UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 17-70162

HEMP INDUSTRIES ASSOCIATION, ET AL.

v.

DRUG ENFORCEMENT ADMINISTRATION, ET AL.

PETITION FOR REVIEW OF RULES
OF DRUG ENFORCEMENT ADMINISTRATION

BRIEF OF PETITIONERS

Patrick D. Goggin, SBN # 182218
Hoban Law Group
870 Market Street, Suite 1148
San Francisco, CA 94102
Telephone: (415) 981-9290

Of counsel:
Robert Hoban (Admitted)
Garrett Graff (Admitted)
Hoban Law Group
730 17th St, Ste 420
Denver, CO 80202

Attorneys for Petitioners

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CORPORATE DISCLOSURE STATEMENT PURSUANT TO RULE 26.1, FEDERAL RULES OF APPELLATE PROCEDURE

Non-governmental corporate Petitioners include Hemp Industries Association; Centuria Natural Foods, Inc.; and, R.M.H. Holdings, Inc. Hemp Industries Association is a trade association. The other Petitioners are privately held corporations, none of them having any parent companies, subsidiaries, or affiliates that have issued shares to the public.

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Hemp Industries Association; Centuria Natural Foods, Inc.; and R.M.H. Holdings, Inc.	)
Petitioners	)
v.	)
Drug Enforcement Administration; Charles Rosenberg, as Acting Administrator, Drug Enforcement Administration	)
Respondents	)

BRIEF OF PETITIONERS

STATEMENT OF JURISDICTION

(a) This is a petition for review of the "Final Rule—Establishment of a New Drug Code for Marihuana Extract," issued by Respondent Drug Enforcement Administration ("DEA") on December 14, 2016, 81 Fed. Reg. 90,194-96 (Dec. 14, 2016) (the "Final Rule"), Excerpts of Record ("ER") at 12-14. The Final Rule apparently flows from the underlying Proposed Rule—Establishment of a New Drug Code for Marihuana Extract, 76 Fed. Reg. 39,039-41 (July 5, 2011) (the "Proposed

Rule"), ER at 9-11, which DEA published more than **five (5) years** before the Final Rule. DEA purported to issue the Final Rule pursuant to the Controlled Substances Act (the "CSA"), 21 U.S.C. §§ 811, 812 & 871(b).

(b) This Court possesses jurisdiction of Petitioners' *Petition for Review* pursuant to 21 U.S.C. §877 (section 507 of the CSA); 5 U.S.C. § 702 (the Administrative Procedures Act ("APA")); and Rule 15 of the Federal Rules of Appellate Procedure. Specifically, section 507 of the CSA, 21 U.S.C. § 877 provides any person aggrieved by the final decision of the Attorney General under the CSA,

> *may obtain review of the decision in the United States Court of Appeals for the District of Colombia or for the circuit in which his principal place of business is located upon petition filed with the court and delivered to the Attorney General within thirty days after notice of the decision.*

21 U.S.C. § 877. Petitioner Hemp Industries Association maintains a principal place of business within California, situated within this Ninth Circuit. Petitioner Centuria Natural Foods, Inc. maintains a principal place of business within Nevada, situated within this Ninth Circuit. The principal place of business of Petitioner R.M.H. Holdings, Inc., a Wyoming corporation, is in the State of Colorado, not within this Circuit; but pursuant to Fed.R.App.P. 15(a)(1), R.M.H.'s interests make joinder to this Petition for Review practicable.

(c) DEA issued the Final Rule on December 14, 2016, to become effective within 30 days, on January 13, 2017. Petitioners timely filed their Petition for Review, ER at 1, on January 13, 2017. 21 U.S.C. §877; Fed. R. App. P. 15(a)(1).

ISSUES PRESENTED FOR REVIEW

1. Is the Final Rule invalid because its assignment of a drug code to "marihuana extract" represents the scheduling of new substances – "marihuana extract" and individual cannabinoids of the *Cannabis sativa L.* plant – in the CSA, despite DEA failing to conduct a formal scheduling action on the record (with proper due process including opportunity for hearing) or having made the specific findings required by the CSA for such scheduling, 21 U.S.C. §811(a)?
2. Is the Final Rule invalid because DEA failed to comply with the 2016 Consolidated Appropriations Act, as extended by the Further Continuing and Security Assistance Appropriations Act, 2017?
3. Is the Final Rule invalid because DEA failed to comply with the Regulatory Flexibility Act?
4. Is the Final Rule invalid because DEA failed to comply with the Congressional Review Act?
5. Is the Final Rule invalid because DEA failed to comply with the Data Quality Act?

STATEMENT OF THE CASE

Petitioners are organizations engaged in the import, cultivation, manufacture, distribution and/or sale of products derived from lawful portions and/or varieties of the *Cannabis* plant, more commonly referred to as non-psychoactive industrial hemp.[1] Notably, over 80 cannabinoids naturally occur within all parts of the *Cannabis* plant.

As previously confirmed by this Ninth Circuit Court of Appeals over a decade ago, certain portions of the *Cannabis* plant are exempt from treatment as controlled substances under the Controlled Substances Act, 21 U.S.C. §§ 802 *et seq*. (the "CSA"). *Hemp Industries Ass'n. v. Drug Enforcement Admin.,* 357 F.3d 1012 (9th Cir. 2004); *Hemp Industries Ass'n v. Drug Enforcement Admin.,* 333 F.3d 1082 (9th Cir. 2003). In accordance with these exemptions, many companies have lawfully imported, manufactured, distributed and sold products containing oils and derivatives from these exempt portions of the plant for decades.

[1] Petitioner Hemp Industries Association ("HIA") is a 501(c)(6) trade association representing approximately 500 farms, non-farm businesses and individuals involved in, or impacted by, the import, cultivation, manufacture, distribution and/or sale of such products lawfully derived from industrial hemp. Petitioners Centuria Natural Foods, Inc. ("Centuria") and R.M.H. Holdings, Inc. ("R.M.H.") are individual corporate petitioners engaged in the same activity.

More recently, Congress universally expanded such exemptions to the entire variety of "industrial hemp" pursuant to the Agricultural Act of 2014, 7 U.S.C. 5940, Sec. 7606 (2014) (the "Farm Bill"); *see discussion infra,* Section I(A)(ii). There, "industrial hemp" is defined as all parts of the *Cannabis* plant below 0.3% delta-9 tetrahydrocannabinol by dry weight. *Id.* Pursuant to the Farm Bill, since 2014, hundreds, if not thousands, of companies across the United States are engaged in the cultivation of industrial hemp as well as the subsequent processing, manufacture, distribution and/or sale of products derived from "industrial hemp." The industrial hemp industry has seen a tremendous spike in commercial activity and an exponential increase in revenue since the enactment of the Farm Bill.

One of the reasons Congress, until 2014, did not distinguish between industrial hemp and psychotropic marijuana is due to technological limitations which existed in 1937 when Congress first defined "marihuana."[2] Because of these technological limitations, Congress then defined "marihuana" broadly, until technological advances allowed for Congress to exempt industrial hemp from

[2] *See* Christen D. Shepherd, *Lethal Concentration of Power: How the D.E.A. Acts Improperly to Prohibit the Growth of Industrial Hemp*, 68 UMKC L. REV. 239, 249–52 (1999) ("describing . . .how ignorance of the role that THC played in the psychotropic properties of marijuana and technological limitations on testing THC levels in the cannabis plants resulted in restrictions that made hemp cultivation 'prohibitively time-intensive'") (as parenthetically summarized by Christine A. Kolosov, *Evaluating The Public Interest: Regulation of Industrial Hemp Under the Controlled Substances Act*, 57 UCLA L. REV. 237, 239 n.10 (2009))

"marihuana," pursuant to the Farm Bill. *Id*; *see also discussion infra*, Section (I)(A)(ii).

Correspondingly, Congress explicitly prohibited federal agencies, including the Department of Justice and, therefore, DEA, from expenditures of any funds in contravention of the Farm Bill, which states:

> *Sec. 763. None of the funds made available by this Act or any other Act may be used--*
> *(1) in contravention of section 7606 of the Agricultural Act of 2014 (7 U.S.C. 5940); or*
> *(2) to prohibit the transportation, processing, sale, or use of industrial hemp that is grown or cultivated in accordance with subsection section 7606 of the Agricultural Act of 2014, within or outside the State in which the industrial hemp is grown or cultivated.*

Consolidated Appropriations Act, 2016, Pub. L. No. 114-113, § 763, 129 Stat. 1175, 2285 (emphasis added), extended by Further Continuing and Security Assistance Appropriations Act, 2017, § 101, 130 Stat. 1005, 1005-06 (2016) (collectively, the Spending Bill"). Accordingly, this prohibition more widely protects industrial hemp nationwide. *Id*.

On December 14, 2016, over five years after issuing its Proposed Rule in 2011 and during which time Congress enacted the Farm Bill, DEA published its "Final Rule—Establishment of a New Drug Code for Marihuana Extract," 81 Fed. Reg. 90,194-96 (the "Final Rule"), ER at 12-14, purportedly assigning a drug code to "marihuana extract." Drug codes are generally assigned to controlled substances in

order for DEA to restrictively authorize and regulate the use of controlled substances. 21 C.F.R. § 1308.03 (1997). However, the CSA does not contain any reference to, and does not define, "marihuana extract." Moreover, the Final Rule schedules the entire *Cannabis* plant, rather than the prohibited portions thereof, and also schedules cannabinoids, which are not controlled *per se*, and that may be derived from a non-*Cannabis* plant or other sources.[3] The DEA even previously

[3] Cannabinoids are known to occur in several plant species besides cannabis. *See generally* Rudolf Bauer et al., CB Receptor Ligands from Plants, 8 Curr. Topics in Med. Chem. 173, 173-86 (2008) (detailing plant species in which cannabinoids are known to occur besides cannabis, including coneflower (Echinacea), oxeye (Heliopsis helianthoides), electric daisy (Acmella oleracea), Helichrysum umbraculigerum, liverwort (Radula marginata), black pepper (Piper nigrum), chocolate (Theobrama cacao) plants, as well as Echinacea purpurea, Echinacea angustifolia, Acmella oleracea, Helichrysum umbraculigerum, and Radula marginata, with lipophilic alkamides (alkylamides) from Echinacea species being the best-known); R. Bauer, P. Remiger, TLC and HPLC Analysis of Alkamides in Echinacea Drugs, 55 Planta Medica 367, 367–71 (1989) (identifying at least 25 different alkylamides, some of which shown affinities to the CB2-receptor); Stefan Raduner et al., Alkylamides from Echinacea Are a New Class of Cannabinomimetics: Cannabinoid Type 2 Receptor-Dependent and -Independent Immunomodulatory Effects, 281 J. of Bio. Chem. 14,192, 14,192-206 (2006) (same); Nigel B. Perry et al., Alkamide Levels in Echinacea purpurea: A Rapid Analytical Method Revealing Differences among Roots, Rhizomes, Stems, Leaves and Flowers, 63 *Planta Medica* 58, 58–62 (1997) (noting that while cannabinoids are found throughout the plant, they are most concentrated in the roots and flowers in some Echinacea species); Xian-guo He et al., Analysis of alkamides in roots and achenes of Echinacea purpurea by liquid chromatography–electrospray mass spectrometry, 815 J. of Chromatography A 205, 205–11 (1998) (same); Allesia Ligresti et al., Kavalactones and the endocannabinoid system: The plant-derived yangonin is a novel CB1 receptor ligand, 66 Pharmacological Research 163, 163–169 (2012); G. Korte et al., Tea catechins' affinity for human cannabinoid receptors, 17 Phytomedicine 19, 19–22 (2010); Jürg Gertsch et al., Beta-caryophyllene is a dietary terpene, 105 Proceedings of Nat'l Academy of

recognized this fact. *See* Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 81 Fed. Reg. 53,688-765, 53,692, 53,698, 53,753 (Aug. 12, 2016) (citing Giovanni Appendino et al., *Cannabinoids: occurrence and medicinal chemistry*, 18 Curr. Med. Chem. 1085 (2011)). Further, this Court previously recognized that naturally occurring tetrahydrocannabinol (THC), a cannabinoid, was never scheduled under the CSA; therefore, the DEA has exceeded its authority. *Hemp Indus. Ass'n. v. DEA,* 357 F.3d 1012, 1014-15, 1018 (9th Cir. 2004).

Thus, the Final Rule operates as a scheduling action versus a mere rulemaking action by DEA. *See generally* CSA, 21 U.S.C. 812. Specifically, the Final Rule purports to schedule "marihuana extract," and all cannabinoids that may be present in any extract from any genus *Cannabis*, for DEA to assign a drug code to such substances. 21 C.F.R. § 1308.03. Significantly, however, DEA did not engage in the appropriate procedures to newly schedule these substances, thereby abusing its authority.

Baselessly, DEA's Final Rule broadly defines "marihuana extract" as, "any extract containing one or more cannabinoids that has been derived from any plant of

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Sciences 9099, 9099–9104 (identifying a common dietary terpene--beta-caryophyllene, a component from the essential oil of cannabis and other medicinal plants--as a selective agonist of peripheral CB2-receptors in living organisms); Giovanni Pcioni et al., Truffles contain endocannabinoid metabolic enzymes and anandamide, 110 Phytochemistry 104, 104-10 (2015).

the genus *Cannabis* . . .” Final Rule, 81 Fed. Reg. at 90,194-96 (*emphasis* added), ER at 12-14. By wrongfully conflating the CSA’s narrow definition of “marihuana” with the entire *Cannabis* plant, this definition of “marihuana extract” wholly fails to reflect the lawfulness of industrial hemp and non-THC cannabinoids derived therefrom.

This Final Rule, made effective on January 13, 2017, has the effect of instantly transforming Petitioners’ long-standing lawful business activities pursuant to the CSA and the Farm Bill into criminal enterprises, pursuant to the DEA’s alleged interpretation of the law. Because drug codes are frequently used by federal, state and local agencies as a simple, *de facto* method to evaluate the legality of a substance in lieu of direct reference to the CSA, DEA’s Final Rule stands to chill the entire legal hemp industry through confusion, misinterpretation and misapplication of law.

Consequently, on January 13, 2017, Petitioners filed the instant Petition for Review, ER at 1, as subsequently amended, petitioning this Court for review of DEA’s Final Rule.

STATEMENT OF FACTS

Industrial hemp is a commonly used term for non-psychoactive varieties of the species *Cannabis sativa L.* which are cultivated for industrial rather than drug purposes. In fact, the founding fathers of the United States drafted the Declaration of Independence and United States Constitution on industrial hemp-derived paper.

Industrial hemp plants presently cultivated in over 30 countries, including France, Germany, Hungary, Canada, China, Russia and now, the United States, are bred to contain less than 0.2 - 0.3 percent by weight of delta-9 tetrahydrocannabinol ("THC") content within the plant. Conversely, marijuana drug varieties are generally bred to contain 3 to 20% THC in the flowering portions of the plant.[4] Due to negligible, if any, THC content, industrial hemp has no potential as a drug of abuse.

As explained *infra*, the statute controlling "marihuana" has, since 1937, excluded at least hemp stalk, fiber, seed and oil, except the resin therefrom.[5] However, in 2014, Congress universally expanded these exclusions to also define and exclude "industrial hemp" from "marihuana."[6] These statutory exclusions enabled U.S. individuals and businesses to legally import, purchase, cultivate, use, manufacture and trade in products derived from industrial hemp. Resultantly, hemp food, oil and fiber products are available throughout the U.S., Canada, the European Union and Asia. These companies dealing in industrial hemp-derived products generally either import such hemp derivatives from the over 30 countries where

[4] This distinction is formally affirmed in Article 28(2) of the United Nations' Single Convention on Narcotic Drugs, 1961, to which the United States is a signatory party, by distinguishing industrial versus drug uses of cannabis. Single Convention, *infra*, at art. 2(9), art. 28(2); Convention on Psychotropic Substances, *infra*, at art. 4(b).

[5] Congress, in the 1970 Controlled Substances Act, directly incorporated the definition of "marihuana" from the 1937 Marihuana Tax Act.

[6] Through Section 7606 of the Agricultural Act of 2014, Congress defined "industrial hemp" and further universally carved the same out from the definition of "marihuana" pursuant to the CSA.

industrial hemp is presently cultivated for use in manufacturing products in the U.S., import already finished products from Canada or Europe, or now, cultivate industrial hemp domestically and manufacture products derived therefrom.

One of the reasons Congress, until 2014, did not distinguish between industrial hemp and psychotropic marijuana is due to the technological limitations which existed in 1937 when Congress first defined "marihuana." Because of these technological limitations, Congress broadly defined "marihuana," until technological advances allowed for Congress to exempt industrial hemp from "marihuana," pursuant to the Farm Bill. *See discussion infra*, Section (I)(A)(ii). Innovations in industrial applications in countries producing industrial hemp are wide-ranging and evolving; hence, Congress' enactment of the Farm Bill.

SUMMARY OF ARGUMENT

DEA, through its Final Rule and other interpretive and directive actions, continuously fails to distinguish between industrial hemp and hemp-derived materials, versus those known as psychotropic marijuana, despite Congress requiring DEA to make these distinctions pursuant to the CSA and the Farm Bill.

Within this Brief, the terms "hemp" and "industrial hemp," used interchangeably, refer to those portions and varieties of the *Cannabis* plant below 0.3 percent THC. Petitioners in this suit take exception to the definition of

"marihuana extract" for two primary reasons: (i) the entire genus *Cannabis* is not unlawful; and, (ii) naturally occurring cannabinoids are not expressly scheduled, come from other plants as well, and are not unlawful *per se*.

(i) The entire genus Cannabis is not unlawful; there are exemptions and express carve-outs under federal law.

The Final Rule fails to recognize that *Cannabis* is not defined as a controlled substance, but rather, "marihuana" is, and there are exempted parts of the plant that are excluded from the definition of marijuana, as set forth in 21 U.S.C. 801(16).

DEA, through its Final Rule, further fails to recognize that the non-exempted parts of the plant (i.e., "marihuana") can be deemed lawful and/or an exception to the CSA if authorized under other federal statutory provisions, such as the 2014 Farm Bill, and the Consolidated Appropriations Act, 2016 (as extended).[7]

(ii) Naturally occurring cannabinoids are not expressly scheduled, and are not unlawful *per se*.

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[7] *See* Agricultural Act of 2014, 7 U.S.C. 5940, § 7606 (2014) (the "Farm Bill") ("Notwithstanding the Controlled Substances Act (21 U.S.C. 801 et seq.), chapter 81 of title 41, or any other Federal law, an institution of higher education (as defined in section 1001 of title 20) or a State department of agriculture may grow or cultivate industrial hemp...."). *See also* Consolidated Appropriations Act, 2016, Pub. L. No. 114-113, § 763, 129 Stat. 1175, 2285 (emphasis added), extended by Further Continuing and Security Assistance Appropriations Act, 2017, § 101, 130 Stat. 1005, 1005-06 (2016) (collectively, the Spending Bill") ("None of the funds made available by this Act or any other Act may be used-- (1) in contravention of section 7606 of the Agricultural Act of 2014 (7 U.S.C. 5940); or (2) to prohibit the transportation, processing, sale, or use of industrial hemp that is grown or cultivated in accordance with subsection section 7606 of the Agricultural Act of 2014, within or outside the State in which the industrial hemp is grown or cultivated.").

The Ninth Circuit has already found that at least one naturally occurring cannabinoid (THC) was lawful so long as it is not derived from "marihuana" or unlawful/unapproved parts of the plant. *Hemp Industries Association v. DEA*, 357 F.3d 1012 (9th Cir. 2004) ("HIA II"). The Court held there that a cannabinoid which comes from exempted parts of the plant is not a controlled substance under the CSA; this is because Congress did not specifically schedule such components. *Id.* Accordingly, the presence of one or more cannabinoids is decidedly not the determining factor as to whether something is a controlled substance or not, and the CSA neither implies or provides otherwise.

The same rationale applies to all naturally occurring cannabinoids that are derived from exempted or otherwise approved parts of the cannabis plant. Combined with the fact the CSA fails to address naturally occurring cannabinoids in any way -- naturally cannabinoids are not even mentioned in the CSA -- further bolsters the point that naturally occurring cannabinoids are not controlled substances, unless they come from a nonexempt part of the plant, or are not authorized under other federal law. Moreover, cannabinoids are not exclusively derived from the *Cannabis* plant, and are not otherwise scheduled.

In short, the notion that naturally occurring cannabinoids from exempted parts of the plant or as authorized under other federal law (even if from other plants, or other than exempted parts of the plant under the CSA, e.g., the Farm Bill) are

controlled substances is false and misleading; Congress would have to specifically schedule naturally occurring cannabinoids, and it has not.

At a bottom line, the Final Rule must be stricken, and enforcement thereof enjoined, accordingly, as it does not follow federal law. In order for the Final Rule to comply with federal law, and to pass muster under this Court's analysis, the definition needs to state something similar to the following:

> Marihuana Extract - "Meaning an extract that has been derived from any portion of the genus Cannabis which is expressly defined as "marihuana" under 21 U.S.C. 801(16), other than the separated resin (whether crude or purified) obtained from the plant. This drug code includes only those extracts that fall within the CSA definition of "marihuana," but does not include materials or products that are excluded from the definition of "marihuana" set forth in under 21 U.S.C. 801(16), or any other federal law which authorizes the cultivation, sale, transportation, production, processing, manufacture, and/or use of "marihuana" or "industrial hemp" (e.g., 7 U.S.C. 5940, "the Farm Bill").

Because the Final Rule does not comport with language similar to the above, which tracks the law, the Final Rule must be stricken, invalidated, and enforcement thereof enjoined.

ARGUMENT

I. DEA'S FINAL RULE REGARDING "MARIHUANA EXTRACT" IS AN ATTEMPTED SCHEDULING ACTION IN VIOLATION OF THE CONTROLLED SUBSTANCES ACT

Unequivocally, DEA's Final Rule equates to a scheduling action regarding "marihuana extract" and cannabinoids derived from the genus *Cannabis*, despite DEA entirely lacking the requisite authority. DEA and its Final Rule fail to

distinguish between industrial hemp and psychotropic marijuana, despite the CSA and, most recently, the Farm Bill, requiring DEA to do so. *See* Final Rule—Establishment of a New Drug Code for Marihuana Extract, 81 Fed. Reg. 90,194-96 (Dec. 14, 2016), ER at 12-14; *c.f.* Controlled Substances Act, 21 U.S.C. 801 *et seq*. (2014) (the "CSA"); Agricultural Act of 2014, 7 U.S.C. 5940, § 7606 (2014) (the "Farm Bill"). The Final Rule seeks to assign a drug code to "marihuana extract," which includes all cannabinoids derived from any genus *Cannabis*, where DEA is only authorized to assign drug codes to controlled substances. *See* 21 C.F.R. § 1308.03. Fundamentally, the Final Rule's definition of "marihuana extract" is flawed due to its reference to the presence of cannabinoids as unlawful and failure to reflect lawful portions and varieties of the *Cannabis* plant.[8]

[8] In addition to adhering to its scheduling authority, DEA must comply with the rulemaking procedures within the Administrative Procedures Act. 21 U.S.C. § 811(a). The Administrative Procedures Act, 5 U.S.C. § 500, *et seq*., allows a reviewing court to "hold unlawful and set aside agency action, findings and conclusions," if the reviewing court finds the agency action to be:

> (A) *arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law*;
> (B) contrary to constitutional right, power, privilege, or immunity;
> (C) *in excess of statutory jurisdiction, authority, or limitations, or short of statutory right*;
> (D) *without observance of procedure required by law*;
> (E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or
> (F) unwarranted by the facts to the extent that the facts or subject to trial de novo by the reviewing court.

Moreover, in the event a substance is not yet contained within the CSA's five schedules, DEA may not newly place a substance in any schedule unless certain required findings are made and certain due process opportunities are provided by DEA. *See* CSA, 21 U.S.C. 812(b). Here, in promulgating the Final Rule, DEA failed to appropriately satisfy the designated procedures to newly schedule a substance not previously scheduled. Even if DEA attempted to follow the appropriately designated procedures, DEA could not make the specific factual findings necessary to confirm a scheduling action. *Id*. Instead, in an attempted circumvention of the CSA, DEA vaguely cited obligations under international treaties as the basis of its actions, obligations that the United States met long ago. Regardless, DEA's actions also fail to appropriately follow the designated procedures to cite international treaty reconciliation.

Importantly, the adverse impact of DEA's position is that DEA maintains all persons desiring to manufacture, distribute, dispense, import, export and/or research substances for which there is a drug code must register with the DEA. *See* CSA, 21 U.S.C. 822. Consequently, this misguided action by DEA has instantly and severely "chilled" the global industrial hemp industry, predominantly involving U.S.

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5 U.S.C. § 706(2) (emphasis supplied). For the reasons detailed herein, this Court should enjoin, set aside and amend the Final Rule under this standard as well.

distribution, import and export of Farm Bill-cultivated and imported hemp-derived products.

A. PETITIONERS' PRODUCTS WERE NOT CONTROLLED SUBSTANCES PRIOR TO PROMULGATION OF THE FINAL RULE

Congress enacted the CSA in 1970, initially scheduling controlled substances via its legislative authority. *See generally* CSA, 21 U.S.C. § 801 *et seq*. Generally speaking, Congressional action is the primary avenue for the revision, addition or amendment of the CSA's schedules. *See, e.g., Gutierrez-Brizuela v. Lynch*, 834 F.3d 1142, 1149 (10th Cir. 2016) (Gorsuch, J., concurring) (noting that "permit[ing] executive bureaucracies to swallow huge amounts of core judicial and legislative power" does not square with the framers' design of separation of powers). Conversely, the Attorney General, who oversees the DEA, is narrowly vested with the authority to promulgate rules and regulations regarding the registration and control of controlled substances. *See* CSA, 21 U.S.C. § 821. Absent an act of Congress, DEA, through the Attorney General, may only add new substances to the schedules of controlled substances in narrowly prescribed circumstances, and only where the Attorney General explicitly satisfies the scheduling requirements set forth in the CSA. *See* CSA, 21 U.S.C. § 811; CSA, 21 U.S.C. § 812(b). When DEA exercises said narrow authority pursuant to 21 U.S.C. § 811, DEA historically catalogues its scheduling actions through its own official publications. *See* DRUG

ENFORCEMENT ADMINISTRATION, LISTS OF: SCHEDULING ACTIONS, CONTROLLED SUBSTANCES, REGULATED CHEMICALS, *last updated* March 2017, *available at* https://www.deadiversion.usdoj.gov/schedules/orangebook/orangebook.pdf [hereinafter Orange Book]. DEA also regularly publishes its "Orange Book," DEA's official publication listing all controlled substances and associated drug codes. Orange Book, *supra*. Unless a substance is scheduled within the CSA, this Court confirmed, "DEA has no authority to regulate drugs that are not scheduled." *Hemp Industries Ass'n. v. Drug Enforcement Admin.,* 357 F.3d 1012, 1016 (9th Cir. 2004).

DEA's Final Rule overbroadly defines "marihuana extract" as "any extract containing one or more cannabinoids that has been derived from any plant of the genus Cannabis . . ." Importantly, however, the CSA does not reference, nor did DEA satisfy the appropriate procedures in order to add to the CSA, "marihuana extract" or cannabinoids derived elsewhere than from "marihuana."

Persons desiring to manufacture, distribute, dispense, import, export and/or research substances for which there is a drug code must register with the DEA. *See* 21 U.S.C. 822. Through the Final Rule, DEA now purports to require persons desiring to engage in activities relating to any components of "marihuana extract" to register with DEA, despite the routine denial by DEA of such registrations.

Subsequent to publication of the Final Rule, DEA's spokesman Russ Baer clarified the intent of DEA's Final Rule:

> *"[Cannabidiol (CBD)] oil and other extracts derived from cannabis (which includes hemp) have been and will continue to be Schedule I controlled substances . . . Under U.S. law (the CSA), the definition of marijuana includes all parts the Cannabis plant that are the source of cannabinoids. Thus, CBD, being a derivative of marijuana is marijuana under U.S. law (and hemp is marijuana). Accordingly, because marijuana is a schedule I controlled substance under the CSA . . . CBD is a schedule I controlled substance under the CSA.*
>
> *DEA cannot provide an exhaustive list of "hemp products" that are exempted from control. Nonetheless, in order to provide clarity to your question, the following are some of the more common "hemp products" that are exempted (non-controlled), provide they are not used, or intended for use, for human consumption: paper, rope, and clothing made from fiber derived from cannabis stalks, industrial solvents made with oil from cannabis seeds, and bird seed containing sterilized cannabis seed mixed with seeds from other plants (or other ingredients not derived from the cannabis plant). Personal care products (such as lotions and shampoos) made with oil from cannabis seeds are also generally exempted*."

See Wallace, Alicia, *Legal Challenge Filed Against DEA's New Marijuana Extract Rule*, THE DENVER POST (Jan. 13, 2017), http://www.thecannabist.co/2017/01/13/hemp-dea-extracts-marijuana-cbd-judicial-review/71387/.

Contrary to DEA's perspective, as voiced through Spokesman Baer, the CSA, Schedule I in particular, is entirely devoid of any mention of "marihuana extract," cannabinoids generally, cannabidiol (CBD), cannabigerol (CBG), cannabinol (CBN) or any other individual cannabinoids other than THC. *See generally* CSA 21 U.S.C. 812. Perhaps more alarming, DEA fails to even make reference to or acknowledge the Farm Bill or its effect to universally exclude "industrial hemp"

from the CSA and from DEA's jurisdictional authority or expenditure of resources. 7 U.S.C. 5940, § 7606 ("*Notwithstanding the Controlled Substances Act . . .*"); *see also* Consolidated Appropriations Act, 2016, Pub. L. No. 114-113, § 763, 129 Stat. 1175, 2285, extended by Further Continuing and Security Assistance Appropriations Act, 2017, § 101, 130 Stat. 1005, 1005-06 (2016) (collectively, the Spending Bill").

Yet, in contradiction of DEA's own Final Rule definition, DEA Spokesman Baer's comments note the lawful status of products containing oils from *Cannabis* seeds. *See* Wallace, *supra*. Interestingly, those same hemp products noted above by DEA Spokesman Baer as exempt contain cannabinoids from parts of the plant that fall within the Final Rule's overbroad definition of "any extract . . . from any plant of the genus Cannabis." *See* Final Rule, 81 Fed. Reg. 90,194-96, ER at 12-14.

Additionally evidencing DEA's misconceptions of the constituents of "marihuana extract" – cannabinoids generally, cannabidiol (CBD), cannabigerol (CBG), cannabinol (CBN) or any other individual cannabinoids other than THC – each of DEA's own publications are also entirely devoid of any mention of non-THC cannabinoids. For example, DEA's publications of its own scheduling actions do not evidence any scheduling actions undertaken regarding "marihuana extract" or any cannabinoids other than THC. *See* DRUG ENFORCEMENT ADMINISTRATION, LISTS OF: SCHEDULING ACTIONS, CONTROLLED SUBSTANCES, REGULATED CHEMICALS. Similarly, DEA's Orange Book also fails to include any reference to

cannabinoids generally, cannabidiol (CBD), cannabigerol (CBG), cannabinol (CBN) or any other individual cannabinoids other than THC. *Id.*

The inclusion of "marihuana" and THC within the CSA and DEA's own publications – to the exclusion of all cannabinoids not expressly listed therein – only serves to encourage the continual spreading of confusion, misinformation and misconceptions underlying the Final Rule. Accordingly, Petitioners respectfully seek relief from this Court, namely, that the Final Rule be stricken, invalidated, and/or amended to render it consistent with congressional intent and codified law. And the DEA must be enjoined from any enforcement action based upon this Final Rule as it is presently worded.

1. CANNABINOIDS, WITH THE EXCEPTION OF TETRAHYDROCANNABINOL, ARE NOT INDEPENDENTLY SCHEDULED AS CONTROLLED SUBSTANCES

DEA's Final Rule defines "marihuana extract" as "any extract containing one or more cannabinoids . . .," as if the presence of cannabinoids is somehow determinative of a substance qualifying as "marihuana extract." *See* Final Rule, 81 Fed. Reg. 90,194-96, ER at 12-14. Within the Final Rule, DEA also addresses a comment requesting DEA's determination of whether the Final Rule applies to an isolated compound of CBD, if not combined with other cannabinols. *Id.* at 90,195, ER at 13. DEA's response confirms CBD, as an independent cannabinoid, is

purportedly subject to the Final Rule, whether within an isolated extract or an extract within other cannabinoids. *Id*.

It is relevant that, in 1970, Congress included "marihuana" and "tetrahydrocannabinols" (THC) within Schedule I of the CSA. *See* CSA, 21 U.S.C. 812(c)(c)(10) and (17). However, more importantly, the CSA is otherwise entirely devoid of any mention of any other materials from the *Cannabis* plant, such as "cannabinoid," "cannabinoids," or "marihuana extract" in any of its schedules of controlled substances. *See generally* CSA, 21 U.S.C. 812.

The CSA does not specifically reference any of the other more than 80 cannabinoids, except for THC, naturally occurring within industrial hemp – i.e. cannabidiol (CBD), cannabigerol (CBG), cannabinol (CBN) and more – as controlled substances. *Id.* Nor does DEA's own published scheduling actions and its Orange Book mention any cannabinoids other than THC. *See* DRUG ENFORCEMENT ADMINISTRATION, LISTS OF: SCHEDULING ACTIONS, CONTROLLED SUBSTANCES, REGULATED CHEMICALS, *supra*.

Therefore, absent an act of Congress or an act of the Attorney General strictly pursuant to 21 U.S.C. 822, cannabinoids (other than THC) are not *per se* controlled substances, and the presence of said cannabinoids do not render a substance unlawful pursuant to the CSA.

This conclusion is especially true given cannabinoids *naturally occur* in a variety of sources: non-*Cannabis* flowers, cacao and even human breast milk. *See n. 3 supra*. DEA even acknowledges cannabigerol (CBG), a cannabinoid found in *Cannabis*, may also be derived from South African Helichrysum (H. umbraculigerum), a South African flower. *See* Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 81 Fed. Reg. 53,688-765, 53,692, 53,698, 53,753 (Aug. 12, 2016) (citing Giovanni Appendino et al., *Cannabinoids: occurrence and medicinal chemistry*, 18 Curr. Med. Chem. 1085 (2011)). How then can DEA or any other regulatory agency practically determine whether any extract containing cannabinoids is derived from *Cannabis* or from a non-*Cannabis* source? Petitioners contend it is unreasonable to believe regulators could materially distinguish between the two. Yet, despite this complete absence of reference to cannabinoids other than THC within the CSA and DEA's own publications, the Final Rule's definition of "marihuana extract" begins: "any extract containing one or more cannabinoids . . . " Final Rule, 81 Fed. Reg. at 90,194-96, ER at 12-14. In addition to the Final Rule, DEA continues to misrepresent the inclusion of independent substances as controlled substances such as CBD and CBG, by assigning codes to these substances.

Because cannabinoids are not, *per se*, controlled substances, the Final Rule wrongly cites the presence of cannabinoids in an extract as a determinative factor of

the substance's qualification as a controlled substance. DEA's Final Rule must be enjoined, stricken or amended to refrain from citing the presence of cannabinoids as a determinative factor of whether a substance is "marihuana extract" and, effectively, a controlled substance.

2. CONGRESSIONAL LEGISLATION EXPRESSLY PROVIDES FOR THE LAWFULNESS OF CERTAIN PORTIONS AND VARIETIES OF INDUSTRIAL HEMP AND DERIVATIVES THEREFROM

Since at least 1937, Congress has enacted legislation relating to the *Cannabis* plant, industrial versus psychotropic marijuana uses and certain exemptions from treatment as a controlled substance – none of which DEA or its Final Rule reflects. Most recently, in 2014, Congress universally exempted "industrial hemp" from the CSA upon the evolution of technology related to industrial hemp cultivation and processing. Before then, Congress exempted certain portions of the plant from the definition of "marihuana," though such definition more broadly defined "marihuana" due to the constraints upon industrial cultivation and processing technology. *See discussion infra*.

When the original definition of "marihuana" was enacted in the Marihuana Tax Act of 1937 ("MTA") and when it was under consideration, Clinton Hester, then-Assistant General Counsel at the Treasury Department, assured the Senate Committee on Finance:

> The production and sale of hemp and its products for industrial purposes will not be adversely affected by this bill. In general, the term "marihuana" is defined in the bill so as to include only the flowering tops, leaves, and seeds of the hemp plant and to exclude the mature stalk, oil, and meal obtained from the seeds of the plant, and sterilized seed, incapable of germination.

Christine A. Kolosov, *Evaluating The Public Interest: Regulation of Industrial Hemp Under the Controlled Substances Act*, 57 UCLA L. REV. 237, 259-260 (2009) (citing Taxation of Marijuana: Hearing on H.R. 6906 Before the S. Comm. on Finance, 75th Cong. 7 (1937) (statement of Clinton M. Hester, Assistant General Counsel, Treasury Department) (emphasis added)).

At the time, Henry Anslinger, then-Commissioner of Narcotics at the Treasury Department assured Mr. Hester, "I would say they are not only amply protected under this act, but they can go ahead and raise hemp just as they have always done it." *Id.* citing Taxation of Marijuana: Hearing on H.R. 6906 Before the S. Comm. on Finance, 75th Cong. 17 (1937) (statement of H.J. Anslinger, Comm'r of Narcotics, Bureau of Narcotics of the Treasury Department).

And later, when the CSA displaced the MTA in 1970, the provision exempting the parts of the hemp plant utilized for industrial purposes from the Act's coverage—the stalk fiber, seed oil, and similar derivatives—was adopted verbatim. "Maintaining this provision would be illogical unless Congress intended that such products could be legally manufactured." *Id.* at 260. In other words, industrial hemp was always excepted from the definition of "marihuana."

And, despite enactment of the Farm Bill in 2014, DEA failed to substantively change its overbroad definition of "marihuana extract" between its 2011 Proposed Rule and promulgation of the Final Rule. Because DEA waited over five years before publishing the Final Rule, during which time Congress enacted the Farm Bill, DEA's Final Rule could not possibly contemplate congressional legislative action with any timeliness or accuracy. Given that DEA's Final Rule directly conflicts with multiple legislative actions of Congress – the CSA and the Farm Bill – and because DEA did not otherwise appropriately engage in its own scheduling actions, DEA's Final Rule must be enjoined, stricken or amended in order to be consistent with congressional intent and codified law.

i. THE UNIVERSAL EXEMPTION OF INDUSTRIAL HEMP PURSUANT TO THE AGRICULTURAL ACT OF 2014 AND DEA'S VIOLATION OF CONGRESSIONAL APPROPRIATION ACTS

In recognition of the technological and scientific advances and understanding related to the *Cannabis* plant and processing derivatives thereof, Congress expressly defined and universally exempted "industrial hemp" from the CSA in enacting the 2014 Farm Bill. *See* Farm Bill, 7 U.S.C. 5940, § 7606; Spending Bill, § 763, 129 Stat. at 2285, extended by Further Continuing and Security Assistance Appropriations Act, 2017, § 101, 130 Stat. 1005, 1005-06 (2016). Yet, the Final Rule

is wholly devoid of any reflection of the Farm Bill's contemplated definition of "industrial hemp" or activities related thereto.[9]

Regarding legislative intent, Sponsor Representative Jared Polis (CO) stated in the Congressional Record that:

> *Today, U.S. retailers sell over $300 million worth of hemp-related goods...somehow it's caught up in a completely unrelated drug war that prevents American farmers from growing this crop and forces us to import it from other countries...Hemp is not marijuana. I'm very disappointed to hear that the DEA is circulating misleading talking points that claim that somehow hemp could be used as marijuana. At the concentration levels specified in our amendment, it is physically impossible to use hemp as a drug.*

159 Cong. Rec. H3897-98 (daily ed. June 19, 2013) (statement of Rep. Polis).

And Co-Sponsor Representative Massie (KY) added to this express intent by stating:

> *So this is not about drugs. This is not about a drugs bill. This is about jobs. And for Kentucky farmers, we need the opportunity. We need the opportunity to compete globally in a global market, and we shouldn't be denied this outlet for another productive crop in Kentucky…If this amendment passes and we're able to do this research in agricultural colleges and universities, then we're not going to have stupid talking points coming from DEA, and we won't have misleading statements that are made.*

159 Cong. Rec. H3897-98 (daily ed. June 19, 2013) (statement of Rep. Massie).

The Final Rule improperly and directly treats industrial hemp as a drug and falsely includes its constituent parts as a Schedule I substance by crafting the

[9] Directly contrary to congressional intent through the Farm Bill and subsequent to publication of the Final Rule, DEA Spokesman Baer opined DEA believes, "[t]he Farm Bill did not remove industrial hemp from the controlled substances . . . and the CSA continue[s] to apply to industrial hemp-related activities." *See* Wallace, *supra*.

"marihuana extract" definition the published pursuant to the Final Rule. For these reasons, the Final Rule clearly runs afoul of the legislative intent and continues the path of misinformation and misleading statements fostered by the DEA in the past, as alluded to by the legislative sponsors.

The Farm Bill initially reads, "[n]otwithstanding the Controlled Substances Act," thus validating congressional intent to universally exclude and carve out "industrial hemp" from the CSA's definition of "marihuana." *See* Farm Bill, 7 U.S.C. 5940, § 7606. "Notwithstanding," by definition, means "in spite of" or "despite." *Black's Law Dictionary* 1094 (8th ed. 2004). In the Farm Bill, for the first time in U.S. history, Congress defined "industrial hemp" as "the plant *Cannabis sativa* L. and any part of such plant, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis." *See* Farm Bill, 7 U.S.C. 5940, § 7606. Importantly, this definition applies to all parts of the *Cannabis* plant and does not discriminate between various portions of the plant.

Concerned about potential DEA overreach – such as the Final Rule – with respect to the Farm Bill, Congress correspondingly prohibited DEA's expenditure of funds contrary to the Farm Bill in order to protect the tenets of the Farm Bill. In three successive budget appropriation acts, Congress most recently set forth:

> *None of the funds made available by this Act or any other Act may be used—*
>
> *(1) in contravention of section 7606 of the Agricultural Act of 2014 (7 U.S.C. 5940); or*
>
> *(2) to prohibit the transportation, **processing, sale**, or use of industrial hemp that is grown or cultivated in accordance with subsection section 7606 of the Agricultural Act of 2014, within or outside the State in which the industrial hemp is grown or cultivated.*

See Spending Bill, § 763, 129 Stat. at 2285, extended by Further Continuing and Security Assistance Appropriations Act, 2017, § 101, 130 Stat. 1005, 1005-06 (2016) (**emphasis** added). Multiple courts subsequently confirmed the validity of these prohibitions on funding and use by the DEA. *See generally U.S. v. Marin Alliance for Medical Marijuana*, 139 F. Supp. 3d 1039 (N.D. Cal. 2015); *U.S. v. McIntosh*, 833 F.3d 1163 (9th Cir. 2016).

By specifically referencing the "processing" and "sale" of industrial hemp and hemp-derived products in the Spending Bill, Congress yet again demonstrated its intent for the Farm Bill to allow for the processing and sale of industrial hemp, which logically includes hemp-derived extracts.

However, here, it is important to contemplate the procedural history of the Final Rule as it correlates to the Farm Bill. DEA initially published the Proposed

Rule and solicited public comment in 2011; because the Farm Bill did not yet exist, the Proposed Rule's definition of "marihuana extract" did not contemplate the exclusion of Farm Bill "industrial hemp." *See* Proposed Rule—Establishment of a New Drug Code for Marihuana Extract, 76 Fed. Reg. 39,039-41 (July 5, 2011) (to be codified at 21 C.F.R. § 1308(11)(d)) (the "Proposed Rule"), ER at 9-11. Thereafter, the Proposed Rule apparently laid dormant for over five years.

During this intervening five-year period, along with the corresponding Spending Bill, Congress enacted the Farm Bill in 2014, defining "industrial hemp" and specifically excluding "industrial hemp" from "marihuana" as defined by the CSA and contemplating the processing and sale of industrial hemp and hemp-derived products. *See* Farm Bill, 7 U.S.C. 5940, § 7606; Spending Bill, § 763, 129 Stat. at 2285, extended by § 101, 130 Stat. at 1005-06 (2016); *see discussion supra,* Section I(A)(ii).

Despite the intervening enactment of the Farm Bill and Spending Bill, in December 2016, DEA re-initiated its efforts pertaining to the Proposed Rule and published the Final Rule without amendment of the five-year-old Proposed Rule. *See* Final Rule, 81 Fed. Reg. at 90,194-96, ER at 12-14. Consequently, the Final Rule failed to reflect the Farm Bill or "industrial hemp" in any form or fashion.

Fundamentally, for the reasons discussed herein, the Final Rule violates the Spending Bill and defies explicit congressional orders. The promulgation of the

Final Rule likely required use of extensive DEA resources and, by the Final Rule conflicting with the Farm Bill, as discussed *supra*, DEA effectively expended resources "in contravention of" the Farm Bill, which Congress expressly prohibited through the Spending Bill. Even more concerning, the Final Rule references as "marihuana extract" any extract from "any plant of the genus Cannabis . . . ," noticeably failing to reflect even any mention of "industrial hemp" or its exclusion from DEA's definition of "marihuana extract." Final Rule, 81 Fed. Reg. at 90,194-96, ER at 12-14.

In light of the failure of DEA's Final Rule to reflect, in any capacity, the Farm Bill, and "industrial hemp," in explicit defiance of the Spending Bill, DEA's Final Rule must be stricken, invalidated, and/or amended to render it consistent with congressional intent and codified law. And the DEA must be enjoined from any enforcement action based upon this Final Rule as it is presently worded.

ii. PORTIONS OF THE CANNABIS PLANT EXEMPTED FROM THE SCHEDULED DEFINITION OF "MARIHUANA"

In 1937, Congress enacted the Marihuana Tax Act, distinguishing between the industrial and drug uses of the *Cannabis* plant via distinct taxation principles. *See* Marihuana Tax Act of 1937, Pub. L. 75-238, 50 Stat. 551 (1937) (prior to 1970 repeal). The Marihuana Tax Act imposed a tax upon drug uses of the *Cannabis* plant,

but protected from taxation industrial uses of the stalks of the *Cannabis* plant. *Id. at 551-552*; *see also* S. Rep. No. 75-900, at 4, 10 (1937).

The Ninth Circuit previously analyzed and confirmed congressional intent when enacting the CSA in 1970 to adopt the Marihuana Tax Act's definition and exclude certain exempted portions of the *Cannabis* plant from treatment as "marihuana" pursuant to the CSA. *Hemp Industries Ass'n. v. Drug Enforcement Admin.,* 357 F.3d 1012 (9th Cir. 2004); *see also United States v. Walton*, 514 F.2d 201, 203 (D.C. Cir. 1975). In *Hemp Indus. Ass'n v. DEA*, this Court reviewed the CSA, which excludes from the definition of "marihuana:"

> *. . . the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.*

Id. at 1014 (quoting 21 U.S.C. 802(16)).[10]

[10] Subsequent to this Court's ruling against DEA over a decade ago, DEA then published text within the Code of Federal Regulations reflecting these exempted parts of the plant. *See 21 CFR § 1308.35*. It is worth noting DEA unilaterally added an unsupported restriction that these exempt parts of the plant cannot be used, or intended for use, for human consumption. *Id.* Regardless, DEA's Final Rule similarly fails to reflect DEA's own published policy within the Code of Federal Regulations and this Court's ruling in *Hemp Industries Ass'n. v. Drug Enforcement Admin.,* 357 F.3d 1012 (9th Cir. 2004) and *Hemp Industries Ass'n v. Drug Enforcement Admin.,* 333 F.3d 1082 (9th Cir. 2003).

When enacting the CSA, Congressional hearings demonstrate Congress' awareness of the presence of cannabinoids, including trace amounts of THC, within the exempted parts of the *Cannabis* plant. *see discussion supra,* Section I(A)(ii). Despite this awareness, Congress subsequently carried forward the Marihuana Tax Act's definition of "marihuana," reflecting these exempted portions of the *Cannabis* plant, revealing Congress expressly intended to render lawful those exempted portions of the *Cannabis* plant and derivatives therefrom.

Over a decade ago, this Court confirmed, "[DEA] cannot regulate *naturally-occurring* THC *not* contained within or derived from marijuana – i.e. non-psychoactive hemp products – because non-psychoactive is not included in Schedule I." *Hemp Industries Ass'n.,* 357 F.3d at 1018 (emphasis in original). By extension, DEA also cannot regulate any other substance – cannabinoids such as CBD, CBG, CBN or other substances – derived from *Cannabis* but which is not contained within or derived from "marihuana."

Contrary to the portions of the plant exempted from "marihuana," DEA's Final Rule references "marihuana extract" as any extract from "any plant of the genus Cannabis . . . ." Thus, because the Final Rule fails to narrowly tailor its formal definition to those non-exempted/controlled portions of the *Cannabis* plant, the Final Rule's definition of "marihuana extract" is overly broad and in excess of DEA's rulemaking authority. Resultantly, the Petitioners request that the Final Rule be

stricken, invalidated, and/or amended to render it consistent with congressional intent and codified law. And the DEA must be enjoined from any enforcement action based upon this Final Rule as it is presently worded.

B. DEA'S MISPLACED INVOCATION OF THE UNITED NATIONS CONVENTIONS ON INTERNATIONAL DRUG CONTROL

DEA purportedly justifies the Final Rule as needed to "allow for more appropriate accounting of [marihuana extracts] consistent with [United Nations] treaty provisions." Final Rule, *supra*, at 90,195, ER at 13. Additionally, DEA asserts:

> *[w]ith respect to those drugs that are subject to control under the Single Convention, the CSA mandates that DEA control such drugs in a manner that will ensure the United States meets its obligations under the Single Convention. 21 U.S.C. 811(d)(1).*

Id. The United States, however, fully met its obligations under the Single Convention prior to the Final Rule. Accordingly, DEA's articulated justification is a contrived excuse in an attempt to skirt scheduling action procedures and overreach to unnecessarily control all cannabinoids, regardless of whether they are a drug of abuse or not, when these non-narcotic cannabinoids are not, *per se*, subject to control under the Single Convention.

1. CANNABIS AND THE UNITED NATIONS CONVENTIONS ON INTERNATIONAL DRUG CONTROL; DEA'S MISAPPLICATION OF 21 U.S.C. § 811(D)(1)

In 1961, the United Nations adopted the United Nations Single Convention on Narcotic Drugs, Mar. 30, 1961, 18 U.S.T. 1407, 520 U.N.T.S. 151 [hereinafter

Single Convention]. One of the Single Convention's primary purposes is to coordinate global measures regulating against drug abuse. *Id.* at res. II, art. 28. Included within the Single Convention is the Control of Cannabis:

> 1. *If a party permits the cultivation of the cannabis plant for the production of cannabis or cannabis resin, it shall apply thereto the system of controls as provided in article 23 respecting the control of the opium poppy.*
>
> 2. *This convention shall not apply to the cultivation of the cannabis plant exclusively for industrial purposes (fiber and seed) or horticultural purposes.*

Id. at art. 28. The Single Convention, in relevant part, includes three cannabis-related definitions:

> b) *"Cannabis" means the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted, by whatever name they may be designated.*
> c) *"Cannabis plant" means any plant of the genus Cannabis,*
> d) *"Cannabis resin" means the separated resin, whether crude or purified, obtained from the cannabis plant.*

Id. at art. 1(1)(b)-(d). Cannabis and cannabis resin are listed on the Single Convention's Schedule I (least stringent) and Schedule IV (most stringent), respectively. *Id.* at "Schedules." Conversely, while "[e]xtracts" and "[t]inctures" of cannabis are added next to the listing of cannabis and cannabis resin in Schedule I (the least stringent), but not Schedule IV, neither "[e]xtracts" nor "[t]inctures" are defined therein. Compare *id.* at "Schedule I" *with id.* at "Schedule IV." Therefore, in lieu of any alternative definition, the inclusion of "[e]xtracts" and "[t]inctures" of

cannabis must logically utilize the definition of "cannabis" pursuant to the Single Convention. Resultantly, the inclusion of "[e]xtracts" and "[t]inctures" of cannabis was intended to narrowly pertain to "cannabis," the various drug forms of the plant as defined by the Single Convention.

At the time of drafting the Single Convention, legislators and regulators did not know or understand that the drug component of "cannabis" is THC. Due to this lack of understanding, the Commentary on Article 28 refers to the cannabis drug component – now known as THC – as "the psychoactive principle," "active principle," "this ingredient," and "dangerous substance." Secretary General of the United Nations, *Commentary on the Single Convention on Narcotic Drugs, 1961*, 312-13 (1973). However, by 1971, in the Convention on Psychotropic Substances on Psychotropic Substances, scientists identified and named the drug principle in cannabis as THC. Consequently, the Convention on Psychotropic Substances listed THC in its Schedule I. United Nations Convention on Psychotropic Substances, "Substances on Schedule 1," Feb. 21, 1971, 32 U.S.T. 543, 1019 U.N.T.S. 175 [hereinafter Convention on Psychotropic Substances]. Still, no other cannabinoid from any genus *Cannabis* is listed within the schedules of either the Single Convention or the Convention on Psychotropic Substances.

In purportedly justifying its action, DEA cites 21 U.S.C. § 811(d)(1)[11] as authority for the Final Rule. In relevant part, § 811(d)(1) states:

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

21 U.S.C. § 811(d)(1). By invoking this section, DEA has inappropriately attempted to avoid the required findings under 21 U.S.C. §§ 811(a) or 812(b) by baselessly citing purported U.S. obligations pursuant to the Single Convention. DEA's citation of international treaty obligations appears to be an attempt to skirt the specific findings and due process requirements otherwise set forth in 21 U.S.C. § 811 and § 812(b).

For the reasons discussed above, neither the Single Convention nor the Convention on Psychotropic Substances require the United States or DEA to promulgate the Final Rule or, as a "mere recordkeeping measure," track "marihuana extract" separately from "marihuana." Consequently, the Final Rule must be stricken, invalidated, and/or amended to render it consistent with congressional

[11] *See also* 21 CFR 1308.46 (2017).

intent and codified law. And the DEA must be enjoined from any enforcement action based upon this Final Rule as it is presently worded.

2. THE UNITED STATES MET ITS OBLIGATIONS UNDER THE UNITED NATIONS CONVENTIONS ON INTERNATIONAL DRUG CONTROL LONG BEFORE THE FINAL RULE

Since its inception in 1970, the CSA has controlled "marihuana" on Schedule I. 21 U.S.C. § 812(c)(10). Additionally, DEA regulates "marihuana" administratively by assigning it the drug code 7360. *See* 21 CFR 1308.11(d)(23) (2017). Taken together, the U.S. has fully controlled "marihuana" since 1970. As noted *supra*, the Single Convention mandates, if a party state allows the cultivation of the cannabis plant for drug purposes (marihuana), the party state must employ the system of controls in Article 23. Single Convention, *supra*, at art. 28. The U.S., however, by virtue of placing "marihuana" within the CSA's Schedule I since 1970, does not federally permit the cultivation of the *Cannabis* plant for drug purposes; thus, Article 23 of the Single Convention is not implicated. Therefore, the U.S. fully satisfied its obligations under the United Nations conventions on international drug control long before the Final Rule.

Further evidencing the lack of justification pursuant to international treaty obligations, the United Nations never notified the United States that the Final Rule was necessary under the Single Convention or the Convention on Psychotropic Substances. In fact, the five-plus year delay between DEA's July 5, 2011 Proposed

Rule and the Final Rule published on December 14, 2016 evidences, in and of itself, there is no urgency whatsoever for the Final Rule. *See generally* Proposed Rule, *supra*, ER at 9-11. Because the U.S. likely could not delay compliance with international treaty obligations for over five years, the substantial and excessive delay further evidences an ulterior motive other than the United States treaty obligations is the driving force behind the Final Rule.

Indeed, on June 24, 2015, DEA's own Deputy Assistant Administrator testified before Congress that a scheduling action would be required to list CBD on a CSA schedule:

> *DEA will also work with HHS to evaluate CBD under section 201 (a) – (c) of the Controlled Substances Act (21 U.S.C. 811(a-c)). To accomplish this, DEA will initiate the review of CBD and request a scientific and medical evaluation and scheduling recommendation for CBD from HHS. Please be advised, although CBD products are currently being evaluated under Investigational New Drug Applications, additional scientific studies may need to be initiated and conducted to assess CBD's abuse liability. Scheduling recommendations are evidence-based, and DEA will provide any assistance necessary to assist HHS in its collection of information critical to its scientific and medical evaluation and formulation of a recommendation.*

Joseph T. Rannazzisi, Deputy Assistant Administrator, DEA, Statement Before the Caucus on Int'l Narcotics Control for a U.S. Senate Hearing Concerning Cannabidiol: Barriers to Research and Potential Medical Benefits (June 24, 2015) (transcript available at https://www.dea.gov/pr/speeches-

testimony/2015t/062415t.pdf).[12] Mr. Rannazzisi' testimony reflects federal precedent that "ensures proper allocation of decisionmaking responsibility between the Attorney General and the Secretary of HEW (now, Health and Human Services)":

> *The Attorney General is directed to determine the CSA schedule that will satisfy the nation's obligation under the Single Convention; to the extent that there is latitude to schedule a substance consistent with treaty obligations, the Attorney General (is) obliged to follow the prescribed procedures in obtaining a medical and scientific evaluation from the Secretary of Health, Education, and Welfare (now Health and Human Services).*

NORML v. DEA, 559 F.2d 735 (D.C. Cir. 1977) (internal quotation omitted) (emphasis added); *see also* 21 U.S.C. § 811(d)(2)-(4).

Accordingly, there is overwhelming evidence and legal authority that DEA improperly invoked 21 U.S.C. § 811(d)(1) and its failure to make the findings after a hearing required by § 811(a) and § 812(b) must invalidate the Final Rule. Accordingly, Petitioners request that the Final Rule be stricken, invalidated, and/or amended to render it consistent with congressional intent and codified law. And the DEA must be enjoined from any enforcement action based upon this Final Rule as it is presently worded.

3. DEA'S FINAL RULE FAILS TO DISTINGUISH BETWEEN MARIHUANA AND INDUSTRIAL HEMP

[12] *See also* S. 3269, 114th Cong. § (3)(b) (2016) (demonstrating congressional understanding that cannabinoids, such as CBD, are not currently controlled substances).

The U.N., the Single Convention and Convention on Psychotropic Substances distinguish between drug and industrial uses of "cannabis," effectively, "marihuana" versus "industrial hemp." Contrarily, under the Final Rule, DEA is essentially scheduling non-drug cannabinoids, portions and varieties of the *Cannabis* plant, while failing to distinguish between "marihuana" and "industrial hemp." DEA may argue that whether the variety from which the cannabinoids are derived is "marihuana" or "industrial hemp" is irrelevant. Contrary to DEA's position, however, because cannabinoids may be derived from lawful portions and varieties of *Cannabis*, including industrial hemp, the distinction between "marihuana" and industrial hemp" is wholly and fundamentally relevant.

The primary purpose of the Single Convention and Convention on Psychotropic Substances includes coordinating global regulation against drug abuse. As discussed *supra*, upon Congress' enactment of the Farm Bill, the U.S. now universally defines "industrial hemp" as an agricultural crop treated separately and distinct from "marihuana" and excluded from the CSA. *See* Farm Bill, 7 U.S.C. 5940, § 7606. Pursuant thereto, the definition of "industrial hemp" is all parts of the *Cannabis* plant, including the flowers and leaves, not just the fiber and seeds, and with less than 0.3% THC. *See* Farm Bill, 7 U.S.C. 5940, § 7606(b)(2). Consistent with the Farm Bill, the Single Convention and Convention on Psychotropic Substances also reflect the distinction between drug and industrial uses of

"cannabis." Single Convention, *supra*, at art. 2(9), art. 28(2); Convention on Psychotropic Substances, *supra*, at art. 4(b).

Further, non-THC cannabinoids are not *per se* controlled by the Single Convention and Convention on Psychotropic Substances. Memorandum from United Nations Office on Drugs and Crime to Ukraine, p. 1, 3 (May 2015) (on file with author) (attached in the ER as Exhibit A, at 22). Accordingly, DEA's failure to distinguish between "marihuana" and "industrial hemp" is an additional fatal flaw of the Final Rule and Petitioners request that the Final Rule be stricken, invalidated, and/or amended to render it consistent with congressional intent and codified law. And the DEA must be enjoined from any enforcement action based upon this Final Rule as it is presently worded.

C. THE FINAL RULE IS NOT ENTITLED ANY *CHEVRON* DEFERENCE

The Final Rule is not entitled to *Chevron* deference – deference to DEA's interpretations – for two reasons: (1) *Chevon* deference is no longer solid, judicial canon; and (2) Congress has spoken directly on the precise question at issue, and the Court must give effect clear congressional intent.

In cases of interpretation bearing "deep 'economic and political' significance," courts must assume that "had Congress wished to assign that question [of interpretation] to an agency, it surely would have done so expressly;" otherwise, Congress did not intend to delegate interpretative powers to an agency that lacks

expertise in crafting policy of the sort. *See King v. Burwell*, 135 S.Ct. 2480, 2488-89 (2015). In following, judges in multiple circuits continue to narrow and curtail *Chevron* deference altogether.[13] And in 2017, Congress the U.S. House of Representatives enacted the Regulatory Accountability Act of 2017, which restricts the delegation to agencies of interpretative powers or authority. H.R. 5, 115th Cong. (2017).[14]

Based on the restrictions implemented on *Chevron* deference by the U.S. Supreme Court, and Congress' present efforts to abolish it, it is clear that *Chevron* deference is no longer judicial canon. Accordingly, this Court should not defer to the DEA's interpretations in determining the propriety of the Final Rule.

To the extent *Chevron* deference is still judicial canon (it is not), the Final Rule should not benefit from it. Under *Chevron*, if Congress has directly spoken to the precise question at issue and congressional intent is clear, "that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *CHW W. Bay v. Thompson*, 246 F.3d 1218, 1223 (9th Cir. 2001) (quoting *Chevron*, 467 U.S. at 843)).

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[13] *See, e.g., Gutierrez-Brizuela v. Lynch*, 834 F.3d 1142, 1149 (10th Cir. 2016) (Gorsuch, J., concurring); *Egan v. Del. River Port Auth*., Case No. 16-1471 (3d. Cir. March 21, 2017) (Jordan, J., *concurring*) *(available at* http://www2.ca3.uscourts.gov/opinarch/161471p.pdf*)*.

[14] H.R. 5 is presently before the Homeland Security and Governmental Affairs Committee in the U.S. Senate.

In this matter, Congress has indeed spoken to the precise questions and the CSA is absolutely unambiguous. Congress exempted hemp stalk, fiber, seed and oil from the definition of "marihuana." 21 U.S.C. § 802(16). Moreover, since 2014, Congress has expressly and universally excluded "industrial hemp" from the control of DEA through the Farm Bill, and further prohibited any expenditure of resources by DEA in contravention to congressional intent related thereto. *See* Farm Bill, 7 U.S.C. 5940, § 7606; *see also* Spending Bill, § 763, 129 Stat. at 2285, extended by Further Continuing and Security Assistance Appropriations Act, 2017, § 101, 130 Stat. 1005, 1005-06 (2016). These codifications of law further evidence clear congressional intent that many of the substances, and constituents thereof, now defined by the DEA as "marihuana extract" would not fall under the jurisdiction, scheduling or otherwise, of the DEA.

For these reasons, the Court should not grant *Chevron* deference to the Final Rule, and Petitioners request that the Final Rule be stricken, invalidated, and/or amended to render it consistent with congressional intent and codified law. And the DEA must be enjoined from any enforcement action based upon this Final Rule as it is presently worded.

D. WITH THE EXCEPTION OF TETRAHYDROCANNABINOL, NEITHER "MARIHUANA EXTRACT" NOR INDIVIDUAL CANNABINOIDS SATISFY THE STATUTORY REQUIREMENTS NECESSARY TO BE SCHEDULED AS CONTROLLED SUBSTANCES

Pursuant to the CSA, section 812(b), substances cannot be listed on Schedule I of the CSA unless certain specific findings are made by DEA. *See* 21 U.S.C. § 812(b); 21 U.S.C. § 811(b); *see Hemp Industries Ass'n*, 357 F.3d at 1016. As noted *supra*, DEA's Final Rule is effectively a scheduling action pertaining to "marihuana extract," thus requiring DEA to prove its burden that DEA validly promulgated the Final Rule. However, for the Final Rule to be valid pursuant to section 812(b) of the CSA, DEA must specifically find:

> *(a) "marihuana extract" has a high potential for abuse;*
> *(b) there is no currently accepted medical use in treatment in the United States for "marihuana extract;" and,*
> *(c) there is a lack of accepted safety for use of the drug or other substance under medical supervision.*

Id. In order to make such specific findings, the Attorney General must solicit the "necessary data, request from the Secretary of [Health] a scientific and medical evaluation, and [the Secretary's] recommendations, as to whether such drug or other substance should be so controlled . . ." *See* 21 U.S.C. § 811(b). "[I]n making such evaluation and recommendations," the Secretary must consider the factors and considerations listed in 21 U.S.C. §§ 811(c)(1-8), as follows:

1. *Its actual or relative potential for abuse.*
2. *Scientific evidence of its pharmacological effect.*
3. *The state of current scientific knowledge regarding the drug or other substances.*
4. *Its history and current pattern of abuse.*
5. *The scope, duration and significance of abuse.*
6. *What, if any, risk there is to public health.*
7. *Its psychic or physiological dependence liability.*

8. *Whether the substance is an immediate precursor of a substance already controlled under [21 U.S.C. 801 et seq.].*

21 U.S.C. §§ 811(c)(1-8).

As explained *infra*, DEA's Final Rule is entirely void of any of the specific findings required and DEA has not solicited the "necessary data," required reports nor recommendations from the Secretary of Health under sections 811(b)-(c) and 812(b) of the CSA or otherwise, to render "marihuana extract" validly listed in Schedule I of the CSA. For this reason, Petitioners request that the Final Rule be stricken, invalidated, and/or amended to render it consistent with congressional intent and codified law. And the DEA must be enjoined from any enforcement action based upon this Final Rule as it is presently worded.

E. THERE EXISTS NO HIGH POTENTIAL FOR ABUSE OF "MARIHUANA EXTRACT" AND HEMP-DERIVED COMPONENTS THEREOF

Unequivocally, the Final Rule does not expressly contain any required specific findings pursuant to sections 811(b) and 812(b) of the CSA or otherwise, that "marihuana extract" presents a high potential for abuse. *See* Final Rule, 81 Fed. Reg. at 90,194-96, ER at 12-14. Given DEA did not solicit any reports from the Secretary of Health denoting the 21 U.S.C. §§ 811(c)(1-8) factors, nor does any evidence provided by DEA reach any similar conclusion, DEA cannot reasonably conclude "marihuana extract," as defined within the Final Rule, presents a high potential for abuse.

To be sure, "marihuana extract," as defined by the Final Rule, overbroadly includes any and all cannabinoids derived from the *Cannabis* plant, including from "industrial hemp," without exception. Final Rule, 81 Fed. Reg. at 90,194-96, ER at 12-14. No cannabinoid, other than THC, is independently scheduled within the CSA. *See generally* 21 U.S.C. 812. Yet, since 1937, Congress adopted a policy that the varietal non-psychoactive industrial hemp, and derivatives therefrom, are excluded from "marihuana" and thus lawful; presumably, in its more than capable wisdom, Congress would not continue to adopt this position for over 80 years if these industrial hemp portions and varieties of the *Cannabis* plant presented a high potential for abuse.

Further to the contrary of DEA's position, DEA itself even admits cannabinoids such as CBD possess no psychoactive effect and, thus, no potential for abuse. Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 81 Fed. Reg. 53,767, 53,778 (Aug. 12, 2016).

For these reasons, even if DEA engaged in the appropriate scheduling actions pursuant to sections 811 and 812 of the CSA, DEA could not reasonably determine all constituents of "marihuana extract," as defined by DEA, present a high potential of abuse. As a result, Petitioners pray that the Final Rule be stricken, invalidated, and/or amended to render it consistent with congressional intent and codified law.

And the DEA must be enjoined from any enforcement action based upon this Final Rule as it is presently worded.

F. THE MANY CURRENTLY ACCEPTED MEDICAL USES AND SAFETY OF USES RECOGNIZED BY DEA, THE FOOD AND DRUG ADMINISTRATION AND STATE LEGISLATURES FOR "MARIHUANA EXTRACT," AND HEMP-DERIVED COMPONENTS THEREOF

With similar incontrovertibility, the Final Rule does not expressly contain any specific findings, pursuant to sections 811(b) and 812(b) of the CSA or otherwise, that there does not exist any currently accepted medical uses for "marihuana extract." *See* Final Rule, 81 Fed. Reg. at 90,194-96, ER at 12-14. Nor does any evidence provided by DEA reach any similar conclusion. *Id.*

Lastly, even if DEA intended to make such a finding, DEA could not find there is no "currently accepted medical use" for "marihuana extract." Such finding requires satisfaction of the following five-factor test:

(1) The drug's chemistry is not known and reproducible;
(2) There do not exist adequate safety studies;
(3) There are not adequate and well-controlled studies proving efficacy;
(4) The drug is not accepted by qualified experts; and,
(5) The scientific evidence is not widely available.

See Marijuana Scheduling Petition; Denial of Petition; Remand, 57 Fed. Reg. 10,499, 10,504-06 (Mar. 26, 1992). DEA's inability to satisfy these factors is especially true given legislative enactments by Congress, state legislatures and rulemaking by the U.S. Food and Drug Administration ("FDA") demonstrating the

exact opposite – there exist, in fact, *many* currently accepted medical uses for several components of "marihuana extract."

For decades, individuals have used products containing oils and derivatives of "industrial hemp" – that are overbroadly contemplated under the definition of "marihuana extract" – as remedies for many health conditions.

To wit, DEA itself admits "[cannabidiol, one of over 80 cannabinoids in the *Cannabis* plant,] is a non-psychoactive cannabinoid that may also be useful in reducing pain and inflammation, controlling epileptic seizures, and possibly even treating psychosis and addictions." *See Dangers and Consequences of Marijuana Abuse, DEA*, pg. 3, (2014), available at: https://web.archive.org/web/20161221020153/https://www.dea.gov/docs/dangers-consequences-marijuana-abuse.pdf. Moreover, as of May 2014, there existed 237 DEA-registered researchers performing studies "with marijuana, marijuana extracts, and non-tetrahydrocannabinol marijuana derivatives that exists in the plant, such as cannabidiol and cannabinol." *Id.*

Additionally, the FDA also understands various components within "marihuana extract" to possess a medical use in treatment of various diseases and health conditions. In particular, the FDA continues to support the clinical trials of at least two new products, Sativex and Epidiolex, for their treatment of, among other conditions, cancer pain, spasticity due to multiple sclerosis and Dravet syndrome.

See FDA and Marijuana: Questions and Answers, available at https://www.fda.gov/NewsEvents/PublicHealthFocus/ucm421168.htm (last visited Apr. 3, 2017); *see also Dangers and Consequences, supra*. The FDA even touts the success of the such studies into Sativex and Epidiolex, along with the alleged reproducibility of the drugs and adequacy and wide availability of the same studies. *Id.* The approval of Sativex and Epidiolex as drugs would correspondingly require supervision of use by a prescribing physician, ensuring there exists an acceptable safety for use of components of "marihuana extract."

Lastly, legislatures in nearly 20 states across the United States enacted legislation specifically authorizing the possession and use of CBD, in many cases, expressly for the treatment of medical conditions such as epilepsy. *See e.g.* H.B. 2238, 97th Gen. Assem., 2d Reg. Sess. (Mo. 2014); Ala. Code § 13A-12-214.2. This CBD-only legislation generally also requires adequate supervision by a licensed physician, further ensuring there exists an acceptable safety for use of components of "marihuana extract."

For these reasons, even if DEA engaged in the appropriate scheduling actions pursuant to sections 811 and 812 of the CSA, DEA could not reasonably determine there does not exist currently accepted medical uses or safety of uses of many of the constituents of "marihuana extract."

As explained *supra*, DEA neither specifically found any, much less all, of the required findings pursuant to sections 811(b) and 812(b) of the CSA, nor could the DEA conclude such findings given the affirmative legislative and rulemaking actions taken by Congress, FDA and numerous state legislatures. Therefore, in no form or fashion could "marihuana extract" qualify as a substance to be listed in Schedule I of the CSA. Therefore, Petitioners request that the Final Rule be stricken, invalidated, and/or amended to render it consistent with congressional intent and codified law. And the DEA must be enjoined from any enforcement action based upon this Final Rule as it is presently worded.

II. THE FINAL RULE VIOLATES THE DATA QUALITY ACT

DEA's misinformation and inconsistent statements regarding industrial hemp, and cannabinoids such as CBD, also violate the Data Quality Act (DQA). *Treasury and General Government Appropriations Act for Fiscal Year 2001, Pub. L. No. 106-554, § 515, 114 Stat. 2763 (2000).* The primary purpose of the DQA is to "ensur[e] and maximize[e] the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies." *Id.* As described *supra*, by consistently misstating the law and facts regarding industrial hemp generally, and CBD in particular, DEA has violated the letter, if not the spirit, of the DQA. *See e.g.* Wallace, *supra*. Misleading statements, such as those by DEA's own spokespeople or those contained within DEA's own publications and publicly

available content, undermine the integrity and reliability of information made available concerning industrial hemp products. Accordingly, DEA's misinformation and inconsistent statements are violative of the DQA. Therefore, for DEA's violation of the Data Quality Act, Petitioners request that the Final Rule be stricken, invalidated, and/or amended to render it consistent with congressional intent and codified law. And the DEA must be enjoined from any enforcement action based upon this Final Rule as it is presently worded.

III. THE FINAL RULE VIOLATES THE REGULATORY FLEXIBLIITY ACT AND CONGRESSIONAL REVIEW ACT

A. REGULATORY FLEXIBILITY ACT AND CONGRESSIONAL REVIEW ACT BACKGROUND

In 1980, Congress passed the Regulatory Flexibility Act ("RFA") mandating federal agencies to consider the impact of proposed regulations on small entities and whether equally effective alternatives exist which would reduce the impact on small businesses. 5 U.S.C. § 601 *et seq*. "Small entity," "small business" and "small business concern" share the same definition as a business "independently owned and operated and which is not dominant in its field of operation." 5 U.S.C. § 601 (3), (6); 15 U.S.C. § 632.

In 1996, Congress strengthened the RFA when it passed the Small Business Regulatory Enforcement Fairness Act ("SBREFA"). Included within the SBREFA

is the Congressional Review Act ("CRA"). 5 U.S.C. § 801 et seq. The CRA mandates:

> *(a)(1)(A) Before a rule can take effect, the Federal agency promulgating such rule shall submit to each House of the Congress and to the Comptroller General a report containing—…*
> *(ii) a concise general statement relating to the rule, including whether it is a major rule….*

5 U.S.C. § 801. [Emphasis added.] A "major rule" is defined as:

> *any rule that the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget finds has resulted in or is likely to result in—*
> *(A) an annual effect on the economy of $100,000,000 or more;*
> *(B) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or*
> *(C) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.*

5 U.S.C. § 804. If the agency action is a major rule:

> *(2)(A) The Comptroller General shall provide a report on each major rule to the committees of jurisdiction in each House of the Congress by the end of 15 calendar days after the submission or publication date as provided in section 802(b)(2). The report of the Comptroller General shall include an assessment of the agency's compliance with procedural steps required by paragraph (1)(B).*

5 U.S.C. § 801. As discussed below, the Final Rule adversely effects the industrial hemp industry in numerous substantial and severe manners, thus implicating status as a "major rule." DEA failed to appropriately designate, to Congress and to the Comptroller General, the Final Rule as a "major rule." Accordingly, the Comptroller General did not conduct the appropriate assessment necessary to satisfy the RFA and

CRA prior to DEA's promulgation of the Final Rule. For these reasons, promulgation of the Final Rule is fatally flawed and violates the RFA and CRA.

Instantly, DEA's Final Rule summarily concludes without any analysis or evidence:

> *[The Final Rule] is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act (CRA)). This rule will not result in: an annual effect on the economy of $100,000,000 or more . . .*

Final Rule, 81 Fed. Reg. at 90,196, ER at 14. DEA also summarily concludes:

> *The Administrator, in accordance with the Regulatory Flexibility Act (RFA), 5 U.S.C. 601–602, has reviewed this rule and by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities. This rule establishes a new drug code for marihuana extracts. DEA already registers persons handling marihuana extracts but within another already-established drug code. Thus, persons who handle these marihuana extracts have already met DEA's registration, security, and other statutory and regulatory requirements. The only direct effect to registrants who handle marihuana extracts will be the requirement to add the new drug code to their registration. Therefore, DEA has concluded that this rule will not have a significant effect on a substantial number of small entities.*

Id. [emphasis added].

Initially, DEA erroneously asserts that the Final Rule will only impact those already registered with DEA. As discussed *supra*, the definition of "marihuana extracts" overbroadly encompasses numerous stakeholders in the industrial hemp industry – businesses dealing in products containing non-viable hemp seed oil, as

confirmed by this Court in the early 2000's; actors engaged in Farm Bill-authorized activities; businesses dealing in importing exempt portions of the *Cannabis* plant; and others. Each of these subsets of stakeholders are adversely impacted by the Final Rule, yet virtually none of these stakeholders are registered with the DEA, as the DEA suggests, nor is the DEA willing to register such stakeholders.

DEA cannot reasonably characterize these subsets of stakeholders as "insubstantial" in number and "small" in stature. Many of these companies are national or multinational publicly traded companies distributing products through national, and even worldwide, retailers.

Accordingly, DEA's statements regarding the economic impacts of the Final Rule misleading and baseless, and in some respects, patently false. This, together with DEA's summary conclusion that the Final Rule is not a major rule violates the RFA and CRA requiring the Rule be held invalid. As a consequence, Petitioners request that the Final Rule be stricken, invalidated, and/or amended to render it consistent with congressional intent and codified law. And the DEA must be enjoined from any enforcement action based upon this Final Rule as it is presently worded.

B. THE FINAL RULE IS A MAJOR RULE

1. THE SIZE AND GROWTH OF THE UNITED STATES INDUSTRIAL HEMP EXTRACT INDUSTRY

SeedCX, an Illinois-based hemp commodities exchange registered as a Swap

Execution Facility by the Commodities Futures Trading Commission ("FTC"), estimated the total 2016 deliverable supply of CBD (in extract form) from industrial hemp in the nation to be approximately 169,000 kilograms. SeedCX, *Estimating Deliverable CBD,* CBD Deliverable Supply (Apr. 3, 2017), https://s3-us-west-2.amazonaws.com/seedcx.com//assets/CBD-Deliverable-Supply.pdf. Of this, approximately 144,000 kg of CBD was sourced from domestically-cultivated industrial hemp grown pursuant to the Farm Bill while the remaining amount – approximately 25,000 kg —was imported. *Id.* SeedCX calculated the cost of production of 1 kg of industrial hemp-derived CBD to be $7,000. SeedCX, *Production Method, A Quick Look at CBD Production Costs* (Apr. 3, 2017), https://s3-us-west-2.amazonaws.com/seedcx.com//assets/Cost-of-Production.pdf. With these figures, the cost of producing CBD exclusively from U.S.-grown industrial hemp was approximately $1 billion in 2016. *Id.* Utilizing an average retail price of $20,000/kg, the retail value of the domestically cultivated, industrial hemp-derived CBD products last year was approximately $2.88 billion. SeedCX, *Hemp Plant Extract Contract Compendium* (Apr. 3, 2017) https://s3-us-west-2.amazonaws.com/seedcx.com//assets/CBD-contract-addendum-v2.pdf. Estimates of total retail U.S. sales of CBD from hemp are difficult to determine due to the nascent nature of the industry, but *Forbes* predicts CBD sales in America could grow by 700% by 2020. *See* Borchard, Debra, *The Cannabis Market that Could Grow*

700% by 2020, FORBES, https://www.forbes.com/sites/debraborchardt/2016/12/12/the-cannabis-market-that-could-grow-700-by-2020/#1edc9b6c4be1(last accessed: Apr. 3, 2017).

Even major national retailers including Costco Wholesale Corp. and Target have recently sold cannabinoid-rich hemp-derived products. *See* Skeritt, Jen*, How Hemp Is Slowly Becoming The New Tobacco For Kentucky Farmers*, THE CANNABIST, http://www.thecannabist.co/2016/12/23/hemp-kentucky-farmers-crop/69917/ (last accessed: Apr. 3, 2017). Total retail sales of hemp products in the U.S. reached $573 million in 2015. *Id*.

SeedCX estimates that deliverable supply of cannabinoid-rich hemp products increased by 144% from 2015 to 2016. SeedCX, *Locating Hemp Production,* State of U.S. Hemp Production (Apr. 3, 2017) https://s3-us-west-2.amazonaws.com/seedcx.com//assets/State-of-U.S.-Hemp-Production.pdf.

For these reasons, and contrary to DEA's summary conclusions, the Final Rule will significantly impact the U.S. economy and small businesses. Few, if any, U.S. businesses involved in the industrial hemp industry are registered with the DEA. Consequently, the Final Rule will substantially impact hundreds if not thousands of businesses and likely result in an annual effect of well over $100,000,000 annually on the economy by instantly transforming these previously lawful operations as subject to DEA registration and drug code assignation,

effectively treating these substances as controlled.

Moreover, the Final Rule's implementation and shuttering of hundreds of U.S. businesses in favor of a single foreign-based pharmaceutical company, Letter from Alice P. Mead, Director, U.S. Professional Relations, GW Pharmaceuticals Ltd., to Michele M. Leonhart, Administrator, DEA, in support of Proposed Rule (Sept. 5, 2011) (on file with DEA and available at https://www.regulations.gov/document?D=DEA-2011-0006-0007), ER at 15, will likely result in a major increase in costs and prices for consumers, individual industries and geographic regions. It is also likely to have adverse effects on competition, employment, investment, productivity, innovation and on the ability of United States-based enterprises to compete with their foreign-based counterparts in domestic and export markets. The Final Rule is, thus, a major rule as defined by the CRA. DEA's declaration that it was not, and the subsequent failure of the Comptroller General to timely issue a report pursuant to 5 U.S.C. § 801, must result in the Court invalidating the Rule. Therefore, Petitioners pray that the Final Rule be stricken, invalidated, and/or amended to render it consistent with Congressional intent and codified law. And the DEA must be enjoined from any enforcement action based upon this Final Rule as it is presently worded.

CONCLUSION

For the reasons set forth above, the Court should find that the Final Rule must be stricken, invalidated, and/or amended to render it consistent with congressional intent and codified law. And the DEA must be enjoined from any enforcement action based upon this Final Rule as it is presently worded.

If the Court finds the Final Rule is valid, the Court should remand the Final Rule to DEA to undertake a proper rulemaking procedure and/or scheduling action, as the case may be; to undertake a proper regulatory flexibility analysis; and should also find that DEA's failure to extend the exemptions from scheduling of certain portions and varieties of the *Cannabis*, and derivatives therefrom, is arbitrary and capricious, and contrary to law.

STATEMENT OF RELATED CASES

Petitioners are not aware of any other cases related hereto.

Respectfully submitted,

/s/ Patrick D. Goggin
Patrick D. Goggin, SBN 182218
Hoban Law Group
870 Market Street, Suite 1148
San Francisco, CA 94102
Telephone: (415) 981-9290

Robert Hoban
Garrett Graff
Hoban Law Group
730 17th St, Ste 420
Denver, CO 80202

CERTIFICATE OF COMPLIANCE PURSUANT TO FED. R. APP.32(a)(7) AND CIRCUIT RULE 32-1

I certify that:

Pursuant to Fed. R. App. P. 32(a)(7)(C) and Ninth Circuit Rule 32-1, the attached opening brief is

__X__ Proportionately spaced, has a typeface of 14 points or more and contains _13,614_ words (opening, answering and the second and third briefs filed in cross-appeals must not exceed 14,000 words; reply briefs must not exceed 7,000 words),

Or is

____ Monospaced, has 105 or fewer characters per inch and contains ___ words or _____ lines of text (opening, answering and the second and third briefs filed in cross-appeals must not exceed 14,000 words or 1,300 lines of text; reply briefs must not exceed 7,000 words or 650 lines of text).

Dated: _April, 3, 2017_____ _*/s/ Patrick D. Goggin*_____
Attorney for Petitioners

CERTIFICATE OF SERVICE

I certify that on April 3, 2017, I served a true and correct copy of the foregoing Brief of Petitioners:

Via PACER, e-filed upon:

Brian Stretch
United States Attorney
Office of the United States Attorney
450 Golden Gate Ave, 11th Floor
San Francisco, CA 94102

John J. Martin
Special Agent in Charge
Drug Enforcement Administration
450 Golden Gate Ave, 14th Floor
San Francisco, CA 94102

The Honorable Loretta Lynch
Attorney General of the United States
U.S. Department of Justice
950 Pennsylvania, NW
Washington, DC 20530

The Honorable Chuck Rosenberg
Drug Enforcement Administration
7000 Army-Navy Dr
Arlington, VA 22202

Wendy H. Goggin
Chief Counsel
Office of General Counsel
Drug Enforcement Administration
8701 Morrissette Dr
Springfield, VA 22152

/s/ Patrick D. Goggin
Patrick D. Goggin,

Dated: April 3, 2017