UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 03-71366

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

REPLY OF PETITIONERS IN SUPPORT OF
URGENT MOTION FOR STAY PENDING REVIEW

Contrary to DEA's portrayal of their position, Petitioners in this case are not seeking to enjoin enforcement of a federal criminal law outlawing any narcotic drug. Rather, Petitioners are merely seeking to prevent the DEA from making new law without following the procedures and making the findings required by Congress for the exercise of such extensive and serious lawmaking authority—namely, the formal rulemaking and findings required by 21 U.S.C. §§811(a) & 812(b), in order for previously lawful substances to be made illegal under the Controlled Substances Act (CSA).

Nor is it the case, as DEA suggests, that the marketing of hemp oil and seed, and oil and seed products, began "in the United States in the last few years based on [Petitioners'] own legal opinion…" DEA Opposition ("DEA Opp.") at 2. The

statutory exclusion of hemp stalk, seed and oil from the federal drug laws dates back to 1937, and was made specifically to support hemp industry.[1] Every year for more than six decades, hemp seed has been lawfully imported and used in quantity for birdseed, and hemp seed and oil products specifically for human consumption have been imported into or made in the U.S. since at least 1989. There is indeed a long history of importation, sale and distribution of edible hemp seed and oil products in the U.S. See Declaration of Candi Penn ("Penn Dec."), attached hereto as Ex. 1, at ¶ 3. That there is an established lawful trade, that would suddenly be criminalized and disrupted, is further evidenced by the fact that in 2002 alone, imports just of hemp oil into the U.S. for food and cosmetic products totaled 228,400 kilograms worth $1,964,775. U.S. International Trade Commission, USITC Database, HTS 1515.90.80.10.[2]

DEA's argument against a stay fails on three basic grounds. *First*, the statute at issue is not ambiguous and DEA's putative "interpretation"—which simply reads the statutory exclusion out of the CSA-- is not entitled to *Chevron*

[1] DEA misrepresents Petitioners' citation of legislative history, which is not relevant to the issue of whether DEA has engaged in a rescheduling action. (Pet. Urgent Motion at 10; DEA Opp. at 12). Rather, Petitioners cited the legislative history, which would include the Senate Report, to simply document that Congress made the statutory exemption for hemp stalk, seed and oil in support of the hemp industry.

[2] The lawfulness of these imports, under current law, was confirmed by a formal interpretation of the Department of Justice, communicated to the U.S. Customs Service (Pet. Urgent Motion Ex. 12). DEA attempts to characterize the DOJ's letters to Customs and DEA as merely the opinion of a "mid-level official." DEA Opp. at 10 n. 12. However, the letter was clearly intended to have a "binding effect … on tribunals outside the agency…." *Splane v. West*, 216 F.3d 1058, 1064 (Fed. Cir. 2000) (emphasis added). Indeed, a subsequent letter from Customs Commissioner Kelley to Office of National Drug Control Policy (ONDCP) Director Barry McCaffrey, dated March 31, 2000, apparently informed ONDCP that the DOJ's controlling interpretation contradicts ONDCP's position. *HIA v. DEA*, No. 01-7662, Pet. Excerpts of Record at 21 (9th Cir., filed Jan 7, 2002). The DOJ and Customs letters were obtained from Customs through a FOIA request filed by the Resource Conservation Alliance, and shared with petitioner HIA.

deference. *Second*, there is no uncertainty at all about whether Petitioners' products contain THC; they do contain miniscule trace THC at non-zero levels and it is only a question of the limit of detection of the testing methodology used. *Third*, a stay would neither nullify an Act of Congress nor enjoin enforcement of the drug laws; it would simply forestall criminalization of a currently legal trade, in a product which DEA has never credibly claimed, and does not now claim in its Opposition, causes any threat or harm of any kind to the public health or safety. The balance of hardships clearly tips in Petitioners' favor.

I. DEA's Rule Is Not Entitled to *Chevron* Deference

Under *Chevron*, "We must first determine whether Congress has directly spoken to the precise question at issue…. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *CHW West Bay v. Thompson*, 246 F.3d 1218, 1223 (9th Cir. 2001), *quoting Chevron USA, Inc. v. Natural Resources Defense Council, Inc*., 467 U.S. 837, 843 (1984). In this case, Congress has indeed spoken to the precise question and the statute is absolutely unambiguous: Congress has exempted hemp stalk, seed and oil from the definition of "Marihuana," notwithstanding the presence of trace insignificant amounts of resin, which THC-containing resin is itself already controlled to the extent it is extracted and concentrated in any way. 21 U.S.C. §802(16).

DEA contends that its final rule (DEA-205F, hereinafter the "Final Clarification Rule") "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." DEA Opp. at 15 (emphasis in original). DEA's "interpretation" is thus to conclude that Congress, having expressly *excluded* hemp stalk, seed and oil from one term listed in Controlled Substances Act Schedule I—Marihuana--nevertheless intended to *include* them in the definition of "THC"—which is another term appearing in the *same* part of the *same* Schedule as "Marihuana." CSA Schedule I(c)(17). The exclusion would thus be rendered absolutely meaningless. That is not an "interpretation" of the CSA; it is simply an effort to read the exclusion out of the statute—to flatly ignore the express provision in section 802(16) legalizing hemp stalk, seed and oil. "In the statute at issue, Congress left no gap, no silence no ambiguity, so 'we must give effect to the plain language that Congress chose.' . . . .The regulation is contrary to the will of Congress as expressed in the governing statute." *Orca Bay Seafoods v. Northwest Truck Sales, Inc*., 32 F.3d 433, 437 (9th Cir. 1994), *quoting U.S. v. Geyler*, 949 F.2d 280, 283 (9th Cir. 1991).

Even if this Court were to proceed to the second step of the *Chevron* analysis, it is clear that reading the exclusion of hemp stalk, seed and oil out of the statute is not a "permissible construction." *Chevron*, 467 U.S. at 843. "[S]tatutes must be interpreted, if possible, to give each word some operative effect." *Walters*

v. Metro Educational Enterprises, Inc., 519 U.S. 202, 209 (1997). By contrast, DEA's rule is a "violation of the bedrock principle that statutes not be interpreted to render any provision superfluous." *Environmental Defense Ctr., Inc. v. Natural Resources Defense Council, Inc*., 319 F.3d 398, 409 (9th Cir. 2003). For these reasons, DEA's rule is not entitled to *Chevron* deference.

DEA purports to interpret the term "THC" in Schedule I to include all THC, whether natural or synthetic, and to cover hemp stalk, seed and oil as any "material, compound, mixture" which "contains any quantity of" THC.[3] DEA Opp. at 10, 13. Surely that logic proves too much, for if excluded parts of a plant were to be included in any "material, compound, mixture or preparation" containing any controlled substance, then poppy seed bagels would be controlled substances as "narcotic drugs", 21 U.S.C. §802(17): even though the seeds are exempted by statute, 21 U.S.C. §802(19), poppy seed bagels are literally a "compound, mixture or preparation which contains any quantity" (21 U.S.C. §802(17)(F)) of opiates (*id*. §802(17)(A)).[4]

In any event, on its face, the definition of "Marihuana" already includes every possible form of natural THC that could be of concern, since it includes

[3] DEA itself in its "Interpretive Rule" states that prior to the CSA, "THC" under the Bureau of Narcotic and Dangerous Drugs (BNDD) meant synthetic THC only, and that "Marihuana" under the 1937 Tax Act controlled natural THC as an extract of the resin. 66 *Fed. Reg.* at 51532. The same language of the BNDD carried forward into the DEA's current regulation of THC, as referring to "synthetic equivalents" only, not natural.

[4] DEA's reliance on *O Centro Espirita Beneficente Uniao de Vegetal v. Ashcroft*, 314 F.3d 463 (10th Cir. 2002), is entirely misplaced: that case involved the Religious Freedom Restoration Act and the question of whether plants constitute preparations arose under the 1971 UN Convention on Psychotropic Substances—not the CSA.

anything derived from the THC-containing resin, including the trace resin that could, in a hypothetical, theoretical sense, be extracted from the otherwise exempted stalk, seed and oil ("except the resin extracted therefrom," 21 U.S.C. §802(16)). DEA itself cites a definition of THC as a chemical "from hemp plant resin" DEA Opp. at 11 n. 8, demonstrating that Congress knew the drug agent, natural THC, was in the trace resin in making the exemption.[5] It is not surprising, therefore, that DEA's own regulation (prior to the Final Clarification Rule) covered only *"[s]ynthetic equivalents*" of the THC in marijuana, 21 C.F.R. §1308.11(d)(27) (emphasis added), or that courts have already interpreted the separate term "THC" in Schedule I to include only synthetic THC. *United States v. McMahon*, 861 F.2d 8 (1st Cir. 1988); *United States v. Wuco*, 535 F.2d 1200 (9th Cir. 1976).

Even if DEA could somehow interpret the word "THC" in CSA Schedule I to include natural THC, however, such an interpretation would be irrelevant to the issue at hand. DEA is not free to "interpret" this word so as to control the specific substances—hemp stalk, seed and oil—that Congress expressly and specifically excluded from control in the wording of the CSA. That is particularly true given that the preamble to each term in Schedule I(c) states, "Unless specifically

[5] DEA itself recognized that the CSA plainly does not currently control hemp seed or oil notwithstanding trace amounts of naturally occurring resin/THC. In an April 18, 1991 affidavit, Charles M. Metcalf, a Senior Investigator of the DEA, stated: "The DEA does not consider sterile marijuana seed … to be a controlled substance, whether or not it contains residue or particulate matter which tests positive for the presence of THC." *HIA v. DEA*, No. 01-71662, Pet. Excerpts of Record at 23 (9th Cir., filed Jan. 7, 2002).

excepted…." Hemp stalk, seed and oil are, of course, specifically excepted in the definition of "Marihuana." DEA claims that "specifically excepted" refers only to substances that DEA has exempted by regulation under 21 U.S.C. §811(g); but DEA cites no authority for this limiting construction and there is none.

For these reasons, DEA's rule is not entitled to *Chevron* deference; it is, rather, a CSA scheduling action taken in contravention of Congressionally-mandated procedures for adding substances to CSA Schedule I. Petitioners are therefore likely to prevail on the merits.

II. Petitioners Have Established Irreparable Injury

DEA contends that Petitioners have not established that they will suffer irreparable injury because they are "uncertain about whether their products contain any THC." DEA Opp. at 17. Contrary to DEA's assertion, Petitioners' declarations do not merely state their products "may" contain THC (*id*. at 16); to the contrary, these producers of hemp seed and oil products have stated that these products do contain THC, but below a certain level of detection. *See, e.g*., Rothenberg Dec. Urgent Motion Ex. 4 ¶6 ("Atlas's hemp seed oil contains less than 3 parts per million of THC"); Stephens Dec. Urgent Motion Ex. 5 ¶5 ("Nature's Path products contain less than 1 parts per million of THC"); House Dec. Urgent Motion Ex. 7 ¶6 ("Hempzels Pretzels contain non-detectable amounts of THC"); Laprise Dec. Urgent Motion Ex. 8 ¶6 ("Kenex's hemp seed, oil and nut

contain less than 4 parts per million of THC and in some cases less than 1 part per million").

That Petitioners' products contain such miniscule amounts of THC as to be below a certain level of detection is small comfort given DEA's statement, in the Final Exemption Rule, DEA 206-F, issued together with the Final Clarification Rule, that:

> [U]sing currently available analytical methodologies and extraction procedures, it is reasonable to reproducibly and accurately detect THC at or below 1 part per million in cannabis bulk materials or products. Should more sensitive assays and analytical techniques be developed in the future, DEA will refine its testing methods accordingly.

Final Exemption Rule, Urgent Motion Ex. 2, 68 *Fed. Reg*. 14119 at 14124 (March 21, 2003). In fact, no producer can truthfully state that its products contain "zero" THC, without referencing the limit of detection ("LOD") of the method used for the laboratory analysis. As explained in the Declaration of Gero Leson, attached hereto as Ex. 2 ("Leson Dec."), THC will invariably be found if a method achieving a sufficiently low LOD is used.

DEA cites a letter from the president of Ruth's Hemp Foods, one of the Petitioners, stating that "no THC can be detected" in the hemp used in her products. In fact, as explained in the Supplemental Declaration of Ruth Shamai, attached hereto as Ex. 3, she was indeed referring to THC being present below the applicable level of detection. Likewise, the statements of The Hemp Food

Association, a promotional vehicle of HempNut Inc., relied on by DEA to the effect that this company's products contain no THC and DEA's Final Clarification Rule is correct and consistent with past practice, DEA Opp. at 16, are baseless. As explained in the Penn Dec. Ex. 1, ¶ 5, and the HIA Position Paper attached thereto, trace amounts of THC were actually found in HempNut's own products.

When DEA's final rule becomes effective, the possession, sale, manufacture and importation of hemp seed and oil products will become a crime. It goes without saying that no one will buy Petitioners' products at that point. It is clear that, unless the rule is stayed, the industry will disappear while the Petition for Review is pending. *See* Penn Dec., Ex. 2 ¶ 6. For this reason, Petitioners will suffer irreparable injury in the absence of a stay.

III. A Stay Would Not Be Detrimental to the Public Interest

Manifestly Petitioners are not, as DEA suggests, asking this Court to "nullify an Act of Congress." DEA Opp. at 18. To the contrary, Petitioners are asking this Court to *enforce* an Act of Congress--namely, 21 U.S.C. §§811(a) and 812(b), the statutory provisions that require certain findings to be made, and a hearing to be held, before a new substance is added to Schedule I of the CSA. No one is asking this court to "enjoin DEA from enforcing the CSA," DEA Opp. at 19; rather, Petitioners are asking the Court to enjoin DEA from amending the CSA without following the procedures, and making the findings, that Congress has established as a prerequisite to such regulatory amendment.

Nowhere in DEA's Opposition is there any suggestion that continuing the current legal status of hemp seed and oil will pose any threat whatsoever to public health or safety—to the "health and general welfare of the American people" that the CSA is designed to protect, DEA Opp. at 19, citing 21 U.S.C. §801(2). In these circumstances, where a stay would not be detrimental to the public interest and is necessary in order to prevent absolutely irreparable harm, the balance of hardships favors the Petitioners.

CONCLUSION

For the reasons stated above, and in Petitioners' Urgent Motion for Stay filed March 28, 2003, the Urgent Motion should be granted and DEA's Final Clarification Rule should be stayed pending review of that rule by this Court.

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Dated: April 14, 2003

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	)	

DECLARATION OF CANDI PENN

1. I, Candi Penn, serve as Executive Director of Petitioner Hemp Industries Association (HIA). I make this Declaration in reply to the Opposition of DEA to Petitioners' Urgent Motion for Stay Pending Review in this appeal. Contrary to DEA's assertions, hemp oil and foods have been on the U.S. market since 1989. When a company signs up as a member of our trade group, we ask for the date that they first began selling hemp products.

2. Hemp seed and fiber have been imported into the US every year since the Marihuana Tax Act passed in 1937, and since the CSA was enacted in 1970. The traditional market for hemp seed was for birdseed, where it was recognized as second to none in promoting healthy plumage and overall development. This is because of hemp seed's extraordinary content of omega 3 and omega 6 Essential Fatty Acids (EFAs), along with a well-balanced protein content second only to soy in the vegetable kingdom.

3. In the last twenty years, the scientific and health communities have increasingly emphasized the importance of consuming enough omega 3, in which our American diet is chronically deficient. The traditional American omega 3 source for human consumption was deep sea fish oil; however, hemp seed and oil have been consumed as a nutritious food around the world by diverse peoples for millennia, and given its preferable bland nutty flavor profile, hemp seed and oil products were introduced beginning in 1989 to fill the demand for a tastier source of omega 3 that could actually be incorporated into foods without sacrificing taste. Hemp seed and oil is also preferable because of concerns about mercury and other environmental toxins

in fish oils. The hemp food market has been rapidly growing every year since 1989, and DEA's characterization that hemp foods have only been on the market for a few years is inaccurate. American consumers have been exercising their ability to consume highly nutritious hemp seed and oil for over a decade, and hemp foods are sold in virtually every health food store in North America, including Trader Joe's, Whole Foods, Wild Oats, and other major chains. Below is a list of notable North American hemp food companies, most of whom are still current members of the HIA manufacturing and marketing hemp foods, with the year they first marketed their hemp food products.

USA

The Ohio Hempery	1989
Original Sources	1990
Boulder Hemp Company	1993
HempNut, Inc.	1994
Hungry Bear Hemp Foods	1994
Nutiva	1995
Hempzel Pretzels	1996
Pacific Hemp Assoc.	1996
Galaxy Global Eatery	1997
Cary Randall	1997
Food Art	1997
Frederick Brewing	1997
Humboldt Hemp Foods	1998
Humboldt Brewing Co.	1999
Govinda's Inc.	1999
Nature's Path, USA	2000
Alpsnack Bar	2001
French Meadow Bakery	2001
Kraftsmen Baking	2002

Canada

Mama Indica's Treats	1992

Hempola, Inc.	1995
Cool Hemp Company	1996
Boom Bar	1996
Kenex, Ltd	1998
Hemp Oil Canada, Inc.	1998
Purity Hemp Products	1999
Ruth's Hemp Foods	2000
Fresh Hemp Foods	2001
HMG Sales	2001

4. To clarify briefly on behalf of HIA member company and fellow petitioner Dr. Bronner's Magic Soaps (in place of a separate declaration), HIA member Alpsnack was Gertrude Spindler's business which formulated and marketed the Alpsnack nutrition bar containing hemp nuts in the US starting in 2001. (Gertrude grew up in Switzerland, where her mother made nutritious nut snacks like Alpsnack in the difficult post-WWII famine years.) Dr. Bronner's Magic Soaps subsequently invested in the exclusive rights to all trademarks, assets and recipes of Alpsnack, in order to develop and market a completely certified organic version of the Alpsnack based on Gertrude's recipes. Although market roll-out of the certified organic Alpsnack nutrition bar under the name "Gertrude and Bronner's Magic Alpsnack" is scheduled for late May this year, the original Alpsnack bar has been on the market since early 2001.

5. DEA relies on statements by former HIA member company HempNut and HempNut's promotional vehicle, the Hemp Foods Association ("HFA"). "Association" is a misnomer as HempNut's president is the sole director of HFA, and none of the major hemp food companies listed as members on the HFA site in fact want to be listed: HempNut/HFA does not speak for a single other North American hemp food company. HempNut/HFA was removed in 2002 from the HIA for misleading the marketplace and slandering competitor companies vis a vis trace insignificant THC content. In particular, HempNut's hemp oil was tested for THC at two Health Canada certified Canadian laboratories and was actually found to contain THC in concentrations significantly higher than those found in oils by any Canadian supplier. Attached as Exhibit 1 to this declaration is HIA's position paper posted for distribution to address any confusion HempNut/HFA's statements had caused in the marketplace and media, specifically Section II regarding unqualified "zero THC" and "no THC" claims. Attached as Exhibit 2 to this

declaration is the HIA's TestPledge program, which reassures consumers that ingesting TestPledge compliant hemp products cannot cause a work-place confirmation drug-test even with unrealistically extensive daily consumption of hemp food products. HempNut resigned from the TestPledge program shortly before HempNut's hemp oil product was tested by the two Canadian laboratories and found in violation of the 5 ppm TestPledge limit for hemp oil.

6. If DEA's Final Clarification Rule (DEA-205F) becomes effective, the existing legal trade in edible hemp seed and oil products—and importation of hemp oil for use in non-edible products such as personal care and body care items—will all become criminalized. In these circumstances, no one will purchase Petitioners' products and the industry will collapse well before this Court has an opportunity to address the merits of our Petition for Review of the DEA's rule.

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 April, 2003.

_____

Candi Penn

UNITED STATES COURT OF APPEALS
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	)	

DECLARATION OF GERO LESON

1. My name is Gero Leson. I submit this Declaration in support of the Petitioners' Urgent 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".

- Coordination of the THC analysis of various hemp seed items for evaluation of claims made by manufacturers.

3. In its "Opposition to Petitioners' Urgent Motion for Stay Pending Review" the Drug Enforcement Agency (DEA) states that "…it is uncertain whether petitioners' food products actually contain THC". Based on my experience with the analysis of hemp seed products, it is in fact certain that many, if not all such products contain measurable amounts of THC, provided a sufficiently low limit of detection (LOD) is used. Testing of hemp seeds and oil for THC required under Canadian law, or conducted by Canadian suppliers for research purposes, routinely finds THC present at levels of 1-2 parts per million (ppm equals milligram per kilogram) if an LOD lower than the 4 ppm currently specified by Health Canada is used. In my opinion, to date, virtually 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. Based on my discussions with Canadian suppliers of hemp seeds and hemp food products, their declarations of "no" or "no detected" THC are in reference to the applicable limit of detection (LOD), i.e. the 4 ppm specified by Health Canada. These suppliers do not claim that their products do not CONTAIN any THC, but rather that it cannot be detected using the Health Canada LOD. Notably, this is the case with the January 31, 2000 letter by Ruth Shamai, president of Ruth's Hemp Foods, which is appended to the DEA's "Opposition to Petitioners' Urgent Motion for Stay Pending Review"

5. During the course of its rule making on "Products and Materials Derived from the Cannabis Plant" the DEA has repeatedly cited statements by Mr. Richard Rose, president of HempNut Inc. and director of Hemp Food Association. These statements suggested that hemp seed products marketed by "…all responsible hempseed importers" in fact do not contain any THC. To evaluate these claims, I purchased in February of 2002, at the request of the HIA, several samples of hemp oil and hulled hemp seeds of the HempNut brand in retail stores in

California. Identical unopened samples were submitted concurrently to two analytical laboratories in Canada, certified by Health Canada to conduct analysis of hemp products for THC. Additional samples of the same product lots were purchased by an independent auditor and kept in safe storage. The two labs found THC levels in HempNut Inc.'s hemp oil to be significantly higher than any hemp oil of Canadian origin whose THC concentrations I have had access to. THC levels in HempNut Inc.'s hulled hemp seeds were comparable to THC levels in other hulled seeds available in the market. This evaluation belies Mr. Rose's claims that his hemp seed products "do not contain any" or "contain zero" THC.

6. 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 if ever 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.

7. Hemp seeds and their derivatives account for only a fraction of many commercially available hemp food products, which effectively dilutes their THC content. Thus, 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. Three of the analytical methods referenced by the DEA for THC analysis appear to be sufficiently sensitive to detect THC at levels of less than 100 parts per billion and would thus find THC in the majority of hemp seed derivatives and a considerable fraction of finished hemp food products currently available in the U.S. market (Final Exemption Rule, Urgent Motion Ex. 2, 68 Fed. Reg. 14119 at 14124 (March 21, 2003).

8. Thus, in my opinion, the language of the DEA's final clarification rule ("...any product that contains *any amount* of THC...") would render virtually all 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 implicit qualification by an analytical LOD, appear to be misleading, if not patently false.

9. 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. 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.

10. 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). For less acutely toxic compounds, such as the trace alcohol in fruit juices present through natural fermentation, FDA considers up to 0.5% to be "non-alcoholic."

11. 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. 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. Tolerance adoption for a specific pesticide invariably involves public review and extensive comment. 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.

12. 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 above referenced assessment of the human health risk from THC in "hemp foods" has shown that 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.

13. The failure to adopt 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 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 THC limits consistently and verifiably with their suppliers of hemp seeds and oil.

14. In my opinion, the U.S. FDA as the federal agency charged with regulating food quality in the U.S. is also the proper agency to set science-based standards for THC in hemp food products. According to my knowledge of the industry, virtually all relevant hemp food producers

and distributors in North America have taken measures to reduce trace THC residues in their products to be able to consistently meet rational numerical regulatory limits for trace THC under the industry's TestPledge program (http://www.TestPledge.com), to address consumer fears regarding the potential impacts of hemp food consumption on workplace drug-testing. 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, 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 community.

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 April, 2003.

_____

Gero Leson