FACSIMILE SHEET

UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
OFFICE OF CHIEF COUNSEL

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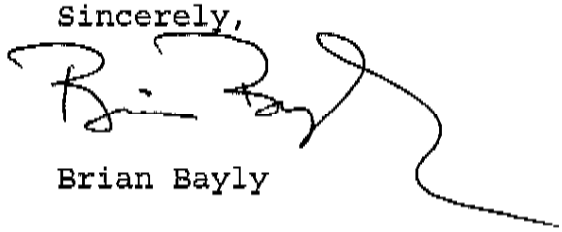
COMMENTS:

Lyle E. Craker, Ph. D., Docket No. 05-16

Julie- Enclosed is a copy of DEA's response to your motion to exclude. I'm also filing a very short supplemental prehearing statement, which seeks to admit Dr. ElSohly's c.v., which is 39 pages.

I apologize that I have to fax these yto you , but I missed our courier deadline. We'll follow with hard copies.

Sincerely,



Brian Bayly

UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

IN THE MATTER OF	)	
	)	**Docket No. 05-16**
	)	
Lyle E. Craker, Ph.D.	)	
	)	

GOVERNMENT'S RESPONSE TO RESPONDENT'S MOTION TO EXCLUDE SOME OF GOVERNMENT'S PROPOSED TESTIMONY AND EXHBITS

The Government, by and through the undersigned attorney, respectfully submits its response to "Respondent's Motion to Exclude Some of Government's Proposed Testimony and Exhibits."

A. Response to Respondent's First Contention: "The Government's Proposed Evidence Regarding Medical Organizations' Support for Medical Marijuana Research is Irrelevant"

i. Government Exhibits 46 and 60 must be admitted as rebuttal evidence

Respondent objects to the admissibility of Government Exhibit (G-) 46, which contains various positions about marijuana by the American Medical Association (AMA). Respondent also objects to the admissibility of G- 60, which is a letter from the Iowa Board of Pharmacy Examiners to an Iowa State Senator. The letter reviews medical marijuana literature and gives reasons why the Pharmacy Board opposes "marijuana for therapeutic purposes." (G-60, pg. 1)

Respondent seeks to exclude this evidence "... because it pertains to whether the health benefits and risks of medical marijuana should be the subject of further research. The ALJ has already acknowledged that this research is ongoing

and excluded this issue from the hearing. (Memorandum and Ruling, at 3-4)." (Respondent's Motion to Exclude at pg. 3)

If the contested evidence were limited only to Respondent's above quoted premise, the Government would agree that G-46 and G-60 should be excluded from evidence. Indeed, G-46, the AMA position statements, endorses further research into potential uses of marijuana. (G-46, pg. 1, ¶ 16, pg. 3, ¶ 4) and G-60, the Iowa Board of Pharmacy Examiners' letter, indicates that it does not oppose further research into the medical use of marijuana. (G-60, pg. 5, ¶ 2)[1]

However, these exhibits should be admitted as rebuttal evidence to the testimony of Richard Doblin, Ph.D., (Dr. Doblin) the sponsor of Dr. Craker and Dr. Craker's application to manufacture (cultivate) marijuana. (Tr.- 579-580) Specifically, Dr. Doblin testified that marijuana has been accepted by qualified experts who accept marijuana as medicine. (Tr.- 622, l. 4-6) The AMA position statements would rebut Dr. Doblin's testimony because these statements do not endorse marijuana as medicine. (G-60, pg. 1, ¶ 2, pg. 2(1), pg. 3, ¶¶ (1) and (2); pg. 4(1). The Iowa Board of Pharmacy Examiners' letter highlighted all the unknown and deleterious qualities of cannabis and, in so doing, did not endorse marijuana as medicine. (G-60, pg 1-2, ¶ 2; pg. 3. ¶¶ 5-6, 8, 10-11, pg. 3-5, ¶ 13, pg. 4, ¶16-18) The AMA position statements (G-46) should be admitted to rebut Dr. Doblin's aforementioned testimony as well.

[1] Indeed, while the parties agree that marijuana research should continue, the Government disagrees with Respondent's attempt to circumvent the present system that permits research under HHS.

Moreover, Respondent, during cross-examination was asked some questions pertaining to R-24, which is an AMA report about "Medical Marijuana." (Tr.- 627-628) In light of this cross-examination, it would not be appropriate to exclude G-46.

ii. Testimony pertaining to whether marijuana is accepted by qualified experts

Pursuant to the "Memorandum to Counsel and Ruling on Motion in Limine," dated August 12, 2005, the ALJ excluded from evidence, *inter alia*, Respondent's Exhibit (R-) 22, Doblin & Kleiman, *Marijuana as Antiemetic Medicine: A Survey of Onocologists' Experiences and Attitudes*, 9 J. Clin. Oncol. 1314-1319 (1991). Prior to the ALJ's ruling, the Government listed "Schwartz, Richard H., M.D., and Voth, Eric, A., M.D., Sheridan, Michael J., Sc. D., *Marijuana to Prevent Nausea and Vomiting in Cancer Patients: A Survey of Clinical Oncologists*, Southern Medical Journal, Vol. 90, No. 2, February 1997" as an exhibit. (G-42) The Government intended that this article be admitted to rebut the Doblin & Kleiman article, R-22. In light of the ALJ's August 12, 2005 ruling, the Government decided not to offer this article into evidence because it would not be necessary to rebut R-22.[2]

The subject matter of R-22, however, was mentioned several times during the testimony of Dr. Doblin. During direct examination, Dr. Doblin was asked how his organization (MAPS) became involved in medical marijuana research.

[2] Prior to seeing Respondent's "Motion to Exclude ...," Government counsel informed Respondent's counsel that the Government would be withdrawing certain Government exhibits, which included G-42.

(Tr.- 490, l. 9-11) Dr. Doblin answered, in part, that "... it started really, I'd say, with my survey of oncologists which I did in '89-90, and that showed me that there was substantial support in the medical community for the use of marijuana for nausea control for cancer chemotherapy." (Tr.- 490, l. 12-16) During cross examination, Dr. Doblin testified that "... there are qualified experts who accept marijuana as medicine." (Tr.- 622, l. 4-6)

Although the Government believes that G-42 should not be admitted unless R-22 is admitted, Dr. Voth should be allowed to testify about the issue of substantial expert support for the use of "medical" marijuana in light of the above-cited testimony. G-60 should be admitted to rebut the latter cited testimony of Dr. Doblin based upon the following.

The Iowa State Board of Pharmacy Examiners' letter (G-60) mentions the Doblin & Kleiman article (G-22), and in the same paragraph, it mentions two sources that critique the Doblin & Kleiman article. (G-60, pg. 3, ¶ 12) The first critique states: "In response, Richard H. Schwartz, M.D., has stated the following: 'I calculate that the "majority" can be no more than 15% to 20% of the original sample and is probably much less.'" *Id.*[3] This same comment notes that a letter from Sandra S. Bennett of the Oregon Federation of Parents for a Drug

Free Youth was critical of the Doblin & Kleiman article because the article failed to disclose Dr. Doblin's relation to MAPS and MAPS' drug agenda. *Id.* In the summary conclusions of the Iowa State Board of Pharmacy Examiners' letter, it mentions these critiques of the Doblin & Kleiman. (G-60, pg. 5, 2nd ¶ under summary)

The Government submits that the aforementioned evidence contained in G-60 should be admitted to rebut the testimony of Dr. Doblin cite herein.

iii Dr. Voth's testimony would be limited to rebuttal only

Respondent argues that Dr. Voth's testimony should be excluded to the extent that it pertains to "... the stance of various medical organizations about medical marijuana." (Respondent's Motion to Exclude at pg. 3, ¶ 3) The Government agrees that there should not be any testimony permitted or considered that pertains to organizations that agree or disagree with "...whether the health benefits and risks of medical marijuana should be the subject of further research." *Id.* However, Dr. Voth should be able to testify that he disagrees with Dr. Doblin's characterizations that marijuana has been accepted as a medicinal drug by qualified experts. (Tr.- 622, l. 4-6)

[3] It is conceivable that this letter was the precursor to the article by Dr. Schwartz and Dr. Voth that rebutted the Doblin & Kleiman study. (G-42; R-22)

B. Response to Respondent's argument that "The Government's Proposed Evidence Regarding the Needs of a Marijuana Manufacturer to bring a Pharmaceutical Drug to Market is from an Unqualified Expert"

Under this argument, Respondent contends that Dr. Voth should not be allowed to testify about the need for another manufacturer because no pharmaceutical company would develop a marijuana medical product without a marijuana supply to insure consistency of dose. (Respondent's Motion to Exclude at pg. 4, ¶ 1) Respondent maintains that this evidence should be excluded because Dr. Voth is not "qualified" to testify about research or developing new drugs. *Id.*

The Government agrees that this proffered testimony should be excluded but not based on the ground that Dr. Voth is not "qualified." The Government submits that the "Memorandum to Counsel and Ruling on Motion in Limine," dated August 12. 2005, precludes this evidence from being introduced.

The Government submits that Dr. Voth can and should testify in rebuttal to Dr. Doblin's testimony that marijuana's chemistry is known and reproducible (Tr.- 621, l. 6-15) and that scientific evidence is widely available about marijuana. (Tr.-

622, l. 6-10) Thus, the Government's disagreement with Respondent's unsupported characterization of Dr. Voth as "unqualified."

First, as a medical practitioner, Dr. Voth is at least as qualified as Dr. Doblin to testify about marijuana. Second, as revealed by Dr. Voth' C.V. (G-36), Dr. Voth has developed a long-standing and comprehensive expertise about marijuana. The Government will proffer Dr. Voth's qualifications during the hearing, so it may premature to rule that Dr. Voth is "unqualified" to testify about the issues on rebuttal.

C. Response to Respondent's argument that "The Government's Proposed Evidence Regarding the Potential Harms of Marijuana Use" should be excluded

Respondent seeks to exclude various exhibits (G-41, 48-50) as well as any testimony of Dr. Voth pertaining to whether marijuana is "viable medicine" and whether the effects of smoking or inhaling the marijuana plant material can result in deleterious health effects. (Respondent's Motion to Exclude at pg. 4, ¶ 2)

First, Respondent maintains that the Administrative Law Judge's (ALJ) Ruling in regard to the Government's Motion in Limine precludes such evidence, i.e., the parties are not permitted

to introduce evidence whether or not marijuana has potential as a prescription medication. (Respondent's Motion to Exclude at pg. 4-5, ¶ 2)

Indeed, the ALJ's ruling found that "... evidence pertaining to marijuana's therapeutic uses is irrelevant to the issue of whether Respondent's registration would be consistent with the public interest." (Memorandum to Counsel and Ruling on Motion in Limine, pg. 4) Consequently, the Government agrees that the costs/benefits of any potential medicinal marijuana are not relevant issues to these proceedings. Such issues are best litigated under 21 U.S.C. § 823(f), as the ALJ explained in her ruling on the motion in limine. (Memorandum to Counsel and Ruling on Motion in Limine, pg. 3-4) In addition, the Government submits that the issues herein should not include second guessing FDA's or HHS' approval of any INDS or research protocols.

Respondent's argument goes well beyond the ALJ's ruling, however, by arguing that any evidence regarding the diversion of marijuana is, likewise, irrelevant because "... the possibility of diversion for other than legitimate purposes is already established by statute." (Respondent's Motion to Exclude

at pg. 5, ¶ 2) Respondent continues the argument by asserting "... evidence relating to the harmful effects of non-medical marijuana use *generally* is simply not relevant to whether granting *this* application- in which Dr. Craker seeks to grow and distribute medical marijuana for FDA-approved research, which, by definition, means the FDA has already considered and passed on the safety of such use- would somehow undermine the DEA's effective controls." (Respondent's Motion to Exclude at pg. 5-6, ¶ 2) [footnote omitted]

The Government submits that the wide-spread abuse of illicit marijuana is relevant and should be admissible. Additionally, the potential for diversion of the marijuana, whether at the source where it is cultivated or downstream after it is distributed from the cultivator (manufacturer) to researchers, research subjects, should be considered.

Title 21 U.S.C. § 823(a)(1) mandates that DEA limit Schedule I and II controlled substance manufacturers to a number of manufacturers who can produce an adequate and uninterrupted supply under adequately competitive conditions in order to ensure "maintenance of effective controls against **diversion**." (Emphasis

supplied.)[4] While Respondent may profess that any marijuana produced and distributed downstream will not be diverted, evidence that shows the amount and extent of abuse of marijuana surely could negate such a claim. Adding another marijuana manufacturer increases the potential illicit, as well as the licit, supply. Thus, the amount or extent of current abuse is very relevant.

In *Johnson Matthey, Inc., Approval of Registration*, 60 Fed. Reg. 26.050, 26,052 (1995), part of the findings in relation to Section 823(a)(1) and diversion were as follows:

> The administrative law judge found that there is insufficient evidence in the record to make any findings as to 21 U.S.C. 823(a)(1). Judge Bittner, referring to the legislative history of the Controlled Substances Act, concluded that 21 U.S.C. 823(a)(1) contemplates that the concern for diversion of controlled substances would determine the maximum number of manufacturers to be registered and, similarly, that concern for insuring an adequate and uninterrupted supply of the same substances would determine the minimum number. However, in the instant case, the administrative law judge found that there is no evidence that registering an additional bulk manufacturer would increase the risk of diversion, nor is there evidence that the two bulk manufacturers currently registered to manufacture methylphenidate are incapable of assuring an adequate supply of the drug.

[4] Title 21 U.S.C. § 823(a)(5) mentions the applicant's past experience and "the existence in the establishment of effective control against diversion." This provision pertains to diversion control based upon the individual manufacturer while Section 823(a)(1) pertains to downstream diversion. Both sections explicitly mention "diversion," and such references belie Respondent's claim that diversion of marijuana is irrelevant.

The above finding in the *Johnson Matthey* final order is a clear indication that DEA does consider the consequences of downstream diversion when assessing Section 823(a)(1).

There is a large number of Schedule I controlled substances that are defined by statute that have a high potential for abuse." 21 C.F.R. § 1308.11; 21 U.S.C. § 812(b)(1)(A). Undoubtedly, if Respondent were seeking to manufacture one of these more obscure Schedule I controlled substances for research purposes, he would argue that such an application should be granted because there would be less diversion potential than there would be for marijuana. The statute may define the controlled substance, but the statute alone cannot address the amount of potential diversion.

Furthermore, the record reflects that Dr. Craker intends to produce and distribute the plant material, as opposed to extracts, of marijuana. (Tr.- 38, l. 1-14; 44-45, l. 2—22, 1-3; 67-68, l. 18-22, 1-8; 231, l. 1-7) Thus, testimony that marijuana is predominantly abused in its plant form, as opposed to extracts, must be relevant. Under this analysis, the deleterious effects of marijuana abuse also should be relevant as well as the extensive abuse rate of marijuana.

Conclusion

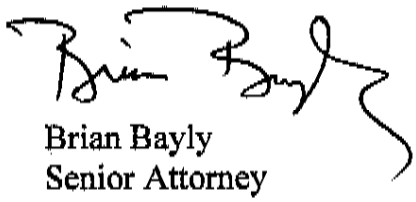
Based upon the foregoing, the Government respectfully requests that the ALJ issue an Order that:

(1) Limits G-46, G-60 and Dr. Voth's testimony for rebuttal purposes only and not admit the documents or Dr. Voth's testimony for the purpose of criticizing marijuana research.

(2) Not permit Dr. Voth to testify about the need for another manufacturer because no pharmaceutical company would develop a marijuana medical product without a marijuana supply to insure consistency of dose. Related testimony from Dr. Voth, however, should be admitted to rebut the testimony of Dr. Doblin.

(3) Exclude various exhibits (G-41, 48-50) as well as any testimony of Dr. Voth pertaining to whether marijuana is "viable medicine" but allow testimony pertaining to the amount of diversion of marijuana and allow testimony about the health effects related to marijuana abuse.

Respectfully submitted,



Brian Bayly
Senior Attorney
Office of Chief Counsel

Dated: October 20, 2005

CERTIFICATE OF SERVICE

On October 20, 2005, I sent, via facsimile machine (202) 661-4810, a copy of the foregoing to counsel for Respondent, Julie M. Carpenter, Esq., Jenner & Block, Washington, D.C., and filed the original and two copies of the foregoing at the DEA Office of Administrative Law Judges by hand delivery.

Brian Bayly