No. 03-71366
No. 03-71603

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

HEMP INDUSTRIES ASSCIATION, ET AL.,
Appelants/Petitioners

v.

DRUG ENFORCEMENT ADMINISTRATION
Appellee/Respondent

PETITION FOR REVIEW OF FINAL RULES
ISSUED BY THE DRUG ENFORCEMENT ADMINISTRATION

BRIEF FOR THE APPELLEE/RESPONDENT

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JURISDICTIONAL STATEMENT

The final rules which are the subject of the petition for review were published by the Drug Enforcement Administration (DEA) in the Federal Register on March 21, 2003. DEA-205F revises the wording of the DEA regulations to make clear that the listing of tetrahydrocannabinols (THC) in schedule I refers to both natural and synthetic THC. 68 Fed. Reg. at 14119; ER 28-35.

Petitioners raise two categories of claims in their petition: (i) that the final rules cannot be sustained when applying the standards of review mandated in Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984); and (ii) that the final rules were not issued in compliance with the Regulatory Flexibility Act, 5 U.S.C. 601-612. Petitioners filed a timely petition for review on March 28, 2003. This Court has jurisdiction over petitioners' Chevron claim pursuant to the administrative appeal provision of the Controlled Substances Act (CSA), 21 U.S.C. 877, and over petitioners' Regulatory Flexibility Act claim pursuant to 5 U.S.C. 611

STATEMENT OF THE ISSUES

1. Whether, under the two-step analysis set forth in Chevron, DEA-205F and -206F must be sustained as a permissible interpretation of the CSA.

2. Whether, in issuing the rules, DEA adhered to requirements of the Regulatory Flexibility Act.

STATEMENT OF THE CASE

Petitioners challenge the two final rules, DEA-205F and -206F, which the agency published on March 21, 2003. The rules were published in proposed form on October 9, 2001. 66 Fed. Reg. 51535 and 51539; ER 13-22. Along with the proposed rules, DEA published an Interpretive Rule, which explained in detail the agency's legal basis for interpreting the CSA listing of "tetrahydrocannabinols" in the manner reflected DEA-205F.[1] 66 Fed. Reg. 51530; ER 8-12.

DEA-205F revises the wording of the DEA regulations to reflect more clearly that the listing of "tetrahydrocannabinols" in schedule I of the CSA includes both natural and synthetic THC. DEA-206F exempts from control certain

[1] On June 30, 2003, in a case involving the same parties as the instant matter, this Court ruled that the Interpretive Rule was actually a legislative rule and, therefore, its issuance without notice and comment violated the APA. Hemp Industries Association v. DEA, 333 F. 3d. 1082 (9th Cir. 2003)(hereafter, "Hemp I"). Because the Interpretive Rule contains details of the agency's explanation for its interpretation of the CSA and was cited in DEA-205F and -206F, it will be referred where appropriate in this document.

cannabis-derived industrial products that contain THC but do not cause THC to enter the human body.[2]

Petitioners are a group of companies which make and/or distribute various products marketed as "hemp"[3] products. According to petitioners, their products contain materials made from sterilized cannabis seeds and/or oil from the seeds, which are excluded from the CSA definition of marijuana. Petitioners state that these products contain "miniscule trace amounts of residual resin, which contain naturally occurring tetrahydrocannabinols ("THC"). Petitioners' Brief at 3.

Petitioners assert that because the CSA excludes certain parts of the cannabis plant from the definition of marijuana, these parts of the plant and products made therefrom (including petitioners' products) must be considered noncontrolled substances regardless of the THC content. Petitioners therefore challenge DEA-205F and -206F as being an improper interpretation of the CSA. Petitioners also assert that DEA failed to comply with the Regulatory Flexibility Act in issuing the rules.

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[2] In accordance with the Administrative Procedure Act, 5 U.S.C. 553(b)(B) and (d)(2), DEA 206F was first published as an interim rule, which took effect immediately on a temporary basis while the agency awaited comments from the public. 66 Fed. Reg. at 51542-51543. This was done to accommodate companies that distribute the products that were exempted from control under the rule. Id.

[3] The term "hemp" is not used in the CSA. Nonetheless, the term will be used in this document where appropriate as it is often used to describe the types of products made from the cannabis plant that are at issue in this proceeding.

STATEMENT OF THE FACTS

A. Statutory Framework

Under the CSA, Congress assigned to the Attorney General responsibility for administering all of the regulatory provisions of the Act. These responsibilities include, among other things, maintaining the schedules of controlled substances in accordance with the Act and publishing amendments to the schedules in the Code of Federal Regulations. Se 21 U.S.C. 811, 812. In addition, the Attorney General is authorized to exempt, by regulation, any compound, mixture, or preparation containing any controlled substance from the application of all or any part of the CSA if he finds such compound, mixture, or preparation meets the requirements of 811(g)(3)(B). Those requirements are that the compound, mixture, or preparation not be for administration to a human being or animal and be packaged in such form or concentration, or with adulterants or denaturants, so that it does not present any significant potential for abuse. Id.

Congress also expressly provided the Attorney General with broad rulemaking authority under the CSA to promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient enforcement of his function under the Act. 21 U.S.C. 871(b).

The functions vested in the Attorney General by the CSA have been delegated to the Administrator of the DEA pursuant to 21 U.S.C. 871(a), as set

forth in 28 C.F.R. 0.100(b). Thus, since the CSA was enacted in 1970, DEA has been the agency responsible for determining under federal law what is, and what is not, a controlled substance.[4] In accordance with the CSA, DEA publishes an updated list of the schedules on an annual basis in the Code of Federal Regulations. 21 C.F.R. 1308.11-1308.15.

THC is an hallucinogenic substance with a high potential for abuse. Congress recognized this fact by placing it in schedule I. Because schedule I controlled substances are those determined to have a high potential for abuse and no currently accepted medical use, the CSA disallows human consumption of such substances, with limited exceptions. The only ways in which a person may lawfully ingest a material, compound, mixture, or preparation containing a schedule I controlled substance are: (i) where the substance is contained in a specifically formulated drug product that has been approved by the Food and Drug

[4] When the CSA was originally enacted, the Attorney General's function under the Act were delegated to the Bureau of Narcotics and Dangerous Drugs (BNDD). In 1973, DEA was established to absorb BNDD and its functions along with those of several other components of federal agencies responsible for drug enforcement. See Reorganization Plan No. 2 of 1973 (reproduced following 28 U.S.C.A. 509). Under the Reorganization Plan of 1973, DEA's major responsibilities include, among others, "development of overall Federal drug law enforcement strategy, programs, planning and evaluation" and "regulation of the legal manufacture of drugs and other controlled substances under Federal Regulations."

Administration (FDA)[5] or (ii) in accordance with a research protocol that has been authorized by the FDA and where the researcher is registered with DEA to conduct such research. See 21 U.S.C. 331, 335, 811(b), 812(b), 823(f), 841(a)(1); 21 C.F.R. 5.10(a)(9), 1301.18, 1301.32; see also United States v. Oakland Cannabis Buyers' Cooperative, 532 U.S. 483, 490 (2001) (use of schedule I controlled substances limited to Government-approved research).

Given the nature of schedule I hallucinogenic controlled substances, the CSA provides that, "[u]nless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of" such substance is a schedule I controlled substance. 21 U.S.C. 812(c), schedule I(c).

B. <u>Marketing of "Hemp" Food Products in the United States</u>

The marketing in the United States of food products containing parts of the cannabis plant is a relatively recent development. As petitioners themselves

[5] At present, Marinol is the only THC-containing drug product that has been approved for marketing by FDA. Marinol is the brand name of a product containing synthetic dronabinol (a form of THC) in sesame oil and encapsulated in soft gelatin capsules that has been approved for the treatment of nausea and vomiting associated with weight loss in patients with AIDS. Because Marinol is the only THC-containing drug approved by FDA, it is the only THC-containing substance listed in a schedule other than schedule I. In 1999, DEA transferred Marinol from Schedule II to Schedule III, thereby lessening the CSA regulatory requirements governing its use as medicine. See 64 Fed. Reg. 35928 (1999).

advised DEA in a December 2001 letter (which was submitted as a comment to the Proposed and Interim Rules):

> The U.S. market for hemp food products was virtually non-existent five years ago. Furthermore, these products have been carried by large natural food retail chains only since 1999.

Consistent with the fact that "hemp" food products were not marketed in the United States until the late 1990's,[6] there is no evidence that Congress ever intended to allow the human consumption of such products. The legislative history of the CSA contains no references to food products (or any industrial products) made from the cannabis plant. The legislative history to the 1937 Marihuana Tax Act (which was repealed and superceded by the CSA) does contain extensive discussion of specific cannabis-derived industrial products that the 1937 Act was intended to allow. However, there is no suggestion in the 1937 legislative history that there was any market in the United States for food products made form the cannabis plant or that the 1937 Act was intended to allow for such food products.

SUMMARY OF ARGUMENT

DEA-205F and -206F constitute a permissible interpretation of the CSA under the two-step analysis of Chevron, which is applied when reviewing agency regulations that have been promulgated through notice-and-comment rulemaking.

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[6] The University of Kentucky report cited by petitioners (ER 50-51) likewise suggests that the United Sates market for "hemp" food is a small market that did not begin to emerge until the late 1990s.

Under step one of Chevron, DEA-205F and -206F give effect to all of the applicable elements of the CSA: (i) the definition of marijuana, which excludes certain parts of the cannabis plant; (ii) the listing of THC in schedule I, which states that "any material, compound, mixture, or preparation, which contains any quantity of… tetrahydrocannabinols" is a schedule I controlled substances outside of FDA-approved, DEA-registered research. DEA-205F and -206F give effect to all of these statutory elements by allowing products excluded from the definition of marijuana to be used for the same industrial purposes that existed at the time of the enactment of the CSA but disallowing human consumption of a schedule I controlled substance outside of FDA-approved, DEA-registered research. Because of the text of the CSA does not unambiguously forbid the manner in which DEA-205F and -0206F construe the statute, the review of the rules must proceed to step two of Chevron.

Under step two of Chevron, the inquiry goes beyond the text of the statute and takes into account the legislative history and other relevant authorities and materials. Step two requires that where an agency is construing the act it administers through notice-and-comment rulemaking, the agency must be accorded deference in view of its expertise and the fact that Congress has entrusted it to administer the act. As long as the agency's construction is permissible, it must be upheld under step two, even if there is another permissible interpretation that the

court would reach if the question were presented de novo. Although the CSA legislative history is silent on the issue here, the legislative history to the 1937 Marihuana Tax Act, from which the CSA definition of marijuana was derived, contains extensive discussion of the specific types of cannabis-derived industrial products that Congress envisioned and intended to allow under the 1937 Act. DEA-205F and -206F allow every one of those industrial products and even some that Congress did not contemplate. The legislative history contains no indication that Congress intended to allow human consumption of cannabis products in the United States. Thus, DEA-205F and -206F are consistent with the legislative history and purpose and structure of the CSA by allowing industrial cannabis products envisioned by Congress under prior legislation while maintaining the CSA prohibition on human consumption of schedule I substances outside of FDA-approved, DEA-registered research.

Once it is determined that DEA-205F and -206F constitute a permissible construction of the CSA, the Chevron inquiry ends without need to consider petitioners' alternative interpretations. In any event, petitioners' assertions that the result of DEA-205F and DEA-206F can only be achieved through formal rescheduling proceedings under 21 U.S.C. 811(a)-(c) misconstrues the nature and purpose of those proceedings and the overall scheduling scheme of the CSA.

Finally, petitioners assertion that the rules were issued in violation of the Regulatory Flexibility Act is without merit as petitioners concede that DEA made the certification required under the Act, which expressly exempts the agency from undertaking the full regulatory analysis.

ARGUMENT

I. APPLYING CHEVRON, DEA-205F AND DEA-206F MUST BE UPHELD AS A PERMISSIBLE INTERPRETATION OF THE CSA

Because DEA-205F and DEA-206F were promulgated through notice-and-comment pursuant to DEA's rulemaking authority under the CSA, the regulations qualify for Chevron deference. See United States v. Mead, 533 U.S. 218, 226-227 (2001). Chevron mandates that the reviewing court apply a two-part test. Under step one, if the statute speaks clearly "to the precise question at issue," the court "must give effect to the unambiguously expressed intent of Congress." 467 U.S. at 842-843. If the statute is instead "silent or ambiguous with respect to the specific issue," then the court proceeds to step two, which requires it to sustain the agency's interpretation if is "based on a permissible construction of the statute." Id.

A. DEA-205F and -206F Must Be Viewed Together For Purposes Of This Chevron Review.

DEA-205F and -206F were issued simultaneously by the agency and published jointly in the Federal Register. The general subject matter of both rules is the same, and the Federal Register text accompanying each rule repeatedly refers

to the other. It is clear that the agency intended the rules to operate in conjunction with once another. Accordantly, for purposes of this review, the two rules must be read together.

Taken together, the rules implement the text of the CSA such that all industrial products made from the parts of the cannabis plant excluded from the definition of marijuana that were marketed in the United Sates at the time of the enactment of the CSA, as well as all such products previously contemplated by Congress as permissible under the Marihuana Tax Act of 1937, are completely exempted from control under the CSA. In addition, many present-day cannabis-derived products that were not marketed in the United States until well after the enactment of the CSA are also excluded from control under the CSA. However, where cannabis-derived products are intended for human ingestion (a use not envisioned by Congress and not introduced in the United States until recently), the rules maintain the schedule I status of THC-containing products, which is consistent with the fundamental CSA principle prohibiting human ingestion of schedule I controlled substances outside of FDA-approved, DEA-registered research.

This construction of the CSA embodied in DEA-205F and -206F is a permissible interpretation under both steps of Chevron review, as explained below.

B. Under step One of Chevron, DEA-205F And -206F conform With The Text Of The CSA; The Rules Are Not "unambiguously Forbidden" By the Text Of the Act

Chevron step one is a pure question of statutory construction and does not involve an analysis of the legislative history or policy goals of the statute. See Chevron, 467 U.S. at 842-843; see also Dept. of Housing and Urban Development v. Rucker, 535 U.S. 125, 132 (2002) (en banc panel of Ninth Circuit properly did not refer to legislative history in step one of Chevron); Rucker v. Davis, 237 F. 3d 1113, 1123 (9th Cir. 2001) (en banc)(legislative history consulted only upon conducting step two of Chevron), rev'd on other grounds, supra, 535 U.S. 125. Nor does step one ask the court to decide which of the parties makes the most persuasive argument in reading the text of the statute. Rather, under step one, the reviewing court must decide "whether the statue unambiguously forbids the Agency's interpretation." Barnhart v. Walton, 535 U.S. 212, 122 S.Ct. 1265, 1269(2002) (emphasis added).

For the Chevron step one analysis of DEA 205F and -206F, the following CSA provisions must be considered:

- 21 U.S.C. 812(c), schedule I(c)(17), which states: "Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of … tetrahydrocannabinols" is a schedule I controlled substance;

- 21 U.S.C. 802(16), the definition of marijuana,[7] which includes all parts of the cannabis plant except for "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";

- 21 U.S.C. 811(g)(3)(B), which permits the DEA Administrator to exempt from control "[a] compound, mixture, or preparation which contains any controlled substance, which is not for administration to a human being or animal, and which is packaged in such form or concentration, or with adulterants or denaturants, so that as packaged it does not present any significant potential for abuse"; and

- 21 U.S.C. 871(b), which permits the DEA administrator to "promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under" the CSA.

- 21 U.S.C. 823(f) and 841(a)(1), which disallow human consumption of schedule I controlled substances outside of FDA-approved, DEA-registered research.

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[7] Although "marihuana" is the spelling used in the CSA, the spelling more commonly used in recent years is "marijuana." See, e.g., generally Oakland Cannabis Buyers' Cooperative, 532 U.S. 483. Therefore "Marijuana" will be used in this brief except when quoting the CSA or the 1937 Marihuana Tax Act.

In promulgating DEA-205F, DEA stated that it interpreted the text of schedule I(c)(17) to refer to both natural and synthetic THC. The agency explained:

> The basic dictionary definition of the word "tetrahydrocannabinols" refers collectively to a category of chemicals – regardless of whether such chemicals occur in nature or are synthesized in the laboratory.[8]
>
> Second, every molecule of THC has identical physical and chemical properties and produces identical psychoactive effects, regardless of whether it was formed in nature or by laboratory synthesis.[9] Likewise, a product that contains THC in a given formulation will cause the same reaction to the human who ingests it regardless of whether the THC is natural or synthetic.

68 Fe. Re. at 14114 (footnotes in original).

It cannot be said that the wording of schedule I(c)(17) or any other provision of the CSA "unambiguously forbids" DEA's interpretation. To the contrary, the common meaning of the term "tetrahydrocannabinols" does include both natural and synthetic THC. It is also beyond dispute that the phrase "any material,

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[8] For example, Merriam-Webster's Collegiate Dictionary (10th Ed. 1999) defines "THC" as "a physiologically active chemical C21H30O2 from hemp plant resin that is the chief intoxicant of marijuana – called also tetrahydrocannabinol;" this definition does not mention synthetic THC.

[9] In this context, "every molecule of THC" refers to every molecule of the same isomer of THC. For example, all molecules of delta9-trans-THC are identical, regardless of whether they are natural or synthetic.

It should also be noted that "Tetrahydrocannabinols" refers to a class of substances which includes delta9-(trans)-THC, its isomers, and other related substances. Collectively, this class will be referred to in this document as "THC," unless otherwise indicated.

compound, mixture, or preparation" (which appears repeatedly in 21 U.S.C. 812) includes plant material and derivatives thereof. See, e.g., schedule I(c)(10) (marijuana) and schedule I(c)(12)(peyote).

To limit "tetrahydrocannabinols" to synthetic THC (and to exclude organic THC) would be to insist on a meaning directly contrary to the CSA text and would impose a rule that is not applied for any of the various other hallucinogenic controlled substances listed in schedule I that are both found in plants and synthesized in the laboratory. For example, DMT, mescaline, psilocybin, and psilocin all are listed in schedule I(c) without reference to natural or synthetic forms of these substances. By listing these chemicals by their names without indicating synthetic or natural, the text of the CSA has always provided that any material, compound, mixture, or preparation containing any quantity of these chemicals – natural or synthetic – is a schedule I controlled substance.

Therefore, on the face of the statute, just as any part of any plant (or any derivative thereof) containing any quantity of DMT, mescaline, psilocybin, and psilocin is a schedule I controlled substance, any part of any plant containing any amount of THC is a schedule I controlled substance.

To counter the foregoing interpretation of the plain language of the statute, petitioners point to the phrase "Unless specifically excepted," which appears at the beginning of schedule I(c). According to petitioners, the parts of the cannabis

plant excluded from the definition of marijuana in 802(16) have been "specifically excepted" from inclusion in any of the CSA schedules. This is a strained reading of the CSA for the following reasons.

There are two clear methods under the CSA whereby a substance included in a schedule – after applying any applicable definition contained in 802 – can be excluded (specifically excepted") from the schedule. The most common method is for DEA to exempt a substance from control by regulation. The CSA specifically authorizes DEA to "exclude" or "exempt"[10] by regulation certain substances that would otherwise be controlled by virtue of the schedules. 21 U.S.C. 811(g)(1) and (3). Pursuant to these subsections, DEA has, by regulation, exempted certain substances from control that would otherwise be included among the scheduled substances. See 21 C.F.R. 1308.21-.35. The other method under the CSA is where Congress itself has excepted a particular substance from control. Congress did so in 811(g)(2) for dextromethorphan.[11]

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[10] While 811(g) uses the terms "exclude … from a schedule" and "exempt … from application of all or any part of this subchapter," 812 uses the term "excepted" from a schedule. Presumably, one point on which the petitioners and the Government would agree is that, within the meaning of the CSA, "excluding" a substance "from a schedule" is equivalent to "excepting" from a schedule. Likewise, to "exempt" a substance "from application of all … of" the CSA has the same effect as "excluding" or "excepting" the substance from all of the schedules.

[11] Dextromethorphan is an isomer of racemorphan, which would make it a schedule II controlled substance under 21 U.S.C. 812(c), schedule II(b)(21), were it not for the exception made by Congress under 811(g)(2).

Second, as with most statutory acts, the definition section of the CSA, by its own terms, applies to all provisions of the Act. Congress accomplished this by stating "as used in this subchapter:" at the beginning of 802. There is no need to repeat in 811 or elsewhere in the Act that the CSA definitions apply to that particular section. Thus, reading the phrase "specifically excepted" in 812 as referring to definitions of the Act is superfluous.

Third, the definition found in 802(16) describes only what is included in the definition of marijuana. Section 802(16) clearly evidences Congress intent to exclude certain parts of the cannabis plant from the definition of marijuana. It is true that the parts of the cannabis plant excluded from the definition of marijuana cannot be considered to fit within the listing of "marihuana" in schedule I(c)(10). However, "tetrahydrocannabinols" is listed separately from "Marihuana." Fitting within either of these two separate listings results in control under the plain meaning of the text of schedule I.

It cannot be said from the face of the statute that the parts of the cannabis plant excluded from the definition of marijuana cannot fit within the listing of other controlled substances or otherwise be subject to control under the Act.[12]

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[12] One of the provisions of the CSA civil forfeiture section states: "All species of plants from which controlled substances in schedules I and II may be derived which have been planted or cultivated in violation of this subchapter… may be seized and summarily forfeited to the United States." 21 U.S.C. 881(g)(1). Subsection 881(g)(3) further states: "The Attorney General, or his duly authorized

Congress could have, but did not, state in the definition of marijuana (or elsewhere in the CSA) words to the effect that those parts of the cannabis plant excluded from the definition of marijuana are not controlled substances and not subject to any of the provisions of the CSA even if they contain tetrahydrocannabinols. Cf. 21 U.S.C. 811(g)(2) ("Dextromethorphan shall not be deemed to be included in any schedule by reason of enactment of this subchapter unless controlled after October 27, 1970 pursuant to the foregoing provisions of this section") (emphasis added); 21 U.S.C. 802(6) ("term 'controlled substance' means a drug or other substance, or immediate precursor, listed in schedule I, II, III, IV, or V … [but] does not include distilled sprits, wine, malt beverages, or tobacco").

Petitioners assert that to construe the phrase "any material, compound, mixture, or preparation, which contains any quantity of … tetrahydrocannabinols" to encompass THC-containing parts of the cannabis plant excluded from the definition of marijuana is to render superfluous the second sentence in the definition of marijuana, which excludes from the definition certain parts of the plant. However, to insist that the definition of "marihuana" applies not only to the term "marihuana" but to the listing of "tetrahydrocannabinols" goes beyond the text of the CSA and fails to give effect to the plain meaning of the words "any

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agent, shall have authority to enter upon any lands, or into any dwelling pursuant to a search warrant, to cut, harvest, carry off, or destroy such plants." Under this section, the entire plant is to be seized and destroyed; federal agents need not leave behind the parts of the plant excluded from the definition of marijuana.

material, compound, mixture, or preparation, which contains any quantity of … tetrahydrocannabinols." Petitioners' reading of the CSA would also negate the principle mandated by Congress under the Act that human consumption of schedule I controlled substances, in any amount, is prohibited outside of FDA-approved, DEA-registered research.

Moreover, DEA-205F and -206F do not render superfluous the part of the definition of marijuana that excludes certain parts of the cannabis plant. This part of the definition is given significant effect through the exemptions in DEA-206F for various cannabis-derived industrial products that were permitted by Congress under the 1937 Marihuana Tax Act.

However, the question of whether the exclusion of certain parts of the cannabis plant from the definition of marijuana has been rendered superfluous by DEA-205F and -206F cannot be fully explored without going beyond the text of the CSA. Questions that cannot be answered without reviewing the legislative history, caselaw, and other relevant materials beyond the text of the statute must be resolved not in step one, but in step two of the Chevron analysis.

As the text of the CSA does not unambiguously forbid interpreting "any material, compound, mixture, or preparation, which contains any quantity of…tetrahydrocannabinols" to include both natural and synthetic THC, this Court must proceed to step two of Chevron to resolve this issue.

Petitioners raise two additional claims for which step one Chevron analysis can be completed more swiftly. First, petitioners claim that DEA-205F is a "scheduling action" and therefore the agency was required to go through the rulemaking proceedings set forth in 21 U.S.C. 811(a), (b), and (c). See Gettman v. DEA, 290 F 3d. 430, 432 (D.C. Cir. 2002)(explaining CSA rescheduling procedures). As DEA Stated in the text accompanying DEA-205F:

> By its express terms, section 811 applies only where DEA seeks to add a substance to a schedule or remove one from a schedule. For example, if DEA were seeking to move a controlled substance form schedule II to schedule III, the agency would be required to follow the procedures set forth in section 811. The final rule being published today, however, does not change the schedule of THC or any other controlled substance. To the contrary, when this final rule becomes effective, on April 21, 2003, THC will remain in the same schedule in which it has been since the enactment of the CSA in 1970: schedule I.

68 Fed. Reg. at 14116. While petitioners continue to assert that DEA-205F is a scheduling action within the meaning of 811, it cannot be said that the test of the CSA unambiguously forbids DEA's interpretation quoted above. Therefore, this claim must be further considered in step two of the Chevron analysis.

Petitioners claim that DEA-206F is arbitrary and capricious because it goes beyond the text of 21 U.S.C. 811(g)(3)(B). Specifically, they assert that the allowance for animal feed containing cannabis seed is improper because 811(g)(3)(B) may be used only to exempt items that are "not for administration to human being or animal." However, the exemption for animal feed in DEA-206F

was not issued pursuant to 811(g)(3). Rather, it was issued pursuant to 21 U.S.C. 871(b), which authorizes the DEA Administrator to "promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under" the CSA. 68 Fed. Reg. at 14119-14120. Under step one of Chevron, it cannot be said that exempting animal feed containing cannabis seed is unambiguously forbidden by the statute. Therefore, no further inquiry needs to be conducted regarding this issue until step two of Chevron.

C. Under Step Tow Of Chevron, DEA-205F And -206F Constitute A permissible Construction of the CSA

Under step two of Chevron, the question is whether the agency's regulation is "based on a permissible construction of the statute." 467 U.S. at 843. In making this determination, "considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer, and the principle of deference to administrative interpretations." Id. At 844 (footnote omitted). Particularly important, "[t]he court need not conclude that the agency construction was the only one it permissibly could have adopted to uphold the construction, or even the reading the court would have reached if the question initially had arisen in a judicial proceeding." Id. At 843 n. 11.

Under step two of Chevron, it is appropriate to go beyond the text of the statute and consider the legislative history and other authorities and materials that

shed light on determining whether the agency regulation is a permissible construction of the statue. See Dept. of Housing and Urban Development v. Rucker, 535 U.S. at 132; Rucker v. avis, 237 F.3d at 1123.

1. <u>The legislative history of the prior act supports DEA-205F and -206F</u>

The legislative history of the CSA contains no discussion of the exclusion of certain parts of the cannabis plant from the definition of marijuana. Nor does the CSA legislative history indicate whether the listing of "tetrahydrocannabinols" is limited to synthetic THC[13] or contain any references to cannabis-derived products made from the parts of the cannabis plant excluded from the definition of marijuana.

As DEA indicated in issuing the rules, the CSA definition of marijuana was adopted essentially verbatim from the Marihuana Tax Act of 1937, which was repealed and superseded by the CSA. 66 Fed. Reg. at 51530. In considering this legislative history of the repealed 1937 Act, it is critical to bear in mind that such legislative history cannot be deemed indicative of the intent of Congress under the CSA. This point was articulated by the First Circuit in New Hampshire Hemp

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[13] The only mention of tetrahydrocannabinols in the 1970 House Report to the CSA is the following in an attached letter from the Department of Health, Education, and Welfare: "[Marijuana] is presently classified in schedule I(c) along with its active constituents, the tetrahydrocannabinols and other psychotropic drugs." H.R. Rep. No. 91-1444 (1970), reprinted in 1970 U.S.C.C.A.N. 4566, 4629. No suggestion is made in this report that the listing of "tetrahydrocannabinols" is limited to synthetic THC.

Council, Inc. v. Marshall, 203 F. 3d 1 (1st Cir. 2000), a case involving the question of whether and how the CSA allows the cultivation of cannabis plants for industrial purposes. In addressing the issue, the First Circuit stated: "While in 1937 Congress had indicated in legislative history that production for industrial uses would be protected (primarily by a relatively low tax), we can find no indication that Congress in 1970 gave any thought to how its new statutory scheme would affect such production." 203 F.3d at 7 (citations omitted). The court explained that basic differences between the 1937 Act and the CSA disallow any insistence that the two act be interpreted the same way:

> Congress' main vehicle for protecting industrial-use plant production in 1937 was not its basic definition of "marijuana," which included plants ultimately destined for industrial use; it was the complex scheme of differential tax rates and other requirements for transfers. That is the regime that was drastically modified in 1970 in favor of a broad criminal ban (subject only to federal licensing), a ban which read literally embraces production of cannabis plants regardless of use.
>
> The possibility remains that Congress would not have adopted the 1970 statute in its present form if it had been aware of the effect on cultivation of plants for industrial uses. But that is only a possibility and not a basis for reading the new statute contrary to its literal language, at least absent a clear indication that Congress intended to protect plant production for industrial use as it existed under the prior tax statute. Nor, given Congress' enlargement of drug crimes and penalties in recent years, would one bank on its adoption of an exception strongly opposed by the DEA as a threatened loophole in the ban on illegal drugs.

Id. (footnote and citation omitted). Thus, as DEA stated in issuing DEA-205F and -206F, the industrial uses of marijuana that were permitted under the 1937 Act are not necessarily permissible under the CSA, even though the definition of marijuana is the same in both acts.

Nonetheless, all of the industrial uses that Congress intended to allow under the 1937 Act are permitted under DEA-205F and -206F. This is confirmed by the legislative history of the 1937 Act. The Senate Report to the Act states:

> From the mature stalks, fiber is produced which in turn is manufactured into twine, and other fiber products. From the seeds, oil is extracted which is used in the manufacture of such products as paint, varnish, linoleum, and soap. From hempseed cake, the residue of the seed after the oil has been extracted, cattle feed and fertilizer are manufactured. In addition, the seed is used as special feed for pigeons.

S. Rep. No. 75-900, 2-3 (1937). The House Report contains a virtually identical statement about the contemplated industrial uses of the cannabis plant. H.R. Rep. No. 75-792, at 1 (1937). Likewise, Congress heard testimony from industry representatives and law enforcement officials regarding the foregoing industrial uses of the cannabis plant. Taxation of Marihuana: Hearings on H.R. 6385 Before the House Comm. on Ways and Means, 75th Cong. 25-26, 38, 43, 44, 46-47, 56, 61, 65, 67, 69-70, 72, 73-74, 77 (1937); Taxation of Marihuana: Hearings on H.R. 6906 Before a Sen. Subcomm. Of the Comm. On Finance, 75th Cong. 5-6, 19-20 (1937).

While the legislative history demonstrates the clear intent of Congress to allow specific industrial uses of cannabis under the 1937 Act, these is no basis to conclude that the Act was intended to authorize human ingestion of anything made form the cannabis plant. The above-cited documents total more than 150 pages of legislative history of the 1937 Act. In all of these pages, there appears to be only one passing reference to the use of cannabis seeds in food – outside of the United States.[14] This statement did not come in response to any question by any member of Congress regarding food, nor did any member of Congress follow up on this statement by asking about food. The witness who made the statement, who appeared on behalf of the seed industry, was not suggesting to Congress that cannabis seeds would or should be used for food in the United Sates. More importantly, the Senate and House Reports cited above, which indicate with particularity the industrial uses of cannabis that Congress had in mind, make no mention of food.

Thus, it is undisputed that DEA-205F and -206F allow for every industrial use of cannabis seeds contemplated by Congress in 1937. It is true, for the reasons explained by the First Circuit in New Hampshire Hemp Council, 203 F.3d. at 7, that the intent of Congress under the 1937 Act is not controlling in construing the CSA. Nonetheless, to the extent that Congress' intent under the 1937 Act is

[14] Hearings on H.R. 6385 at 61 (statement of Ralph Lozier, General Counsel, National Institute of Oilseed Products).

persuasive in construing the intent of Congress under the CSA, DEA-205F and -206F must be deemed a permissible construction of the CSA under step two of Chevron since the rules allow for everything Congress had in mind under the 1937 Act.

In fact, DEA-205F and -206F even go beyond the expressed intent of Congress under the 1937 Act by allowing the use of personal care products (e.g. shampoos, soaps, lotions, and lip balm), made from the cannabis plant. There is no mention in the 1937 legislative history of any cannabis products applied directly to the human body.[15] Nonetheless, DEA expressly exempted these items from control pursuant to 21 U.S.C. 811(g)(3)(B) based on the reasoning articulated in the text accompanying the rules. 68 Fed. Reg. at 14119. Petitioners do not dispute that this exemption is permissible under 811(g)(3)(B).[16]

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[15] The legislative history does contain references to "soaps" made using oil from cannabis seeds. However, there is no indication whether this was a reference to hand soaps or soaps used in industrial processes.

[16] DEA-206F defines "human consumption" as "either: (i) Ingested orally or (ii) Applied by any means such that THC enters the human body." 68 Fed. Reg. at 14121. DEA acknowledged that it is unaware of any scientific evidence definitively answering the question of whether personal care products made using oil from the cannabis seeds cause THC to enter the human body. 68 Fed. Reg. at 14122; 66 Fed. Reg. at 51542. Nonetheless, DEA assumed based on the available information that such products did not cause THC to enter the human body and, therefore, unless and until evidence to the contrary arises, all personal care products are considered exempted under the rules. Id.

Petitioners assert that the legislative history compels that the CSA be construed to treat THC-containing cannabis seeds and oil as non-controlled substances because some of the witnesses who testified before Congress in 1937 indicated that the "active principle" in marijuana (not understood at the time to be THC)[17] was contained in the resin attached to cannabis seeds but not to the extent to cause a "narcotic effect."[18] This assertion is incorrect for the following reasons.

First it should be noted that, due to improvements in technology, there have been significant advances since 1937 in the scientific understanding about THC and concentrations of THC in the various parts of the cannabis plant. It was not until just a few years ago that scientists reported the first definitive finding of THC not only in the form of "exterior contamination of the seeds by the resin in the leaves," but also within the seed itself after thorough cleaning. Samir A. Ross, et al., GC-MS Analysis of the Total delta9-THC Content of Both Drug- and Fiber Type Cannabis Seeds, J. Anal. Toxicol., Vol. 24: 715 (2000).

But even assuming, arguendo, that Congress knew in 1937 that cannabis seeds contained THC and nonetheless intended under the 1937 Act to allow for

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[17] It was not until the early 1960s that THC was isolated and synthesized in the laboratory. 66 Fed. Reg. at 51532

[18] Although marijuana has often historically been mistakenly called a "narcotic," both marijuana and THC are properly classified under the CSA as "hallucinogenic" substances. See 21 U.S.C. 812(c), schedule I(c)(10), (17).

certain industrial uses of such seeds,[19] it cannot be insisted that DEA-205F and -206F must be rejected under Chevron as an improper interpretation of the CSA based on the fact that the rules do not allow for human consumption of THC-containing cannabis food products. Again, the legislative history of the repealed 1937 Act cannot mandate any particular interpretation of the CSA. See New Hampshire Hemp Council, supra. In any event, DEA-205F and -206F give fair meaning to the intent under the 1937 Act by allowing for every industrial use contemplated by Congress under the former act. It is a fundamental principle of

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[19] In their brief, petitioners accurately point to testimony of some of the witnesses who believed that the seeds did contain the "active principle." However, other witnesses testified to the contrary. For example, one of the seed industry representatives, some of whose testimony is quoted in petitioners' brief, testified:

> The point I make is this: There is no respectable authority, and I measure, my words, because I want to be a fair man talking to a fair-minded committee – there is no respectable authority to be found for the statement that this deleterious element is present either in the seed or in the oil of this plant, even in an infinitesimal quantity.

Hearings on H.R. 6385 at 62 (italics added). Congress take on this testimony, expressed in the Senate Report, was the following:

> The term "marihuana" is defined so as to bring within its scope all parts of the plant having the harmful drug ingredient, but so as to exclude the parts of the plant in which the drug is not present. The testimony before the committee showed definitely that neither the mature stalk of the hemp plant nor the fiber produced therefrom contains any drug, narcotic, or harmful property whatsoever and because of that fact the fiber and mature stalk have been exempted from the operation of law.

S. Rep. No. 900 (1937).

Chevron that where there is a range of permissible interpretations, "[t]he court need not conclude that the agency construction was the only one it permissibly could have adopted to uphold the construction, or even the reading the court would have reached if the question initially had arisen in a judicial proceeding." 467 U.S. at 843 n. 11. Thus, so long as DEA-205F and -206F permissibly construe the intent of Congress under the CSA, petitioners' alternative construction of statue cannot override that of the agency entrusted by Congress to administer the act – even if the Court finds petitioners' construction more compelling.

2. <u>The prior regulation does not preclude DEA-205F and -206F.</u>

In Hemp I, this Court analyzed the version of the DEA regulation regarding THC (21 C.F.R. 1308.11(d)(27)) that was promulgated following enactment of the CSA and concluded it was limited to synthetic THC. Although DEA expressed the view in the Interpretive Rule that the regulation includes both natural and synthetic THC, in view of the Court's ruling in Hemp I, it will be assumed for purposes of this brief that the prior regulation was limited to synthetic THC.[20]

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[20] In Hemp I, this Court stated that in the DEA regulations, "the Administrative Controlled Substance Code Number found opposite the heading 7370 referred in the past to synthetic THC only" but that "[t]oday 7370 refers to THC generically." 333 F.3d at 1090 n. 8 (citing a publication by Alexander Shulgin). Some clarification is warranted. In every issue of the Code of Federal Regulation from 1971 until the present, the only Administration Controlled Substance Code Number listed next to "tetrahydrocannabinols" has been 7370. In his publication, Mr. Shulgin included many of the additional control numbers used by DEA for purposes of gathering data for the System to Retrieve Information from Drug

The prior regulation is no obstacle to upholding DEA-205F and -206F. Chevron makes clear that "an initial agency interpretation is not carved in stone." 467 U.S. at 863. "On the contrary, the agency, to engage in informed rulemaking, must consider varying interpretations and the wisdom of its policy on a continuing basis." Id. As long as the agency regulations fits within the range of permissible interpretations and the agency provides a reasoned basis for any departure from past practice or interpretations, the agency is free to depart from a prior interpretation. See id. At 862-863 (rejecting notion that agency "interpretation is not entitled to deference because it represents a sharp break with prior interpretations of the Act"); cf. Rust v. Sullivan, 500 U.S. 173, 186-187b(1991) (upholding agency regulations under Chevron as permissible interpretation of the statute, even though regulations were a departure from past agency policy, where

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Evidence (STRIDE). This database contains information on the analysis and quantification of laboratory exhibits submitted to DEA forensic laboratories from federal, state, and local agencies. The data is used by DEA to determine the scope of, and trends in, drug trafficking, which is used for, among other things, scheduling decisions. The more expansive code numbers used for STRIDE purposes have always contained a separate listing for "organic" (7371) and "synthetic" (7370) THC. Thus, for purposes of STRIDE data, DEA does consider whether illicit conduct relating to THC involves THC from natural or synthetic sources. That the agency does so could support DEA's interpretation that both natural and synthetic THC are controlled or could be seen as nonconclusive on this issue.

head of agency "amply justified his change of interpretation with a 'reasoned analysis'").[21]

It is true that it has been the general practice of DEA in the past to treat sterilized cannabis seeds as noncontrolled even if they contain trace amounts of THC due to resin or leaves. However, DEA made this historical allowance for bird seed, which, as petitioners concede, was essentially the only reason that sterilized cannabis seeds were used in the United States from the time of the enactment of the CAS until the late 1990s. Up until that time, the question of human consumption of cannabis seeds was a nonissue for DEA. Once the agency became aware that cannabis seeds were being used for human consumption in the late 1990s, it assessed the situation and determined that it was legally permissible and sound policy to interpret the CSA to prohibit the human consumption of such seeds if they contain THC. As DEA explained at length in the text accompanying

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[21] For this reason, any prior statements by former agency officials – regardless of their rank within the agency – cannot be used as a basis to preclude DEA-205F and -206F. For example, the 1975 statement of the then-acting DEA Administrator that sterilized seeds are not controlled under the CSA need not be scrutinized to determine whether it was based on a careful analysis of the issue or merely agency dicta. 40 Fed. Reg. 44164, 44167. Likewise, there is no reason to attempt to ascertain the meaning of the following statement contained in the same agency order (id. At 44166) (italics added):

> Resin is found in all parts of the cannabis plant, including the leaves and the psychoactive element tetrahydrocannabinol (THC) is found in tall parts of the plant. It is possible to extract THC from a separated cannabis leaf to make hash oil – a highly potent drug. THC is controlled in schedule I of the Act.

the rules, this approach would allow for the uninterrupted use of sterilized cannabis seeds in bird seed and other industrial uses of such seeds, while maintaining the rule under the CSA that human ingestion of schedule I controlled substances be disallowed outside of FDA-approved. DEA-registered research.

3. <u>Caselaw and other relevant materials support DEA-205F and -206F</u>

There is no caselaw specifically addressing the question of whether the parts of the cannabis plant excluded from the definition of marijuana are controlled if they contain THC. Nor are there cases addressing whether Congress intended to allow human ingestion of THC-containing cannabis foods. However, there are cases that involved somewhat related questions. DEA examined some of these cases in the Interpretive Rule. 66 Fed. Reg. at 51530-51533. One of the cases is United States v. Walton, 514 F2d 201, 203-204 (D.C. Cir. 1975), in which the District of Columbia Circuit stated:

> Looking at the legislative history of [the 1937 Marihuana Tax Act], we find that the definition of marijuana was intended to include those parts which do not… The legislative history is absolutely clear that Congress meant to outlaw all plants popularly known as marijuana to the extent those plants possessed THC.

As DEA stated in the Interpretive Rule, courts have come to varying conclusions about the natural versus synthetic THC issue. See Untied States v. McMahon, 861 F.2d 8 (1st Cir. 1988); United States v. Lochan, 674 F.2d 960 (1st Cir. 1982); United States v. Wuco, 535 F.2d 1200 (9th Cir. 1976). DEA explains in

the Interpretive Rule why these cases are not determinative of the issue. 676 Fed. REg. at 51532-51533. While an individual sentence or two can be isolated from each of these cases to support one viewpoint or another, none of these cases (including Walton) is so compelling as to command that DEA-205F and -206F are impermissible when applying the deference owed to the agency under Chevron.[22]

As for petitioners contention that DEA-205F is a "scheduling action" and therefore the agency was required to go through the rescheduling proceedings set forth in 21 U.S.C. 811(a)-(c), there is nothing illuminating in the caselaw or legislative history. However, the agency's statement in the text accompanying the rule speaks directly to the issue:

> By its express terms, section 811 applies only where DEA seeks to add a substance to a schedule or remove one from a schedule. For example, if DEA were seeking to move a controlled substance from schedule II to schedule III, the agency would be required to follow the procedures set forth in section 811. The final rule being published today, however, does not change the schedule of THC or any other controlled substance. To the contrary, when this final rule becomes effective, on April 21, 2003, THC will remain in the same schedule in which it has been since the enactment of the CSA in 1970: schedule I.
>
> Nor would engaging in the rescheduling procedures set forth in section 811 be consistent with the purpose of this rule. Section 811 sets forth the procedures to determine whether a particular substance

[22] The long line of "species defense" cases, some of which are cited above, stand for an interesting proposition. Despite the fact that the CSA clearly states that "marihuana" means the species "Cannabis sativa L.," this Court has observed that the circuits are in agreement that any species of cannabis – not merely "Cannabis sativa L." – fits within the definition of "marihuana." See United States v. Kelley, 527 F.2d 961 (9th Cir. 1976)(collecting and examining cases).

> meets the criteria for placement in a particular schedule. The purpose of this rule is not to determine whether THC meets the criteria for classification in schedule I; rather, this rule serves to clarify that the longstanding placement of THC in schedule I includes both natural and synthetic THC. There is no question about whether THC meets the criteria for placement in schedule I.

68 Fed. Reg. at 14116; see also Gettman 290 F.3d at 432 (explaining nature of CSA rescheduling procedures).

In addressing this issue, among the other legal principles that DEA considered (see 68 Fed. Reg. at 14124) were the following. To establish a violation of the CSA, the government does not have to prove that the controlled substance in question was of sufficient quantity to produce a psychoactive effect. United Sates v. Nelson, 499 F. 2d 965 (8th Cir. 1974). It is legally sufficient to demonstrate a violation of the CSA based on the presence of any measurable amount of a controlled substance. See, e.g., United States v. Holland, 884 F2d 354, 357 (8th Cir. 1989), cert. denied, 493 U.S. 997 (1989). The CSA is structured such that "any material, compound, mixture, or preparation," including plant material, "which contains any quantity of" THC or other schedule I hallucinogenic substance is a schedule I controlled substance. See O Centro Espirita Beneficiente Uniao De Vegetal v. Ashcroft, 314 F3d. 463, 466 (10th Cir. 2002) (tea-like mixture made from a plant which contains dimethyltryptamine (DMT), a schedule I hallucinogenic substance listed in schedule I(c)(6), deemed a schedule I controlled substance); see also United States v. Allen, 990 F.2d 667 (1st Cir. 1993)(conviction

based on evidence that defendant possessed bag of mushrooms containing psilocybin, a schedule I hallucinogenic substance); United States v. Green, 548 F.2d 1261 (6th Cir. 1977)(synthetic DMT); United States v. Hussein, 230 F.Supp.2d 109 (D. Me. 2002)(khat, a plant containing the schedule I stimulant cathinone, is a schedule I controlled substance).

For the more than three decades that the CSA has been in effect, DEA has been the agency responsible for administering all of the regulatory provisions of the Act, including scheduling decisions under 811. As Chevron dictates, "considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer, and the principle of deference to administrative interpretations." 467 U.S. at 844 (footnote omitted). This is particularly so where, as here, there is a lack of authority to the contrary.

Petitioners overlook an important fact in arguing that DEA must engage in a 811 scheduling action in order for THC-containing cannabis-derived food products to be controlled substances. Congress never expressed any intent to allow human consumption of such products. As petitioners acknowledged in 2001: "The US. market for hemp food products was virtually non-existent five years ago. Furthermore, these products have been carried by large natural food retail chains only since 1999." At around the time petitioners began marketing food products in the United States, they sought DEA's opinion on the legal status of the products in

view of their possible THC content. After careful deliberation, the agency addressed the legal status of these products in a the proper legal manner, through notice-and-comment rulemaking along with a detailed explanation of the agency's interpretation. Up until that point, there had never been any court rulings or official agency pronouncements on the subject of cannabis-derived food products. This was an issue of first impression. Thus, it is incorrect to suggest that cannabis-derived food products – which only emerged in the country in the late 1990s – had an official legal status as noncontrolled substances prior to the issuance of DEA-205F and -206F. Once DEA-205F and -206F were announced, it was evident that the first agency rules on the subject would be identical in effect as the practice under the Marihuana Tax Act. THC-containing cannabis food products, however, would not be added by the agency to the list of items that were considered permissible from 1937 through the enactment of the CSA. Because THC-containing cannabis food products had no established exemption status under the CSA prior to the issuance of the rules, it is not the case that they must be "added" to the schedules to effectuate the interpretation of the CSA embodied in DEA-205F and -206F.

To further illustrate the point, if a previously known organic material derived from a plant were discovered for the first time to naturally contain THC, such material would automatically be a controlled substance by operation of the

CSA. Petitioners mention grapefruit juice in their brief. Of course, grapefruit juice does not contain THC; nor are there any known plant materials other than those derived from the cannabis plant that naturally contain THC. If, however, for the sake of argument, grapefruit juice hypothetically were found to contain THC, the language of 21 U.S.C. 812(c), schedule I(c)(17) would automatically make it a controlled substance – regardless of the percentage of THC in the juice and regardless of whether it could cause a psychoactive effect. DEA would not have to engage in the formal scheduling procedures set forth in 811(a)-(c) in order to "add" such a substance to schedule I.

Another reason that petitioners' "rescheduling" argument fails under Chevron step two is that it would provide a loophole in the law that might be exploited by drug traffickers. As DEA explained in the text accompanying DEA-205F (68 Fed. Reg. at 14114), if natural THC were a noncontrolled substance, those portions of the cannabis plant that are excluded from the CSA definition of marijuana (the stalks and sterilized seeds of the plant) would be legal, noncontrolled substances – regardless of their THC content. As a result, it would be legal to import into the United Sates, and to possess, unlimited quantities of cannabis stalks and sterilized seeds – again, regardless of their THC content and without any regulatory control whatsoever under the CSA. Anyone could then obtain this raw cannabis plant material to produce an extract that could contain a

substantial concentration of THC – all without legal consequence. This would give drug traffickers an essentially limitless supply of raw plant material from which they potentially could produce large quantities of a potent extract that would be considered a noncontrolled substance and, therefore, entirely beyond the reach of law enforcement. To provide a safe harbor to drug traffickers would be plainly at odds with the purpose and structure of the CSA.[23]

Petitioners dismiss DEA's concern about cannabis-derived THC extracts as being economically infeasible. That such activity does not appear to be taking place at the moment does not rule out that it will occur in the future. If it were to become a permanent rule that pure cannabis plant extracts of any THC content can be imported and distributed in the Untied States without any control, traffickers might indeed develop methods to take advantage of this loophole. Even if this were only a remote possibility, Congress has assigned to DEA the responsibility for making policy decisions about the best methods to discourage and prevent illicit drug activities. Under Chevron, such policy concerns of the agency must be accorded great deference. See Chevron, 467 U.S. at 865-866; see also New Hampshire Hemp Council, 203 F.3d at 7 ("given Congress' enlargement of drug

[23] As one United States Court of Appeals has stated, "a reading of the [CSA] and its legislative history makes it apparent that Congress, in legislating against drug use, intended to encompass every act and activity which could lead to proliferation of drug traffic. Nothing in the statute indicates any congressional intent to limit the reach of this legislation, which is described in its title as "Comprehensive." United States v. Everett 700 F.2d 900, 907 (3d Cir. 1983)(internal citations omitted).

crimes and penalties in recent years," one cannot "bank on its adoption of an exception strongly opposed by the DEA as a threatened loophole in the ban on illegal drugs.")

Again, under the step two of Chevron, the agency's permissible interpretation of 811 scheduling provisions must be upheld even if there are other permissible interpretations and even if the Court would have reached another conclusion if the question initially had arisen in a judicial proceeding. See 467 U.S. at 843 n. 11.

Another issue not specifically addressed in the legislative history or caselaw is petitioners' claim that DEA's allowance for animal feed containing cannabis seed is arbitrary and capricious. Petitioners' two points here are: (i) DEA's exemption authority under 21 U.S.C. 811(g)(3)(B) may be used only for items that are "not for administration to a human being of animal" and (ii) DEA should have conducted a scientific analysis comparing the abuse potential of cannabis animal feed mixtures with that of cannabis food products or made the same exception for cannabis food products.

As noted above in the step one analysis, the exemption for animal feed in DEA-205F was not issued pursuant to 811(g)(3)(B). Rather, it was issued pursuant to 21 U.S.C. 871(b), which authorizes the Attorney General (and DEA by delegation) to "promulgate and enforce any rules, regulations, and procedures

which he may deem necessary and appropriate for the efficient execution of his functions under" the CSA. 68 Fed. Reg. at 14119-14120. DEA explained at length in both proposing and finalizing the rule precisely why the agency was exercising its discretionary authority to exempt animal feed containing cannabis seed. 66 Fed. Reg. at 51540-51541; 68 Fed. REg. at 14120-14121. The main reason was that Congress expressly contemplated and intended to allow under the 1937 Act the use of sterilized cannabis seeds in bird seed. Id. Petitioners and DEA are in agreement that bird seed was the primary cannabis product lawfully marketed in the Untied States under the Marihuana Tax Act and at the time of the enactment of the CSA and for decades thereafter. Ensuring that this longstanding legitimate industrial market could continue uninterrupted in accordance with the expressed intent of Congress under prior legislation was not arbitrary and capricious.

There is no requirement in the CSA that DEA conduct any "scientific" analysis as a prerequisite for exempting an item from control. What was required, and what the agency did, was to provide a careful and reasoned explanation for exercising its discretionary authority. The agency stated: "DEA believes it is appropriate to exempt from application of the CSA animal feed mixtures containing such seeds, provided the seeds are mixed with other ingredients (not derived from the cannabis plant) in a formulation designed, marketed and

distributed for animal consumption (not for use for humans)." 68 Fed. Reg. at 14120. The agency then proceeded to provide a detailed explanation for adopting this approach. Id. At 14120-14121.

As for the point that DEA should have also made an exemption for cannabis food products, or established minimum acceptable amounts of THC in food products, these are also matters committed to the sound discretion of the agency. DEA offered well-reasoned explanations on both of these subjects. Under Chevron, petitioners may not properly ask this Court to choose their policy preferences over that of the agency:

> Judges are not experts in the field, and are not part of either political branch of the Government. Courts must, in some cases, reconcile competing political interests, but not on the basis of the judges' personal policy preferences. In contrast, an agency to which Congress has delegated policy-making responsibilities may, within the limits of that delegation, properly rely upon the incumbent administration's views of wise policy to inform its judgments. While agencies are not directly accountable to the people, the Chief Executive is, and it is entirely appropriate for this political branch of the government to make such policy choices – resolving the competing interests which Congress itself either inadvertently did not resolve, or intentionally left to be resolved by the agency charged with the administration of the statute in light of everyday realities.
>
> When a challenge to an agency construction of a statutory provision, fairly conceptualized, really centers on the wisdom of the agency's policy, rather than whether it is a reasonable choice within a gap left open by Congress, the challenge must fail. In such a case, federal judges – who do not have constituency – have a duty to respect legitimate policy choices made by those who do. The responsibilities for assessing the wisdom of such policy choices and resolving the struggle between competing view of the public interest

> are not judicial ones: "Our Constitution vests such responsibilities in the political branches."

467 U.S. at 865-866 (citation omitted).

On the issue of poppy seeds, petitioners contend that poppy seeds and cannabis seeds are identical for purposes of control under the CSA and, therefore, DEA should make the same allowance for cannabis seeds as is made for poppy seeds. DEA addressed this squarely in the text accompanying the rules, explaining the differences between the control of opiates and the control of hallucinogens under the CSA. 68 Fed. Reg. at 14116. It is also important to recognize that the exemption in federal law for poppy seeds has always been for the specific and sole purpose of using the seeds in food. The CSA exemption for poppy seeds was carried forward from the Opium Poppy Control Act of 1942, Pub. L. No. 77-797, 56 Stat. 1045, which was repealed and superseded by the CSA, Cf. Atlantic Supply Co. v. United States, 34 Cust. Ct. 40 (Cust. Ct. 1955)(discussing use of poppy seeds in food); Stutz v. Bureau of Narcotics, 56 F.Supp. 810 (N.D. Cal. 1944)(discussing Opium Poppy Act). In contrast to the longtime allowance in federal law for the use of poppy seeds in food, the use of cannabis seeds in foods developed only well after the enactment of the CSA, and there is no indication that Congress ever intended to allow such use for cannabis seeds.

Accordingly, under step two of Chevron, DEA-205F and -206F must be upheld as a permissible interpretation of the CSA.[24]

III. DEA-205F AND -206F WERE ISSUED IN COMPLIANCE WITH THE REGULATORY FLEXIBILITY ACT

Petitioners claim that, in issuing DEA-205F and -206F, DEA violated the Regulatory Flexibility Act, 5 U.S.C. 601-612 (RFA), by failing to perform the regulatory flexibility analysis required under the Act. RFA requires an agency to conduct an initial and final regulatory analysis in the manner set forth in 5 U.S.C. 603 and 604. However, RFA expressly states: "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 entitles." 5 U.S.C. 605(b). The agency is required to publish such certification in the Federal Register with the proposed and final rules, "along with a statement providing the factual basis for such certification." Id. The

[24] Petitioners' argument, and the argument made by amicus DKT Liberty Project, that DEA-205F constitutes a taking without compensation in violation of the Fifth Amendment is wholly without merit. DEA's issuance of the final rules raise no constitutional concerns. As discussed above, the CSA does not require DEA to conduct a formal rescheduling hearing before accomplishing the result of DEA-205F and -206F. Assuming that this Court concludes, as we believe it should, that the issuance of the rules comported with the CSA and the principles of Chevron, no constitutional issue is presented. Petitioners cite no authority (and none exists) for the proposition that even if DEA-205F and -206F were promulgated in accordance with the CSA, they somehow run afoul of constitutional limits on takings.

agency must also produce a copy of the certification to the Small Business Administration (SBA). Id.

Petitioners effectively concede that there is no merit to their RFA claim because they acknowledge that DEA made the certifications required by 605(b). DEA published the certifications along with the statement of factual basis in the Federal Register notices accompanying the proposed and final rules and provided copies of each to the SBA. 66 Fed. Reg. at 51535-51538, 51543-51544; 68 Fed. REg. at 14117-14118, 14125. Petitioners do not contend that the certifications or statements of factual basis were invalid. Therefore, it is undisputed that no regulatory flexibility analysis was required. Accordingly, petitioners' RFA claim need not be further considered.

Nonetheless, we note the following. In order to provide a factual basis for the certification, and in an abundance of fairness to any members of industry who might be impacted by the rules, DEA did an assessment of the economic impact of the rules on all cannabis-related industries – even those whose activities were being exempted from control under the rules. Id. Under RFA, this type of economic assessment is not the same as the "initial regulatory flexibility analysis" and "final regulatory flexibility analysis" and need not adhere to the requirements for such analyses set forth in 603 and 604. Even so, DEA made every effort to

accurately assess the possible economic impact on the various industries and to explain that assessment in detail in the Federal Register.

Interestingly, DEA appears to have overestimated the economic impact of the rules on the cannabis food industry. In the proposed rules, DEA estimated the total annual sales of such products in the United States to be approximately $20 million. The comments from industry estimated the figure to be $6 million. 68 Fed. Reg. at 14118. It is therefore difficult to understand petitioners' objective in asking that the agency be ordered to reassess the extent of the economic impact on the industry.[25]

Petitioners also contend that DEA failed to conduct the proper regulatory flexibility analysis under RFA 605(b) with respect to the manufacturers of cannabis-derived personal care products. Again, for the reasons provided above, this analysis was not required under the express terms of the RFA. Still, a brief point is warranted in response to petitioners' claim that the rules will "destroy the manufacture of body care products in the U.S., using oil imported from Canada and other foreign countries, since the importation of such oil, regardless of its intended use, would be banned by the rule." Brief at 45.

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[25] Petitioners also quote a statement from the SBA, which reiterates the RFA concern expressed by petitioners. As the date of this report indicates (2002), it was submitted by the SBA in response to the proposed rule, not the final rule. In any event, the SBA statement, as with petitioners' brief, does not assert that the Administrator's certification was improper. Therefore, no final RFA analysis was required.

First, it should be repeated that the rules exempt virtually all personal care products (except pure cannabis seed oil) entirely from control under the CSA. Most of the petitioners are Canadian companies whose finished products may be imported into the United States and distributed here entirely exempt from the CSA control. While pure cannabis seed oil is not exempted from control, DEA made clear in the rules that this does not mean that the product will be "banned." On the contrary, pure cannabis seed oil, if it contains THC, will be considered a schedule I controlled substance under the rules, which means that manufacturers and importers would have to comply with the corresponding CSA regulatory requirements. See 66 Fed. REg. at 51543; 68 Fed. Reg. at 14123. Petitioners fail to recognize that the CSA and DEA regulations expressly permit the industrial use of schedule I substances, provided the company has obtained the appropriate registration and any required permits and otherwise complies with the applicable regulations. The import registration fee is $438 per year and these is no fee for import permits. See 21 C.F.R. 1301.13(e)(1).

In any event, the agency complied fully with the RFA for the reasons provided above.

CONCLUSION

For the foregoing reasons, this Court should deny petitioners' request that this Court invalidate DAE 205F and -206F.

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