UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 01-71662

HEMP INDUSTRIES ASSOCIATION, ET AL.

v.

DRUG ENFORCEMENT ADMINISTRATION, ET AL.

PETITION FOR REVIEW OF RULE OF
DRUG ENFORCEMENT ADMINISTRATION

BRIEF OF PETITIONERS

STATEMENT OF JURISDICTION

(a) This is a Petition for Review of an "Interpretive Rule" issued by respondent Drug Enforcement Administration ("DEA") on October 2, 2001, 66 Fed. Reg. 51530 (Oct. 9, 2001), Excerpts of Record ("ER") at 2. The "Interpretive Rule" was issued pursuant to the Controlled Substances Act, 21 U.S.C. §§802 et seq.

(b) As demonstrated below, the "Interpretive Rule" is a final substantive rule. Accordingly, this Court has jurisdiction under section 507

of the Controlled Substances Act ("CSA"), 21 U.S.C. §877, which provides that any person aggrieved by a final decision of the Attorney General under the CSA "may obtain review of the decision in the United States Court of Appeals for the District of Columbia or for the circuit in which his principal place of business is located upon petition filed with the court and delivered to the Attorney General within thirty days after notice of the decision." Petitioners Hemp Industries Association and Nutiva, Inc. have their principal places of business in California, within this Circuit.

(c) The "Interpretive Rule" was issued by DEA on October 2, 2001. Petitioners timely filed their Petition for Review on October 19, 2001. 21 U.S.C. §877; Fed. R. App. P. 15(a)(1).

ISSUES PRESENTED FOR REVIEW

1. Is DEA's "Interpretive Rule" actually a final, substantive legislative rule that was issued in violation of the Administrative Procedure Act because it was issued without notice or opportunity for comment?

2. Is DEA's "Interpretive Rule" the scheduling of a new substance under the Controlled Substances Act, undertaken in violation of that Act because DEA failed to conduct a formal rulemaking on the record after opportunity for hearing as required by 21 U.S.C. §811(a)?

STATEMENT OF THE CASE

The Petitioners include Hemp Industries Association; Nutiva, Inc.; Tierra Madre, LLC; Hemp Oil Canada, Inc.; North Farm Cooperative; Kenex, Ltd.; Nature's Path Foods USA, Inc.; and Hempola, Inc. These companies manufacture, distribute and/or sell, in the United States, processed hemp seed or oil, or food and beverage products containing processed hemp seed or oil, which seed, oil or products may contain non-psychoactive miniscule trace amounts of residual resin which contains naturally occurring tetrahydrocannibinols ("THC"). Hemp Industries Association is a trade association representing more than 250 hemp oil, hemp seed and hemp fiber, food, clothing, beverage and bodycare companies and retailers of such products. Hemp seed and oil, and products made from such seed and oil, have never been treated as controlled substances under the CSA. Petitioners have been lawfully importing and distributing seed and oil, and/or manufacturing and selling food and beverage products made from such seed and oil, for many years.

On October 9, 2001, with no opportunity for notice and comment, DEA published its "Interpretive Rule" purporting to "interpret" the CSA and DEA's own regulations to mean that "any product that contains any amount of THC is a schedule I controlled substance. . . . ." ER at 5 (emphasis

added). This "Interpretive Rule," made effective immediately upon publication, has the effect of instantly transforming Petitioners' long-standing business activities into a criminal offense.

Simultaneous with its publication of the "Interpretive Rule," DEA published a "Proposed Rule and Request for Comments," 66 Fed. Reg. 51535 (Oct. 9, 2001), ER at 13. The "Proposed Rule" would amend the language of DEA's regulations, 21 C.F.R. §1308.11, to have exactly the same effect as the "Interpretive Rule." Thus, DEA has initiated a notice and comment rulemaking on a "proposed" rule which is identical to the "interpretive" rule that DEA put into effect immediately—without any notice or comment.

DEA also published, on the same date, an "Interim Rule" exempting from the "Interpretive Rule" products that are not used, or intended for use, for human consumption. 66 Fed. Reg. 51539 (Oct. 9, 2001), ER at 7. Because Petitioners' food and beverage products are used, or intended to be used, for human consumption, Petitioners' products are not covered by this exemption; thus, the importation, manufacture and sale of such products has been rendered unlawful by the "Interpretive Rule." Further, although the "Interim Rule" purports to provide a 120-day "grace period" for companies which possess hemp seed and oil products containing trace THC and

intended for human consumption to "dispose" of such products, the "Interim Rule" makes clear that it is immediately unlawful for any person to "manufacture or distribute such a product with the intent that it be used for human consumption within the United States." ER at 11. Thus, the manufacture and distribution by Petitioners of their various products is illegal right now.

Because the "Interpretive Rule" is actually a final, substantive, legislative rule, Petitioners sought review in this Court by filing their Petition for Review on October 19, 2001. Inasmuch as DEA determined to act by issuing the "Interpretive Rule" without undertaking any rulemaking proceeding, there is no administrative record other than the three rules themselves ("Interpretive", "Proposed" and "Interim").

Simultaneously with the filing of their Petition for Review, pursuant to Fed. R. App. P. 18(a)(2) and Circuit Rule 27-3, Petitioners filed an Urgent Motion for Stay Pending Review of DEA's "Interpretive Rule." As of the time of preparation of this Brief, briefing on the Motion had been completed and the Motion has been submitted.

STATEMENT OF FACTS

Industrial hemp is a commonly used term for a group of varieties of the species Cannabis sativa L. that are cultivated for industrial rather than

drug purposes. It can be grown as a fiber and/or seed crop. For seed, hemp is harvested when the seed is mature and ready for combining. U.S. Dept. of Agriculture, "Industrial Hemp in the United States: Status and Market Potential" 7, 10 (Jan. 2000)("USDA Study"). As explained below, the statute controlling marijuana has, since 1937, excluded hemp seed and oil. This statutory exclusion has enabled U.S. individuals and businesses to legally purchase, use, and trade in sterilized hempseeds, hempseed oil, hempseed cake, hemp fiber and products made therefrom. Hemp food, oil and fiber products are available throughout the U.S., Canada, the European Union and Asia.

The seed is botanically an "achene" or small nut. Seeds are separated and cleaned; oil is predominantly extracted through a mechanical "cold pressing" process. See Thompson, Berger & Allen, "Economic Impact of Industrial Hemp in Kentucky" Fig. 1 at 5 (Univ. of Kentucky Center for Business & Economic Research, July 1998)("Kentucky Study"). Most of the seed's value is derived from either dehulling the whole seed and/or crushing it for oil.

According to the USDA Study, "Hemp seeds can be used as a food ingredient or crushed for oil and meal. The seed contains 20 percent high-quality digestible protein, which can be consumed by humans. . . The oil can

be used both for human consumption and industrial applications." USDA Study at 15. The oil content of hemp seeds varies from 30% to 40%. Hemp seed oil typically contains 75-80% of the poly-unsaturated essential fatty acids (EFA's) that are needed by, but not naturally produced by, the human body. I. Bocsa and M. Karus, The Cultivation of Hemp: Botany, Varieties, Cultivation and Harvesting 38 (1998). According to the Kentucky Study, the basic reasons for use of hemp oil in foods are that "hemp oil has a better profile of key nutrients, such as essential fatty acids and gamma-linolenic acid, than other oils,. . . and a similar profile of other nutrients, such as sterols and tocopherols."

This superior nutritional profile makes hemp seed and oil ideal for a wide range of food applications. Hulled hemp seeds resemble sesame seeds in appearance and are comparable to sunflower seeds in taste. They may be incorporated in baking or simply added to foods such as soups or salads. Consumption of hulled hemp seed blended in shakes or drink mixes offers an alternative to meet both daily protein and EFA needs. Hemp nuts may be ground and turned into nut butter for spreads and sandwiches. In the U.S., research is being conducted to use hulled or whole hemp seeds in the production of "hemp milk" as an alternative to soy or rice based non-dairy milks, a category that is now the largest selling in the natural foods business.

The USDA study identifies food products containing hemp ingredients to include roasted hulled seed, nutrition bars, tortilla chips, pretzels and beer. Id. Firms have also attempted to develop products including cheese, margarine and candy bars. Kentucky Study at 7. Because it is tasty and less sensitive to heat than other high omega-3 oils, particularly flax oil, hemp oil can be used for cold dishes like sauces, flavorings, and dressings, and for low-heat cooking and sautéing. Leson and Pless, Hemp Foods and Oils for Health (1999).

The companies currently selling hemp seed and oil food, beverage and nutritional products in the U.S., including the Petitioners, generally either import hemp seed and oil from Canada or Europe for use in manufacturing products in the U.S., or import already finished products from Canada or Europe. Non-psychoactive industrial hemp plants grown in Canada and Europe are bred to contain less than three-tenths of one percent (< 0.3%) by weight of THC in the upper portion of the flowering plant. (USDA Study at 7), in full compliance with Article 28(2) of the United Nations' Single Convention on Narcotic Drugs, 1961, to which the U.S. is a signatory party. ("This Convention shall not apply to the cultivation of the cannabis plant exclusively for industrial purposes (fiber and seed) or horticultural purposes"). The meat of the hemp seed (or nut) itself contains only

miniscule traces of THC, usually much less than 0.5 parts per million (ppm, equivalent to microgram per gram - µg/g) of THC; however, the "[p]resence of THC in hemp seed products is predominantly caused by external contact of the seed hull with cannabinoid-containing resins in bracts and leaves during maturation, harvesting, and processing." Leson, Pless, Grotenhermen, Kalant and ElSohly, "Evaluating the Impact of Hemp Food Consumption on Workplace Drug Tests," 25 JOURNAL OF ANALYTICAL TOXICOLOGY 691, 692 (Nov./Dec. 2001). Consequently, hemp oil may contain trace amounts of THC from the trace resin residue on the outer shells. See Ross et al., "GC/MS Analysis of the Total delta-9-THC Content of Both Drug and Fiber Type Cannabis Seeds" (2000). "Since 1998, more thorough seed drying and cleaning appears to have considerably reduced THC levels in seeds and oil available in the U.S." Leson, Pless, Grotenhermen, Kalant and ElSohly, supra, at 692. Currently, THC levels in hulled seeds produced in Canada are typically less than 2 ppm and in hemp seed oil, 5 ppm, which are "sufficiently low to prevent confirmed positives [in urine drug-testing for marijuana] from the extended and extensive consumption of hemp foods." Leson, Pless, Grotenhermen, Kalant and ElSohly, supra at 691.

SUMMARY OF ARGUMENT

The "Interpretive Rule" is, as a matter of law, actually a substantive, legislative rule. Prior to issuance of the "Interpretive Rule," sterilized hemp seed and hemp seed oil, and oil and seed products, were not controlled substances under the CSA notwithstanding the presence of miniscule amounts of THC. Hemp seed and oil are specifically excluded from the statutory definition of "marijuana." And both the statutory definition of "THC" and DEA's own regulations, by their plain terms and as interpreted by the courts, cover only synthetic THC, not naturally occurring THC present in the excluded parts of the marijuana plant.

Contrary to DEA's contentions in the "Interpretive Rule," existing law has never covered hemp seed and oil. First, DEA contends that the congressional exemption of hemp seed and oil from the definition of "marihuana" was based on the mistaken assumption that the excluded portions of the marijuana plant did not contain THC. In fact, the relevant legislative history clearly demonstrates that the 1937 Congress that enacted this exemption was well aware that hemp seed and oil contain trace amounts of resin with the active drug (later identified as THC), but that Congress was nevertheless convinced that such amounts are not sufficient to be harmful.

Second, the history of federal control of THC demonstrates that naturally occurring trace THC in the excluded parts of the marijuana plant has never been controlled as THC. DEA concedes the language of regulations issued by the Bureau of Narcotics and Dangerous Drugs ("BNDD") prior to enactment of the CSA was limited to synthetic THC. Contrary to DEA's contention, that limitation was present even though BNDD had authority to regulate natural THC not included as "marihuana." The language of the earlier regulations was carried forward into DEA's current regulations, clearly establishing that such current regulations do not cover naturally occurring THC.

The Department of Justice, of which DEA is a part, and DEA itself have long acknowledged that under current law hemp seed and oil are not controlled substances notwithstanding trace amounts of naturally occurring THC.

Given that hemp seed and oil are not currently controlled substances, DEA's "Interpretive Rule" is, as a matter of law, a legislative, substantive rule. First, the rule has the force of law, transforming conduct that was previously lawful into a serious federal crime. Second, the "Interpretive Rule" imposes new obligations and effects a change in existing law, since DEA has itself recognized that companies like Petitioners will have to

dispose of their existing inventories. Third, the "Interpretive Rule" is clearly inconsistent with a pre-existing legislative regulation, namely, DEA's own existing regulations which exclude from CSA Schedule I hemp seed and oil notwithstanding trace amounts of naturally occurring THC. Fourth, DEA is issuing the "Interpretive Rule" pursuant to legislative power delegated by Congress, since DEA has simultaneously published a "Proposed Rule" that amends the language of DEA's regulations and does so explicitly pursuant to statutory authority to establish the Schedules of controlled substances under the CSA.

Since the "Interpretive Rule" is actually a substantive, legislative rule, DEA's promulgation of the "Interpretive Rule" without notice or opportunity for comment violates the Administrative Procedure Act, 5 U.S.C. §553. Further, since DEA is in effect placing a new substance—hemp seed and oil with trace amounts of natural THC—on Schedule I, its promulgation of the "Interpretive Rule" violates the CSA itself, which requires that such scheduling be undertaken through formal rulemaking on the record with certain specified findings—a formal rulemaking DEA has not even initiated, let alone completed.

For these reasons, the "Interpretive Rule" is invalid and should be set aside.

ARGUMENT

STANDARD OF REVIEW

The controlling question in this case is whether DEA's "Interpretive Rule" is truly an interpretive rule or rather, is a substantive, legislative rule. "Whether an agency pronouncement is interpretive or substantive is a legal question that we review de novo." Gunderson v. Hood, 268 F.3d 1149, 1154 (9th Cir. 2001); accord, Southern Cal. Aerial Advertisers' Ass'n v. FAA, 881 F.2d 672, 677 (9th Cir. 1989).

I. DEA'S PURPORTED "INTERPRETIVE RULE" IS A SUBSTANTIVE, LEGISLATIVE RULE

The processed hemp seed and oil, and products made from such seed and oil, which Petitioners import, manufacture, distribute and/or sell, were not controlled substances under the CSA prior to issuance of the "Interpretive Rule." The "Interpretive Rule" thus instantly renders criminal conduct which was lawful prior to issuance of the rule.[1] The "Interpretive Rule," notwithstanding its label, has the force of law, effects a change in existing law, effectively revokes the current legislative regulation having the force of law and was made pursuant to legislative power delegated by Congress. For these reasons the rule is substantive, not interpretive.

A. Petitioners' Products Were Not Controlled Substances Prior to the "Interpretive Rule"

The law prior to the "Interpretive Rule" clearly excluded Petitioners' products, i.e., hemp seed and oil and products made from such seed and oil. The CSA controls two materials relevant here: "Marihuana," 21 U.S.C. §812(c), Schedule I (c)(10) and "Tetrahydrocannibinols" ("THC"), 21 U.S.C. §812(c), Schedule I(c)(17). The CSA, and DEA's regulations, treat the naturally-occurring trace amounts of THC in hemp seed and oil neither as "Marihuana" nor as "THC."

1. Hemp Seed and Oil Are Not "Marihuana"

CSA Schedule I (c)(10), 21 U.S.C. §812(c) covers "Marihuana," which is defined to include "all parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture or preparation of such plant, its seeds or resin." 21 U.S.C. §802(16). The Cannabis sativa plant itself is covered in Schedule I regardless of its THC content. New Hampshire Hemp Council, Inc. v. Marshall, 203 F.3d 1 (1st

[1] Indeed, the impact of the "Interpretive Rule" on Petitioners, given the investments they have made in reliance on the existing law, may well raise an issue of unconstitutional takings.

Cir.), cert. denied, 531 U.S. 828 (2000). Thus, industrial hemp plants themselves are controlled under Schedule I.

The CSA definition of "Marihuana," however, explicitly provides that:

> Such term does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from 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. §802(16) (emphasis added).

The express language of the CSA thus provides that hemp oil, cake and sterilized seed are not controlled as "Marihuana" under Schedule I of the CSA.

2. Hemp Seed and Oil Are Not Controlled as THC

CSA Schedule I(c)(17), covers "any material, compound, mixture or preparation, which contains any quantity of" THC. 21 U.S.C. §812(17). DEA's regulations provide that "THC" refers to "[s]ynthetic equivalents of the substances contained in the plant, or in the resinous extractives of Cannabis, sp., and/or synthetic substances, derivatives, and their isomers. . ." 21 C.F.R. §1308.11(d)(27)(emphasis added). Thus, it is clear that "THC", as used in CSA Schedule I, does not refer to the organic, naturally-occurring THC found in hemp oil, cake and sterilized seed, but only to synthetic THC.

This construction was recognized in United States v. McMahon, 861 F.2d 8 (1st Cir. 1988). In that case, the Court found that hashish and sea-hash were controlled only by Schedule I(c)(1) as "marihuana" (as a derivative of the resin) and not by Schedule I(c)(17), because "the substance referred to in Schedule I(c)(17) is synthetic, not organic THC." 861 F.2d at 11. This Circuit is in accord as demonstrated by the Court's decision in United States v. Wuco, 535 F.2d 1200 (9th Cir.), cert. denied, 429 U.S. 978 (1976). In Wuco, the U.S. Department of Justice conceded that the listing of "Tetrahydrocannabinols" in Schedule I is limited to synthetic THC; this Court agreed that "organic THC . . . is not the synthetic THC defined as a Schedule I controlled substance." Id. at 1202. Thus, it is clear from the plain statutory language of the CSA, and from the plain language of DEA's regulations, that "THC" as set forth in CSA Schedule I does not include the miniscule trace organic THC occurring in non-psychoactive hemp oil, cake and sterilized seed.

3. The Law Has Never Covered Hemp Seed and Oil With Trace Amounts of Natural THC

In its "Interpretive Rule," DEA claims that the existing law already covers naturally-occurring trace THC in hemp seed and oil. That contention is based on two propositions advanced by DEA: first, that the congressional exemption of hemp seed and oil from the definition of "marihuana" was

based on the mistaken assumption that the excluded portions of the marijuana plant did not contain THC; and second, that DEA's current regulations were always intended to include naturally-occurring, as well as synthetic, THC. Neither proposition withstands scrutiny.

(a) The Legislative History of the Definition of "Marijuana" Makes It Clear That Congress Intended to Exclude Sterilized Hemp Seed and Oil Notwithstanding Trace Amounts of THC (i.e. Drug-Containing Resin)

DEA argues, first, that "the 1970 Congress did not address the possibility that portions of the cannabis plant excluded from the definition of marijuana might contain THC." ER at 3. In DEA's view, "it is evident that the 1937 Congress exempted certain portions of the cannabis plant based on the assumption (now refuted) that such portions of the plant contain none of the psychoactive component now known as THC." Id. To the contrary, the legislative history clearly demonstrates that the 1937 Congress was well aware that hemp seed, and the oil derived from it, contain trace amounts of the drug-containing resin (the active constituent of which, natural THC, was subsequently identified in the early 1960's), but that Congress was convinced that such amounts are not sufficient to be harmful.

At hearings before the House Ways and Means Committee in April 1937, Clinton Hester, Assistant General Counsel for the Treasury

Department, testified that, "As the seeds, unlike the mature stalk, contain the drug, the same complete exemption could not be applied in this instance." Hearings on H.R. 6385, 7th Cong., 1st Sess. 8 (April 1937). Similarly, H.J. Anslinger, Commissioner of Narcotics of the Bureau of Narcotics of the Treasury Dept., stated that the Bureau had "urged the States to revise their definition so as to include all parts of the plant, as it now seems that the seeds and portions other than the dried flowering tops contain positively dangerous substances." Id. at 19. However, later, Dr. Herbert J. Wollner, consulting chemist for the Treasury Department, clarified for the Committee that:

> The active principle in marihuana appears to be associated with an element which is located or found in the flowering tops and on the under side of the leaves of the plant. . . . The resin contains an ingredient which the chemical technologist refers to as cannabinone or cannabinol, alternatively….[S]eeds contain a small amount of that resin, apparently on their outer surface according to quite a number of investigators depending upon the age of that seed….

Id. at 52-54 (emphasis added).

At the same time, the Ways and Means Committee heard considerable testimony to the effect that the very small amounts of the "active principle", i.e., THC, potentially present in hemp seed and oil would not have any harmful effect or potential for abuse. Mr. Wollner goes on to testify that the

"small amount of that resin" is indeed negligible and harmless and technically very difficult to extract and concentrate (and thus economically prohibitive):

> Mr. Buck [Rep. Frank Buck (D-Cal)]: Does the oil from the seed contain any of this deleterious matter?
> Mr. Wollner: That would in a large measure depend upon the condition of the seed and the condition of manufacture, but I would say in any event the oil would not contain a large amount of this resin….
> Mr. Buck: Would it contain enough to have any harmful effect on anyone, if taken internally?
> Mr. Wollner: I would say no; it would not contain such an amount.
> Mr. Fuller [Rep. Claude Albert Fuller (D-Ark.)]: As I understand it, you say the oil does not contain much, if any, of the drug?
> Mr. Wollner: It does contain some of the drug, but not much. It would appear, offhand, to be rather difficult to separate, but processes might possibly be developed for that purpose.
> Mr. Fuller: It would not be useful for the purpose for which they are using marihuana.
> Mr. Wollner: No.
> Mr. Fuller: So, so far as the oil from the seed is concerned, it is harmless, as far as human use is concerned.
> Mr. Wollner: That is right.

Id. at 54 (emphasis added). Similarly, during the testimony of Ralph Lozier, general counsel of the National Institute of Oilseed Products, before the Committee, the following exchange took place indicating congressional awareness of the insignificant harmless quantity of trace resin in the seed:

> Mr. Lozier: … No one will contend, or no respectable authority will assert, that this deleterious principle is found either in the seed or the oil….. . .If the committee please, the hemp seed, or the seed of cannabis sativa, L., is used in all the Oriental nations

> and also in a part of Russia as food. It is grown in their fields and used as oatmeal. Millions of people every day are using hemp seed in the Orient as food. They have been doing that for many generations, especially in periods of famines.
> Mr. Fuller: I do not think that the gentlemen who have presented the case on behalf of the committee, or the Government, have claimed that it was present in the oil.
> Mr. Lozier: They have said it was in the seed.
> Mr. Fuller: He said there was very little in the seed. He said there would be no injurious effect from the little there was in the seed.

Id. at 61 (emphasis added).

The Committee's report on the bill it reported out, H.R. 6906, makes clear that the Committee recognized that "marihuana is a dangerous drug found in the flowering tops, leaves and seeds of the hemp plant,…," H. Rep. 792, 75th Cong. 1st Sess. 1 (1937) (emphasis added), but that whatever amount was present in the seeds would not be harmful or have the potential for abuse:

> 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 and the valuable industrial articles produced therefrom in which the drug is not present.

Id. at 3-4 (emphasis added).

Likewise, the Senate Finance Committee heard testimony making clear that hemp seed and oil contain trace amounts of resin (i.e. THC), but that these miniscule amounts would not have any harmful effect or be

capable of abuse. In July 1937 hearings before the Finance Committee, Mr. Hester of the Treasury Department testified that:

> Mr. Hester: The flowering tops, leaves and seeds of the hemp plant contain a dangerous drug known as marihuana….
> Senator [Prentiss Marsh] Brown [(D-Mich.)]: Say you are in this situation. You have a plant that produces several articles that are valuable commercially.
> Mr. Hester: That is right.
> Senator Brown: At the same time, as a byproduct the leaves and the seeds can be used for marihuana?
> Mr. Hester: That is right.

U.S. Senate Finance Committee, Hearings on H.R. 6906, 7th Cong., 1st Sess. 9 (1937)(emphasis added). Commissioner Anslinger made clear to the Finance Committee his understanding that, while hemp seed definitely contained resin (i.e. THC), it was likely that sterilization would render its effects harmless:

> Senator Brown: Do I understand that the seed is ground up, too, and used to any extent?
> Mr. Anslinger: Well, we have heard of them smoking the seed.
> Senator Brown: Does it produce the same effect?
> Mr. Anslinger: I am not qualified to say. We have not made any experiments to that, but we do know that the seed has been smoked. I think that the proposition of the seed people sterilizing the seed by heat and moisture will certainly do a lot to kill this traffic.

Id. at 13. At the same time, the Finance Committee heard testimony from Matt Rens, of Rens Hemp Company of Brandon, Wisconsin, explaining that:

> No evidence has been obtained, either by scientific investigation or by practical observation to indicate that hemp seed, as handled in the trade, contains an appreciable proportion of the chemical

> substances which cause the narcotic effect. . . . A recent and thorough-going inquiry indicates that there are no biological tests or other researches which show that narcotic-producing substances are present in the seeds in a sufficient proportion to be harmful, in fact, there is nothing that shows that true seeds cause any of the narcotic effects. …
> The technical evidence given in the [House] hearings. . . shows that the seed does not contain an appreciable proportion of the narcotic substances. The [House] hearings also show that the seed was considered so harmless as to warrant omitting sterilized hemp seed from the definition of marihuana. . . . There is also no evidence, either practical or technical, to show that hemp seed has ever been used to produce the drug effect.

Id. at 24 (emphasis added). After hearing such testimony, the Finance Committee followed the House Ways and Means Committee in concluding that, while hemp seed does contain trace resin (i.e., THC), it should be excluded from the definition of marijuana because such seed does not contain enough resin/THC to be considered a "harmful drug:"

> The flowering tops, leaves, and seeds of the hemp plant contain a dangerous drug known as marihuana. . . .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 the law.

S. Rep. 900, 75th Cong., 1st Sess. 1, 4 (1937) (emphasis added).

DEA cites an excerpt from this Senate Finance Committee Report to support the notion that Congress exempted "certain portions of the cannabis plant from the definition of marijuana based on the assumption (now refuted) that such portions of the plaint contain none of the psychoactive component known as THC." 66 Fed. Reg. at 51531, ER at 3. Yet the very language cited by DEA from that Report—the language set out above—states explicitly the Committee's understanding that "neither the mature talk of the hemp plant nor the fiber produced therefrom" contain any "drug" property. No reference is made in that phrase to the seeds of the hemp plant. It is thus obvious that the Committee did understand that the seeds do contain the "drug" property; indeed, the Committee report states explicitly that the "seeds of the hemp plant contain a dangerous drug…." Yet the Committee, and ultimately Congress, excluded nonviable hemp seed and oil from the definition of marijuana. The only logical conclusion is that Congress was fully aware that hemp seed and oil do contain trace amounts of resin (THC), but that Congress excluded hemp seed and oil anyway because it was understood that these trace amounts were insufficient to be abused or to be economically extracted and concentrated for drug purposes.

Thus, contrary to DEA's suggestion, the legislative history of the 1937 law shows that Congress was indeed aware that hemp seed and oil

contain trace amounts of resin/THC, but that Congress nevertheless excluded such seed and oil from the definition of "marijuana" because Congress also understood that these trace amounts would not be harmful or capable of abuse.

(b) The Historical Control of THC Under Federal Law Indicates That Schedule I Does Not Cover Naturally Occurring Trace THC in Hemp Seed and Oil

In an effort to demonstrate that the naturally occurring trace THC in the excluded parts of marijuana, i.e., hemp seed and oil, are currently covered by Schedule I of the CSA, DEA has constructed a post-hoc rationalization based on the history of control of THC under federal law. In fact, that history only serves to demonstrate that naturally occurring trace THC in the excluded parts of the marijuana plant has never been, and is currently not, controlled as "THC" in Schedule I of the CSA or DEA's regulations. (To be sure, 100% pure natural THC refined from the resin of the flower would be controlled as "marijuana," as a derivative of the resin).

As DEA concedes, until 1971 natural THC was federally controlled only under the Marihuana Tax Act, and the definition of THC "included natural THC (to the extent such THC was contained in, or derived from, those portions of the cannabis plant included in the definition of marijuana)." Interpretive Rule, 66 Fed. Reg. at 51532, ER at 4. Since hemp

seed and oil were portions of the plant excluded from the definition of marijuana, it is clear that naturally occurring THC in those portions was not controlled.

DEA points out that, "in the late 1960's, when synthetic THC began showing up in the illicit market, federal officials concluded that federal control over the drug was necessary to prevent abuse." Id. According to DEA, at that time, control of synthetic THC could only be accomplished pursuant to the Drug Abuse Control Amendments of 1965, P.L. 89-74, 79 Stat. 226 ("DACA"). DEA explains that a 1968 Bureau of Narcotics and Dangerous Drugs regulation promulgated pursuant to DACA was limited to synthetic THC because DACA prohibited BNDD from promulgating a regulation that would list under DACA any substance included in the definition of marijuana under the Marihuana Tax Act of 1937. Id. Indeed, section 3 of DACA provided that the Secretary of Health, Education and Welfare could designate "any drug which contains any quantity of a substance which the Secretary…has found to have…a potential for abuse because of its depressant or stimulant effect…; except that the Secretary shall not designate…marihuana as defined in section 4761, of the Internal Revenue Code…" DACA, §3(a), adding 21 U.S.C. §321(v)(3).

This language clearly left BNDD free to designate any substance which was not included in the definition of marihuana in the Marihuana Tax Act. Since naturally occurring THC in sterilized hemp seed and oil were excluded from that definition, BNDD was entirely free to designate such THC under DACA. Nevertheless, BNDD's regulation was identical to the current listing of THC in the DEA regulations, and was limited to synthetic THC. DEA contends that since "natural THC (derived from marijuana) fit within the definition of marijuana and was thereby controlled under the Marihuana Tax Act, the BNDD regulations listing THC had to exclude such natural THC." 66 Fed. Reg. at 51532, ER at 4. Natural THC occurring in the excluded parts of marijuana did not fit within the definition of marijuana; was not controlled by the Marihuana Tax Act; and therefore could legally have been controlled by BNDD in 1968. That BNDD chose not to do so only makes clear that the 1968 BNDD language was intended to, and did, exclude naturally occurring THC in hemp seed and oil. BNDD implicitly affirmed the congressional finding that the trace THC found in hemp seed and oil posed no potential for abuse or other harm. It follows that DEA's current regulation—which is identical to the 1968 BNDD language--likewise excludes such naturally occurring THC.

DEA further contends that when Congress enacted the CSA in 1970, it listed "Tetrahydrocannabinols" in Schedule I "without having to distinguish between natural and synthetic." Id. But at the same time, Congress separately listed "Marihuana" in Schedule I. If Congress truly intended the listing of THC to include all forms of THC, natural and synthetic, however and wherever occurring, such separate listing of marihuana would have been entirely superfluous. Indeed, the manifest intent of Congress is explained by the question DEA itself raises: "Why would Congress exempt certain portions of the cannabis plant from the CSA definition of marijuana if such portions would nonetheless be subject to CSA control to the extent they contain THC?" 66 Fed. Reg. at 51531, ER at 3. The answer is clear: such portions are not subject to CSA control, notwithstanding the presence of trace naturally-occurring THC.

Following enactment of the CSA, BNDD carried forward its 1968 regulatory language—excluding naturally occurring trace THC-- into its 1971 regulations, 36 Fed. Reg. 4950 (March 13, 1971), adding new 21 C.F.R. §308.11(d)(17). That 1971 language, in turn, is identical to DEA's current regulation. That history makes clear that the current regulatory language does not include any naturally-occurring THC.

DEA makes much of the fact that the general term "Tetrahydrocannabinols" was added to the beginning of the listing in its regulation, above the references to "synthetic equivalents." But if that listing was not intended to be limited to synthetic THC, there would be no reason for the listing of synthetic equivalents—rather, the one word would automatically include all forms of both naturally occurring and synthetic THC. It is obvious that the language under the word "Tetrahydrocannabinols" in DEA's regulation is intended to define what is included in that listing. Indeed, it makes no more sense for DEA to list "Marihuana" separately in its regulation, with hemp seed and oil excluded only to be re-included as "THC," then it would have for Congress to do the same thing.

It is clear that DEA's reliance on the general term "Tetrahyrdocannabinols" simply proves too much. Under DEA's reasoning, DEA could find that the CSA currently includes poppy seeds (commonly consumed on bagels), which are explicitly exempted from the CSA in the statutory definitions of "opium poppy" and "poppy straw," 21 U.S.C. §§802(19),(20), based on the fact that poppy seeds contain trace amounts of natural opiates, which have no abuse potential but which are in themselves

clearly and unambiguously controlled under CSA, Schedule II(a)(1), 21 U.S.C. §812(c).

The history and structure of federal control of THC, then, makes clear that "THC" as listed in Schedule I of the statute, and in DEA's regulation, excludes the naturally occurring trace THC in hemp seed and oil.

4. The Department of Justice Interprets the CSA to Exclude Hemp Seed and Oil

That hemp oil, cake and sterilized seed are not currently controlled by the CSA Schedules has been confirmed by the Criminal Division of the U.S. Department of Justice, of which DEA, of course, is a part. In a letter to the DEA Administrator dated March 23, 2000, ER at 17, John Roth, Chief of the Narcotic and Dangerous Drug Section of the Criminal Division of the U.S. Department of Justice, referring to the exclusion of hemp oil, cake and sterilized seed from the definition of "Marihuana" in 21 U.S.C. §802(16), stated:

> Therefore, products derived from this portion of the cannabis plant commonly referred to as "hemp" are explicitly excluded from regulation under the Controlled Substances Act.
>
> It has been suggested that "hemp" products containing THC are subject to regulation under 21 U.S.C. §812(17). However, 21 U.S.C. §812(17) refers only to synthetic THC, not the THC naturally occurring within marijuana. The pertinent regulation, 21 C.F.R. §1308.11(d)(27), defines THC as "synthetic equivalent of the substances contained in the plant. . . ."

> Thus, it appears we are not able to regulate or prohibit the importation of "hemp" products based on any residual or trace content of naturally occurring THC. . . .
> [I]t is our legal opinion that we presently lack the authority to prohibit the importation of "hemp" products, absent regulatory language that interprets, or legislative action to modify, the definition of marihuana contained in 21 U.S.C. §802(16).

(emphasis added).

Significantly, an identical letter, dated March 22, 2000, ER at 19, was sent by Mr. Roth to then-U.S. Customs Commissioner Raymond W. Kelley. Thus, this statement of the current legal scope of the CSA was not merely a temporary "prior interpretation," but was intended to have a "binding effect … on tribunals outside the agency…." Splane v. West, 216 F.3d 1058, 1064 (Fed. Cir. 2000). Indeed, a subsequent letter from Commissioner Kelley to Office of National Drug Control Policy (ONDCP) Director Barry McCaffrey, dated March 31, 2000, ER at 21, apparently informed ONDCP that the Department of Justice's controlling interpretation contradicts ONDCP's position.

As long ago as 1991, DEA recognized that the CSA plainly does not currently control hemp seed or oil notwithstanding trace amounts of naturally occurring THC. In an April 18, 1991 affidavit, ER at 23, Charles M. Metcalf, a Senior Investigator of the DEA, stated:

> …I am a Senior Investigator employed by the Drug Enforcement Administration (DEA) and am assigned to the DEA Office of

> Diversion Control, Registration Section…I am fully familiar with the facts stated herein…
> 7. The DEA, and my office in particular, is aware that sterile marijuana seed sold as birdfeed is likely to contain residue and particulate vegetable matter which will test positive for the presence of THC, the active ingredient in marijuana.
> 8. The DEA does not require sterile marijuana seed placed into commerce as birdfeed to be free from all such residue and particulate matter.
> 9. The DEA does not consider sterile marijuana seed sold as birdfeed to be a controlled substance, whether or not it contains residue or particulate matter which tests positive for the presence of THC.
> 10. As detailed in the Affidavit of Susan Miller, Forensic Chemist, DEA, when evaluating material which visually appears to be primarily marijuana seed, the DEA's determination of whether the material constitutes a controlled substance must be made by viability testing of the seeds, rather than separate THC analysis of the residue and particulate matter.

(emphasis added).

Likewise, Susan Miller, a DEA forensic chemist, stated in a corresponding April 11, 1991 affidavit, ER at 26:

> "I am a Forensic Chemist employed by the Drug Enforcement Administration…
> 2. …It is recognized by the DEA laboratory system that the residues associated with marihuana seeds can and most often do, produce positive THC results using the standard chemical tests for marihuana…. For seed evidence, the chemist must prove by microscopic examination that the seeds have the physical characteristics of marihuana seeds, and the chemist must also prove that the seeds are viable…. Viability is the critical aspect of the analysis because the law specifically states that sterilized seeds incapable of germination are not included in the term "marijuana" and are therefore not controlled.

(emphasis added).

Thus, to identify whether or not the substance in question, hemp seed, is controlled, DEA ascertains only whether or not the seeds are viable, as viable marijuana seeds are defined as controlled, and sterilized hemp seeds are not, notwithstanding the presence of trace natural THC.

For these reasons, it is clear that the CSA and DEA's current regulations do not cover sterile hemp seed and oil, notwithstanding the presence of trace amounts of naturally occurring THC

B. DEA'S Rule is Legally a Substantive Rule

DEA contends, naturally, that its "Interpretive Rule" is indeed an interpretive rule, exempt from the notice and comment requirements of section 553 of the APA. 66 Fed. Reg. at 51533, ER at 5. But "[t]he label an agency attaches to its pronouncement is clearly not dispositive." Gunderson, supra, 268 F.2d at 1154 n. 27. "An agency may not escape the notice and comment requirements . . . by labeling a major substantive legal addition to a rule a mere interpretation." Appalachian Power Co. v. EPA, 208 F.23d 1015, 1024 (D.C. Cir. 2000). See Yesler Terrace Community Council v. Cisneros, 37 F.3d 442, 449 (9th Cir. 1994)(agency cannot avoid notice and comment rulemaking "simply by characterizing its decision" as

something other than a substantive rule). For four reasons, DEA's purported "Interpretive Rule" is legally a substantive rule.

First, the sine qua non of interpretive rules is that they "do not have the force and effect of law and are not accorded that weight in the adjudicatory process." Shalala v. Guernsey Memorial Hospital, 514 U.S. 87, 99 (1995). But DEA's "Interpretive Rule" clearly does have the force of law. Needless to say, sale and distribution of a Scheduled I controlled substance are serious federal criminal offenses. See 21 U.S.C. §841(a) & (b)(1)(C)(sentence up to 20 years for distribution of Schedule I controlled substance). Clearly DEA intends to enforce its "Interpretive Rule" to ban edible hemp seed and oil, and oil and seed products, as Schedule I controlled substances. Indeed, DEA concedes that, "upon publication of this [interpretive] rule, some manufacturers and distributors of THC-containing 'hemp' products will have in their possession existing inventories of products that will be considered controlled under the interpretive rule…." Interim Rule, 66 Fed. Reg. 51539 at 51543, ER at 7 (emphasis added).

Second, this Court has explained that "Interpretive rules 'simply clarify or explain existing law or regulations.' . . . They do not conclusively affect the rights of private parties." Yesler, 37 F.3d at 449, quoting Linoz v. Heckler, 800 F.2d 871, 877 (9th Cir. 1986). "Substantive rules, in contrast,

create rights, impose obligations, or effect a change in existing law…..." Yesler, 37 F.3d at 449; accord, Linoz, 800 F.2d at 877. DEA's "Interpretive Rule" clearly creates new obligations and changes existing law. As demonstrated above, before the "Interpretive Rule," sale and distribution of edible hemp seed and oil, and seed and oil products, were not unlawful at all. Now such activities are serious crimes. As noted, DEA concedes that companies like Petitioners will, upon issuance of the "Interpretive Rule," find themselves with inventories of edible hemp oil and seed products that "will be considered controlled under the interpretive rule…." Interim Rule, 66 Fed. Reg. 51539 at 51543, ER at 7. Indeed, were it not for the fact that the "Interpretive Rule" in fact imposes new obligations, and effects a change in existing law, it clearly would not have necessary for DEA to allow a 120-day grace period for Petitioners and like companies to dispose of such inventories—albeit while making clear that even during that grace period, use, manufacture and distribution of such products are immediately illegal. Id.

Third, if a new rule is inconsistent with a preexisting legislative regulation, the new rule is itself a legislative rule that cannot be "immune from APA notice and comment." Chief Probation Officers of Cal. v. Shalala, 118 F.3d 1327, 1336 (9th Cir. 1997). If a rule "amends an existing

legislative rule, then it cannot be interpretive." Gunderson, supra, 268 F.3d at 1154; accord, D.H. Blattner & Sons, Inc. v. Secretary of Labor, 152 F.3d 1102, 1109 (9th Cir. 1998). In this case, DEA's "Interpretive Rule" is clearly inconsistent with the pre-existing legislative regulation, namely, DEA's own Schedule I regulation which on its face, as interpreted by the U.S. Department of Justice and as applied, excluded from Schedule I hemp oil and seed with trace amounts of naturally-occurring THC. Surely neither DEA, nor any agency, can be heard to claim that it is merely "interpreting" an existing legislative regulation by substantively changing that existing regulation, having the force of law, to criminalize previously lawful conduct. Again, were the "Interpretive Rule" not in fact a legislative rule inconsistent with the existing legislative rule, it would not have been necessary for DEA to promulgate its special "Interim Rule" exempting certain products from the "Interpretive Rule" and providing a grace period for affected companies to dispose of their existing inventories of non-exempt hemp seed and oil, and seed and oil products.

Finally, if an "interpretation" or policy is promulgated "pursuant to legislative power delegated by Congress—rather than [the agency's] own interpretive power over a congressional enactment--. . . the resulting rule, a fortiori, was legislative." Chief Probation Officers, supra, 118 F.3d at 1336.

That DEA in this case is acting pursuant to delegated legislative power is made clear by the fact that DEA has issued a "Proposed Rule" which accomplishes exactly the same change in law that is effected by the "Interpretive Rule"—that is, putting on Schedule I any product that contains any amount of THC, even if such THC is naturally occurring in parts of the cannabis plant excluded from the CSA definition of "marijuana." In the Proposed Rule, that change in law is effectuated through an amendment of the actual language of DEA's regulations. See Proposed Rule, 66 Fed. Reg. at 51538, ER at 16, amending 21 C.F.R. §1308.11—Schedule I. And DEA is explicitly promulgating that amended regulatory language rule pursuant to legislative authority delegated by Congress: "This proposed rule is being issued pursuant to 21 U.S.C. 811, 812 and 871(b). Sections 811 and 812 authorize the Attorney General to establish the schedules in accordance with the CSA and to publish amendments to the schedules. . . ." Proposed Rule, 66 Fed. Reg. at 51535, ER at 13.

In this regard, the March 2000 opinion of the Chief of the Narcotic and Dangerous Drug Section of the Department of Justice, addressed to the Administrator of DEA, is highly relevant. See ER at 17. As noted above, this letter states that "it is our legal opinion that we"—that is, the Department of Justice including DEA—"presently lack the authority to

prohibit the importation of 'hemp' products. . . ." ER at 18 (emphasis added). One factor that automatically makes a rule a legislative rule rather than an interpretive one is "whether in the absence of the rule there would not be an adequate legislative basis for enforcement action or other agency action to confer benefits or ensure the performance of duties; . . ." American Mining Congress v. Mine Safety & Health Admin., 995 F.2d 1106, 1112 (D.C. Cir. 1993). By providing the previously missing legal authority, to criminally prohibit a new class of substances, pursuant to authority delegated by Congress, and in derogation of the scope of the existing regulation, i.e., Schedule I of the CSA, DEA through its "Interpretive Rule" is by any measure promulgating a substantive, legislative rule. See Chief Probation Officers, supra, 118 F.3d at 1335-37.

For these reasons, the "Interpretive Rule" is in fact a substantive, legislative rule.

II. ISSUANCE OF THE "INTERPRETIVE RULE" VIOLATED THE APA

The APA, 5 U.S.C. §553, requires that agency regulations be promulgated through advance notice of rulemaking with an opportunity for public comment. "When an agency promulgates regulations other than interpretative rules, general policy statements or rules for its own

organization, the APA generally requires prior notice and comment." Flagstaff Medical Center, Inc. v. Sullivan, 962 F.2d 879, 885-86 (9th Cir. 1992). "The exceptions to section 553 will be 'narrowly construed and only reluctantly countenanced.'" Alcaraz v. Block, 746 F.2d 593, 612 (9th Cir. 1984)(citations omitted). When an agency promulgates a substantive rule in violation of APA section 553, the rule is invalid. E.g., Malone v. Bureau of Indian Affairs, 38 F.3d 433, 439 (9th Cir. 1994).

In this case, DEA's "Interpretive Rule" was promulgated without notice or opportunity for comment. Because the rule is a substantive legislative rule, it has been promulgated in violation of section 553 of the APA, and is therefore invalid.

III. ISSUANCE OF THE "INTERPRETIVE RULE" VIOLATED THE CSA

The sole purpose and effect of the "Interpretive Rule" is to add to Schedule I a previously unscheduled substance--hemp seed and oil--overriding the congressional exemption of hemp seed and oil from the CSA. The current definitions of "marihuana" and "THC" in the CSA already cover any form of substance with potential for abuse. In particular, hypothetical 100% natural THC refined from the flower/resin is already covered under the definition of "marihuana" as a derivative of the resin. As demonstrated

above, however, hemp seed and oil are neither "marihuana" nor "THC" under the CSA, notwithstanding the presence of trace naturally-occurring THC in such seed and oil. Thus, through the "Interpretive Rule", DEA is attempting to place a new substance—hemp seed and oil—on Schedule I.

The CSA delegates to the Attorney General the power, by rule, to add to a CSA schedule "any drug or other substance", but only if the Attorney General makes certain findings prescribed in the statute. 21 U.S.C. §811(a). Pursuant to 21 U.S.C.§812(b), substances cannot be listed on Schedule I "…unless the findings required for such schedule are made with respect to such drug or other substance." The findings required for Schedule I are as follows:

> (1) Schedule I. -
>
> (A) The drug or other substance has a high potential for abuse.
>
> (B) The drug or other substance has no currently accepted medical use in treatment in the United States.
>
> (C) There is a lack of accepted safety for use of the drug or other substance under medical supervision. 21 U.S.C. §812(b)(1).

Section 811(a) further provides that "Rules of the Attorney General under this subsection shall be made on the record after opportunity for a hearing pursuant to the rulemaking procedures prescribed by" the APA. Id. (emphasis added). Section 553(c) of the APA provides that, "When rules

are required by statute to be made on the record after opportunity for an agency hearing, sections 556 and 557 of this title apply instead. . . ." Under sections 556 and 557, the agency must support its rule with substantial evidence based on a rulemaking record; there must be an oral hearing; parties must be afforded the opportunity for cross-examination; and parties must be permitted to present proposed findings and conclusions, and present exceptions to initial and recommended decisions.

Section 811(a) of the CSA follows the exact language of the APA that requires formal rulemaking. See United States v. Florida East Coast Railway, 410 U.S. 224, 241 (1973). Thus, to add a new substance to a CSA schedule, the DEA must undertake a formal rulemaking process.

In this case, DEA issued its "Interpretive Rule" without undertaking the formal rulemaking process required by the CSA, and without making any of the findings required by the CSA to add a new substance to Schedule I. For this reason, too, the "Interpretive Rule" is invalid.

CONCLUSION

For the reasons set forth above, the Court should rule that DEA's "Interpretive Rule" is invalid and order that it be set aside.

STATEMENT OF RELATED CASES

Pursuant to Circuit Rule 28-2.6, Petitioners are unaware of any related cases other than the Urgent Motion for Stay Pending Review filed by Petitioners in this same docket.

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

I certify that:

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

____ Proportionately spaced, has a typeface of 14 points or more and contains 9,029 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: January 7, 2001 _____

Attorney for Petitioners