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 RULE
OF DRUG ENFORCEMENT ADMINISTRATION

REPLY BRIEF FOR PETITIONERS

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Petitioners	)
v.	)
Drug Enforcement Administration; Charles Rosenberg, as Acting Administrator, Drug Enforcement Administration	)
Respondents	)

REPLY BRIEF FOR PETITIONERS

SUMMARY OF ARGUMENT

"*Congress knew what it was doing and its intent to exclude non-psychoactive hemp from regulation is entirely clear.*"[1]

In many respects, Drug Enforcement Administration's ("DEA") *Brief of Respondents* ("*Respondents' Brief*") operates a blatant disregard and affront to the plain language of multiple laws as set forth by Congress and binding jurisprudential

[1] *See Hemp Industries Association v. DEA*, 357 F.3d 1012, 1018 (9th Cir. 2004) ("*HIA II*").

precedent set forth by this Court, all whilst validating Petitioners' claims from its *Brief of Petitioners* ("*Petitioners' Brief*"). For the reasons discussed more fully in *Petitioners' Brief* and herein, Petitioners respectfully request this Court find the Final Rule must be stricken, invalidated, and enforcement thereof enjoined.

Respondents' Brief confirms that its Final Rule concerning "marihuana extract" is effectively a rule concerning "cannabis extract." Conceptually, "marihuana," as defined by the federal Controlled Substances Act (the "CSA"), specifically cites a certain species, *Cannabis sativa L.*; conversely, the Final Rule more broadly cites "the genus Cannabis." For this reason alone, Respondents' contention that the Final Rule is narrowly tailored to "marihuana," and consistent with the CSA as provided for by Congress, is in clear and unequivocal error.

The same logic applies to Petitioners' other arguments concerning the plain language of the Final Rule. Respondents attempt to rely upon their *Clarification of the New Drug Code (7350) for Marijuana Extract* (the "*Clarification*") in stating that the Final Rule does not include, and was not intended to include, those parts of the *Cannabis* plant found by this Court to "fit[] within the plainly stated exception to the CSA definition of marijuana." *See HIA II,* 357 F.3d at 1018. Yet, the plain language of Respondents' Final Rule says precisely the opposite and fails to provide any comparable exemption; in other words, Respondents' *Clarification* is essentially an admission that the Final Rule is not narrowly tailored to the definition of

"marihuana." Thus, the informal *Clarification* is insufficient to meaningfully amend and correct this fatal flaw.

Moreover, as more fully discussed in *Petitioners' Brief*, the Final Rule's definition of "marihuana extract" fails to exclude derivatives from "industrial hemp," as defined by the Agricultural Act of 2014 (the "Farm Bill"). Respondents openly admit the same, noting the Final Rule "does not purport to override the [Farm Bill]," instead arguing Respondents are not required to promulgate rules and definitions which reflect the law. *Resp. Br.* at 13-14, 32. Again, Respondents' position operates an apparent and obtuse recalcitrance for explicit congressional action.

Similarly, though Respondents' definition of "marihuana extract" suggests the presence of cannabinoids as the determining factor of a substance being deemed "marihuana extract," Respondents openly admit cannabinoids may be found in parts of the *Cannabis* plant which the CSA does not control. *Id.* at 26-27. Respondents also agree that cannabinoids may be found in other sources besides *Cannabis* and that "DEA is not seeking to schedule cannabinoids." *Id.* at 28. Contrary to Respondents' admissions and asserted positions, the Final Rule's plain language brazenly collapses all cannabinoids which *could possibly* be derived from the genus *Cannabis* (whether lawfully derived or not) into "marihuana extract."

Consequentially, the Final Rule's plain language does not – and cannot – comport with existing law and jurisprudence.

The collective sum of Final Rule's numerous fatal flaws lead to actual and continued imminent threat of harm to Petitioners and other similarly situated parties, establishing Petitioners' standing. As more fully discussed herein, there exist numerous instances of:

(a) Respondents' citing non-scheduled substances and non-existent drug codes – like the one the Final Rule purports to establish – to justify the seizure and destruction of certain products;

(b) Sister federal, state and local law enforcement and regulatory agencies citing Respondents' statements and the Final Rule as justification for enforcement actions and criminal prosecutions, including the seizure of products and demanded surrender of prior regulatory approvals;

(c) Public misrepresentations and misstatements by Respondents, sometimes specifically mentioning members of Petitioner Hemp Industries Association ("HIA") as "clandestine," citing hemp and derivatives therefrom to be illegal;

(d) Ancillary service providers, such as insurers, refusing provision of services to businesses lawfully engaged in hemp-related activities; and,

(e) Significant disruption and interruption in the businesses of Petitioners, causing substantial economic and other damages.

For these reasons, Respondents' contention that the Final Rule is a "mere recordkeeping measure" and that Petitioners lack standing to challenge the Final Rule entirely lacks merit.

Likewise, Respondents' other justiciability argument, concerning waiver, is baseless; Respondents had an opportunity to address the root of this litigation in the administrative forum. At least one comment submitted during notice-and-comment posed the overarching issue raised here: the Final Rule's definition of "marihuana extract" encompasses substances not previously controlled under the CSA. Additionally, due to the intervening enactment of the Farm Bill, exceptional circumstances exist to excuse any waiver (though no waiver occurred). As such, the issues now before this Court have not been waived.

For any one, much less all, of the fatal flaws and exhibitions of overt and subversive recalcitrance inherent to Respondents' Final Rule, Petitioners respectfully request this Court find the Final Rule must be stricken, invalidated, and enforcement thereof enjoined.

ARGUMENT

I. RESPONDENTS OPENLY ADMIT FATAL FLAWS OF THE FINAL RULE AS INCONSISTENT WITH PREVAILING LAW AND BINDING JURISPRUDENCE.

The many number of flaws, admissions, and concessions contained within *Respondents' Brief*, and the conflicts of Respondents' asserted positions with their conduct in practice, underscore the necessity and validity of this action and Petitioners' claims; these flaws fly in the face of existing congressional enactments and this Court's binding precedent.

As an initial issue, the Final Rule's definition of "marihuana extract" inappropriately deviates from congressional law in several respects:

(1) Respondents mistakenly reference "any genus *Cannabis*" versus "marihuana," as set forth in the CSA;

(2) The reference of the mere presence of cannabinoids which *may* be derived – but are not exclusively derived – from "any genus *Cannabis*";

(3) The failure to exclude those parts and derivatives of the *Cannabis* plant exempted from the definition of "marihuana" pursuant to the CSA; and,

(4) The failure to exclude "industrial hemp," and derivatives therefrom, as provided for in the Farm Bill.

Despite Respondents admitting on many occasions that the above inconsistencies exist, Respondents' Final Rule and its fatal flaws remain formally

unchanged and Petitioners continue to face actual and continued imminent threat of ongoing harm. For these reasons, Respondents' Final Rule violates DEA's own rulemaking authority as well as the Administrative Procedures Act.[2] Petitioners respectfully request this Court find the Final Rule be stricken, invalidated, and enforcement thereof enjoined.

A. The Final Rule Continues to Reference Cannabinoids as a Determinative Factor, Despite Respondents' Admitting Such Are Not, *Per Se*, Controlled Substances.

In relevant part, the Final Rule defines "marihuana extract" as "an extract *containing one or more cannabinoids* . . ." ER 12.[3] *Respondents' Brief* concedes: (a) cannabinoids are not independently scheduled nor does DEA seek to regulate the same; (b) cannabinoids naturally occur in certain lawful and exempted portions and varieties of the *Cannabis* plant; and, (c) cannabinoids may also be derived from non-*Cannabis* sources. *Resp. Br.* at 27-30.

Contrastingly, Respondents' Final Rule continues to reflect language that the mere presence of cannabinoids is a determinative factor of a substance being deemed "marihuana extract." This position fails to consider the reality – one Respondents admit – that some cannabinoids obtained from "marihuana" may be lawfully

[2] Section I of *Petitioners' Brief* more fully discusses the legal standards with which Respondents must comply, including 21 U.S.C. §§ 811(a), 812(b) and the Administrative Procedures Act, 5 U.S.C. § 500, *et seq*. An agency action may be set aside if it violates these standards.
[3] "ER" refers to Excerpts of Record.

obtained from lawful sources, such as those parts of the "genus *Cannabis*" excluded from "marihuana," and from "industrial hemp," as provided for by the Farm Bill.

However, because cannabinoids may be lawfully derived, Respondents would then need to evaluate a substance to determine whether lawfully or unlawfully derived. Respondents fail to articulate methodologies by which Respondents, or any other agency, may evaluate whether a substance constitutes "marihuana extract" or is exempted. Absent a methodology, any products containing cannabinoids – regardless of amount or source of cannabinoids – are subjected to actual and imminent threat of seizure and/or destruction by Respondents and other federal, state and local agencies, as exemplified by Petitioners' and similarly situated parties' experiences. FER, Exhibits B – L. Even more offensive, this conduct occurs generally without due process ever given to an aggrieved party. Under the Final Rule, Respondents and sister agencies effectively "collapse" the distinctions between lawfully-derived and unlawfully-derived cannabinoids, treating all as "marihuana extract."

Respondents wield self-perceived plenary power and do, in fact, hold cannabinoids out to be illegal *per se*, demonstrating actual and threatened harm, disclaimed by Respondents in *Respondents' Brief*. For example, Respondents have published materials specifically citing cannabidiol ("CBD") as being a "Schedule 1 controlled substance" per the CSA. *See* Alicia Wallace, *In the DEA's words: Agency*

stance on CBD, hemp products and the Farm Bill, THE CANNABIST, THE DENVER POST, July 5, 2017 (available at http://www.thecannabist.co/2017/07/05/dea-statement-cbd-hemp-farm-bill-controlled-substances-act/83100/); *see also* DRUG ENFORCEMENT ADMINISTRATION, DEA Eases Requirements for FDA-Approved Clinical Trials on Cannabidiol (Dec. 23, 2015) (available at https://www.dea.gov/divisions/hq/2015/hq122315.shtml).

Moreover, contemporaneous with the Final Rule's promulgation, Respondents justified the seizure and destruction of certain materials of a member of HIA, specifically citing the presence of cannabigerol ("CBG") as illegal – even citing a four-digit drug code, purportedly for CBG, that does not exist within the *Code of Federal Regulations* or Respondents' own Orange Book. FER, Exhibit B.[4] Deferring to Respondents, sister federal, state, and local agencies cite Respondents and the presence of cannabinoids when (mistakenly) deeming substances illegal. *See, e.g.*, FER, Exhibit C.

Stated differently, though Respondents now disclaim any attempt to regulate cannabinoids, the Final Rule's plain language and practical application thereof results in the exact opposite: the presence of cannabinoids renders a substance "marihuana extract," allegedly subject to regulation. For these reasons, Petitioners

[4] "FER" refers to Petitioners' Further Excerpts of Record, filed contemporaneously herewith.

respectfully request this Court find the Final Rule must be stricken, invalidated, and enforcement thereof enjoined.

B. Respondents' *Clarification* Admits the Final Rule's Definition is Flawed and that Respondents Cannot Regulate Exempt Parts of the Plant.

In contrast to the plain language of the Final Rule, during the pendency of this action, Respondents informally published their *Clarification* and subsequently argued the same in *Respondents' Brief*, admitting Respondents maintain no jurisdiction to regulate those parts of the plant expressly excluded from the CSA definition of "marihuana." DEA, Diversion Control Division, *Clarification of the New Drug Code (7350) for Marijuana Extract* (2017) (available at https://www.deadiversion.usdoj.gov/schedules/marijuana/m_extract_7350.html) (cited herein as "*Clarification*"); *Resp. Br.* at 27-30. Despite Respondents' informal efforts to validate the Final Rule's overly broad definition of "marihuana extract," it remains undisputed (and confessed by Respondents) the Final Rule – as formally promulgated – is fatally flawed. Consequentially, Petitioners respectfully request this Court find the Final Rule must be stricken, invalidated, and enforcement thereof enjoined.

The fact Respondents informally published the *Clarification* demonstrates the Final Rule's inherent impropriety. More importantly, the Final Rule flies in the face of congressional enactments confirmed by this Court in the early 2000s. *See Hemp*

Industries Association v. DEA, 333 F.3d 1082, 1088 (9th Cir. 2003) ("*HIA I*"); *HIA II*, 357 F.3d at 1018. The plain language of the Final Rule regulates "any extract from one or more cannabinoids from the genus Cannabis." ER 12. However, both *Respondents' Brief* and the *Clarification* admit, "[i]f a product consisted solely of parts of the cannabis plant excluded from the CSA definition of marijuana, such product would not be included in the new drug code (7350) or in the drug code for marijuana (7360)." *Clarification*; *see also Resp. Br.* at 27.

In 2004, this Court found "non-psychoactive hemp" derived from those certain parts of the plant exempted from the definition of "marihuana" "fits within the plainly stated exception to the CSA definition of marijuana. . . . Congress knew what it was doing and its intent to exclude non-psychoactive hemp from regulation is entirely clear." *HIA II*, 357 F.3d at 1018. Consistent with Respondents' *Clarification*, the plain language of the Final Rule's definition of "marihuana extract" undisputedly fails to exempt those parts of the plant exempted by Congress and judicially confirmed by this Court.

Though Petitioners acknowledge Respondents' efforts to informally clarify the Final Rule to redress flaws contained therein, the plain language of the Final Rule unambiguously contravenes the CSA's exclusions from "marihuana" and this Court's prior rulings.

1. Respondents' newly created standards are both insolvable and insufficient.

Despite the informal efforts to validate the Final Rule, Respondents attempt to justify the Final Rule as only regulating extracts containing more than "trace" amounts of cannabinoids and only those cannabinoids derived from "marihuana." *Id.* Respondents' distinctions are without a difference. Respondents, and sister agencies relying upon Respondents' interpretations of law, fail to articulate how to evaluate these distinctions and standards in practice. *See* FER, Exhibit E. Respondents' distinctions are neither reflected in the plain language of the Final Rule nor comport with the plain language of the CSA, Farm Bill, and other sources of law.

This unfounded "trace" versus "non-trace" standard violates Respondents' definition of "marihuana extract."[5] By definition, an extract containing even trace amounts of cannabinoids derived from parts of the plant exempted from "marihuana" or from "industrial hemp" would, on one hand, qualify as "marihuana extract" (per the Final Rule), yet on the other hand, be exempted from the Final Rule (per the *Clarification*). *Compare* ER. 12, *with Clarification*. If Respondents cannot clearly understand and articulate the standard, Respondents cannot be expected to

[5] Respondents fail to articulate an objectively measurable distinction between "trace" and "non-trace," further rendering hopelessly insolvable an already ill-advised standard.

accurately disseminate the law, nor can other agencies be expected to accurately and appropriately apply and enforce the law.

Even if the "trace" versus "non-trace" standard could pass muster (it cannot), discussed *infra* in Section I.B.2., Respondents continuously fail to articulate any methodology with which to evaluate whether a substance is comprised of parts or varieties of the *Cannabis* plant, or derivatives thereof, which are lawfully sourced. Without an objective standard expressly enacted or promulgated, Respondents are left – unchecked – to create standards as they see fit. The practical result is the summary conclusion by Respondents and sister agencies relying thereupon that any extract containing cannabinoids is illegal.

In its *Clarification*, Respondents cite twenty-year-old "scientific literature" that "it is not *practical*" for cannabinoids to be obtained from exempted portions of the *Cannabis* plant. *Clarification* (emphasis added). Respondents are wrong. First, Respondents' own language admits that it is indeed *possible* to obtain cannabinoids from the exempted portions of the *Cannabis* plant. *See Clarification* (use of "not practical" versus "impossible"). Next, by ignoring scientific and technological developments which occurred over at least two decades, Respondents fail to recognize that technology exists to concentrate any amount of extracted cannabinoids. *See, e.g.*, U.S. Patent No. 8,937,191 B2 (filed Dec. 20, 2012) (issued Jan. 20, 2015).

Such scientific and technological developments undermine Respondents' position on (1) the impracticality of extracting cannabinoids from exempted parts of the *Cannabis* plant and (2) failing to articulate a methodology to determine cannabinoid source. Without an articulated methodology, Respondents' cannot determine whether any given extract is derived from:

1. Exempted portions of the *Cannabis* plant;[6]
2. "Industrial hemp," cultivated pursuant to the Farm Bill;
3. "Marihuana," as defined by the CSA; or,
4. Non-*Cannabis* sources altogether.

The simple answer and reality of the practices to date of Respondents and their sister federal, state and local agencies: they cannot and do not make any definitive evaluation or source determination, thus summarily "collapsing" all extracts containing cannabinoids into "marihuana extract." This contradicts the CSA, Farm Bill, and this Court's prior rulings.

[6] The Final Rule's failure to reference or expressly exclude derivatives of the exempted parts of the *Cannabis* plant necessarily causes all extracts from *Cannabis* to be deemed "marihuana extract." Even products such as those containing hempseed oil extracts are encompassed within Respondents' current definition of "marihuana extract."

2. An informally published clarification does not possess sufficient effect to amend the Final Rule.

DEA's *Clarification* is insufficient as an informal publication seeking to validly clarify or amend the Final Rule. By posthumously publishing the *Clarification* in hopeful avoidance of formal amendment of the Final Rule, the *Clarification*'s plain language presents an inherent conflict with the Final Rule.

Although agencies may issue interpretive rules without notice-and-comment, agencies must use notice-and-comment when promulgating legislative rules. *HIA I*, 333 F.3d at 1087. Legislative rules have the "force of law." *Id*. One factor this Court has used to determine whether a rule has the "force of law" is whether the rule "effectively amends a prior legislative rule." *Id*. (citing *Shalala v. Guernsey Memorial Hospital*, 514 U.S. 87, 112 (1995)).

Here, the *Clarification* is undoubtedly a legislative rule. The *Clarification* amends the Final Rule by, among other things, limiting the plain language of "any plant of the genus Cannabis" to mean only the CSA's definition of "marihuana." As such, the *Clarification* effectively amends the Final Rule, and has the "force of law." *See HIA I*, 333 F.3d at 1087. Without engaging "the time-consuming procedures of the APA," the *Clarification* is invalid. *Id*. at 1091. "An agency is not allowed to change a legislative rule retroactively through the process of disingenuous interpretation of the rule to mean something other than its original meaning." *Caruso*

v. Blockbuster-Sony Music Entertainment Centre at the Waterfront, 193 F.3d 730, 737 (3d Cir. 1999) (quoted with favor in *HIA I*, 333 F.3d at 1091).

Because the plain language of Respondents' Final Rule and *Clarification* operate in direct conflict with one another, and the *Clarification* is merely informal, Respondents weave an even deeper web of misstatements and misleading publications. Respondents essentially admit a violation of the Information Quality Act, discussed *infra* in Section IV.A. Taken together, it is easily understandable, if not uncontrovertibly likely, that Respondents and sister federal, state and local agencies will remain befuddled by the information disseminated by Respondents on this topic.

In sum, *Respondents' Brief* and their *Clarification* present more confounding issues and unfounded standards than they resolve. For failure to exclude those parts of the plant exempted from the definition of "marihuana," a direct affront to this Court's binding precedent, Petitioners respectfully request this Court find the Final Rule must be stricken, invalidated, and enforcement thereof enjoined.

C. Respondents Concede They Maintain No Jurisdiction over the Farm Bill.

Like the *Clarification*'s admission, Respondents' admit and confirm Respondents retain no jurisdiction over Farm Bill activities authorized.

Respondents' position appears consistent with the testimony of its Acting Administrator and Respondent, Chuck Rosenberg. On April 4, 2017, the day after

Petitioners' Brief was filed, Administrator Rosenberg testified before a subcommittee of the House Judiciary Committee, in response to a question related to Respondents' treatment of hemp farmers, "No . . . [the DEA is] not looking to harass those who abide by [the Farm Bill]." *Hearing on Oversight of the Drug Enforcement Administration and Bureau of Alcohol, Tobacco, Firearms and Explosives before the Subcomm. On Crime, Terrorism, Homeland Security and Investigations of the H. Comm. on the Judiciary*, 115th Cong. (2017) (statement of Acting Administrator Chuck Rosenberg, DEA) (video recording available at https://www.c-span.org/video/?c4665923/rep-goodlatte-asks-dea-harassing-hemp-farmers) ("*Rosenberg Testimony*").

As the *Rosenberg Testimony* echoed, Congress specifically prohibited Respondents from expending resources "in contravention of the [Farm Bill]; or to prohibit the *transport, processing, sale or use*" of industrial hemp, or derivatives therefrom, within or outside of the state in which the hemp is cultivated. Consolidated Appropriations Act 2016, Pub. L. No. 114-113, 129 Stat. 1175 (§ 763); Consolidated Appropriations Act 2017, Pub. L. 115-31 (§§ 538, 773) (collectively, the "Spending Bill") (*emphasis* added). Because "industrial hemp" extracts necessarily contain *Cannabis*-derived cannabinoids, enforcement of the Final Rule's plain language unavoidably violates both the Farm Bill and Spending Bill.

Notwithstanding Respondents' disclaimer of jurisdiction, this inherent flaw in the Final Rule lead to enforcement actions against, and significant disruption and damages to, Petitioners and similarly situated parties.

II. PETITIONERS POSSESS STANDING TO CHALLENGE THE FINAL RULE.

Respondents ask this Court to put the proverbial cart before the horse with respect to standing, arguing that Petitioners do not have standing because the Final Rule imposed no new requirements on Petitioners. But that is the controversy before this Court – that the Final Rule creates new obligations and prohibitions not previously included in the CSA. Respondents and Petitioners appear to be prepared to address this issue, but it is properly reserved for argument on the merits, not over standing. Indeed, the fact Respondents and Petitioners disagree on the reach of the Final Rule establishes the existence of an "actual controversy." *See* U.S. Const., Art. III, Sec. 2.

In a case similar hereto, this Court established the standing standard to appeal a DEA action: "[P]laintiffs must clearly demonstrate that they have suffered an "injury in fact"--an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical." *HIA I*, 333 F.3d at 1086 (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 559 (1992)). In that case, Respondents argued that petitioners could not demonstrate an injury in

fact because no agency had enforced the newly issued rule, e.g. seized property or commenced criminal proceedings. *Id*.

This Circuit, however, relied on earlier precedent, *City of Auburn v. Qwest*, 260 F.3d 1160, 1171 (9th Cir. 2001), to dispel Respondents' argument. Notably, "[i]f [p]romulgation of the challenged regulations present[s] plaintiffs with the immediate dilemma to choose between complying with newly imposed, disadvantageous restrictions and risking serious penalties for violation, the controversy is ripe." *HIA I*, 333 F.3d at 1086 (citing *Qwest*, 260 F.3d at 1171); *see also Qwest*, 260 F.3d at 1171 (quoting *Abbott Lab. v. Gardner*, 387 U.S. 136, 154 (1967)) ("There is no question . . . that petitioners have sufficient standing as plaintiffs: the regulation is directed at them in particular; it requires them to make significant changes in their everyday business practices; if they fail to observe the Commissioner's rule they are quite clearly exposed to the imposition of strong sanctions."). Under these standards, Petitioners have standing.

A. The Final Rule Imposes an Immediate Dilemma on Petitioners.

The Final Rule imposes new obligations on Petitioners. Specifically, the Final Rule improperly expands the reach of the CSA to touch Petitioners' business practices, previously legal under the CSA exemptions to "marihuana" and under the Farm Bill. Discussed *supra*, the plain language of the Final Rule makes Petitioners' business illegal. Petitioners are thus faced "with the immediate dilemma to choose

between complying with newly imposed, disadvantageous restrictions and risking serious penalties for violation." *HIA I*, 333 F.3d at 1086.

That Respondents' dispute Petitioners' argument that the Final Rule imposes new restrictions does not undermine Petitioners' standing. If anything, it buttresses the need for this Court to resolve the controversy on the merits, thereby resolving the dilemma the Final Rule has posed Petitioners.

B. Petitioners Face Concrete, Particularized, and Actual Enforcement Action and Economic Damages.

Since the issuance of the Final Rule, Petitioners[7] have faced and continue to face enforcement actions brought by Respondents and sister federal, state, and local law enforcement and regulatory agencies based on the plain language of the Final Rule, instantly transforming Petitioners' lawful businesses into illegal enterprises.

One week prior to DEA's promulgation of the Final Rule, DEA asserted, in writing, to a member of Petitioner HIA that CBG is illegal and cited a four-digit drug code purportedly associated thereto. FER, Exhibit B. The CSA undoubtedly does

[7] An institution may sue on behalf of its members when: "(a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization's purpose; and (c) neither the claim asserted nor the relief requested requires the participate of individual members in the lawsuit." *Hunt v. Wash. State Apple Advertising Comm'n*, 432 U.S. 333, 343 (1977); *Nuclear Energy Institute, Inc. v. EPA*, 373 F.3d 1251, 1290 (D.C. Cir. 2004). Respondents have not refuted this standard; if Petitioner HIA's member(s) have faced concrete, particularized, and actual enforcement actions based on the Final Rule sufficient for standing to challenge the Final Rule, Petitioner HIA possesses standing as well.

not include CBG as a controlled substance. Petitioners are neither aware, nor does either the *Code of Federal Regulations* or Respondents' Orange Book support, that there exists a four-digit drug code for CBG. This example – aptly timed just before the promulgation of the Final Rule – demonstrates Respondents' overeager willingness to wield non-existent drug codes for non-scheduled substances to serve as the basis for the seizure and destruction of cannabinoids.

On December 14, 2017, curiously the same day as Respondents promulgated the Final Rule, the Alcohol and Tobacco Tax and Trade Bureau ("TTB") demanded the surrender of another Petitioner HIA member's previously TTB-approved malt beverage formula containing hemp oil. There, TTB cited Respondents' prior publications asserting CBD is scheduled within the CSA. *See* DEA Eases Requirements for FDA-Approved Clinical Trials on Cannabidiol, *supra*. Subsequently, on December 30, 2016, TTB admitted it entirely "defers to the [DEA] in its interpretation of the CSA." FER, Exhibit D. Again, Petitioners remain actually and imminently threatened by the exhibited plenary deference of sister agencies to Respondents. In this sense, not only do Respondents present a threat, but the potential of each and every federal, state and local agency across the country mistakenly deferring to Respondents on these issues indeterminately multiplies the imminent threat.

To that end, since promulgation of the Final Rule, the Bismarck Police Department ("Bismarck PD") raided and seized hemp-derived products from multiple retailers in May 2017. Bismarck PD specifically cited Respondents' own recitation of 21 C.F.R. 1308.11 and specifically referenced the drug code for "marihuana extract." FER, Exhibit C. Moreover, Bismarck PD announced, via press release, that such products "became a controlled substance in December of 2016," again referencing the Final Rule. Press Release, Bismarck Police Department, Police Contact Local Merchants Who May Be Selling Illegal Products (May 12, 2017) (FER, Exhibit M).

Similarly, on December 23, 2017, the North Dakota Department of Agriculture issued a letter to Healthy Oilseeds, LLC, a registered cultivator of industrial hemp, mistakenly asserting Healthy Oilseeds, LLC could not continue to operate within a DEA license. *See* FER, Exhibit L.

Most recently, Respondents published a statement in THE DENVER POST's *The Cannabist* specifically alleging a particular high-profile member of HIA as being a "clandestine" operation whose products are entirely illegal. FER, Exhibit K; Alicia Wallace, *supra*. DEA's statement is a direct affront to Administrator Rosenberg's testimony before Congress that Respondents would not harass those operating pursuant to the Farm Bill. *Rosenberg Testimony*, *supra*. Though direct impacts of

Respondents' statement remain to be fully realized, it is reasonably expected such statements will continue to cause substantial and adverse impacts.

Additionally, U.S. Customs and Border Protection ("CBP") increasingly seizes products suspected to contain "marihuana extract." Since the Final Rule, CBP now frequently cites the presence of any tetrahydrocannabinol ("THC") *or* the presence of cannabinoids generally as the basis for seizure and immediate destruction of product. FER, Exhibit E.

To exemplify the reach of the Final Rule, Petitioner HIA represents the interests of 195 parties engaged in activities implicated by Respondents' Final Rule, accounting for approximately 35% of HIA's membership. Many within HIA's membership report adverse impacts and enforcement actions since Respondents' issuance of the Final Rule in December 2016. Correspondingly, the responding membership of HIA report, in the aggregate report, a loss of revenue approximating tens, if not hundreds, of millions of dollars since December 2016. FER, Exhibit E. Correspondingly, a number of HIA members provided information concerning the economic and other harms and disruption suffered as a result of the Final Rule. FER, Exhibits B, D, E, H, I, J, K.

Taken collectively, the above examples highlight the incalculable harm and threats, both actual and imminent, that Petitioners and others engaged in lawful

hemp-related activities face on a daily basis in light of the Final Rule. Such examples underlie, and demonstrate, Petitioners' standing in the instant matter.

III. THE ISSUES RAISED BY PETITIONERS HAVE NOT BEEN WAIVED.

This Court possesses jurisdiction to hear the issues raised by Petitioners; such issues have not been waived. Respondents assert Petitioners waived their concerns related to the Final Rule because Petitioners did not present such arguments to Respondents prior to the Final Rules' issuance. Respondents are incorrect.

At its core, Respondents suggest agencies may flout established law and clear congressional intent, provided no aggrieved party presents any legal inefficiencies prior to final agency action. Under Respondents' overreaching argument, if no such presentation occurred, an aggrieved party (and this Court) is powerless to prevent Respondents from acting contrary to congressional directive.

Moreover, Respondents' position is legally flawed. *Respondents' Brief* provided a framework for the doctrine of waiver with a patchwork of U.S. Supreme Court precedent addressing an agency's *adjudicative* powers and numerous D.C. Circuit opinions. This Circuit, however, has provided a pointed summary of the waiver doctrine and its reach:

> *[W]e will not invoke the waiver rule in our review of a notice-and-comment proceeding if an agency has had an opportunity to consider the issue. This is true even if the issue was considered* sua sponte *by the*

> *agency or was raised by someone other than the petitioning party. . . . We have also recognized that, so long as a statute does not require exhaustion, we may excuse waiver in exceptional circumstances.*

Portland General Elec. Co. v. Bonneville Power Admin., 501 F.3d 1009, 1024 (9th Cir. 2007) (internal citations omitted).

Accordingly, Petitioners' have not waived the issues raised instantly. First, Respondents had an opportunity to consider the issues with the Proposed Rule and Final Rule raised by Petitioners instantly. Second, the CSA does not require exhaustion, and exceptional circumstances exist that justify this Court's hearing of the issues. The issues raised by Petitioners thus have not been waived, and this Court may duly consider them.

A. Respondents Had an Opportunity to Consider Petitioners' Arguments in the Administrative Forum.

This Court held it "will not invoke the waiver rule in our review of a notice-and-comment proceeding if an agency has had an opportunity to consider the issue. This is true even if the issue . . . was raised by someone other than the petitioning party." *Portland General*, 501 F.3d at 1024; *see also Unemployment Compensation Comm'n of Alaska v. Aragon*, 329 U.S. 143, 155 (1946) (agency must have "an opportunity to consider the matter, make its ruling, and state the reasons for its action").

Such an opportunity need not be facilitated by the petitioners; issues raised in others' comments preserve petitioners' ability to argue the issue during judicial

review. *Portland General*, 501 F.3d at 1024; *see also Universal Health Servs., Inc. v. Thompson*, 363 F.3d 1013, 1018 (9th Cir. 2004) ("It is undisputed that *none* [of the comments] presented the specific arguments proffered by the hospitals in these cases.") (emphasis added); *id*. at 1019 (". . . neither they *nor anyone else* had raised them during the relevant comment periods.") (emphasis added).

In this case, Respondents possessed an opportunity to address the legal deficiencies in the Final Rule now raised by Petitioners. During the public comment period, Sherrie Berry commented on the Proposed Rule: "[Cannabidiol] is currently exempt as a schedule 1 drug and no DEA license is required to purchase it." ER 20. This is the main crux of Petitioners' argument: the Final Rule includes substances, *e.g.* cannabidiol, that were not previously controlled under the CSA.

This comment provided Respondents the opportunity to address concerns that the Proposed Rule affected substances not previously scheduled under the CSA. Respondents had more than five years to address these concerns before promulgating the Final Rule. Instead of addressing them, however, DEA dismissed Ms. Berry's comment by focusing on a discrete portion of her comment concerning the extraction of isolated CBD. ER 12.

Despite having more than five years to address the concern that cannabinoids generally, including CBD, were not previously scheduled under the CSA, Respondents chose to ignore this concern. Respondents summarily dismissed Ms.

Berry's concern by propagating its faulty premise that CBD cannot be extracted without amounts of other cannabinoids being present. Respondents' focus on extraction practicalities does not change the fact that it had a "fair opportunity" to address the notion that CBD – one of the cannabinoids explicitly noted in the Proposed Rule – would be newly included in Schedule I of the CSA. Accordingly, Petitioners' issues have not been waived, and Petitioners have properly asked this Court to rule on them.

B. Exceptional Circumstances Excuse Petitioners from Previously Raising the Instant Issues Administratively.

Even if waiver would normally prevent this Court from hearing Petitioners' arguments (it does not), exceptional circumstances exist that support the Court's consideration of the issues. Initially, the CSA does not require exhaustion. *See* 21 U.S.C. § 877. The CSA's provision on justiciability matters mentions only that persons aggrieved by final DEA action may seek judicial review of said action. *Id.*

As the CSA does not explicitly require exhaustion, this Court may excuse waiver when exceptional circumstances are present. *Portland General*, 501 F.3d at 1024. To analyze exceptional circumstances, courts consider an "agency's interest in applying its expertise, correcting its own errors, making a proper record, enjoying appropriate independence of decision and maintaining an administrative process free from deliberate flouting" and "the interest of private parties in finding adequate redress for their grievances." *See, e.g., Universal Health*, 363 F.3d at 1021.

Petitioners have not deliberately flouted the administrative process in this case. Importantly, two of three Petitioners were not in existence when the Proposed Rule's comment period ended. Respondents accepted comments on the Proposed Rule until September 6, 2011. Petitioners Centuria Natural Foods, Inc. and R.M.H. Holdings, Inc. registered with their respective states in 2014 and 2015, respectively, more than three and four years, respectively, after the comments period ended.

More significantly, a substantial change in law affected the substance of the Proposed Rule, yet Respondents did not reopen the comments period, or otherwise attempt to address the Farm Bill's impact on the Proposed Rule. This change in law also justifies excusing waiver (if there were waiver in this case, and there is not). *See generally Japanese Village, LLC v. FTA*, Case Nos. 14-56837, 14-56973 (9th Cir. Dec. 6, 2016).

Additionally, Petitioners have raised purely legal issues with respect to the Final Rule. Namely, the Final Rule flouts congressional directive and intent not only in the CSA, but also in the Farm Bill. Congress enacted the Farm Bill during the five-year period between Respondents' introduction of the Proposed Rule and the promulgation of the Final Rule. Respondents' issuance of the Final Rule despite this change in law, and without addressing how this change in law affects the Final Rule or its enforcement, furthers the need for this Court to weigh in on the purely legal questions raised by Petitioners. *See id*. Finally, the Final Rule's flouting of

congressional edicts is a miscarriage of justice in and of itself that shall be furthered if Respondents are able to escape judicial oversight of its flouting. *See id*.; Section I, *supra*.

Accordingly, should this Court determine the issues raised by Petitioners have been waived (they have not), this Court should excuse such waiver for the reasons listed above.

C. Petitioners' Concerns with the Clarification Certainly Have Not Been Waived.

The waiver rule in no way applies to Petitioners' issues with the *Clarification*. Respondents issued the *Clarification* subsequent to the filing of the instant petition. Neither Petitioners nor any third-party had an opportunity to comment on the *Clarification* because Respondents provided no opportunity for interested parties to provide such. Accordingly, Petitioners could not possibly have waived their arguments concerning the *Clarification*.

In essence, Respondents recognized the need for amendments to the Final Rule based on the lengthy duration between Proposed Rule and Final Rule, and intervening changes in the law, and Respondents attempted to amend the same without notice-and-comment. Now, Respondents unproductively chastise Petitioners for raising the recognized deficiencies and ineffective *Clarification* before this Court, seeking guidance on whether Respondents have adhered to the

law. Respondents' own labored actions subsequent to the issuance of the Final Rule necessitate excusing any waiver that may have occurred (and none has).

IV. RESPONDENTS' FLOUTED OTHER CONGRESSIONAL MANDATES IN ISSUING THE FINAL RULE.

Beyond the CSA and Farm Bill, Respondents have flouted other congressional mandates in issuing the Final Rule: (1) the Information Quality Act ("IQA"), (2) the Regulatory Flexibility Act ("RFA"); (3) the Congressional Review Act ("CRA"); and (4) 21 U.S.C. § 811(d)(2)-(4). To address Respondents' contravention of these acts as well, the Final Rule should be stricken and/or amended, and Respondents should be enjoined from enforcing it.

A. Information Quality Act.

Respondents suggest that their violations of the IQA are of no matter for two reasons: (1) Petitioners did not raise IQA concerns in the administrative forum; and (2) it is an open question in the Ninth Circuit whether a private party may sue to enforce the IQA. Respondents arguments fail.

First, Petitioners had no prior opportunity to raise their IQA concerns. The web of misstatements and misleading publications deepened after Respondents closed notice-and-comment on the Proposed Rule, and after intervening legislation—the Farm Bill—significantly impacted the reach and legality of the Proposed Rule. Specifically, Respondents issued the *Clarification* after closing

notice-and-comment on the Proposed Rule, and importantly, after issuing the Final Rule. There is no way, therefore, Petitioners could have pursued administrative recourse to correct the misinformation Respondents disseminated; Respondents foreclosed every meaningful opportunity for Petitioners to do so.

Second, as Respondents correctly point out, this Circuit has not foreclosed the possibility that a private party may enforce the IQA with judicial action. *Harkonen v. U.S. Dep't of Justice*, 800 F.3d 1143, 1148 (9th Cir. 2015). Given Respondents' blatant obstruction for meaningful administrative process with respect to the legality of the Final Rule, including Respondents' flouting of the IQA, Petitioners should be permitted to challenge Respondents' actions under the IQA, and Respondents' actions should be found violative.

B. Regulatory Flexibility Act.

With respect to the RFA, Respondents failed to fulfill their obligations and, again, hope Petitioners and this Court will simply look away. When an agency head certifies that a proposed rule will have no significant impact on a substantial number of small businesses, the agency must publish within the proposed rule "a statement providing the factual basis for such certification." 5 U.S.C. § 605(b). Respondents assert that they complied therewith, but Respondents' factual basis for their assertion that small businesses are not impacted by the Final Rule is flawed. *See, e.g.*, FER, Exhibits C, D, E. Indeed, Respondents' purported factual basis

underlying their RFA certification is the crux of this lawsuit—whether the Final Rule imposes new obligations on the industrial hemp industry (without following the proper procedural mechanisms), significantly impacting the industry.

C. Congressional Review Act.

Petitioners concede that the language of the CRA precludes judicial review. 5 U.S.C. § 805. That does not mean, however, that this Court must ignore Respondents' procedural shortcuts, including under the CRA. When considered in conjunction with Respondents' mounting breaches of congressionally-imposed procedure, the CRA is another example of the Final Rule's improper conception.

D. Single Convention.

Finally, Respondents failed to address their evasion of 21 U.S.C. § 811(d)(2)-(4) of the CSA. These statutory provisions require Respondents to coordinate with the Secretary of State and Secretary of Health and Human Services if U.S. obligations under international treaties like the Single Convention require control of a substance. 21 U.S.C. § 811(d); *see also NORML v. DEA*, 559 F.2d 735, 747 (D.C. Cir. 1977); *Hearing Concerning Cannabidiol: Barriers to Research and Potential Medical Benefits before the Caucus on Int'l Narcotics Control of the U.S. Senate* , 114th Cong. (2015) (statement of Deputy Assistant Administrator Joseph T. Rannazzisi, DEA) (transcript available at https://www.dea.gov/pr/speeches-

testimony/2015t/062415t.pdf). The Single Convention is the international treaty Respondents claim justifies the procedure used to effect the Final Rule.

Respondents provide no evidence of coordination with the State Department in the form of a notification to the Secretary of State from the Secretary-General of the United Nations or the Commission on Narcotic Drugs of the United Nations regarding U.S. noncompliance with the Single Convention with respect to marijuana extracts. *See* 21 U.S.C. § 811(d)(2). Respondents similarly provide no evidence of coordination with the Health and Human Services Department regarding its "scientific and medical evaluations . . . respecting [marihuana extracts]." *See id*. Given the five-year lull between the Proposed Rule and Final Rule, Respondents have no justification for failing to coordinate with the required departments or to demonstrate that the United Nations required this action.

For all these reasons as well, Petitioners respectfully request this Court strike and/or amend the Final Rule, and enjoin Respondents from enforcing, or otherwise implementing, the Final Rule.

CONCLUSION

For the above reasons and those in *Petitioners' Brief*, the Court should strike, invalidate, and/or amend the Final Rule to render it consistent with congressional intent and codified law. Respondents must be enjoined from any enforcement action based upon this Final Rule as it is presently worded.

To this end, Respondents must meaningfully address the following:

(1) Citing *Cannabis* versus "marihuana," as the CSA provides;

(2) Referring to the mere presence of cannabinoids which *may* be derived – by are not exclusively derived – from "any genus *Cannabis*;"

(3) Failing to exclude parts and derivatives of the *Cannabis* plant exempted from the definition of "marihuana" pursuant to the CSA;

(4) Failing to exclude "industrial hemp," and derivatives therefrom, as the Agricultural Act of 2014 provides;

(5) Failing to previously articulate the "trace" versus "non-trace" standard, and to allow Petitioners and others due process concerning the same; and,

(6) Failing to previously articulate any methodology through which Respondents can evaluate whether substances are derived from lawful sources.

If the Court finds Respondents had authority to issue the Final Rule, the Court should remand the Final Rule to be promulgated under all necessary procedural mechanisms, as the case may be.

Respectfully submitted,

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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 reply brief is

__X__ Proportionately spaced, has a typeface of 14 points or more and contains _6,993_ 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: July 28, 2017

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CERTIFICATE OF SERVICE

I certify that on July 28, 2017, I served a true and correct copy of the foregoing Reply Brief for Petitioners:

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Dated: July 28, 2017

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

PETITIONERS' STATUTORY ADDENDUM TO REPLY BRIEF

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STATUTORY ADDENDUM

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REGULATORY FLEXIBILITY ACT

5 U.S.C. § 605

605. Avoidance of duplicative or unnecessary analyses

(a) Any Federal agency may perform the analyses required by sections 602, 603, and 604 of this title in conjunction with or as a part of any other agenda or analysis required by any other law if such other analysis satisfies the provisions of such sections.

(b) Sections 603 and 604 of this title shall not apply to any proposed or final rule if the head of the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. If the head of the agency makes a certification under the preceding sentence, the agency shall publish such certification in the Federal Register at the time of publication of general notice of proposed rulemaking for the rule or at the time of publication of the final rule, along with a statement providing the factual basis for such certification. The agency shall provide such certification and statement to the Chief Counsel for Advocacy of the Small Business Administration.

(c) In order to avoid duplicative action, an agency may consider a series of closely related rules as one rule for the purposes of sections 602, 603, 604 and 610 of this title.

CONGRESSIONAL REVIEW ACT

5 U.S.C § 805

805. Judicial review

No determination, finding, action, or omission under this chapter shall be subject to judicial review.

Consolidated Appropriations Act 2017, Pub. L. No. 115-31, §§ 538, 773

SEC. 538. None of the funds made available by this Act may be used in contravention of section 7606 (''Legitimacy of Industrial Hemp Research'') of the Agricultural Act of 2014 (Public Law 113–79) by the Department of Justice or the Drug Enforcement Administration.

SEC. 773. 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 section 7606 of the Agricultural Act of 2014, within or outside the State in which the industrial hemp is grown or cultivated.

U.S. Constitution

Art. III, Sec. 2

The judicial power shall extend to all cases, in law and equity, arising under this Constitution, the laws of the United States, and treaties made, or which shall be made, under their authority;--to all cases affecting ambassadors, other public ministers and consuls;--to all cases of admiralty and maritime jurisdiction;--to controversies to which the United States shall be a party;--to controversies between two or more states;--between a state and citizens of another state;--between citizens of different states;--between citizens of the same state claiming lands under grants of different states, and between a state, or the citizens thereof, and foreign states, citizens or subjects.

In all cases affecting ambassadors, other public ministers and consuls, and those in which a state shall be party, the Supreme Court shall have original jurisdiction. In all the other cases before mentioned, the Supreme Court shall have appellate jurisdiction, both as to law and fact, with such exceptions, and under such regulations as the Congress shall make.

The trial of all crimes, except in cases of impeachment, shall be by jury; and such trial shall be held in the state where the said crimes shall have been committed; but when not committed within any state, the trial shall be at such place or places as the Congress may by law have directed.