UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Hemp Industries Association, et al.,	)	
	)	
Petitioners	)	
v.	)	
	)	
Drug Enforcement Administration, et al.,	)	No. 01-71662
	)	
Respondents	)	
	)	

PETITIONERS' REPLY TO
RESPONDENTS' MEMORANDUM IN OPPOSITION TO
PETITIONERS' EMERGENCY MOTION FOR STAY

Following the filing by Petitioners of their Emergency Motion for Stay on February 6, 2002, the Court's Motions Attorney apparently contacted counsel for DEA to inquire whether DEA was planning to commence enforcement action while the Petitioners' Urgent Motion for Stay is pending. In response, DEA's counsel notified the Court that DEA would extend the grace period for an additional 40 days, to "allow the Court to rule on the motion prior to the expiration of the grace period." Letter from Daniel Dormont, Esq. to Susan Christian, Esq., February 7, 2002. A ruling on the Urgent Motion prior to the expiration of the extended grace period would, indeed, obviate the need for any earlier decision on an emergency basis. DEA's letter would thus have provided a basis for Petitioners to withdraw their emergency motion.

In responding to the Emergency Motion, however, DEA has, at this late hour, and with all briefing on the Urgent Motion and on the merits fully completed, introduced a

host of new arguments to suggest that no interim relief, or indeed any relief, should be granted at all. Petitioners reply to those arguments herein.

The briefing on the merits of this case makes clear that this case is about the action of respondent Drug Enforcement Administration ("DEA") to change the law, without notice or opportunity for comment, to criminalize the production and sale of edible hemp seed and oil products, which has always been lawful. The reason Petitioners have sought a stay pending review—and now an emergency stay—is that the prospect of violating what, after all, is a criminal statute, has caused Petitioners' customers to discontinue carrying Petitioners' products. See Petitioners' Emergency Motion for Stay filed February 6, 2002 and Declarations attached thereto.

In its Memorandum opposing Petitioners' Emergency Motion, DEA responds to this straightforward situation by inviting hemp food producers to knowingly misrepresent to the Government the trace naturally-occurring tetrahydrocannabinol (THC) content of their products and by pretending that companies producing, importing and selling hemp food products—now suddenly banned under a criminal statute that makes such activity a felony—should not be concerned because DEA has not immediately begun confiscating products and arresting people.

I. PETITIONERS CANNOT REPRESENT THAT THEIR PRODUCTS DO NOT CONTAIN "ANY" THC

DEA's "Interpretive Rule" treats as a Schedule I controlled substance, under the Controlled Substances Act, any edible hemp seed or oil product "containing any amount of THC." 66 Fed. Reg. at 51533, Excerpts of Record (ER) at 5 (emphasis added). To be sure, the amounts of trace natural residual THC in Petitioners' products are miniscule. The maximum trace THC content in hemp seed imported into and used in the U.S. is

generally less than 2 parts per million (ppm, equals 2 milligrams per kilogram), and the maximum THC content quantity in hemp seed oil is generally less than 5 ppm. Leson, Pless, Grotenhermen, Kalant and ElSohly, "Evaluating the Impact of Hemp Food Consumption on Workplace Drug Test," 25 JOURNAL OF ANALYTICAL TOXICOLOGY 691, 692 (Nov./Dec. 2001). In fact, virtually all shelled hemp seed and oil in the U.S. market contains less than 4 ppm (i.e., 0.0004%, or four ten-thousandths of one percent), which is the limit of quantification ("LOQ") of the protocol of Canada's federal health agency, Health Canada. Therefore, hemp products companies can generally represent that the hemp seed and oil in their products "does not contain any THC according to the Health Canada protocol."

No producer can truthfully state, however, that its products contain "zero" THC, without referencing the LOQ or limit of detection ("LOD") of the method used for the laboratory analysis. As explained in the Declaration of Gero Leson, attached hereto as Exhibit 1 ("Leson Dec."), "even the seed meat or hemp nut, i.e. the portion of hemp seeds least contaminated externally with THC, contains low yet measurable quantities of THC." Leson Dec. ¶ 5. Thus, for example, Petitioner Hemp Oil Canada, Inc. has tested its own products, using enhanced analytical techniques, which achieve an LOD of less than 50 parts per billion, and found miniscule trace amounts of THC in even hulled seeds at concentrations of at least 100 parts per billion. See Declaration of Shaun Crew, attached hereto as Exhibit 2 ("Crew Dec."), at ¶¶ 4-5, and study attached thereto as Exhibit A at 7. The laboratory analysis further confirmed that "it would appear from the results that achieving a 'THC Free' status is not achievable in terms of a true zero."

Crew Dec., Exhibit A at 2. Thus, DEA's phrase "...containing *any amount* of THC..." is meaningless unless it references an LOD or LOQ.

The one producer cited repeatedly by DEA in its Memorandum as being able to comply with the rule's provisions is HempNut, Inc. (and the "Hemp Food Association," a promotional vehicle of HempNut's owner and president). DEA Memorandum at 1, 10 & Exhibits 1-4. It is understandable that this company, which is not a Petitioner, would approach DEA's new rule by taking the position that its products contain "zero THC," since its products undoubtedly contain less than 4 ppm or even 1 ppm of THC, levels which are lower than the LOQ/LOD's of the common THC detection protocols. But that position is not truthful in that it conceals the fact that trace THC will invariably be found if a method achieving a lower LOD is used.[1]

Because of the ambiguity of an unqualified "zero" limit, other agencies of the federal government, such as the Environmental Protection Agency ("EPA") which regulates pesticide residues in food, have largely abandoned the "zero tolerance" concept underlying the DEA's "Interpretive Rule". These agencies now routinely establish finite (non-zero) thresholds for allowable quantities (tolerances) in food for highly toxic substances, including carcinogenic pesticides. See Leson Dec. ¶¶8-10. These tolerances

[1] Alone among HIA's membership, HempNut maintains DEA's "Interpretive Rule" is correct and consistent with past practice, and has suggested that HempNut can comply with the "Interpretive Rule" because its products contain "no THC". However, HempNut has joined the Hemp Industries Association's TestPledge program to assure consumers with a wide margin of safety that they will not confirm positive in a workplace drug test for marijuana even when unrealistic amounts of hemp oil and shelled seed are consumed on a daily basis. See Exhibit 3 attached hereto. TestPledge hemp food companies voluntarily test each and every batch of hemp oil and/or shelled seed used in their products for trace THC content, which must show less than 5 ppm THC in hemp oil and 1.5 ppm in shelled seed. HempNut's participation in this program confirms that even HempNut implicitly acknowledges that hemp seed and oil contain trace THC. Furthermore, Petitioner Nature's Path in fact routinely purchases its shelled hemp seed in part from HempNut, but refuses to represent without qualification that its products contain no THC because such a representation may prove false in the event that a sensitive enough laboratory analysis is performed, at some point, that is capable of detecting trace THC at levels below 1 ppm.

are based on extensive studies showing that the resulting health risk is acceptably low and compliance can be verified through sampling and analysis.

However, without offering any rationale based on the toxicity and psychoactivity of THC, DEA has refused to specify any limit of detection or acceptable threshold for THC in food, no matter how low.[2] As a result, Petitioner companies—unless they are willing to lie to the Government, or cause others to lie, which is of course a criminal offense in itself, 18 U.S.C. §1001—cannot simply tell their customers (distributors and retailers of edible hemp products), without qualification, that such products do not contain "any" THC.

II. PETITIONERS CONTINUE TO SUFFER IMMEDIATE AND IRREPARABLE HARM

Because DEA's "Interpretive Rule" renders instantly criminal the production, possession and sale of edible hemp oil and seed products, Petitioners' customers have discontinued buying their products in recent weeks. This action is not limited to one distributor, but has been taken by numerous natural foods distributors and retail chains across the industry. See Crew Dec. ¶3; Declaration of Arran Stephens, attached hereto as Exhibit 4 ("Stephens Dec.") ¶5; Declaration of Jean Laprise, attached hereto as Exhibit 5 ("Laprise Dec."), ¶ 5. It is hardly surprising that established, law-abiding companies do not want to commit a felony.

[2] A recent assessment of the human health risk from THC in "hemp foods" shows that the THC doses ingested via hemp foods are, even when assuming very high daily consumption, far too low to cause psychoactivity or other undesirable health effects. See Leson Dec. ¶ 11. In that regard, the Government of Canada has formally objected to DEA's "Interpretive", "Interim" and "Proposed" rules in a letter submitted to DEA during the comment period for the "Proposed" rule because DEA failed to follow the WTO Agreement on Sanitary and Phyto-Sanitary Measures (SPS Agreement). The SPS Agreement requires that DEA's rules be based upon a valid "risk assessment" process that includes taking available scientific evidence into account, and that resulting trace THC standards be no more restrictive than necessary to achieve the appropriate level of public health protection.

DEA's response is, first, simply to confirm that even during its "grace period," use, manufacture and distribution of edible hemp products is unlawful. DEA Mem. at 5. Second, DEA belittles the concerns of Petitioners and their customers by joking that, when the grace period ends, DEA is not about to "swoop down upon distributors in a wave of enforcement action." Id.

The fact is that DEA has never disavowed its intent ultimately to enforce the prohibition on possession of Schedule I controlled substances, with respect to edible hemp seed and oil products. That DEA has not yet taken any enforcement action by seizing hemp products or explicitly threatened to do so, DEA Mem. at 6, is irrelevant. If "'promulgation of the challenged regulations presents plaintiffs with the immediate dilemma to choose between complying…and risking serious penalties for violation,' the controversy is ripe." City of Auburn v. Qwest Corp., 260 F.2d 1160, 1171, cert. denied, 122 S. Ct. 809 (2002), citing Reno v. Catholic Soc. Servs., Inc., 509 U.S. 43, 57 (1993).

Third, DEA suggests that its "Interpretive Rule" did not change any practice or policy of the U.S. Customs Service. DEA Mem. at 6-7. To be sure, Petitioners do not challenge any action of Customs before this Court, and Customs can, indeed, routinely hold and test any shipment of any goods to ensure that entry documents are correct. DEA Mem. at 7.

The fact is, however, that the very impetus for development and issuance of the Interpretive Rule was to confer on Customs the authority to bar hemp seed imports into the U.S., based on trace infinitesimal THC content. The Department of Justice confirmed to Customs that current law confers no authority to ban or restrict importation of hemp products. Letter from John Roth to Customs Commissioner Kelly, March 22,

2000, ER at 19. The White House Office of National Drug Control Policy (ONDCP) then implored Customs and DEA to adopt a ban on hemp products because DOJ's confirmation of existing law would permit the continued "importation of products" from hemp "seeds, stem, fiber specifically designed for human ingestion." Memorandum from ONDCP General Counsel to Chief Counsel of US Customs Service, April 10, 2000, with March 28, 2000 "Discussion Paper" attached, attached hereto as Exhibit 6 (document obtained through FOIA request by Resource Conservation Alliance). Further, the communication by Customs to Petitioner Nutiva, on February 5, 2002, that Nutiva's shipment (notwithstanding that it was ultimately released) would be held until testing for THC was completed (Declaration of John Roulac, Attached as Exhibit 1 to Petitioners Emergency Motion for Stay Pending Review at ¶¶ 7,9), represents a clear warning to the hemp food industry that there is a new de facto Customs policy in effect, as no Petitioner has had any similar experience with Customs since March of 2000. Moreover, the Customs Service also has advised at least one state official that, under the "Interpretive Rule," Customs would begin to test for THC content and that DEA could require Customs, at any time, to implement a testing protocol down to parts per billion. See Declaration of Cynthia Thielen, attached hereto as Exhibit 7. Such a situation requires importers to live in constant uncertainty about the lawfulness of importing their products, as long as the "Interpretive Rule" remains in effect.

Finally, DEA contends that it has not required any particular type of testing to show that a hemp product contains no THC. DEA Mem. at 9-10. That is precisely the problem. As noted above, producers of edible hemp oil and seed products cannot truthfully represent that their products contain "no THC", without qualification. What

DEA told distributors and retailers, according to DEA's own admission, is that "'hemp' food and beverage products are only exempt from control if they contain no THC." DEA Mem. at 9; Collier Declaration attached as Exhibit 5 to DEA Mem., at ¶¶ 4-5. Through this cynical game, DEA has forced Petitioners and similarly situated companies, and their customers, to choose between lying to the Government and risking criminal prosecution for distribution, importation and/or sale of Schedule I controlled substances.

In these circumstances, it is absurd for DEA to suggest that Petitioners have "misrepresented" their perilous situation. And it is disingenuous for DEA to suggest that distributors' and retailers' decisions to discontinue selling Petitioners' products are somehow irrational decisions that such distributors and retailers made on their own initiative. DEA Mem. at 3. The harm Petitioners are suffering results directly from DEA's issuance of its "Interpretive Rule."

III. PETITIONERS HAVE MET THE RQUIREMENTS FOR A STAY

Petitioners have amply demonstrated, in their Urgent Motion and Reply, and in their principal and reply briefs on the merits, that they have the requirements for a stay. In summary, Petitioners are likely to succeed on the merits because DEA has issued a substantive, legislative rule without notice or opportunity for comment, in violation of the APA and CSA. DEA continues to misrepresent Petitioners' position with respect to the distinction between an interpretive and legislative rule. Petitioners do not contend that DEA's "Interpretive Rule" is a binding legislative rule merely because of its "impact" on Petitioners' business. That Petitioners' business is suddenly rendered illegal by DEA's rule has nothing to do with "impact;" rather, that fact demonstrates that the rule imposes new obligations and effects a change in existing law—the key indicia of a substantive,

legislative rule. See Yesler Terrace Community Council v. Cisneros, 37 F.3d 442, 449 (9th Cir. 1994).

Petitioners have established irreparable injury because their harm is certain, direct and immediate, as shown by the Declarations attached to this Reply. That harm (loss of sales and production) is irreparable because there is no possibility that adequate compensatory relief will be available at a later date through an action for damages, against anyone. E.g., Greene v. Bowen, 639 F. Supp. 554, 563 (E.D. Cal. 1986).

IV. THE REMEDY SOUGHT BY PETITIONERS IS COMMONPLACE IN ACTIONS BROUGHT UNDER THE ADMINISTRATIVE PROCEDURE ACT

DEA suggests that Petitioners seek to have DEA ordered to "refrain from interpreting the law in a certain manner," DEA Mem. at 13, which DEA contends would be "unprecedented" and "unconstitutional." That contention is utter nonsense.

Petitioners do not, of course, seek to have DEA enjoined from interpreting anything. Petitioners have demonstrated that DEA's rule is not interpretive at all, but legislative and substantive. Because the rule was promulgated in violation of section 553 of the Administrative Procedure Act, the rule is invalid. E.g., Malone v. Bureau of Indian Affairs, 38 F.3d 433, 439 (9th Cir. 1994). The rule is also invalid because it was promulgated in violation of the requirements of the Controlled Substances Act, requiring a formal rulemaking on the record and requiring that certain findings be made before a new substance (hemp seed and oil) is added to Schedule I.

The order sought by Petitioners is simple. It would invalidate the "Interpretive Rule" and order DEA to undertake a scheduling proceeding, with notice, opportunity for comment as required by the APA and a formal rulemaking on the record, in accordance

with the APA and sections 811(a) and 812(b) of the CSA. It is, of course, commonplace for Courts of Appeals to issue such orders.

Indeed, DEA concedes that a reviewing court may "order an agency to engage in notice and comment rulemaking prior to the issuance of a legislative rule." DEA Mem. at 15. DEA then, once again, contends that its rule is somehow not "binding" because DEA has "given the rule all the earmarks of an interpretive rule." Id. Earmarks or not, the "Interpretive Rule" makes it criminal, as of October 9, 2001, to possess, sell, produce, import or distribute any edible hemp food product. By every standard, that rule is legislative.

CONCLUSION

For the foregoing reasons, Petitioners' Urgent Motion for Stay should be granted, before the expiration of the extended grace period.

Respectfully submitted,

_____

Patrick Goggin, SBN # 182218
1458 Waller Street, # 3
San Francisco, CA 94117
Telephone: (415) 710-3981

Of counsel:
Joseph E. Sandler
John Hardin Young
Sandler, Reiff & Young, P.C.
50 E Street, S.E.
Washington, D.C. 20003
Telephone: (202) 479-1111

Dated: February 22, 2002

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 01-71662

Hemp Industries Association, et al.,	)	
	)	
Petitioners	)	
v.	)	
	)	
Drug Enforcement Administration, et al.,	)	**No. 01-71662**
	)	
Respondents	)	
	)	

DECLARATION OF GERO LESON

1. My name is Gero Leson. I submit this Declaration in support of the Petitioners' Emergency Motion for Stay Pending Review.

2. My educational background is in sciences (M.S. Physics, University of Cologne, Germany, 1984; Doctorate in Environmental Science and Engineering (D.Env.), UCLA, 1993). During my career of more than 15 years in applied environmental research and consulting, I have worked extensively in the following areas relevant to this case:

- Management of and participation in numerous projects involving the analysis for and quantification of low levels of environmental contaminants in various media, involving extensive first hand experience with analytical techniques, such as the GC method also used for the analysis of delta-9-tetrahydrocannabinol (THC);
- Observation of and active involvement in several regulatory rulemaking processes for the control of environmental pollutants and in their implementation and enforcement;
- Principal researcher in a toxicological study on "Evaluating the Impact of Hemp Food Consumption on Workplace Drug Tests" (Journal of Analytical Toxicology: 25, Nov/Dec 2001). The study identified daily oral THC doses at which confirmed positive urine tests for marijuana are avoided.
- Co-author, with Dr. Franjo Grotenhermen, M.D. – an internationally acknowledged authority on THC pharmacology, of the study "Assessment of Exposure to and Human Health Risk from THC and other Cannabinoids". This literature study critically evaluated the potential health risk of trace THC in hemp food items. The study concludes that THC levels currently achieved in hemp seeds and oil are sufficiently low to avoid psychoactivity and other undesirable health effects with a wide margin of safety. The study has been submitted to Health Canada in support of

the agency's current reassessment of the potential health impacts from THC residues in "hemp foods".

3. In my opinion, to date, no chemical analysis of commercial North American hemp seeds and their immediate derivatives, hulled seeds and oil, would have found THC at non-detectable levels, provided that the most sensitive currently available method of analysis was used.

4. Declarations of "no" or "no detected" THC now made by Canadian suppliers of hemp seeds reference the applicable limit of detection (LOD) or limit of quantification (LOQ). Health Canada currently specifies an LOQ of 4 parts per million (ppm) for THC in hemp seeds and oil (equals 4 milligram per kilogram). Many suppliers use methods achieving a lower LOD of 1-2 ppm to demonstrate that their products contain less than these levels of trace THC.

5. Several scientific studies have developed and/or employed even more sensitive methods to detect and quantify THC at levels of 50 parts per billion (0.05 ppm) and less. Such methods require considerable additional efforts relative to sample preparation, equipment calibration and possibly repeated analyses. These studies have demonstrated that even the seed meat or hemp nut, i.e. the portion of hemp seeds least contaminated externally with THC, contains low yet measurable quantities of THC. For example, a comprehensive study (2000) by Petitioner Hemp Oil Canada at Websar Laboratories, St. Anne Manitoba, has shown that the lowest THC levels found in carefully dehulled seeds from a range of certified hemp varieties still exceeded 0.1 parts per million. Due to the unavoidable contamination of hemp nuts by hull-borne THC residues during commercial hulling, THC levels in commercially available hemp nut will thus rarely be lower than 0.1 ppm. Hemp oil has been found to generally contain higher trace THC concentrations than whole or hulled seeds. These findings illustrate that whether a hemp seed product contains "any quantity of THC" depends critically on how sensitively one analyzes for it.

6. Hemp seeds and their derivatives account for only a fraction of many commercially available hemp food products, which effectively dilutes their THC content. However, unless only nutritionally insignificant amounts (less than 1%) of hemp seeds are used in a product, the THC residues introduced by hemp seeds and oil will be detectable in a sample of such product, provided a sensitive analytical method achieving an LOD of 5 ppb and less is used.

7. Thus, in my opinion, the language of the DEA's interpretive rule ("...any product that contains *any amount* of THC...") would render any currently available hemp food product a schedule I controlled substance. Conversely, claims by suppliers of such

products that their products contain “zero” or “no” THC, without specification of an LOD or LOQ, appear to be misleading.

8. Environmental and food safety regulatory practice in the U.S. now avoids use of the terms “any”, “any measurable quantity” or “zero” when specifying rational, enforceable levels of a toxic contaminant in food, air, water, or waste. The concept of “zero tolerance” has been used in the past, for example, to regulate carcinogenic pesticide residues under the Delaney Clause, but is now used predominantly to set *unenforceable contaminant goals* for compounds of known *high toxicity*. This practice acknowledges that target contaminants will always be detectable in a medium of concern, provided that sufficiently sensitive analytical methods are used. The practice also acknowledges that, as analytical techniques advance, allowing detection and quantification of lower contaminant levels, the above terms are scientifically meaningless and unenforceable, unless referencing an LOD/LOQ. Instead, environmental contaminants and food toxins are now regulated by assessing the health risk caused by their presence and by limiting this risk through adoption of maximum acceptable contaminant levels or tolerances, and corresponding monitoring protocols as necessary.

9. For highly toxic, generally carcinogenic contaminants, such as 3,4,7,8-TCDD (commonly called “dioxin”), regulations may set a “zero goal” yet will always support it by enforceable limits. For example, under the Safe Drinking Water Act, the federal EPA has adopted an unenforceable “Maximum Contaminant Level Goal” for 3,4,7,8-TCDD of “zero” and an enforceable “Maximum Contaminant Level” of 0.03 parts per trillion (ppt) with a LOD of 0.005 ppt (40 CFR, Parts 141.50, 141.61 and 141.24).

10. Congress and EPA also have, over the last two decades, moved away from the earlier use of the “zero tolerance” concept in foods as applied to residues of pesticides causing acute and chronic toxicity, including cancer. This policy change was driven largely by the difficulties with the enforcement of a “zero tolerance” approach, considering the advancement in analytical techniques, reduction in LOD and the resulting shift in the effective compliance standard. The 1996 Food Quality Protection Act (FQPA) wrote into law this change in legislative and regulatory philosophy by requiring that EPA adopt *health based* tolerances, which assure “with reasonable certainty that no harm will result from exposure to pesticide residues in food”. Tolerances, i.e. the maximum amount of a pesticide that may remain on or in food, are adopted by EPA based on extensive studies of a compound’s toxicity, assessments of human exposure through various pathways and the corresponding health risk. Particular consideration is given to sensitive populations, such as children. Tolerance adoption for a specific

pesticide invariably involves public review and extensive comment. Residues of carcinogens in food are deemed acceptable if the resulting cancer risk does not exceed a specific lifetime cancer risk, typically in the range of one to ten in one million. Older references to "zero tolerance" for pesticides can still be found in 40 CFR, Part 180, but are gradually being eliminated as EPA reevaluates the health risk caused by pesticides already in use.

11. THC is characterized by a low acute toxicity and is not a known or probable carcinogen. Synthetic THC in pill form (called "dronabinol" or "Marinol®", a Schedule III substance) in fact offers therapeutic benefits, and is routinely prescribed by doctors at doses significantly higher than those conceivably ingested via hemp foods to AIDS and chemotherapy patients to alleviate nausea and stimulate appetite. The THC doses ingested via hemp foods are, even under very conservative consumption scenarios, far too low to cause therapeutic effects, much less psychoactivity and other undesirable health effects. Thus, the DEA's adoption of a de facto "zero" limit does not appear to be justified by a high risk to public health caused by trace THC residues in food. Even then such a "zero" limit is still inconsistent with recent health-based approaches by other federal agencies to the protection of the U.S. food supply.

12. DEA's failure to adopt in its interpretive rule a finite (non-zero), verifiable THC standard for food appears to have caused in the regulated community the same uncertainty that has motivated other federal agencies to abandon the "zero tolerance" concept when regulating food-borne toxins. Personal communication with producers and distributors of hemp foods and evidence offered by the DEA (Exhibit 5 to "DEA's Memorandum in Support of Respondents Opposition to Petitions' Emergency Motion for a Stay") demonstrate that the DEA's use of a de facto "zero" limit is preventing the regulated community from taking *informed* action to achieve compliance with the rule; for example, by enforcing quantitative trace THC limits consistently and verifiably with their suppliers of hemp seeds and oil.

13. In my professional opinion, the presence of trace levels of THC in "hemp foods" requires the development of rational and enforceable regulatory limits to protect the public from undesirable health effects and avoid interference with workplace drug testing programs. Virtually all relevant hemp food producers and distributors in North America appear to acknowledge the need for such control, have taken measures to reduce trace THC residues in their products, and claim to be able to consistently meet rational numerical regulatory limits for trace THC. Yet, the wording of the DEA's rule ignores commonly accepted scientific and regulatory principles. These imply that quantitative attributes such as "any" or "no" should not be used in regulatory language without

reference to a LOD or LOQ, preferably in conjunction with a standardized analytical protocol. Otherwise, the respective rule fails to properly define the realm of compliance, is ambiguous and creates uncertainty in the regulated communicate, and will, in my opinion, remain unenforceable.

I declare under penalties of perjury that the foregoing is true and correct to the best of my knowledge, information and belief. Dated this ___ day of February, 2002.

_____

Gero Leson

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Hemp Industries Association, et al.,	)	
	)	
Petitioners	)	
v.	)	
	)	
Drug Enforcement Administration, et al.,	)	**No. 01-71662**
	)	
Respondents	)	
	)	

DECLARATION OF REP. CYNTHIA THIELEN

1. My name is Cynthia Thielen. I am serving my sixth term as an elected Republican State Representative in the Hawaii House of Representatives, representing the 49th District. I currently serve as Assistant Republican Floor Leader in the Legislature, and am the co-sponsor of the state legislation which authorized the Hawaii Industrial Hemp Research Project in 1999.

2. I have learned firsthand of the nutritional benefits of hemp seed and recognize that there is a fast growing market for hemp seed and hemp seed oil foods and body care products.

3. I have been in regular communication with U.S. Government officials, for the last five years, concerning industrial hemp and its legal status.

4. On August 15, 2000, I spoke to a U.S. Customs official in the Laboratories and Scientific Services to obtain the Customs' method for determining the presence of THC in hemp seed, oil and products. As a result of this conversation I was sent a copy of the U.S. Customs Laboratory Methods protocol for detecting trace THC.

5. When the Drug Enforcement Administration published its new "Interpretive Rule" banning hemp foods, seed and oil containing any amount of THC, I contacted U.S. Customs again on December 12, 2001. The U.S. Customs official informed me that Customs would begin to test hemp seed, oil and food products for the presence of any THC whatsoever and not measure for a minimum level. That official also explained to me that DEA has authority to set hemp seed THC testing standards for Customs and that the testing sensitivity could be changed by DEA at any time to test for the presence of THC down to parts per billion.

6. The Hawaii Legislature established the Hawaii Industrial Hemp Research Project with the intent that industrial hemp could be a replacement crop for our dying sugar industry. Research commenced in 1999 to develop a seed variety appropriate for our latitude. The industrial hemp crops would be used primarily for food, nutritional and body care products. DEA's new

"Interpretive Rule" would effectively kill this economic opportunity for Hawaii.

I declare under penalties of perjury that the foregoing is true and correct to the best of my present knowledge, information and belief. Dated this __ day of February, 2002.

_____

Cynthia Thielen