UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 01-71662

Hemp Industries Association, et al.,	)
	)
Petitioners	)
v.	)
	)
Drug Enforcement Administration, et al.,	)
	)
Respondents	)
	)

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

Pursuant to Rule 27(a)(4) of the Federal Rules of Appellate Procedure, Petitioners hereby reply to the Opposition of Respondents Drug Enforcement Administration ("DEA") and Asa Hutchinson, as Administrator, to Petitioners' Urgent Motion for Stay Pending Review.

First, contrary to DEA's contention, Petitioners clearly have standing to seek review of DEA's purported "Interpretive Rule."

Second, that DEA merely purports to "interpret" existing law does not make its rule "interpretive" for purposes of the Administrative Procedure Act ("APA"). The rule clearly imposes new obligations on Petitioners and is intended to be binding on tribunals outside the agency.

Finally, certain of the Petitioners have suffered injury since the "Interpretive Rule" was issued, in the form of lost sales and imminent threats to the continuation of their business. These losses are irreparable since there is no possible action against DEA,

or anyone else, for monetary damages to recover such losses in the event Petitioners ultimately prevail on their Petition for Review.

I. PETITIONERS HAVE STANDING TO SEEK REVIEW OF THE "INTERPRETIVE RULE"

DEA contends that Petitioners have failed to demonstrate that they will suffer any "injury in fact" from the "Interpretive Rule" because there is no "genuine threat of imminent prosecution," citing Thomas v. Anchorage Equal Rights Commission, 220 F.3d 1134, 1140 (9th Cir. 2000)(en banc), cert denied, 531 U.S. 1143 (2001). Memorandum in Support of Respondents' Opposition to Petitioners' Motion for a Stay ("DEA Opp. Mem ") at 13. Contrary to the implication of DEA's argument, however, when contesting a statute, "'it is not necessary that the [plaintiff] first expose himself to actual arrest or prosecution to be entitled to challenge the statute. . . .'" Babbitt v. United Farm Workers National Union, 442 U.S. 289, 298 (1979), citing Steffel v. Thompson, 415 U.S. 452, 459 (1974)(bracketed language in original). See also Doe v. Bolton, 410 U.S. 179, 188 (1973)(persons against whom criminal statutes directly operate in the event they engage in prohibited conduct "assert a sufficiently direct threat of personal detriment. They should not be required to await and undergo a criminal prosecution as the sole means of seeking relief"); Conant v. McCaffrey, 172 F.R.D. 681, 689-90 (N.D. Cal. 1997)(in challenge to policy regarding enforcement of marijuana laws, plaintiffs subject to policy were not required to await and undergo criminal prosecution in order to seek relief).

Rather, "[i]f 'promulgation of the challenged regulations presents plaintiffs with the immediate dilemma to choose between complying with newly imposed, disadvantageous restrictions and risking serious penalties for violation,' the controversy

is ripe." City of Auburn v. Qwest Corp., 260 F.3d 1160, 1171 (9th Cir. 2001), pet. for cert. filed (Oct. 9, 2001), citing Reno v. Catholic Soc. Servs., Inc., 509 U.S. 43, 57 (1993). In this case, Petitioners face the immediate dilemma to choose between shutting down their business of selling hemp oil and seed, and oil and seed products, containing trace amounts of THC, and risking serious criminal penalties for violation of the Controlled Substances Act. For this reason, the controversy is ripe and Petitioners have standing.

Consideration of the relevant factors, moreover, leads to the conclusion that there is indeed a "genuine threat of imminent prosecution" in this case. First, there is no question in this case of whether the Petitioners have articulated a "concrete plan" to violate the law in question, Thomas, supra, 220 F.3d at 1139. In San Diego County Gun Rights Committee v. Reno, 98 F.3d 1121 (9th Cir. 1996), this Court distinguished a situation where plaintiffs merely asserted a wish to engage in prohibited activity from the situation in Babbitt, where the plaintiffs "alleged that they had previously engaged in and would continue to engage in acts regulated under the challenged legislation." 98 F.3d at 1127. See, to the same effect, City of Auburn, 260 F.3d at 1171. In the instant case, Petitioners are not merely planning to violate the law; rather they have already, for years, been engaged in the conduct which the "Interpretive Rule" suddenly makes illegal—namely, the manufacture, sale and/or importation of edible hemp seed and oil, and seed and oil products, containing trace amounts of naturally-occurring THC.

Second, DEA contends that it has not threatened to commence criminal proceedings against Petitioners. DEA Opp. Mem. at 14. Manifestly, however, DEA has not taken the trouble to issue the "Interpretive Rule" merely as a hypothetical exercise. It

may be assumed that DEA intends to continue to enforce the drug laws, since that is the agency's core mission. The "Interpretive Rule" sweeps Petitioners' products within the scope of those laws.

Contrary to DEA's assertion, Petitioners' products, intended for human consumption, contain miniscule trace amounts of naturally-occurring THC. See Supplemental Declaration of John Roulac, Ex. 1 hereto at ¶ 3 (there is a minute quantity of THC in hemp bars, chips and cans of seeds); Declaration of Joseph Hickey, Ex. 5 to Petitioners' Motion at ¶5 (HEMPMYLK hemp beverage contains one part per million ("ppm") of THC or less); Declaration of Shaun Crew, Ex. 6 to Petitioners' Motion at ¶6 (oil products contain less than 2 ppm of THC and seed products contain less than 0.5 ppm). Thus, Petitioners' products have, as a result of the "Interpretive Rule," become "controlled substances" under Schedule I of the CSA. Their manufacture, importation and sale are now a serious criminal offense. Were that not the case, of course, it would not have been necessary for DEA, in its companion "Interim Rule," to provide a 120-day grace period for Petitioners and similarly situated companies to dispose of these products. See Interim Rule, Ex. 3 to Petitioners' Motion, 66 Fed. Reg. 51539 at 51543.

In these circumstances, that DEA has not yet prosecuted or specifically threatened to prosecute anyone is irrelevant. In Babbitt, supra, the Court held that, even though a criminal penalty provision "has not yet been applied and may never be applied," the controversy was ripe and plaintiffs had standing where plaintiffs had already engaged in the forbidden conduct; the "State has not disavowed any intention of invoking the criminal penalty provision;" and plaintiffs "are thus not without some reason in fearing prosecution for violation of the ban. . . ." 442 U.S. at 302.

Finally, there is indeed a history of past prosecution against Petitioners' products. In August, 1999, a shipment of hemp birdseed which Petitioner Kenex, Ltd. was attempting to export to the U.S. was seized by the U.S. Customs Service based on a DEA advisory that any THC was a controlled substance. Supplemental Declaration of Jean Marie Laprise, attached hereto as Exhibit 2 at ¶5. Customs also issued recall notices for fifteen prior shipments of hemp oil, fiber and nut products, and imposed $500,000 in fines. Id. at ¶8. Customs eventually dropped all charges and fines, and returned the seized shipment (which became worm-infested while impounded), apparently as a result of concluding that DEA in fact lacked legal authority to impose a zero-content trace natural THC standard on hemp oil and seed products. Id. at ¶¶6-7. The manifest purpose of the "Interpretive Rule" is to confer on DEA precisely the legal authority that was missing in the 1999 Kenex birdseed seizure case.

For these reasons, Petitioners' challenge to the "Interpretive Rule" is ripe and they have standing to seek its review by this Court.

II. THE "INTEPRETIVE RULE" IS LEGALLY A SUBSTANTIVE, LEGISLATIVE RULE

Contrary to DEA's assertions, the "Interpretive Rule" is, in legal contemplation, a substantive, legislative rule, subject, at a minimum, to the prior notice and comment requirements of section 553 of the APA. DEA argues, first, that its statements "leave no doubt of the agency's intention that the rule be viewed as interpretive, not legislative." DEA Opp. Mem. at 9. But "[i]t is well-established that 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.3d 1015, 1024 (D.C. Cir. 2000). The agency's own label is not dispositive; "we do not classify a rule as

interpretive just because the agency says it is." Chamber of Commerce v. OSHA, 636 F.2d 464, 468 (D.C. Cir. 1980).

Second, DEA contends that the "Interpretive Rule" "neither creates new rights or obligations nor effects a change in existing law." DEA Opp. Mem. at 9. To the contrary, DEA itself concedes that "upon publication of this rule, some manufacturers and distributors of THC-containing 'hemp' products will have in their possession existing inventories of such products that will be considered controlled under the interpretive rule and. . .not exempted from control under this interim rule." Interim Rule, Ex. 3 to Petitioners' Motion, 66 Fed. Reg. 51539 at 51543 (emphasis added). In other words, the "Interpretive Rule" changes existing law. And, again, were it not for the fact that the "Interpretive Rule" indeed 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 their inventories—albeit while making clear that even during that grace period, use, manufacture and distribution of such products are immediately illegal. Id.

In that 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 Ex. 11 to Petitioners' Motion. 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. . . ." (emphasis added). DEA argues that "the subsequent approval of the Interpretive Rule by the Attorney General effectively overrides" this earlier opinion. DEA Opp. Mem. At 11. That is precisely the point. 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—not merely changing a past agency policy or practice as suggested by DEA. See Chief Probation Officers of Cal. v. Shalala, 118 F.3d 1327, 1335-37 (9th Cir. 1997).

Finally, DEA suggests that the "Interpretive Rule" would not be binding on "tribunals outside the agency," citing Splane v. West, 216 F.3d 1058 (Fed. Cir. 2000). See DEA Opp. Mem. at 8, 9. Yet DEA clearly expects to be able to prosecute persons selling or distributing edible hemp oil and seed products containing trace amounts of THC; otherwise issuance of the "Interpretive Rule" would have been pointless. Thus the "Interpretive Rule" is intended to be binding in enforcement proceedings. And DEA also expects that the Customs Service will enforce the "Interpretive Rule," since as a result of issuance of the rule, the subject hemp seed and oil products have become controlled substances, "the CSA prohibits the importation of schedule I controlled substances," Interim Rule, 66 Fed. Reg. at 51543, and the Customs Service enforces bans on the importation of particular products. It begs credulity for DEA to imply that it does not believe that the courts or Customs Service are bound to follow the "Interpretive Rule."

For these reasons, the "Interpretive Rule" is indeed properly characterized as a substantive, legislative rule and Petitioners are likely to prevail on the merits of their Petition.

III. PETITIONERS WILL SUFFER IRREPARABLE INJURY

DEA argues that Petitioners have failed to establish irreparable injury. First, DEA suggests that Petitioners "are unsure" whether their food and beverage products contain THC and would therefore be considered illegal under the "Interpretive Rule." To the contrary, Petitioners have clearly stated that their products contain miniscule, trace amounts of naturally-occurring THC. See Supplemental Roulac Dec. at ¶3; Hickey Dec. at ¶5; Crew Dec. At ¶6.

Second, DEA argues that not all of the Petitioners are threatened with loss of their entire business, because some of them manufacture and sell products that are not subject to the "Interpretive Rule." DEA Opp. Mem. at 16. In fact, even in the few weeks since the "Interpretive Rule" was issued, some of the Petitioners have suffered severe losses that imminently threaten their survival. See Supplemental Roulac Dec., Exhibit 1 hereto, at ¶7 (monthly sales have dropped 50%; company behind in paying creditors; future of company is in jeopardy); Supplemental Laprise Dec., Exhibit 2 hereto at ¶3 (sales of hemp nut and hemp oil, accounting for _ of company's revenues, have already dropped to zero); Supplemental Declaration of Shaun Crew, Exhibit 3 hereto at ¶¶4, 9 (orders cancelled, further financing dried up). In the absence of interim relief, these losses will only continue to grow and more and more of the Petitioners will be faced imminently with the question of survival.

In any event, the key factor is not whether such injuries put all of the Petitioners out of business, but whether the injuries are both substantial and irreparable. That the injury to these companies is substantial is made clear by the Declarations attached to the Motion and the Supplemental Declarations attached to this Reply. And these financial losses are irreparable because there is no possibility that "adequate compensatory or other corrective relief will be available at a later date," Colorado River Indian Tribes v. Town of Parker, 776 F.2d 846 (9th Cir. 1985), citing Sampson v. Murray, 415 U.S. 61 (1974). Clearly Petitioners cannot bring a claim for monetary damages against DEA or anyone else in the event that they prevail on the merits of their Petition for Review. See e.g., Greene v. Bowen, 639 F. Supp. 554, 563 (E.D. Cal. 1986)(where doctor faced monetary injury from application of regulation, injury was irreparable because doctor "will have no apparent action against anyone to recover the monetary loss"). [1]

For these reasons, Petitioners have demonstrated that they will suffer irreparable harm in the absence of a stay pending review.

IV. THE BALANCE OF HARDSHIPS TIPS IN PETITIONERS' FAVOR

The DEA has failed to articulate any public interest whatsoever in the immediate implementation of its "Interpretive Rule." DEA invokes the general obligation of federal agencies to "enforce laws enacted by Congress" and the general public health and safety interest in enforcing the laws relating to controlled substances. DEA Opp. Mem. At 19. But DEA fails to cite any imminent threat to public health or safety from the products which are the subject of this rule—hemp seed and oil, and oil and seed products—or any

[1] In addition to hemp food companies and consumers, Petitioner HIA's membership includes environmentalists, farmers, and state lawmakers who have spent years to research, develop and commercialize industrial hemp food and fiber products and create markets therefor, whose efforts are also being irreparably harmed by DEA's interpretive rule.

other public interest factor whatsoever that makes it imperative that this rule be put into effect immediately without notice and comment.

Further, DEA claims that the year it took to promulgate the Interpretive Rule merely "reflects upon the careful and thorough research DEA undertook." DEA Opp. Mem. at 19. Had DEA taken that same period to undertake a rulemaking process, of course, including a hearing on the record as required by the Controlled Substances Act, Petitioners never would have needed to bring this litigation.

DEA has already initiated a rulemaking proceeding on a Proposed Rule (Ex. 3 to Motion) that is identical to the "Interpretive Rule." In balancing the harms, no harm would be done by continuing the status quo while DEA's rulemaking proceeds. The balance of hardships favors staying the "Interpretive Rule" until this Court can act on the merits of the Petition for Review.

CONCLUSION

For the reasons set forth in the Urgent Motion for Stay Pending Review, and in this Reply, Petitioners' Urgent Motion for Stay should be granted.

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