY

A. Strict Scrutiny Review for Suspect Class

The United States Supreme Court has long held strict scrutiny analysis must abide wherever members of a suspect class show: (1) a discriminatory intent was a "motivating factor" in enacting the challenged law, and (2) the law has a disparate impact on a suspect class. Village of Arlington Heights v. Metro. Hous. Dev. Corp., 429 U.S. 252 (1977); Department of Agriculture v. Moreno, 413 U.S. 528 (1973). In addition, a discriminatory intent need not be the only, or even ultimate, purpose for the law. Personnel Administrator of Massachusetts v. Feeney, 442 U.S. 256, 279 (1979); Village of Arlington Heights, *supra*, 429 U.S. at 265-266. Rather it need only be a motivating factor in the selection *or* reaffirmation of a "particular course of action at least *in part* because of, not merely in spite of, its adverse effects upon an identifiable group. Feeney, *supra,* 442 U.S. at 279, emphasis added. Further, courts may infer a discriminatory purpose where a totality of circumstances, including a disparate impact, evidence a discriminatory intent. Washington v. Davis, 426 U.S. 229, 240 (1976). The defense contends that the direct testimony of James Nolan, Ph.D., supports a finding that strict scrutiny applies in

this case.

B. Active Rational Basis Review

Recent Supreme Court opinions have made clear the rational basis standard of review is not a meaningless exercise, particularly in the context of Equal Protection challenges based upon disparate treatment of the States, such as those here presented, where the structure of the government itself (Equal Sovereignty) informs the right-based analysis (Equal Protection). (*See*, Shelby County v. Holder, 133 S. Ct. 2612 (2013) (voting), and United States v. Windsor, 133 S. Ct. 2675, 2693 (2012) (marriage). In Windsor, *supra*, Justice Kennedy employed a considered rational basis review focusing on whether "[d]iscriminations of an unusual character especially require careful consideration." *Id.*, citing Romer v. Evans, 517 U.S. 620 (1996) (sexual orientation), applying a heightened rational basis review; *see also,* Massachusetts v. United States Health & Human Services Agency, 682 F.3d 1, 11-12 (1st Cir. 2012) (marriage), "Supreme Court precedent relating to federalism-based challenges to federal laws reinforce the need for closer than usual scrutiny."

In Romer, *supra*, 517 U.S. 620 (1996), the Supreme Court set the stage for the application of a heightened rational basis review where a Colorado state constitutional amendment prohibited all legislative, executive or judicial action classifying homosexual persons as a protected class. *Id.* at 624. Although the State of Colorado proffered various arguments to show the amendment was narrowly tailored to serve compelling interests, the Supreme Court applied the mere rational basis standard, and found the amendment failed even this deferential review. *Id.* at 631, 632. In so holding, the high Court noted:

> Even in the ordinary equal protection case calling for the most deferential of standards, *we insist on knowing the relation between the classification adopted and the object to be attained.* The search for the link between classification and objective gives substance to the Equal Protection Clause; it provides guidance and discipline for the legislature, which is entitled to know what sorts of laws it can pass; and it marks the limits of our own authority. *Id.* at 632, emphasis added.

Since 2012, however, the Supreme Court has employed this active review in cases where legitimate, and even compelling, governmental interests have been proffered. Relying on Romer, *supra*, and Department of Agriculture v. Moreno, 413 U.S. 528 (1973), both Equal Protection

cases that applied a heightened rational basis review, the Windsor Court interwove the structural argument of federalism with the rights-based challenge under Fifth Amendment, holding:

> The States's decision to give this class of persons the right [in issue] conferred upon them a dignity and status of immense import. When the State used its historic and essential authority to define [that right] in this way, its role and its power in making the decision enhanced the recognition, dignity, and protection of the class in their own community. Windsor, *supra*, at 2692.

The Supreme Court again employed a heightened review in Shelby County v. Holder, *supra*, where the "rational basis with a bite" test was applied, even though the government presented arguably compelling reasons to differentiate between the States. As both Windsor and Shelby County involved an Equal Protection challenge premised in part on disparate treatment between the states, the high Court demanded the government present evidence to support a rational basis, rather than merely deferring to some possible conceivable interest (or, as in Windsor, a compelling interest). So too should this Court.

C. Defendant Prevails Under Rational Basis Review.

"[E]ven the standard of rationality as we so often have defined it must find some footing in the realities of the subject addressed by the legislation." Heller v. Doe, 509 U.S. 312, 321 (1993).

Even under rational basis review, however, the Government can not assert contradictory justifications in response to the defendant's constitutional claims. As the Ninth Circuit has stated contradictory rationales will defy a rational basis. In Merrifield v. Lockyer, 547 F.3d 978 (9th Cir. 2008), the Court held, "the government has undercut its own rational basis" by asserting a rationale as to one claim that controverted their rationale as to another claim in a manner so contradictory that it "undercuts *the principle of non-contradiction* [and] fails to meet the relatively easy standard of rational basis review."[64] *Id.* at p. 991-992.

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[64] This "principle of non-contradiction" relied upon in Merrifield is derived from Aristotle, the father of deductive reason, in *Metaphysics IV* (English translation located online at http://dhspriory.org/thomas/Metaphysics4.htm#4), and works to prevent the Government from asserting a rationale as to the Equal Sovereignty claim that contradicts any asserted as to the distinct Equal Protection challenges.

Thus far, the prosecution strategy in defending against this Motion has been an attempt to discredit the overwhelming medical and scientific evidence demonstrating that cannabis' Schedule I designation is no longer footed in reality. Thus, in order to prevail over the defendant's distinct Equal

In the present case, it is impossible for the Government to justify the legislation and policies which allow, and indeed promote, the widespread distribution of "medical marijuana," while at the same time defending its status as one of the most dangerous drugs in the nation, which by definition means it has no medicinal qualities. Additionally, the evidence presented at the hearing held in this matter clearly demonstrates that the classification of marijuana as a Schedule I controlled substance has no footing in the realities of preventing the use of substances which have a *high* potential for abuse, *no* use in medical treatment, and *lacks* accepted safety for use under medical supervision, as is the subject addressed in *21 U.S.C 812(b)(1)*. Further, the Government cannot articulate a policy justification for the classification of marijuana as one of the most dangerous drugs in the nation when their own policies facilitate its distribution, and their own statutes recognize its medical value.

VII. CONCLUSION

The foretelling of Gonzalez v. Raich, 545 U.S. 1, 28 *fn* 37 (2005), that someday evidence may "cast serious doubt on the accuracy of the findings that require marijuana to be listed in Schedule I" is now realized. Accordingly, regardless of the level of scrutiny applied, *21 U.S.C. Sections 812, Schedule I (c)(10), (17)*, as applied through *21 U.S.C. Sections 841, 846*, as charged here, must be found unconstitutional for the foregoing reasons, and in the interests of the justice so clearly denied by the current Schedule I designation, based not in science, nor medicine, and utterly unsupported by the Government's own conduct.

Dated: January 5, 2015

Respectfully submitted,

/s/ Zenia K. Gilg
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HEATHER L. BURKE
Attorneys for Defendant
BRIAN JUSTIN PICKARD

Sovereignty challenge, they must reconcile their asserted justification that cannabis may rationally be considered the most dangerous drug in the Nation with any justification that it is *at the same time* deserving of lessened enforcement in those States where cannabis distribution has proliferated. To be sure, no such justification is conceivable, as any rationale as to the latter claim would be inherently contradict and defy the our canons of the deductive reasoning and rationality upon which our system of law is premised.

Exhibit WW

DECEMBER 9, 2014

RULES COMMITTEE PRINT 113-59

TEXT OF HOUSE AMENDMENT TO THE SENATE AMENDMENT TO H.R. 83

[Showing the text of the Consolidated and Further Continuing Appropriations Act, 2015]

In lieu of the matter proposed to be inserted by the Senate, insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Consolidated and Further Continuing Appropriations Act, 2015''.

SEC. 2. TABLE OF CONTENTS.

The table of contents of this Act is as follows:

(b) Nothing in subsection (a) shall limit the use of funds necessary for any Federal, State, tribal, or local law enforcement agency or any other entity carrying out criminal investigations, prosecution, or adjudication activities.

SEC. 535. The Departments of Commerce and Justice, the National Aeronautics and Space Administration, and the National Science Foundation shall submit spending plans, signed by the respective department or agency head, to the Committees on Appropriations of the House of Representatives and the Senate within 45 days after the date of enactment of this Act.

SEC. 536. None of the funds made available by this Act may be obligated or expended to implement the Arms Trade Treaty until the Senate approves a resolution of ratification for the Treaty.

SEC. 537. None of the funds made available by this Act under the heading ''Pacific Coastal Salmon Recovery'' may be used for grant guidelines or requirements to establish minimum riparian buffers.

SEC. 538. 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, Mis-

sissippi, 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.

SEC. 539. 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. 540. (a) None of the funds made available by this Act may be used to relinquish the responsibility of the National Telecommunications and Information Administration during fiscal year 2015 with respect to Internet domain name system functions, including responsibility with respect to the authoritative root zone file and the Internet Assigned Numbers Authority functions.

(b) Subsection (a) of this section shall expire on September 30, 2015.

SEC. 541. (a) IN GENERAL.—During the period beginning on January 1, 2015, and ending on December 31, 2015, the provisions of chapter 3 of title II of the Trade Act of 1974 (19 U.S.C. 2341 et seq.), as in effect on December 31, 2014, shall apply, except that in applying and

Exhibit XX

U.S. Department of Justice

Executive Office for United States Attorneys

Office of the Director

Room 2261, RFK Main Justice Building
950 Pennsylvania Avenue, NW
Washington, DC 20530

(202) 252-1000

MEMORANDUM - Sent via Electronic Mail

DATE: OCT 2 8 2014

TO: ALL UNITED STATES ATTORNEYS
ALL FIRST ASSISTANT UNITED STATES ATTORNEYS
ALL CRIMINAL CHIEFS
ALL APPELLATE CHIEFS
ALL OCDETF COORDINATORS
ALL TRIBAL LIAISONS

FROM: Monty Wilkinson
Director

SUBJECT: Policy Statement Regarding Marijuana Issues in Indian Country

ACTION REQUIRED: None. Information Only.

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With a number of states legalizing marijuana for use and production, some tribes have requested guidance on the enforcement of the Controlled Substance Act (CSA) on tribal lands by

the United States Attorneys' offices. With these requests in mind, the Attorney General's Native American Issues Subcommittee has reviewed the Memorandum from the Deputy Attorney General, dated August 29, 2013, regarding marijuana enforcement ("Cole Memorandum") and considered its impact on Indian Country.

The Cole Memorandum provides guidance to United States Attorneys on the proper prioritization of marijuana enforcement in their districts given the number of states that have moved to legalize marijuana for medicinal, agricultural, or recreational use. Specifically, the Cole Memorandum lists eight federal law enforcement priorities where the Department will focus its limited investigative and prosecutorial resources in all states. These eight priorities are as follows:

- 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 cover or pretext for the trafficking of other illegal drugs or 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.

The Cole memorandum contains the additional directive that "nothing herein precludes investigation or prosecution, even in the absence of any one of the factors . . . , in particular circumstances where the investigation and prosecution otherwise serve an important federal interest."

Indian Country includes numerous reservations and tribal lands with diverse sovereign governments, many of which traverse state borders and federal districts. Given this, the United States Attorneys recognize that effective federal law enforcement in Indian Country, including marijuana enforcement, requires consultation with our tribal partners in the districts and flexibility to confront the particular, yet sometimes divergent, public safety issues that can exist on any single reservation.

Nothing in the Cole Memorandum alters the authority or jurisdiction of the United States to enforce federal law in Indian Country. Each United States Attorney must assess all of the threats present in his or her district, including those in Indian Country, and focus enforcement efforts based on that district-specific assessment. The eight priorities in the Cole Memorandum will guide United States Attorneys' marijuana enforcement efforts in Indian Country, including in the event that sovereign Indian Nations seek to legalize the cultivation or use of marijuana in Indian Country. Consistent with the Attorney General's 2010 Indian Country Initiative, in

evaluating marijuana enforcement activities in Indian Country, each United States Attorney should consult with the affected tribes on a government-to-government basis. When in the judgment of a United States Attorney, significant issues or enforcement decisions arise that may implicate this policy statement, each United States Attorney should keep the Executive Office for United States Attorneys, the Office of Tribal Justice, and the Office of the Deputy Attorney General informed of those matters, in advance of any determination on how to proceed, in order to keep the Department's leadership apprised of significant issues and to maintain consistency throughout the Department.

cc: All United States Attorneys' Secretaries