IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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.	)
Petitioners,	)
v.	)
Drug Enforcement Administration; Asa Hutchinson, as Administrator, Drug Enforcement Administration	)
Respondents.	)

MEMORANDUM IN SUPPORT OF RESPONDENTS' OPPOSITION TO PETITIONERS' MOTION FOR A STAY

INTRODUCTION

On October 2, 2001, the Administrator of the Drug Enforcement Administration (DEA) issued an interpretive rule regarding the listing "Tetrahydrocannabinols" (THC) in Schedule I of the Controlled Substances Act (CSA). See 66 Fed. Reg. 51530 (Oct. 9, 2001). In the Interpretive Rule, the Administrator interpreted the CSA and DEA regulations to declare any product that contains any amount of THC to be a schedule I controlled substance, even if such product is made from portions of the cannabis plant that are excluded from the CSA definition of "marihuana." The Interpretive Rule sets forth in detail the Administrator's findings supporting his determination that the plain language of the CSA leads to the conclusion that all products containing any amount of THC are schedule I controlled substances. (66 Fed. Reg. at 51533). The Interpretive Rule does nothing more than interpret existing statutory and regulatory requirements. It does not effect a change in existing law.

Simultaneous with publication of the interpretive rule, DEA published a proposed rule which revises the wording of the DEA regulations to make clear that the listing THC in schedule I refers to both natural and synthetic THC and an interim rule, which exempts from control certain THC-containing industrial products, which are not used or intended for use for human consumption. 66 Fed. Reg. at 51535, 51539. Petitioners do not challenge these rules.

Petitioners, an assortment of companies that manufacture, distribute and/or sell processed hemp seed or oil, or food and beverages products containing processed hemp seed or oil, filed a motion for a stay pending review with this Court on October 21, 2001. Petitioners argue that DEA's Interpretive Rule is in fact a legislative rule that requires notice and comment pursuant to the Administrative Procedure Act ("APA"). Petitioners further allege that they will be irreparably harmed unless a stay is granted.

JURISDICTION

Petitioners assert that this Court has jurisdiction over their Petition for Review and their Urgent Motion for Stay pursuant to the CSA's appeal provision, 21 U.S.C. § 877, because DEA's Interpretive Rule is a "final decision." Petitioners correctly quote § 877 as providing that "[a]ll final determinations, findings, and conclusions" of DEA under the CSA are subject to review by the United States Court of Appeals. It appears that no United States Court of Appeals has ever entertained a motion for a stay of an interpretive rule pursuant to § 877. Therefore, there is a lack of precedent as to whether a DEA interpretive rule fits in the category of “final determinations, findings, and conclusions” subject to review under section § 877. Nonetheless, the government will assume, for purposes of having this matter resolved by this Court, that the challenge to an

interpretive rule is subject to review under § 877. For the same reason, the government does not dispute Petitioners' assertion that they have satisfied the requirements of FRAP 18(a)(2)(A) and Ninth Circuit Rule 27-3(b)(4) in seeking the requested stay. However, because there is no merit to Petitioners' claim that the interpretive rule is a legislative rule, Petitioners' motion for a stay must be denied.

STATUTORY AND REGULATORY FRAMEWORK

The CSA 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. 21 U.S.C. § 871(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 functions vested in the Attorney General by the CSA have been delegated to the Administrator of DEA pursuant to 21 U.S.C. § 871(a). 28 C.F.R. § 0.100.

STANDARD OF REVIEW

Petitioners seek a stay pending this Court's review of their appeal. The central question before this Court - whether the interpretive rule is, in fact, an interpretive rule or, as Petitioners contend, a legislative rule - arises in the context of a motion for stay of an agency action. The stay of an administrative interpretive ruling is an "extraordinary remedy." 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) (quoting In Re Haberman Manufacturing Co, 147 U.S. 525 (1893)). Rather, deciding whether to grant or deny a stay "is an exercise of judicial discretion. The propriety of its issue is dependant upon the circumstances of the particular case." Id. at

10-11 (citing Virginia Railway v. United States, 272 U.S. 658, 672-73 (1926)). In fact, "[s]tays are sparingly granted. They are a disfavored remedy because they interrupt the ordinary process of judicial review and postpone relief for the prevailing party." Dellums v. Smith, 577 F. Supp. 1456, 1457 (N.D. Cal. 1984).

The marked reluctance of the courts to grant a motion to stay an agency action is based on the deference the courts give to the expertise of the agencies. As the court stated in Air Line Pilots Ass'n v. CAB, 215 F.2d 122, 125 (2d Cir. 1954), decisions relating to the specialized or technical areas of an agency are best left to the discretion of the agency, which regulates and has expertise in these areas. Clearly, the courts recognize that decisions relating to the specialized or technical areas of an agency are best left to the discretion of the agency, which regulates and has expertise in these areas.

As rare as it is for a court to stay an agency's interpretation of the law in a legislative rule, it would be rarer still for a court to stay an agency's interpretation contained in an interpretive rule. The reason for this becomes evident when examining the requirements for a stay, which are well established:

(1) Whether the petitioner made a strong showing that it is likely to prevail on the merits;

(2) whether the petitioner will be irreparably injured absent a stay;

(3) whether the issuance of a stay will substantially injure the other parties interested in the proceedings; and

(4) where the public interest lies.

Hilton v. Braunskill, 481 U.S. 770, 776, 107 S. Ct. 2113 (1987). See also Warm Springs Dam Task Force v. Gribble, 565 F.2d 549, 551 (9th Cir. 1977) (per curiam); Miller v. Carlson, 768 F. Supp. 1341, 1342 (N.D. Cal. 1991).

ARGUMENT

I. PETITIONERS WLL NOT SUCCEED ON THE MERITS

A. The Interpretive Rule is properly characterized as interpretive rather than legislative.

Petitioners argue that they will succeed on the merits because DEA's Interpretive Rule is "legally a final, substantive legislative rule which DEA has issued without notice and comment as required by the APA, 5 U.S.C. § 553, and without formal rulemaking on the record after opportunity for hearing as required by the CSA." (Petitioners' Motion for Stay at 8). Petitioners advance several arguments to support their clam that the Interpretive Rule is substantive and therefore legislative, but for the reasons detailed below, these arguments are without merit and this Court should not grant Petitioners' stay motion.

Although the APA defines neither legislative rules nor interpretive rules, the general characteristics of these pronouncements are well settled. A "substantive" or "legislative" rule is a rule which "is intended to have and does have the force of law." National Latino Media Coalition v. F.C.C., 816 F.2d 785, 787-788 (D.C. Cir. 1987). "A valid legislative rule is binding on all persons, *and on the courts*, to the same extent as a congressional statute." Id. (emphasis added). Also characteristic of a legislative rule is that it "effect[s] a change in existing law or policy or which affect[s] individual rights and obligations," Paralyzed Veterans of America v. West, 138 F.3d 1434, 1436 (Fed. Cir.

1998), or "creates rights, assigns duties, or imposes obligations, the basic tenor of which is not already outlined in the law itself." La Casa Del Convaleciente v. Sullivan, 965 F.2d. 1175, 1178 (1st Cir. 1992).

Interpretive rules "do not have the force of law and even though courts often defer to an agency's interpretive rule they are always free to choose otherwise." National Latino Media Coalition v. F.C.C., 816 F.2d at 787-788. An "interpretive rule, on the other hand, is a rule that clarif[ies] or explain[s] existing law or regulations," Paralyzed Veterans of America, 138 F.3d. at 1436, or that "reflects an agency's construction of a statute that has been entrusted to the agency to administer." Syncor Int'l Corp. v. Shalala, 127 F.3d. 90, 94 (D.C. Cir. 1997). Interpretive rules do not create new law independent of existing statutes or regulations, but merely state what the agency thinks the existing statutes or regulations, but merely state what the agency thinks the existing statutes and regulations require. See Splane v. West, 216 F.3d 1058, 1063 (D.C. Cir. 2000).

The "paradigmatic" example of an interpretive rule is one that relies upon the language and legislative history of a statute to determine the congressional intent underlying the statute. Metropolitan School Dist., 969 F.2d. 485, 489-90, 492 (7th Cir. 1992); see also Shalala v. Guemsey Memorial Hosp., 514 U.S. 87, 99 (1995) ("prototypical example of an interpretive rule" is that "issued by an agency to advise the public of the agency's construction of the statutes and rules which it administers")(citations and internal quotation omitted); General Motors Corp. v. Ruckelhaus, 742 F.2d. 1561, 1565 (D.C. Cir. 1984) (rule is interpretive when agency's "entire justification … is comprised of reasoned statutory interpretation, with reference to

the language, purpose and legislative history of [the statute]"), cert. denied, 471 U.S. 1074 (1985).

Recently, the United States Court of Appeals for the Federal Circuit examined Supreme Court cases in this area and arrived at a test, which is particularly helpful in this case, for distinguishing interpretive rules from legislative rules. In Splane v. United States, 216 F.3d. 1058 (Fed. Cir. 2000), the Court concluded that, in order for a rule to have the "force and effect of law" (and thereby be a legislative rule), it must have a "binding effect … on tribunals *outside* the agency, not on the agency itself." Id. At 1064 (italics original).

Viewed against these established standards, it is readily apparent that DEA's rule regarding any product that contains THC to be a Schedule I controlled substance is an interpretive, and not legislative, rule. To begin with, DEA's statements throughout the rule leave no doubt of the agency's intention that the rule be viewed as interpretive, not legislative. DEA titled the rule an "interpretive rule" and refers to it as such throughout the text of the rule. While an agency's characterization of a rule as interpretive "is not controlling, it nevertheless is of weight in determining whether a ruling is legislative or interpretive." Taunton Mun. Lighting Plant v. Department of Energy, 669 F.2d. 710, 715 (Temp. Emer. Ct. App. 1982). Furthermore, DEA's Interpretive Rule neither creates new rights or obligations nor effects a change in existing law. Rather, it merely interprets existing statutory and regulatory provisions based upon an extensive examination of the language, purpose, and history of those provisions.

The foregoing factors make clear that the interpretive rule neither creates new rights or obligations nor effects a change in existing law. It is telling that Petitioners do

not assert that any federal court or other tribunal outside DEA is bound to follow DEA's interpretation of the law contained in the interpretive rule.

A further indication that the rule is interpretive is the practical reality of what would happen if DEA attempted to bring a criminal or civil action against a company or individual based on the interpretive rule and the defendant challenged that interpretation. In such a hypothetical case, DEA would not be entitled to Chevron deference as it would if were relying on a legislative rule that had gone through the notice-and-comment process. See generally United States v. Mead, 121 S.Ct. 2164 (2001).

Petitioners' primary "factual" basis for their appeal consists of declarations which contain their subjective view that the interpretive rule represents a change in how DEA has historically interpreted the law.

Petitioners also present to this Court an internal legal opinion letter from a Department of Justice section chief and mention in a footnote the statement of an individual DEA chemist ten years ago. The letter was written in response to a request for advisory guidance for enforcement personnel, and was never intended to represent, nor can it be regarded as, the opinion of the Attorney General or the Assistant Attorney General for the Criminal Division. Furthermore, opinions of individual government employees are irrelevant for the simple reason that they are not (and were not) rules and are not binding on any court. Under the APA, all rules (interpretive and legislative) must be published in the Federal Register. 5 U.S.C. 552, 553. Petitioners are noticeably at a loss to cite a single prior document published by DEA in the Federal Register (or any other document that constitutes an official DEA ruling) which addresses the issue in the interpretive rule, let alone one that offers an interpretation contradictory to that contained

in the interpretive rule. See Orengo Caraballo v. Reich, 11 F.3d. 186, 196 (D.C. Cir. 1993) ("Only where a second rule repudiates or is irreconcilable with a prior legislative rule, the second rule must be an amendment of the first, and must itself be legislative.") (italics original; citations and internal quotations omitted). In any event, Petitioner's reliance on this letter is misplaced, for the subsequent approval of the Interpretive Rule by the Attorney General effectively overrides the earlier opinion of a Criminal Division section chief.

Perhaps the best explanation of why Petitioners' claim is erroneous is found in a case that they themselves cite, Chief Probation Officers of California v. Shalala, 118 F 3d. (9th Cir. 1997). In that case, this Court made clear that an interpretive rule may be inconsistent with an agency's "past practice" without rendering the rule a legislative rule. Prior agency interpretations, "which themselves did not go through the formal rulemaking procedures, cannot be regulations having the force of law." Id. at 1334. The Court stated: "The prior agency [practice and interpretation] simply represented the Agency's prior (short-lived) interpretation or the statute. The Agency was free to change that interpretation." Id. Here, DEA's interpretive rule is not inconsistent with past agency practice. Nonetheless, Chief Probation Officers of California underscores that Petitioners' references to past statements by individual government employees, and their own subjective beliefs about how the law has historically been viewed, do not constitute past agency rules and have no bearing on whether the interpretive rule at issue in this case is indeed interpretive.

B. There Is No Case or Controversy and Petitioners Have No Standing to Appeal.

Article III, § 2, cl. 1 of the Constitution limits the "judicial power" of the United States to the resolution of "cases" or "controversies." Valley Forge Christian College v. Americans United for Separation of Church and State, Inc., 454 U.S. 464, 470 (1982). This Court must presume that it lacks jurisdiction "unless the contrary appears affirmatively form the record." Renne v. Geary, 501 U.S. 312, 315 (1991). The doctrines of standing, mootness, and ripeness, each or which imposes requirements on the substance of plaintiffs' claim, ensure that a federal court's power has been properly invoked. See Allen v. Wright, 468 U.S. 737, 750 (1984).

As the party seeking to invoke federal jurisdiction, Petitioners bear the burden of establishing their standing. LSO v. Stroh, 205 F. 3d. 1146, 1152 (9th Cir. 2000). To do so, plaintiffs must demonstrate each of the "irreducible constitutional minimum[s]" of standing. Luian v. Defenders of Wildlife, 504 U.S. 555, 559 (1992).

> First, plaintiffs must clearly demonstrate that they have suffered an "injury in fact"-an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical. Second, there must be a causal connection between the injury and the conduct complained of—the injury has to be fairly traceable to the challenged action of the defendant. Third, it must be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.

Id. At 560-61 (citations, internal quotations, and footnote omitted). Because plaintiffs fail on the threshold matter of establishing any injury in fact, the Court need only concern itself with the first issue.

In Thomas v. Anchorage Equal Rights Commission, 220 F. 2d. 1134, 1138-39 (9th Cir. 2000) (en banc), cert. denied, 121 S.Ct. 1078 (2001), this Court held that 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." The "Thomas factors" employed by this Court to evaluate the genuineness of the claimed threat of prosecution include: (i) whether the party claiming the threat has articulated a "concrete plan" to violate the law in question rather than an expressed intent to violate the law on some uncertain day in the future – if and when a chance to engage in illegal conduct arises; (ii) whether the prosecuting authorities have communicated a specific warning or threat to initiate proceedings, directed at the particular plaintiffs; and (iii) the history of past prosecution or enforcement under the challenged statute. Id. at 1139.

Here, Petitioners make no assertion that DEA or any other federal law enforcement agency has seized their products or commenced criminal proceedings against them as a result of the interpretive rule, or even threatened to do so. In fact, Petitioners are not even sure if their products are illegal under DEA's interpretation of the law contained in the interpretive rule. They state that their products "may contain" THC (Motion for Stay at 2) and, therefore, their businesses *may* be adversely affected by the interpretive rule. (DEA stated expressly that any product which contains no THC, nor any other controlled substance, is not a controlled substance. 61 Fed. Reg. At 51542.) Petitioners thereby present this Court with the quintessential speculative claim of harm that has consistently been held insufficient to establish standing. Even if this Court were now addressing the appeal itself (rather than the motion for the stay), this uncertain allegation by Petitioners would fail to establish standing. That failure is even more pronounced at this stage of the proceedings, where Petitioners must satisfy the formidable burden of demonstrating likelihood of success on the merits.

II. PETITIONERS HAVE FAILED TO ESTABLISH IRREBARABLE INJURY

Petitioners' argue that absent a stay of DEA's "Interpretive Rule," the individual Petitioner companies will suffer irreparable injury, because their business activities may have been rendered illegal. (Petitioners Motion for Stay at 18). Petitioners' argument is both misleading and fails to satisfy the irreparable injury prong.

In evaluating the harm which will occur both if the stay is issued and if it is not, one must look 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).

Petitioners concede that they are unsure whether their food and beverage products contain THC and would therefore be considered illegal under the interpretation contained in the interpretive rule. Thus, Petitioners cannot even make a threshold showing of alleged injury, much less irreparable injury. Furthermore, Petitioners claim they will all suffer irreparable injury because they will have to shut down their operations "relating to importation, nutritional and beverage products". (Petitioners Motion for Stay at 18). Petitioners provide sworn declarations attesting to the harm each particular company may suffer, but cannot offer other documentation to back up their assertions. Even accepting these declarations at face value, they are inadequate proof on which to grant a stay. The declarations do not indicate how much of their business would be affected or whether they could continue to operate because their production output includes products that are not the subject of the interpretive rule. For example, some of the declarations seem to suggest that economic loss will result because they will cease production and distribution of body care products, animal feed products and industrial products. These declarations

make no mention of the fact that on the same day the interpretive rule was published, DEA issued an interim rule (66 Fed. Reg. 51539), which exempts from control these very products (i.e., products containing THC that are not intended for human consumption). This omission makes it difficult to assess the amount of their business that would be adversely affected if the interpretive rule were enforced as law.

A careful examination of Petitioners' declarations reveal that although DEA's Interpretive Rule may cause Petitioners to cease production of a portion of their current output, the majority of the companies will continue to exist because their production output includes products that are not affected by the Interpretive Rule. Thus, although Petitioners may suffer some economic harm, it cannot be considered irreparable or substantial, given that the company itself would continue to exist. In addition, a careful reading of these declarations also brings into question the likelihood that these harms would actually occur as most of the declarations state that the Interpretive Rule merely "threatens" to shut down their business. See Hickey Dec., Exhibit 5 at ¶¶ 8-9 ("Since 1997, Tierra Madre has invested … $2 million to develop and commercialize industrial hemp food and fiber products …"; Herriott Dec., Exhibit 7 at ¶ 3 ("Our company's business consists of research, development, and manufacture of hemp products and distribution of … soap, lip balm, massage oil, moisture cream…"); Slagh Dec., Exhibit 8 at ¶¶ 4, 10 ("Our company markets & distributes these products to food cooperatives, buying clubs and retailers. Included in the products that we carry are various hemp products… as well as more than 20 hemp oil based body care products by Jason's and Sun Dog and soaps by Dr. Bronner's Magic Soaps Company.")(emphasis added); and LaPrise Dec., Exhibit 9 at ¶¶ 3, 9 ("Our company's business consists of … (b) importing

and distributing certified hemp seed to farmers; (d) producing value added products such as … hemp fibre matting, animal bedding, bio-composites, and building materials.") See State of Ohio v. Nuclear Regulatory Commission, 812 F. 2d 288, 291 (6th Cir. 1987) (economic loss does not constitute "irreparable injury," in and of itself, for purposes of determining whether a stay is required).

Based on these statements contained in the declarations, it may well be the case that many of the products that Petitioners carry are either (i) not the subject of the interpretive rule or (ii) exempt from control by the interim rule. Such vague and speculative assertions fail to amount to a showing of irreparable harm necessary to obtain the extraordinary remedy of a stay.

III. PETITIONERS HAVE FAILED TO SHOW THAT THE BALANCE OF HARDSHIPS TIPS IN THEIR FAVOR OR THAT THE PUBLIC INTEREST FAVORS A STAY

Petitioners argue that the balance of hardships tips in their favor when one balances the fact that individual Petitioner companies will be forced to shut down their businesses relating to the manufacture and ale of hemp seed and oil and seed and oil products with their allegation that DEA does not believe that hemp poses any threat to the public health or safety as evident by the fact that it took DEA almost a year to issue the Interpretive Rule. (Petitioners' Motion for Stay at 19). Petitioners' argument is wholly meritless.

Petitioners' assessment of the balance of harms and the public interest overlooks essential considerations. At stake is whether the Executive Branch will be permitted to carry out its constitutional obligation to enforce laws enacted by Congress. Issuing a stay that would order an agency to abandon that obligation by ceasing to interpret the law it

administers – particularly on a subject for which the public needs clarification – would be unwarranted. Further, when it comes to enforcing the laws relating to controlled substances, Congress has made clear this is an area of paramount importance to the public health and safety. See 21 U.S.C. 801(2) ("The illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people.") Therefore, as enforcement and administration of the CSA has been committed to the sound discretion of the DEA Administrator, any undue interference with the ability of the Administrator to carry out his functions under the act is contrary to the public interest.

The fact that DEA took almost a year in which to promulgate the Interpretive Rule should be read only to reflect the fact that in response to numerous public inquiries as to the interpretation of the CSA with regard to THC, DEA responded in a measured and deliberative manner, and reflects on the careful and thorough research DEA undertook to present a well reasoned explanation of its interpretation of the law.

Thus, as Petitioners' argument that it will suffer irreparable economic injury is speculative at best and as the public interest and safety are at stake, along with the Executive Branch's ability to carry out its constitutional obligations, Petitioners have failed to show that the balance of hardships tips in their favor and this Court should not grant Petitioners' request for a stay. See Federal Trade Comm'n v. World Wide Factors, Inc., 882 F.2d. 344, 347 (9th Cir. 1989) ("when a district court balances the hardships of the public interest against a private interest, the public interest should receive greater weight").

CONCLUSION

Petitioners have failed to make the required showing for a stay pending review. For the reasons stated above, the United States respectfully requests that the petition for stay be denied.

Respectfully submitted,

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