IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

HEMP INDUSTRIES ASSOCIATION, et al. Petitioners, v. DRUG ENFORCEMENT ADMINISTRATION, et al. Respondents	No. 03-71366

OPPOSITION OF THE DRUG ENFORCEMENT ADMINISTRATION TO PETITIONERS' URGENT MOTION FOR STAY PENDING REVIEW

INTRODUCTION AND SUMMARY

Petitioners have asked this Court to grant urgent equitable relief for the purpose of allowing them to violate federal law and a validly promulgated regulation which directly implements the law. The request must be denied.

Petitioners are a group of companies who manufacture and distribute products made from the cannabis plant, which they refer to as "hemp" products.[1] According to petitioners, some of these products "may" contain tetrahydrocannabinols (THC). THC is a schedule I hallucinogenic controlled substance under the Controlled Substances Act (CSA). 21 U.S.C. § 812(c), schedule I(c)(17). Since its enactment in 1970, the CSA has always stated that "any material, compound, mixture, or preparation, which contains any quantity of" THC is a schedule I controlled substance. *Id.* The regulation that petitioners challenge here, DEA-205F (66 Fed. Reg. 14114

[1] "Hemp" is not a term used in federal law. Rather, "hemp" is a term used by petitioners and other companies who market "hemp" products to refer to the stalks and seeds of the cannabis plant or to cannabis plants grown to produce "hemp" products. *See New Hampshire Hemp Council, Inc. v. Marshall*, 203 F.3d 1 (1st Cir. 2000) (upholding requirement that persons who wish to grow cannabis plants to produce "hemp"obtain a DEA registration), *cert. denied*, 531 U.S. 828 (2000); *see also* 66 Fed. Reg. at 51536 and n. 1 (discussing "hemp" products and plants other than cannabis that are referred to as "hemp").

(March 21, 2003); Petitioners' Exhibit 1), revises the DEA regulations to make clear that the listing of THC in schedule I refers to THC from any source – natural or synthetic.

It is uncertain whether petitioners' food products actually contain THC. Some producers of these "hemp" products – including at least one of the petitioners – have declared that their products contain *no detectable amount of THC.* As explained below, this fact is critical in evaluating whether petitioners have demonstrated that DEA-205F will cause them irreparable harm, which they must establish to be entitled to the stay that they request. Absent a showing that their products contain THC, petitioners face no harm whatsoever as a result of DEA-205F, since DEA has stated repeatedly in the Federal Register that any "hemp" product which contains no THC is a *legal, non*controlled substance.

Even if petitioners' food products contain THC, DEA-205F is legally sound and warrants no stay. The regulation follows directly from the governing statute and was promulgated through notice-and-comment rulemaking in accordance with the Administrative Procedure Act (APA). Accordingly, *Chevron*[2] deference must be applied when reviewing the regulation. In the text accompanying the proposed and final regulations, DEA painstakingly analyzed the language of the statute, the relevant historical statutes and implementing regulations, the legislative history, and the caselaw – which collectively demonstrate that the regulation is a fair reading of the statute. Given the deference to which the agency is entitled under *Chevron*, petitioners cannot demonstrate any likelihood of prevailing on the merits.

There is also no validity to the portrayal of petitioners as being treated unfairly or suddenly caught off guard by the regulatory process that resulted in the promulgation of DEA-205F. A hasty reading of petitioners' motion might lead to the false impression that petitioners have been making their "hemp" food products for decades and that, all along, they had every reason to believe that the products were lawful regardless of THC content. In fact, the products

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[2] *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984)

that petitioners make and distribute did not exist when Congress enacted the CSA in 1970. Petitioners' own declarations submitted to this Court indicate that none of their products existed prior to 1998.[3] Their declarations further suggest that petitioners chose to begin marketing these products in the United States in the last few years based on their own legal opinion – not that of DEA or any other federal agency – that their products are legal regardless of whether they contain THC. Specifically, petitioners chose to believe that the provision of the CSA making "any material, compound, mixture, or preparation, which contains any quantity of" THC a schedule I controlled substance was inapplicable to their food products, and they elected to expand their commercial ventures into the United States without first obtaining an official determination that their reading of the statute was correct. Indeed, their declarations indicate that some of the petitioners only began to market their food products *after* DEA announced that it would be promulgating regulations clarifying that any amount THC in such products is prohibited.[4]

As explained below, petitioners' failure to meet their burden under *Chevron* is particularly pronounced at this juncture, where they are seeking a stay pending appeal of a regulation that has been promulgated through notice-and-comment rulemaking. Petitioners cannot demonstrate the requirements for such unusual interference with the administrative function of the executive branch.

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[3] Petitioners' declarations are vague as to precisely when they began marketing their products in the United States. Some of the declarations fail to specify the date that they began marketing their products in the United States; others indicate that their product launch began in 1998 or later, but fail to indicate whether this marketing was initially limited to Canada.

[4] For example, Petitioners' Exhibit 3, paragraph 4, indicates that the declarant's company only started to develop its "hemp" food product "in the past year" and that it does not plan to begin marketing the product until May, 2003.

BACKGROUND

Since its enactment in 1970, the CSA has always provided that anything ("any material, compound, mixture, or preparation") that contains "any quantity"of THC is a schedule I controlled substance (except for products that have been approved as medicine by the Food and Drug Administration (FDA) and products that DEA has exempted by regulation). 21 U.S.C. § 812(c), schedule I(c)(17). However, DEA never had occasion to address the legal status of cannabis-derived food products until such products started to appear in the United States in the late 1990s and the agency started to receive numerous inquiries about the legal status of these products. Among those who asked DEA to address the issue were some of the petitioners. (Respondents' Exhibit 4.)[5] As the agency assigned by Congress to administer the CSA, DEA was obligated to advise the public, in a clear manner, whether or not the products were controlled substances. Accordingly, after analyzing the issue and engaging in deliberations with other components of the Department of Justice and the executive branch, DEA announced on November 30, 2000 that it would be publishing a series of rules to address the legal status of the products. 65 Fed. Reg. 74024, 74025 (Respondents' Exhibit 1). The announcement specified that DEA would be issuing three rules: (i) an interpretive rule to explain DEA's interpretation of existing law with respect to THC and products that contain THC; (ii) a proposed rule to revise the DEA regulations to reflect more clearly the agency's interpretation of the law; and (iii) an interim rule to immediately exempt from control certain industrial cannabis products. *Id.* DEA repeated this announcement on May 14, 2001. 66 Fed. Reg. 25624, 25625. (Respondents' Exhibit 2.)

Consistent with the prior announcements, DEA published the three rules in the Federal Register on October 9, 2001. 66 Fed. Reg. 51529. As a courtesy to all members of the public, DEA granted a 120-day grace period for anyone with existing inventories of THC-containing

[5] In addition, on August 30, 1999, counsel for Kenex Ltd. (one of the petitioners) met in person with counsel for DEA to present Kenex's position on the issue.

food products to dispose of such products without liability. 66 Fed. Reg. at 51543. Petitioners then filed with this Court an appeal of the first of the three rules (the Interpretive Rule) in *Hemp Industries, et al. v. DEA*, No. 01-71662, which now appears moot.[6] After completing the notice-and-comment proceedings for the second and third rules (DEA-205 and DEA-206) in accordance with the APA, DEA published the final rules on March 21, 2003.

The first final rule, DEA-205F, revises the wording of the DEA regulations to make clear that the listing of THC in schedule I refers to both natural and synthetic THC. This is consistent with the text of the CSA, which lists THC in schedule I without limitation to natural or synthetic origin. 68 Fed. Reg. At 14114. The second final rule, DEA-206F, finalizes the interim rule, which exempts from control THC-containing industrial products, personal care products, processed plant materials used to make such products, and animal feed mixtures. 68 Fed. Reg. at 14119. The combined effect of DEA-205F and DEA-206F is to maintain the CSA's disallowance of human consumption of schedule I drugs outside of FDA-approved research or FDA-approved medical products,[7] while allowing the use of industrial cannabis-derived products that were historically allowed (prior to the enactment of the CSA) and allowing the use of "hemp" personal care products (e.g., soaps, lotions, and shampoos) that have arisen in the market in recent years. *Id.*

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[6] On April 7, 2003, this Court issued an order, in appeal no. 01-71662, directing petitioners to show cause within 14 days as to why the appeal is not moot. The issue in that appeal was whether DEA's publication of the Interpretive Rule without engaging in notice-and-comment violated the APA. The APA expressly exempts interpretive rules from notice-and-comment. However, petitioners argued that the Interpretive Rule was actually a legislative rule. As DEA asserted in its briefs and oral argument to this Court, the publication of the Interpretive Rule alongside the proposed rule underscored the distinction between the two rules: the Interpretive Rule was the agency's interpretation of existing law and not binding on the courts, while the proposed rule proposed to revise the DEA regulations in a manner that would be binding on the courts once the agency completed the notice-and-comment rulemaking process. As this Court's April 7, 2003 order suggests, now that DEA has completed notice-and-comment proceedings, the appeal appears moot.

[7] *See* 21 U.S.C. §§ 823(f), 841(a)(1); *see also United States v. Oakland Cannabis Buyers' Cooperative*, 532 U.S. 483 (2001). At present, Marinol® is the only THC-containing drug product that has been approved for marketing by the FDA. 68 Fed. Reg. at 14119 n. 2.

DEA-205F is the subject of this appeal. Petitioners oppose this regulation because they contend it "may" render their products illegal because such products "may" contain THC. However, in seeking to enjoin DEA-205F, petitioners do not represent the views of all "hemp" food product manufacturers. To the contrary, as explained below, one member of this industry, the Hemp Food Association, recently expressed strong support for DEA-205F and declared that it will have no adverse effect on the sales of "hemp" food products produced using modern, sound manufacturing practices, which eliminate THC from the products. (Respondents' Exhibit 5.)

STATUTORY AND REGULATORY FRAMEWORK

DEA-205F was promulgated 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 in the Code of Federal Regulations, Part 1308 of Title 21. Section 871(b) authorizes the Attorney General to promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient enforcement of his functions under the CSA. These functions vested in the Attorney General by the CSA have been delegated to the Administrator of DEA. 21 U.S.C. § 871(a); 28 C.F.R. § 0.100(b). In addition, the APA provides each agency with inherent authority to issue rules regarding the laws that it administers. 5 U.S.C. §§ 552, 553.

THE UNDERLYING LEGAL DISAGREEMENT BETWEEN THE PARTIES

DEA's Interpretive Rule (Respondents' Exhibit 3) squarely addressed the legal issue which remains the point of contention underlying this appeal. The DEA Administrator stated in the Interpretive Rule that, in enacting the CSA, "Congress expressly exempted certain portions of the cannabis plant [the stalks, sterilized seeds, fiber made from the stalks, and oil made from the seeds] from the definition of marijuana." 66 Fed. Reg. at 51530. The Administrator then stated: "At the same time, however, Congress expressly declared in the scheduling provisions of the CSA that 'any material, compound, mixture, or preparation, which contains any quantity of

. . . Tetrahydrocannabinols [THC]' is a schedule I controlled substance. 21 U.S.C. § 812(c), schedule I(c)(17)." *Id.* The Administrator noted that these two provisions of the CSA led several persons to ask DEA in the late 1990s about the legal status of "hemp" products made from the portions of the cannabis plant that are excluded from the definition of marijuana. The Administrator stated:

> In DEA's view, the answer lies in the plain language of the CSA, which states that "any material, compound, mixture, or preparation, which contains any quantity of . . . Tetrahydrocannabinols" is a schedule I controlled substance. The CSA does *not* state that any material, compound, mixture, or preparation containing THC is only a controlled substance if it fits within the definition of marijuana.

Id.

The Administrator candidly acknowledged that several members of the public disagreed with DEA's interpretation of the statute. *Id.* The Administrator specified that many members of the public had expressed to DEA the view – which petitioners continue to assert – that the definition of marijuana should be the sole determining factor in deciding which parts of the cannabis plant are controlled substances and that the listing of THC in the CSA was meant to be limited to synthetic THC. In light of this disagreement, the Administrator set forth in the Interpretive Rule the most extensive legal analysis ever published on the subject. The Administrator addressed the relevant legislative history of the CSA as well as the legislative history of the long-defunct Marihuana Tax Act of 1937, from which the CSA's definition of marijuana was derived. The Administrator addressed the history of federal control of THC, going back to the regulations which preceded the DEA regulations. The Administrator examined the caselaw on the subject. All legal authority was considered in the Interpretive Rule – even that which did not support DEA's interpretation.

To properly consider petitioners' current *Chevron* challenge to DEA-205F, the entire Interpretive Rule along with the full text accompanying DEA-205F and DEA-206F must be read. Although no single portion of the foregoing documents captures the depth of DEA's reasoning, the following is one key portion of the Interpretive Rule that supports DEA's interpretation:

[In] *United States v. Walton*, 514 F.2d 201 [(D.C. Cir. 1975)], [t]he court stated:

> Looking at the legislative history of [the Marihuana Tax Act of 1937], we find that the definition of marijuana was intended to include those parts of marijuana which contain THC and to exclude 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. *Id.* at 203-204.

> Thus, it is evident that the 1937 Congress exempted certain portions of the cannabis plant from the definition of marijuana based on the assumption (now refuted) that such portions of the plant contain none of the psychoactive component now known as THC. Although the 1970 Congress did not revisit this issue when it carried forward the 1937 definition of marijuana, it did separately specify that "any material, compound, mixture, or preparation, which contains any quantity of . . . Tetrahydrocannabinols" is a schedule I controlled substance. This is consistent with the conclusion of the Court of Appeals in *Walton* that, in enacting both the 1937 Act and the CSA, "Congress meant to outlaw all plants popularly known as marijuana to the extent those plants possessed THC."

66 Fed. Reg. at 51530-51531.

Virtually all of the legal arguments raised by petitioners in this appeal were previously considered by DEA and addressed in either the Interpretive Rule or the text accompanying DEA-205F and DEA-206F.

REASONS WHY THE STAY SHOULD BE DENIED

The standards governing the issuance of a stay pending appeal are well established. Under either Fed. R. Civ. P. 62(a) or Fed. R. App. P. 8(a), a court considering a motion for a stay pending appeal must consider the following factors:

> (1) whether the stay applicant has made a strong showing that it is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies.

Hilton v. Braunskill, 481 U.S. 770, 776 (1987) (citing *Virginia Petroleum Jobbers Assoc. v. Federal Power Commission*, 259 F.2d 921, 925 (D.C. Cir. 1958)).

The foregoing four-part inquiry has been applied by the courts where a party seeks a stay of an administrative agency order. *See Virginia Petroleum Jobbers Assoc.*, 259 F.2d at 925. However, the stay of an administrative agency order pending judicial review is a "rare event."

Busboom Grain Co., Inc. v. Interstate Commerce Commission, 830 F.2d 74, 75 (7th Cir. 1987). It is "not a matter of right, even if irreparable injury might otherwise result to the appellant." *Scripps-Howard Radio v. Federal Communications Commission*, 316 U.S. 4, 10 (1942). In view of the four factors for granting a stay set out in *Hilton*, "it is evident that the federal courts must be exceedingly careful in granting the extraordinary relief of a stay of an agency order." *Middlewest Motor Freight Bureau v. United States*, 433 F.2d 212, 241-242 (8th Cir. 1970), *cert. denied*, 402 U.S. 999 (1971).

The Supreme Court has explained: "The existence of power in a reviewing court to stay the enforcement of an administrative order does not mean, of course, that its exercise should be without regard to the division of function which the legislature has made between the administrative body and the court of review." *Scripps-Howard Radio*, 316 U.S. at 10. "[A] presumption of regularity attaches to the actions of government agencies . . . ." *United States Postal Service v. Gregory*, 534 U.S. 1, 10 (2001). Federal officials, such as the DEA Administrator, are designated by statute as the President's delegates to discharge his constitutional responsibility to "take Care that the Laws be faithfully executed" and, "in the absence of clear evidence to the contrary, courts presume that they have properly discharged their official duties." *United States v. Armstrong*, 517 U.S. 456, 464 (1996) (citations and internal quotations omitted).

The marked reluctance of the courts to grant a motion to stay an agency action is further based on the deference the courts give to the expertise of agencies in the specialized or technical areas which they regulate. *See Air Line Pilots Assoc. v. Civil Aeronautics Board*, 215 F.2d 122, 125 (2d Cir. 1954) (denying stay of regulation pending review).

As rare as it is for an agency action to be stayed pending review, it is rarer still for a court to grant a stay pending review of an agency regulation that has been promulgated through notice-and-comment and is therefore owed *Chevron* deference. Petitioners cite not a single case in which a party asserting a *Chevron* challenge to an agency regulation that was promulgated

through notice-and-comment rulemaking obtained a stay pending review on the merits. Even in *Chevron*, where the Court of Appeals vacated an agency regulation as being based on an interpretation of the law with which the Court disagreed (a decision that was reversed by the Supreme Court), no stay was sought or imposed pending review of the regulation. *See generally* 685 F.2d 718 (D.C. Cir. 1982).

Here, petitioners fail to demonstrate why this Court should grant the extraordinary remedy of a stay pending review of a notice-and-comment regulation. As explained below, the factors that must be considered for such a stay uniformly require denial of petitioners' request for relief.

I. IN VIEW OF *CHEVRON*, PETITIONERS CAN ESTABLISH NO LIKELIHOOD OF SUCCESS ON THE MERITS

A. Given The *Chevron* Deference To Which The Agency Is Entitled, DEA-205F Must Be Sustained As A Permissible Interpretation Of The Statute

As DEA-205F was promulgated through notice-and-comment pursuant to DEA's rulemaking authority under the CSA, *Chevron* is controlling on the merits of this appeal. *See generally United States v. Mead*, 533 U.S. 218 (2001). *Chevron* mandates that the reviewing court apply a two-part test. 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," the court must sustain the agency's interpretation if it is "based on a permissible construction of the statute." *Id.* at 843.

In enacting the CSA, Congress stated that "any material, compound, mixture, or preparation, which contains any quantity of" THC is a schedule I controlled substance. 21 U.S.C. § 812(c), schedule I(c)(17). The plain meaning of these words is that any material, compound, mixture, or preparation, which contains any quantity of THC – natural or synthetic – is a schedule I controlled substance. As DEA stated in the text accompanying DEA-205F (and in the Interpretive Rule):

> 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 Fed. Reg. at 14114 (footnotes in original). Thus, under the first part of the *Chevron* analysis, this Court may uphold DEA-205F without further inquiry.

Alternatively, if this Court were to conclude that the CSA definition of marijuana renders ambiguous the issue of whether the listing of THC in schedule I refers to all forms of THC (natural or synthetic), *Chevron* requires the Court to sustain the agency's interpretation under DEA-205F if it is "based on a permissible construction of the statute." The Supreme Court in *Chevron* provided instructions which are particularly apt in view of petitioners' arguments in this appeal. The Court stated that "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. Furthermore, "*[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 (italics added).

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[8] For example, Merriam-Webster's Collegiate Dictionary (10th ed. 1999) defines "THC" as "a physiologically active chemical $C_{21}H_{30}O_2$ from hemp plant resin that is the chief intoxicant in 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 Δ^9-(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 Δ^9-(trans)-THC, its isomers, and other related substances. Collectively, this class will be referred to in this document as "THC," unless otherwise indicated.

Petitioners fail to adhere to these *Chevron* principles. Petitioners give no weight to DEA's expertise as the agency that has administered the CSA for three decades. Petitioners further disregard *Chevron* by suggesting that their interpretation of the CSA should be substituted for that of DEA as the "better" reading of the statute. This is particularly evident where petitioners ask this Court to base its decision on certain parts of the testimony in the legislative history of the Marihuana Tax Act of 1937. As DEA explained in the Interpretive Rule, not only is the legislative history of the 1937 Act not controlling on the CSA, but petitioners rely on selected witness testimony without acknowledging the contrary views expressed in the more critical document, the Senate Report to the Act. *See* 66 Fed. Reg. at 51531.[10]

The Interpretive Rule along with the text accompanying DEA-205F and DEA-206F overwhelmingly demonstrate that DEA-206F is a permissible construction of the CSA. Therefore, applying *Chevron*, petitioners are unable to demonstrate any likelihood of prevailing on the merits of their appeal.

B. Petitioners' Alternative Reading Of The Statute Is Unpersuasive And Entitled To No Deference

As noted above, *Chevron* dictates that the task of the reviewing Court is not to choose between two competing interpretations of the statute. Rather, the Court must accept the agency's construction of the statute if it is permissible – regardless of whether another interpretation is equally or even more persuasive. Thus, once this Court concludes that DEA-205F is a permissible construction of the CSA, it need not consider whether petitioners' alternative

[10] Further underscoring their lack of adherence to *Chevron*, petitioners rely heavily on internal government letters they obtained wherein a former mid-level official of the Department of Justice expressed his opinion in March 2000 regarding the THC issue. (Petitioners' Exh. 12.) (When and from whom petitioners obtained the letters is unexplained.) Under *Chevron*, the letters are entirely inconsequential to the issue in this appeal: whether DEA-205F must be upheld as a permissible interpretation of the CSA.

interpretation is tenable. Nonetheless, we demonstrate below why petitioners' arguments in favor of their interpretation are unsound.

Petitioners' first argument in support of their claim that the listing of THC in schedule I of the CSA is limited to synthetic THC pertains to the phrase "any material, compound, mixture, or preparation," which appears at the beginning of 21 U.S.C. § 812(c), schedule I(c). According to petitioners, the words "any material, compound, mixture, or preparation" "clearly connote only *synthetic* or manufactured substances, not parts of a plant." (Motion for stay at 11; italics in original). This is an erroneous assertion. As a threshold matter, the ordinary dictionary definitions of the words "material, compound, mixture, or preparation" certainly include plant materials and products made from such plant materials. Furthermore, one need only read the CSA to see that plants are indeed included among the "material[s], compound[s], mixture[s], or preparation[s]" in the list of schedule I hallucinogenic substances. *See* schedule I(c)(10) (marijuana) *and* schedule I(c)(12) (peyote). Finally, the United States Court of Appeals for the 10th Circuit recently had occasion to confirm that the listing of hallucinogenic controlled substances in schedule I of the CSA does include plant materials that contain such substances and derivatives thereof. In *O Centro Espirita Beneficiente Uniao De Vegetal v. Ashcroft*, 314 F.3d 463, 466 (10th Cir. 2002), the schedule I hallucinogenic substance at issue was dimethyltryptamine (DMT) (schedule I(c)(6)), and the Court's ruling made clear that a tea-like mixture made from a plant which contains DMT is itself a schedule I controlled substance.[11]

Petitioners further misconstrue the CSA with respect to the phrase "Unless specifically excepted," which begins the preamble to each of the subsections of schedules I, II, and III. Petitioners argue that the term "specifically excepted" in this context means that Congress meant to list substances in a particular schedule and then "except" parts of those substances from

[11] Petitioners cite two cases, *United States v. McMahon* and *United States v. Wuco*, purportedly in support of their erroneous interpretation of the words "any material, compound, mixture, or preparation." Neither of these cases makes this mistaken interpretation. DEA addressed these cases in depth in the Interpretive Rule. *See* 66 Fed. Reg. at 51532-51533.

control by limiting their definitions. This reading of the statute would render superfluous the term "specifically excepted" since the definition of a given term in the CSA already delineates the scope of that term; there is no need to refer in the preambles of the schedules to any limits contained in definitions as "specifically excepting" a substance from control. Petitioners provide no analysis or legal authority to support this erroneous interpretation. In actuality, the phrase "specifically excepted" refers to substances that DEA has, by regulation, excluded from control pursuant to 21 U.S.C. § 811(g). The list of such substances is found in the DEA regulations immediately following the current schedules. *See* 21 C.F.R. §§ 1308.21 - 1308.35. An example of a regulation that "specifically excepts" substances from control is DEA-206F, which exempted various industrial "hemp" products that do not cause THC to enter the human body. *See* 68 Fed. Reg. at 14119, 66 Fed. Reg. at 51539 (codified at 21 C.F.R. § 1308.35).

Petitioners next contend that, in order to control natural THC, DEA would have to undertake a rescheduling action. DEA explained why this contention is erroneous in the text accompanying DEA-205F:

> Some commenters expressed the view that this rule is a rescheduling action within the meaning of 21 USC 811 and that DEA should have gone through the procedures set forth in that section prior to issuing this rule.[12] These comments appear to be based on a misunderstanding of the nature of the procedures under section 811. 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.

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[12] Under 21 U.S.C. 811, to change the schedule of a controlled substance, DEA must first request from the Secretary of Health and Human Services a scientific and medical evaluation and scheduling recommendation and follow additional procedures set forth in section 811. However, as discussed above, section 811 is inapplicable where, as in this final rule, DEA is *not* changing the schedule of a controlled substance.

> 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 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.[13] Even those commenters who suggested that this rule should be issued under section 811 do not dispute that all THC (natural or synthetic) meets the criteria for placement in schedule I. As discussed above, the chemical THC has the identical physical and chemical properties, and produces the same psychoactive effects, regardless of whether it is natural or synthetic. For these reasons, section 811 is inapplicable to this rule.

68 Fed. Reg. at 14116 (footnotes in original).

In their motion for a stay (page 15), petitioners respond to the above-quoted statement by reasserting that DEA must undertake a rescheduling action for the portions of the cannabis plant that are excluded from the definition of marijuana (the stalks, sterilized seeds and oil from such seeds). This assertion remains wrong. The point of DEA-205F is not that certain parts of the cannabis plant are controlled substances, per se. Rather, DEA-205F makes clear that anything *that contains THC* – natural or synthetic – including parts of the plant excluded from the definition of marijuana, is a controlled substance. As the above block quote from DEA-205F indicates, no scheduling determination is warranted here. The presence or absence of THC in "any material, compound, mixture, or preparation" is the determining factor. Congress stated plainly that the presence of "any quantity"of a schedule I hallucinogenic substance renders the "material, compound, mixture, or preparation" a schedule I controlled substance – without the need to show that such "material, compound, mixture, or preparation" independently meets the criteria for placement in schedule I.

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[13] The criteria for placement in schedule I are: "no currently accepted medical use in treatment in the United States," "a lack of accepted safety for use . . . under medical supervision," and "a high potential for abuse." 21 U.S.C. 812(b)(1).

II. PETITIONERS HAVE FAILED TO ESTABLISH THAT THEY WILL SUFFER IRREPARABLE INJURY WITHOUT A STAY

Critical to determining whether petitioners face any risk of harm from DEA-205F is whether or not their food products actually contain THC. Yet, not one of petitioners' declarations states with any degree of confidence that their food products contain THC. The declarations state only that their products "may" contain THC. In fact, one of the petitioners has stated in more certain terms that her "hemp" food products do *not* contain THC. The President of Ruth's Hemp Foods wrote a letter to DEA in 2000 in which she stated:

> In fact, no THC can be detected in the hemp that we grow. In our food products, hemp is a minority ingredient. I challenge any lab anywhere to detect any THC in our food products.

(Respondents' Exhibit 4; emphasis in original.)

DEA has made it abundantly clear, in both the proposed and final rules, that "hemp" products which contain no THC are entirely *legal* under the CSA:

> Any portion of the cannabis plant, or any product made therefrom, or any product that is marketed as a "hemp" product, that is *both excluded from the definition of marijuana* and *contains no THC* – natural or synthetic – (nor any other controlled substance) is not a controlled substance. Accordingly, such substances need not be exempted from control under this final rule since they are, by definition, noncontrolled.

68 Fed. Reg. at 14122; *see also* 66 Fed. Reg. at 51542 (same).

Shortly after DEA-205F was published, on March 31, 2003, another member of the "hemp" food industry, the Hemp Food Association, made an even stronger statement about the lack of THC in its food products and expressed its support for the final rule:

> The new DEA Rule also clarified that hemp for human consumption may not contain any THC, which is the basis by which all responsible hempseed importers have operated for years. . . . In theory, even trace THC on hempseed can cause a positive drug test, so good manufacturing practices require it to be removed by cleaning or shelling before using in food.

(Respondents' Exhibit 5.)

The Hemp Food Association statement goes on to explain why it believes DEA-205F is actually beneficial to the "hemp" food industry:

> Hempseed importers have previously announced their ability to comply with the new Rule concerning hempseed for human consumption. All now comply with the Rule, some for years. Recent negative publicity has resulted in a market implosion for these foods greater than DEA could have accomplished, and many hemp food companies have gone out of business or dropped products. By clarifying what is necessary to achieve DEA-exempt legal status for hemp as food, DEA has removed a significant legal barrier for importers. It is expected that this clarification will ease the confusion for all parties involved in importing hempseed.

Id.

In evaluating the harm which might occur depending on whether a stay is issued, the Court looks to three factors: (1) the substantiality of the injury alleged, (2) the likelihood of its occurrence, and (3) the adequacy of the proof provided. *Cuomo v. United States Nuclear Regulatory Commission*, 772 F.2d 972, 974 (D.C. Cir. 1985). For a stay to be warranted, "the injury must be both certain and great; it must be actual and not theoretical." *Wisconsin Gas Co. v. Federal Energy Regulatory Commission*, 758 F.2d 669, 674 (D.C. Cir. 1985), *cited with approval in California Energy Commission v. Johnson*, 767 F.2d 631, 634 (9th Cir. 1985). "Injunctive relief will not be granted against something merely feared as liable to occur at some indefinite time." *Id.*

Here, petitioners seek to alarm this Court by submitting declarations which repeat, as if by rote, and in conclusory fashion, that DEA-205F "threatens" to "immediately" "shut down" their businesses. However, upon closer inspection, the declarations fail to support their contention that immediate relief is required. To the contrary, petitioners' declarations express uncertainty about whether their food products contain any THC. As noted above, one of the petitioners has declared, in a statement not prepared for this litigation, that she is certain no THC can be found in her products. Another member of the "hemp" food industry, also quoted above, claims that removing THC from the products is the norm in the industry and that DEA-205F

provides helpful clarification. Petitioners do not cite any incidents in which the United States seized their food products based on a determination that the products contained THC.[14]

Simply put, petitioners' claim of irreparable harm is highly speculative and their sparse factual allegations are inadequate to justify the extraordinary remedy of court-imposed, pre-review stay of an agency regulation that has been promulgated through notice-and-comment rulemaking.

III. A STAY WOULD HARM THE GOVERNMENT AND BE DETRIMENTAL TO THE PUBLIC INTEREST

By asking this Court to "stay" DEA-205F pending review, petitioners are not simply asking to suspend enforcement of the regulation; they are asking this Court to nullify an act of Congress by limiting 21 U.S.C. § 812(c), schedule I(c)(17) to something less than what follows from the plain wording of the statute. *See Heart of Atlanta Motel v. United States*, 85 S. Ct. 1, 2 (1964) ("a temporary injunction against enforcement is in reality a suspension of an act, delaying the date selected by Congress to put its chosen policies into effect. Thus, judicial power to stay an act of Congress, like judicial power to hold that act unconstitutional, is an awesome responsibility calling for the utmost circumspection in its exercise."); *see also Tennessee Valley Auth. v. Hill*, 437 U.S. 153, 194 (1978) ("Once Congress, exercising its delegated power, has decided the order of priorities in a given area, it is for the Executive to administer the laws and for the courts to enforce them when enforcement is sought.").

Alternatively, even if this Court were to reject the foregoing argument and conclude that § 812(c), schedule I(c)(17) is ambiguous with respect to the natural versus synthetic THC issue,

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[14] In view of the uncertainty as to whether petitioners' products contain any substance that renders them illegal under DEA-205F, there is a serious question whether petitioners have standing to raise these preenforcement challenges to DEA-205F. *See Thomas v. Anchorage Equal Rights Commission*, 220 F.3d 1134, 1138-39 (9th Cir. 2000) (en banc) (neither the mere existence of a proscriptive statute nor a generalized threat of prosecution satisfies the "case or controversy" requirement of the standing or ripeness analysis; there must be a "genuine threat of imminent prosecution"), *cert. denied*, 531 U.S. 1143 (2001).

CONCLUSION

For the foregoing reasons, this Court should deny petitioners' urgent motion for a stay pending review.

Respectfully submitted,

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April 8, 2003

EXHIBIT 4

To: Donnie Marshall DEA From: Ruth Shamai 416-588-4210 1/31/00 13:11:54 Page 1 of 1

Ruth's

HEMP FOODS

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January 31, 2000

Mr. Donnie Marshall
Drug Enforcement Administration
700 Army Navy Drive
Arlington, VA 22202
fax # (202) 307-4689

Dear Mr. Marshall,

My company contracts the growing of hemp with Canadian farmers and manufactures hemp foods, such as hemp tortilla chips, salad dressings, wraps, pasta and more. These are distributed throughout Canada entirely within the hemp and food regulations in Canada.

The hemp seed is an excellent food source. It contains a higher percentage of essential amino acids (in other words, more and better protein) than soy, making it a great alternative to meat, and a wonderful food for vegetarians. It is also not genetically modified, and so is increasingly preferred to soy by people opposed to GMO's. The hemp seed is also a unique source of essential fatty acids, containing Omega 6, Omega 3 and GLA.

As per Canadian regulations, our hemp is tested for THC before being used commercially, and is legal only when 10 ppm or less THC is found. In fact, no THC can be detected in the hemp that we grow. In our food products, hemp is a minority ingredient. I challenge any lab anywhere to detect any THC in our food products.

Hemp is grown in Canada under the most stringent conditions in the world. It is related to marijuana in the same way that the poppy seeds in a muffin are related to heroin.

As I'm sure you are aware, the US is Canada's biggest export market. Although my products are not currently sold in the US, many people have asked for them.

The American people deserve the same benefit from hemp food as Canadians already enjoy. I urge you to open your border to Canadian hemp products.

If you have any comments or questions, please contact me at the above numbers.

Yours truly,

Ruth Shamai

President,
Ruth's Hemp Foods

Board Member,
North American Industrial Hemp Council

Monday, March 31, 2003

New DEA rule legalizes hemp

Hemp Food Association

SEBASTOPOL, California — Beginning April 21, 2003, Cannabis Hemp will be legal to import, under a new Rule recently issued by the U.S. Drug Enforcement Administration (DEA). The Rule is a clarification of the gray area under which hemp importers have operated for years, namely, that hemp is exempt from drug laws even if it contains trace amounts of the drug Tetrahydrocannabinol (THC), found in almost all Cannabis.

While UN Treaties and the Controlled Substances Act of 1970 allow for legal importation of and commerce in Cannabis Hemp products per se, until now no formal exemption was made for the drug THC which can be found in trace amounts in some hemp products, such as textiles, clothes, paper, industrial oil, cosmetics, and shampoo. Although there is no concern that this trace THC is being diverted to drug uses, it was nevertheless of concern to those in the business of importing and/or selling popular hemp items, including such large companies as The Body Shop, Patagonia, Armani, and Staples Office Supplies.

The new DEA Rule also clarified that hemp for human consumption may not contain any THC, which is the basis by which all responsible hempseed importers have operated for years. (For 5,000 years it has been one of mankind's oldest and most important food crops, as hempseed is a very good source of omega-3 essential fatty acids and complete protein, and is used in many natural foods and nutraceuticals.) In theory, even trace THC on hempseed can cause a positive drug test, so good manufacturing practices require it to be removed by cleaning or shelling before using in food.

Some fear that DEA's new reasonable position regarding hemp imports might be a trojan horse, an attempt to lull the industry into compliance before striking. But public statements by the recent DEA Director and a DEA spokesman reveal that DEA is making a good faith effort to ease the burden on hemp importers, without compromising public safety. And considering the agency's recent crackdown on medicinal marijuana clubs and pot pipe makers, one would hope DEA's new openness on hemp would be a welcome sight to suspicious hemp importers and activists.

"It's understandable that the layperson might be suspicious of DEA's intentions, considering its track record," said Richard Rose, President of HempNut, Inc., Director of the Hemp Food Association, and the father of the modern American hempseed foods movement. "But it's very clear to those of us who daily accept the risks associated with the business of importing food-grade hempseed that DEA wants to be rid of the burden of regulating a non-drug food and fiber crop, without appearing to be soft on drugs. We should all applaud DEA's efforts to legalize hemp the only way the agency can, since it's up to Congress to change the law," says Rose.

By removing the uncertainty for the 95% of hemp imports not for human consumption, DEA has opened the door for investment and legitimization of the industry. For instance, the loss of the market for bird seed in 1999 was particularly hard on a farmer's hempseed co-operative in Canada, which was stuck with thousands of tons of hempseed but no demand. With the new Rule DEA paves the way for re-opening that market, and the expansion of new ones.

Hempseed importers have previously announced their ability to comply with the new Rule concerning hempseed for human consumption. All now comply with the Rule, some for years. Recent negative publicity has resulted in a market implosion for these foods greater than DEA could have accomplished, and many hemp food companies have gone out of business or dropped products. By clarifying what is necessary to achieve DEA-exempt legal status for hemp as food, DEA has removed a significant legal barrier for importers. It is expected that this clarification will ease the confusion for all parties involved in importing hempseed.

Since hempseed is the value driver for hemp farmers, and US farmers need an existing market before they will be allowed to plant hemp, this Rule is likely the first step DEA will use to transfer authority for hempseed as a food crop to the US Department of Agriculture, which had jurisdiction until 1970.

In the latest version of the Rule, DEA includes many of the more popular comments from the 115,000 it

received from the public, as well as their answers to them. Comparing the initial version of the Rule with the most recent one, clearly they are going far out of their way to explain it, and to show that they are in good faith. DEA took the public's comments to heart, made the new Rule more understandable by explaining more of it, and has taken steps to show that the Rule is necessary, legal, and compliance obtainable.

If one compares the initial version of the Rule to the latest, the number of words increased by 34% for the Clarification, and 24% for the Exemption, for a total of 14,428 words, an increase of 27%. Coupled with the fact that DEA is allowing a Schedule I Controlled Substance to be imported legally for the first time (on hemp not for human consumption), and this is an extraordinary event in the history of DEA and hemp! Legal hemp, legal THC on hemp, and a public explanation about it as long as a many books.

Hemp Hemp Hooray! Hemp is now legal! Long live Hemp!

Related article:

THC Issue Threatens Hemp Industry Growth
April 2001

For more information, contact:

Hemp Food Association
URL: www.hempfood.com

CERTIFICATE OF SERVICE

I hereby certify that on this 8th day of April, 2003, I served the foregoing "OPPOSITION OF THE DRUG ENFORCEMENT ADMINISTRATION TO PETITIONERS' URGENT MOTION FOR STAY PENDING REVIEW," in accordance with Ninth Circuit Rule 27-1 and Federal Rule 25(b), by causing the original and four copies to be sent to this Court by overnight mail, and by causing copies to be served upon the following counsel by overnight mail:

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