

UNITED STATES DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

IN THE MATTER OF

LYLE CRAKER, PH.D.

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Docket No. 05-16

**GOVERNMENT'S RESPONSE TO RESPONDENT'S
POST-FINAL ORDER MOTIONS**

The Government, by and through the undersigned attorney, responds to two motions that Respondent submitted after the Final Order was issued. The first is Respondent's "Request for Opportunity under 5 U.S.C. § 556(e) to Respond to New Officially Noticed Evidence and Motion for Reconsideration," submitted on January 30, 2009, (hereinafter "First Request"). The second is "Respondent's Supplemental Brief in Support of Request for Opportunity under 5 U.S.C. § 556(e) to respond to New Officially Noticed Evidence and Motion for Reconsideration," submitted on March 11, 2009 (hereinafter "Supplemental Brief").¹

Since the Deputy Administrator took official notice of certain facts in the Final Order, the Deputy Administrator allowed Respondent to file a response to have "an opportunity to show the contrary" to such officially- noticed facts. 5 U.S.C. § 556(e).

¹ On February 9, 2009, the Deputy Administrator issued an Order accepting Respondent's First Motion. On the same date, the Deputy Administrator allowed Respondent to submit its Supplemental Brief by March 11, 2009, allowed the Government to respond by March 26, 2009, and extended the effective date of the Final Order until April 1, 2009. The Government asked the Deputy Administrator to extend the time to file its response and extend the effective date of the Final Order. By Order, dated March 26, 2009, the Deputy Administrator allowed the Government to file its response by April 13, 2009, and extended the effective date of the Final Order until May 1, 2009.

Respondent's Supplemental Brief incorporated all the arguments submitted in his First Request. (Supp. Brief pg. 1, n.1) The Government's response answers Respondent's objections in the order that they appear in Respondent's First Request but cites and responds to the Supplemental Brief as well. Respondent added one issue and two exhibits in its Supplemental Brief that was not in its First Request. That issue is addressed last in this response.

Issue 1

Respondent maintains that the Deputy Administrator "dismissed" evidence relating to one researcher's (Dr. Russo) inability to obtain marijuana from NIDA for its privately funded research project because the proposed study was rejected before HHS and NIDA changed its policy in May 1999. (First request pg. 4)

In relation to Dr. Russo's study and other studies, the Final Order found:

Bearing in mind that Respondent had the burden of proving any proposition of fact that he asserted in the hearing, 21 CFR 1301.44(a), nothing in Mr. Doblin's testimony, or any other evidence presented by Respondent, established that HHS denied Dr. Russo's request for marijuana under the new procedures implemented by the agency in 1999. Indeed, Respondent produced no evidence showing that HHS has denied marijuana to any clinical researcher with an FDA-approved protocol subsequent to the adoption of the 1999 guidelines

(F.O. pg. 25-26)

Respondent seeks new evidence, found on MAPS website, to show that the Russo study was denied after May 1999 under the new guidelines. (Supp. Brief pg. 13 and Exhibit C)

Respondent attempts to justify this new evidence on the rationalization that since the Deputy Administrator took judicial notice of material on MAPS website relating to

Dr. Abrams, then the Deputy Administrator should take judicial notice of MAPS website relating to Dr. Russo. (First Request 4-5)

Respondent does have a right to challenge officially noticed material, but this right surely does not extend to allowing Respondent to add new evidence because it was in physical proximity to officially noticed evidence. Just because the Deputy Administrator took official notice of documents related to Dr. Abrams does not give Respondent the right to add evidence on an entirely new topic, i.e. the issues relating to Dr. Russo.

As the Deputy Administrator noted in the quote above, it was Respondent's burden to demonstrate that Dr. Russo's protocol was denied prior to the new guidelines being implemented in 1999. The Deputy Administrator's finding herein is based on the evidence in the record and not on any officially noticed evidence. As such, Respondent should not be allowed belatedly to bolster his case.

In *Robert M. Golden, M.D., Revocation of Registration*, 61 Fed. Reg. 24,808, 24,812 (1996), the Deputy Administrator held that a party had a heavy burden to introduce newly discovered evidence, and such evidence had to be unavailable and relevant to the matters in dispute. Given the dates of the material now proffered by Respondent to be admitted into evidence, Respondent's request runs afoul of the *Golden* standard.

Moreover, the proffered February 1, 2000 response letter to Dr. Russo explicitly invites Dr. Russo to resubmit his protocol. (Supp. Brief Exhibit C) To conclude that marijuana is not available for research based on this letter is highly dubious because Dr.

Russo could have re-submitted his protocol, there is no evidence that the denial of the protocol is incorrect and DEA has no legal authority to overrule HHS/NIDA policy.

Issue 2

One of Respondent's themes was that NIDA, through its peer review system, denied giving NIDA marijuana to researchers because NIDA did not find that their protocols had merit. (Respondent's Proposed Findings pg. 41-43²; Supp. Brief pg. 11). Because Respondent believes this system stymies research because NIDA review is an extra step that marijuana researchers must undertake that other researchers do not have to take, the "supply" of marijuana is unduly limited. (Supp Brief pg. 9-10)

One of the researchers whose protocol was denied by NIDA was Dr. Donald Abrams. (Supp. Brief pg. 11-12) The Deputy Administrator took official notice of an April 19, 1995 letter from NIDA, authored by Dr. Alan Leshner, to Dr. Abrams. (F.O. 23, n. 24; 86, n. 84) This letter denied Dr. Abrams' original request for NIDA marijuana to conduct research. *Id.* The Final Order noted that, although NIDA denied Dr. Abrams' initial request for NIDA marijuana due to design and scientific issues with his protocol, Dr. Abrams restructured his protocol, which NIDA approved. (F.O. pg. 86, n. 84)

Respondent now proffers testimony of Dr. Abrams and Dr. Leshner to show that the protocol only was approved after it was revised to explore harms of marijuana instead of benefits in treating AIDS wasting syndrome. (First request pg. 8; Supp. Brief pg. 12)

² "Proposed Findings" refer to Respondent's Proposed Findings of Fact, Conclusions of Law and Argument.

Respondent also proffered the testimony of Dr. Doblin to rebut the Leshner letter. (First request pg. 8) Respondent also asks the Deputy Administrator to take official notice of Dr. Doblin's critique in the Leshner letter found on MAPS website. (First request pg. 8, www.maps.org/mmj/ricklesh.html)

First, Respondent should not be heard on this issue because Dr. Abrams' revised protocol was accepted by NIDA. (F.O. pg. 23-24, n. 25) Certainly, Dr. Abrams could have challenged NIDA's reasons for denying the initial protocol and could have pursued remedies with HHS/NIDA to have his first protocol accepted. Thus, Dr. Abrams has waived any issue challenging the first protocol, and Respondent should not have any standing to resurrect this issue with new evidence. Moreover, the fact that Dr. Abrams chose to revise his protocol and that NIDA accepted his revised protocol makes Respondent's request to re-open this hearing on this issue superfluous.

Second, under any circumstances, no testimony from Dr. Doblin should be allowed. The record reflects that Dr. Doblin does not have the qualifications to critique the underlying reasons why the Chemic studies were rejected by the NIDA peer review group. Dr. Doblin has no degree in pharmacology, biochemistry or botany; neither does he have a medical degree. (Tr.- 709, l. 9-15)³ Dr. Doblin never worked for HHS or any branch of this agency. (Tr.- 709-710, l. 20-22, 1-22) Dr. Doblin never has worked for a DEA registered pharmaceutical company. (Tr.- 711, l. 1-6) The Government is not aware that Dr. Doblin was ever qualified as an expert to critique the underlying validity of the protocols as is required under 21 C.F.R. § 1316.59(b).

Issue 3

The Deputy Administrator took official notice of two reports from Chemic Laboratories regarding the testing of the device known as the Volcano Vaporizer and a 2003 MAPS newsletter about the studies of this device. (F.O. 26-27, n. 30; 29, n. 32) Both these reports pertained to the ingesting marijuana through the Volcano Vaporizer.

Respondent argues: “The Deputy Administrator infers from, among other evidence, these officially noticed documents that ‘[i]f Chemic had a valid basis to challenge HHS’s denial of its request for marijuana, it presumably had remedies available to challenge the agency action either within HHS or in the courts ...**Respondent produced no evidence showing that Chemic has pursued any such remedies.**” (Emphasis supplied) (First request pg. 9; Supp. Brief pg. 13-14; F.O. 29, n. 33.)

First, even if the burden of proof was not on Respondent, DEA has absolutely no proof requirement to demonstrate what steps Chemic took to pursue its remedies with HHS/NIDA to have its protocol approved. Indeed, as noted at least three times in the Final Order, Respondent’s complaints about the NIDA protocol reviews should be made to HHS. (F.O. pg. 29, n. 33, 39, 82)

In any event, the Deputy Administrator did not take official notice of these reports from Chemic Laboratories to support its legal finding that Chemic’s remedies lie with (or against) HHS/NIDA and not DEA. Indeed, this legal conclusion does not need any factual support that is not already in the record. The Deputy Administrator took official

³ “Tr.” Refers to pages in the transcript of the administrative hearing.

notice of these reports to place in context Chemic's steps in attempting to obtain NIDA marijuana for its Volcano Vaporizer. (F.O. pg. 26-27 and n. 30.)

In addition, the record reflects that Dr. Doblin does not have the qualifications to critique the underlying reasons why the Chemic studies were rejected by the NIDA peer review group. Dr. Doblin has no degree in pharmacology, biochemistry or botany; neither does he have a medical degree. (Tr.- 709, l. 9-15) Dr. Doblin never worked for HHS or any branch of this agency. (Tr.- 709-710, l. 20-22, 1-22) Dr. Doblin never has worked for a DEA registered pharmaceutical company. (Tr.- 711, l. 1-6) The Government is not aware that Dr. Doblin was ever qualified as an expert to critique the underlying validity of the protocols as is required under 21 C.F.R. § 1316.59(b).

Dr. Steven Gust, testifying on behalf of NIDA, testified that NIDA would work with researchers to cure deficiencies and this goal would include Chemic. (Tr.- 1733-1734, 1739-1740, 1751-1752) Dr. Gust also testified that NIDA had approved many other protocols and that the scientific bar was set low to approve protocols. (Tr.- 1700, l. 18-20, 1740) In light of this testimony, new evidence about Chemic's further attempt to have its protocol approved would add little of value to the record.

Issue 4

As previously discussed, Respondent seeks to find that the "supply" is inadequate because three researchers were not able to obtain marijuana from NIDA because their protocols were deemed insufficient. Respondent now wants to add new evidence that other researchers would have submitted research protocols to DEA but were discouraged because of their beliefs that NIDA would reject their protocols. (Supp Brief pg. 14) This

evidence purportedly would show that NIDA is too strict with its protocols, and, therefore, there is a lack of supply of marijuana.

The Government objects to this “new evidence.” Speculative testimony from other researchers that they were discouraged from submitting protocols to NIDA is just not the type of compelling evidence that should be admitted under these circumstances. Such evidence could have and should have been presented at the hearing. Respondent must show that this evidence was unavailable and would be material and relevant to the matters in dispute. *Robert M. Golden, M.D., Revocation of Registration*, 61 Fed. Reg. 24,808, 24,812 (1996). Respondent certainly cannot meet the first standard under the *Golden* standard because such evidence was available at the time of the hearing. . Moreover, as the *Golden* final order noted, a party bears a heavy burden when seeking to admit new evidence.

Again, DEA does not have the legal authority to overrule HHS/NIDA policy. Researchers who believe their protocols were denied on improper grounds should and must seek relief with NIDA

Issue 5

Respondent first argues (or more accurately reargues) that since no Government agency takes physical possession of the marijuana produced by Dr. ElSohly (hereinafter “U. Miss.”) as literally required by Article 23 ¶ 2(d), then Respondent should be registered because he would operate under the same circumstances. (Supp. Brief pg. 18-19; Respondent’s Proposed Findings pg. 67) In support of this argument, Respondent again argues that the United Kingdom does not take physical possession of the marijuana

grown by its sole-licensed cultivator, GW Pharmaceuticals (“GW”), and the United Kingdom complies with the Convention under this arrangement. (Supp. Brief pg. 19-20; Respondent’s Proposed Findings pg. 69-70)

Respondent highlights the fact that the Deputy Administrator took official notice of a 2005 report by the International Narcotics Control Board (“INCB”) of the United Nations. This report stated: “Articles 23 and 28 of the [Single] Convention provide for a national cannabis agency to be established in countries where the cannabis plant is cultivated licitly for the production of cannabis, even if the cannabis produced is for research purposes only.” (Supp. Brief pg. 20; F.O. pg. 52-53)

Respondent wants to “rebut” this evidence with a 2001 INCB report, which “commended the U.K. for its medical marijuana research; GW conducted this research with marijuana if cultivated privately.” (Supp. Brief 20) Respondent also seeks to introduce INCB reports for not just 2001, but also for the years 2006 – 2008, to show that these reports did not criticize or sanction the United Kingdom for the arrangement it had with GW. *Id.*⁴

Respondent also argues that the Final Order was mistaken when it noted that the U.S. agency responsible for complying with the Convention for control over marijuana was NIDA/HHS instead of DEA. (Supp. Brief 20-21)

⁴ Respondent, in its first request, sought to rebut this INCB report with another quote from the same report, which states, “The Board notes that since the last report of the Board was published, the Government of the United Kingdom has established a national cannabis agency.” Respondent has not repeated this claim in its Supplemental Brief. (Supp. Brief pg. 20-21) In any event, whether the United Kingdom has a national cannabis agency or not has no relevance to how DEA interprets the Convention.

The Government responds as follows. The INCB reports that Respondent seeks to introduce to “rebut” the INCB comment that was cited in the Final Order are not really rebuttal. What Respondent really intends to show is that these INCB reports endorse the U.K.’s relationship with GW in terms of complying with the Convention.

As the Final Order correctly explained, the United Kingdom’s measures for adhering to the Convention are not necessarily relevant to how the United States interprets the convention. (F.O. pg. 52) Moreover, as the Final Order noted, GW’s marijuana production is distinguishable from Respondent wants to do because GW is producing marijuana extract while Respondent seeks to disseminate whole-plant marijuana to any number of researchers. (F.O. pg. 52, n. 55) Another distinction is that the United Kingdom is dealing only with one manufacturer, while, if Respondent’s application were granted, the United States would have to regulate two distinct marijuana manufacturers.

Admitting the INCB reports for what they do not say for the proposition that the INCB endorses the United Kingdom’s implementation of the Convention is a very dubious proposition. Doing so is tantamount to repealing statutes by implication, and U.S. courts are very reluctant to find such repeals. See, *Mortion v. Mancari*, 417 U.S. 535, 94 S. Ct. 2474, 41 L. Ed. 2d 290 (1974) (holding that an Indian preference statute was not repealed by the subsequent passage of the Equal Employment Opportunity Act of 1972).

The Government would object to the admission of these reports. But even if the Deputy Administrator received these reports into evidence, they should not affect the ultimate findings already made by the Deputy Administrator.

Issue 6

The Final Order made several findings that rejected Respondent's argument that "medicinal marijuana" existed under the Convention. (F.O. 53-57) One of these findings was that the term "medicinal opium" was obsolete because such products were no longer referred to in various standard pharmacy publications. (F.O. pg. 54-55) One of the publications of which the Deputy Administrator took official notice was the FDA's "Orange Book," 2008 edition. (F.O. pg. 54, n. 58) This footnote found that there was "no listing of any opium containing product" in the "Orange Book." *Id.*

Respondent took exception to the finding that the term "medicinal opium" was obsolete. (F.O. pg. 53-55) Respondent now seeks to add to the record three exhibits that show that there are opium products on the market. (First Request, pg. 12; Supp. Brief pg. 23-24, Exhibits F, G and H) Such evidence would rebut the finding that the term "medicinal opium" is obsolete.

Respondent also argues that the Deputy Administrator erred in finding that "medicinal cannabis" did not exist in the United States. (F.O. pg. 56-57; Supp. Brief pg. 24-25) Specifically, Respondent maintains that "Article 23's medicinal exemption" does apply to "medicinal marijuana." (Supp. Brief pg. 24-25) By way of background, Respondent initially argued that the marijuana he intended to cultivate would be developed as "medicinal" marijuana. Therefore, according to Respondent, this type of

“medical” marijuana (or cannabis) would be exempt from the Convention’s requirement that the Government have the exclusive rights for maintaining stocks of marijuana or, in other words, the Government’s monopoly to control marijuana, under Article 23 ¶ 2(e). (Respondent’s Proposed Findings, pg. 67; F.O. pg. 48)

The Government will address Respondent’s second argument, i.e., that Respondent’s marijuana should be exempt from Article 23 because it is “medicinal cannabis” under Article 23, ¶ 2(e), first.

As noted in the Final Order, Respondent seeks to develop medical marijuana, so “medical marijuana” does not even exist yet by Respondent’s own admission, i.e., marijuana “... has [not] undergone the process necessary to adapt it for medicinal use.” Article I ¶ 1(o) (F.O. 53, 56-57) So even if the definition of “medicinal opium” under Article 1, ¶ 1(o) also applies to marijuana, Respondent’s argument fails. In order to understand this argument some background on the applicable articles in the Convention is in order.

Respondent’s underlying argument is that the Convention defined “medicinal” marijuana (“cannabis”) as that “which has undergone the process necessary to adapt it for medicinal use.” (F.O. 53) This definition, however, found in Article I ¶ 1(o) of the Convention, applies by its explicit terms only to opium. Respondent’s rationale for replacing “opium” for marijuana in the cited definition is based on the language of Article 28 ¶ 1: “If a Party permits the cultivation of the opium plant for the production of opium or opium resin, *it shall apply thereto the system of controls* as provided in article 23 respecting the control of the opium poppy.” (Emphasis supplied.) Thus, when one

reads Article 23 of the Convention and applies it to cannabis, one would simply substitute the word “cannabis” for “opium” throughout the article as noted in the citation to Article 28 ¶ 1 above. Therefore, according to Respondent’s rationale, the marijuana he proposes to grow should fit under the Article 23, ¶ 2(e) “medicinal cannabis” exception and not be subject to the general restrictions imposed on bulk cannabis (and bulk opium) under Article 23.

This argument is not consistent with the plain language of the Convention. Article 28 ¶, as noted by the emphasized language quoted from this article in the preceding paragraph, only applies to *the system of controls*. In other words, when substituting “cannabis” for “opium” in Article 23, such substitution is mandated only when the Party implements the controls over the bulk product. There is nothing in Article 28 that would permit substituting “cannabis” for “opium” when Article 28 refers to the exceptions. Thus, Respondent’s substitution of “medicinal cannabis” under the definition in Article 1 ¶ 1(o) for “medicinal opium” is misplaced.

The Government now responds to Respondent’s first argument that the Deputy Administrator erred in finding that the term “medicinal opium” was obsolete and that the Deputy Administrator erred in supporting this finding by taking official notice of the “Orange Book.”. The fact that Respondent is offering evidence to show there are “medicinal opium” products but not offering evidence to show that there are “medicinal products” re-enforces the conclusion that “medical” marijuana or cannabis does not exist.

Given the latter arguments, the issue of admitting exhibits that show opium medical products exist is inconsequential.

Issue 7

The Final Order discussed the interpretation of 21 C.F.R. § 1301.33(b)⁵, and how this regulation should be interpreted in the context of the facts. (F.O. pg. 106- 108) To reinforce the rationale, the Final Order cited a quote from Assistant Attorney General Moschella found in the legislative history.⁶ (F.O. pg. 108, n. 111)

Respondent seeks to rebut this “evidence” with the testimony and written statements of an expert economist, Professor Scherer. (First request pg. 12-13) Such evidence would entail showing that the current NIDA “monopoly” is inadequate competition. Respondent’s proffer would also include testimony or evidence about the relationship between competition and promoting technical advances. (First request pg. 13; Supp. Brief, Exhibit E)

Respondent sought to expand its request for “new evidence” or “to rebut officially noticed facts” by adding additional quotes from Assistant Attorney General Moschella found later in the same legislative history: “It is possible that there can be adequate competition within the meaning of Section 823(a) with just a single manufacturer [of a single drug], provided that manufacturer can produce the substance in sufficient quantity and quality ... without charging unreasonable prices.”

⁵ “In order to provide adequate competition, the Administrator shall not be required to limit the number of manufacturers in any basic class to a number less than that consistent with maintenance of effective controls against diversion solely because a smaller number is capable of producing an adequate and uninterrupted supply.”

⁶ “The meaning of [21 CFR 1301.33(b)] can be restated as follows: If DEA determines there is inadequate competition among the existing manufacturers of the particular controlled substance that the applicant seeks to produce (e.g., substantial overcharging by the existing manufacturers due to an insufficient number of competing manufacturers of that controlled substance), and provided further that granting the applicant’s registration (and thereby increasing the total number of manufacturers) is consistent with maintenance of effective controls against diversion, DEA is not required to deny the application solely because the number

First, citations from legislative history do not constitute “a material fact” as that term is used in 5 U.S.C. § 556(e). Parties are free to support statutory or (in this case) regulatory interpretations with legislative history. But there is nothing in the final order that even impliedly used the quote of Assistant Attorney General Moschella as a fact. The final order merely cited this part of the legislative history in support of its interpretation of Rule 1301.33(b).

Second, this legislative history was used to validate the Deputy Administrator’s interpretation of Rule 1301.33(b). The proffered testimony and statement from Dr. Scherer and the subsequent quote found later in the same legislative history do not refute or even relate to the legislative history quote noted in the final order. Respondent should not be allowed to use this quote as a pretext to delve into issues that do not relate to why the legislative history was cited by the Deputy Administrator.

Issue 8

Respondent’s arguments that its registration would be consistent with the Single Convention treaty (“Convention”) are inconsistent and unconvincing. First, Respondent argues: “The Convention calls for a single government agency to take possession of all marijuana. The Deputy Administrator asserts that the United States agency designated for this purpose is NIDA” (Supp. Brief pg. 17) “Specifically, the Deputy Administrator identified NIDA/HHS as the U.S. ‘agency’ responsible for implementing the Convention-required controls over marijuana. Leonhart Order 49-50.” Respondent

of manufacturers currently registered can adequately supply the market for that controlled substance in terms of quantity and quality of product.”) (emphasis in the original).

maintains that it is DEA, and not NIDA, that is the government agency solely responsible for regulating the manufacture of marijuana for purposes of the Convention based upon the various regulations imposed by DEA. (Supp. Brief pg. 17, 21)

But Respondent's prior arguments, not to mention the facts, rebut this assertion. Respondent initially emphasizes that NIDA has a monopoly over the marijuana that can legally be used for research. (Supp. Brief pg. 1-2) Respondent further argues that NIDA's monopoly has "resulted in a complete dearth of privately-funded medical marijuana research" (Supp. Brief pg. 2) Respondent's assertions constitute a tacit admission that NIDA does exercise control over who receives the marijuana produced by U. Miss.

Indeed, NIDA's authority, under HHS, to grant or deny medical marijuana research has a much more direct impact on "regulating marijuana" than DEA's enforcement of its various registration, recordkeeping and security regulations, because NIDA's decision may determine that a researcher cannot obtain marijuana. Such a decision by NIDA would be the ultimate form of regulation, i.e. a prohibition from even handling the substance at all.

DEA does defer (and legally must defer) to HHS's policy, which is implemented by NIDA. In reality, Respondent would like DEA to be the sole agency to regulate marijuana (and circumvent HHS's NIDA policy) but that is not how the current system operates.

Then Respondent notes that U. Miss. "grows additional marijuana *outside* his contract with NIDA." (Supp. Brief pg. 19) Respondent maintains that since U. Miss. is

allowed to distribute marijuana to a private company, DEA must be consistent in its interpretation of the Convention and allow Dr. Craker to distribute marijuana to researchers as well. *Id.* (Supp. Brief pg. 19, n. 11)

As explained in the final order, DEA permitted U. Miss. to distribute “preparations” of marijuana, i.e. extracted THC, which is an exception to the prohibition to engage in wholesale distribution of marijuana under Article 23, ¶ (1)(e) of the Convention. (F.O. pg. 59-60) In its motion for reconsideration, Respondent argues that this arrangement violates the Convention because DEA permits U. Miss. “to *manufacture* marijuana outside of his NIDA contract and without taking possession of it.” (Supp. Brief pg. 19, n. 11)

Respondent’s argument here is not consistent with the applicable Convention Article. Article 23 ¶ (2)(d) requires that “cultivators of the [marijuana] shall be required to deliver their total crops of [marijuana] to the Agency.” Article 23 ¶ (2)(e) directs that the “Agency” shall have the “*exclusive right of ... wholesale trading and maintaining stocks other than those held by manufacturers of [marijuana] alkaloids, medicinal [marijuana] or [marijuana] preparations. Parties need not extend this exclusive right to...[marijuana] preparations.*” (Emphasis supplied.) The applicable language is quite clear that the exclusive right of wholesale trading need not apply to preparations. Respondent’s argument is that U. Miss. is operating outside of this exemption because U. Miss. is growing the marijuana from which it makes the preparation.

But this argument is not supported by the plain language of the Article 23. U. Miss. is engaging in trading of a marijuana extract, i.e., a preparation, which is

permissible under Article 23 ¶ (2)(d). U. Miss. extracts the THC from the marijuana before it ever distributes. So U. Miss. is trading in a “preparation” as it is permitted to do under Article 23(2)(e). This arrangement is in stark contrast to what Respondent seeks to do, i.e., to send plant marijuana to various researchers.

Issue 9

Respondent argues that Dr. Doblin’s weekly habit of abusing marijuana for recreational use cannot fall under Factor 6, 21 U.S.C. § 823(a)(6), “such other factors as may be relevant to and consistent with the public health and safety[,]” because such conduct should fall under 21 U.S.C. § 823(a)(5). Section 823(a)(5) pertains to, in part, “effective controls against diversion.” Respondent maintains that the Final Order already found no diversion risk under Section 823(a)(5), and Factor 6, which entails “other” conduct, cannot be utilized to make another ruling on the issue of “effective controls against diversion” (Supp. Brief pg. 25-26)

In response, Section 823(a)(5) pertains to the applicant as opposed to persons who are related to the applicant. First, under this factor, the Deputy Administrator must consider the applicant’s “past experience in the manufacture of controlled substances.” Such “past experience” has to be assessed based on the applicant’s past history and not on a related person whose past experiences in manufacturing controlled substances would not fall under this factor.

Second, this factor also pertains to the “**establishment** of effective controls against diversion.” (Emphasis supplied.) Again, it is the applicant, and not necessarily persons related to the applicant, that has the duty to establish the controls. In *Brokeridge, Inc.*;

Denial of Application, 50 Fed. Reg. 10,548 (1985), the Deputy Administrator found that a conviction of the general manager of the applicant for failing to keep records relating to firearm sales fell under “such other factors” under 21 U.S.C. §§ 823(b)(5) and 823(e)(5). In the present case, the utilization of Section 823(a)(6) instead of 823(a)(5) is consistent with the *Brokeridge* construction of the analogous sections.

In *Jefferson County Pharmaceutical Association, Inc. v. Abbott Laboratories, et al.*, 460 U.S. 150, 103 S. Ct. 1,011, 74 L. Ed. 2d 882 (1983), the Supreme Court reversed a circuit court decision, which dismissed an anti-trust suit brought under the Robinson-Patman Act. In relation to the construction of the act, the Supreme Court explained: “Because the Act is remedial, it is to be construed broadly to effectuate its purposes.” 460 U.S. at 159. (Citations omitted.) The Controlled Substances Act, particularly Sections 823 and 824, is remedial and should, likewise, be construed liberally. Given the deference that courts give to an agency’s construction of its own statutes, there is no reason to accept Respondent’s hyper technical construction of Section 823(a)(6).

In any event, even if the agency accepted the Respondent’s argument, the argument would be a mere pleading argument. As such, DEA could use the same facts to find that there is a lack of effective controls against diversion under Section 823(a)(5).

Respondent also argues that the focus should only be on Dr. Craker and whether he might divert marijuana. (Supp. Brief- pg. 26-27) Respondent maintains that Dr. Craker simply will distribute the marijuana to researchers and that Dr. Doblin will have nothing to do with such distribution practices. *Id.* Therefore, Dr. Doblin’s routine abuse of marijuana is irrelevant. *Id.*

But Dr. Doblin is not just a passive sponsor. The Final Order noted that Dr. Doblin arranged to have persons who used marijuana in the passionate use program and persons who used “buyers’ club” (illicit) marijuana send their marijuana to Chemic for testing. (F.O. pg. 26-27) As the Deputy Administrator noted, the use of marijuana under these circumstances is unauthorized in violation of 21 U.S.C. § 841(a)(1). (F.O. pg. 26-27, n. 28)

Moreover, Dr. Doblin took a very active role in sponsoring the application. Dr. Doblin sought the registration so he could develop marijuana into an FDA approved prescription medicine. (Tr.- 603, l. 2-22; 604, l. 1-4) Dr. Doblin’s organization, MAPS, was planning to develop its own marijuana prescription medicine from the marijuana supplied by Dr. Craker. (Tr.- 647-648, l. 7-25, 1-5) Dr. Doblin would direct Dr. Craker where to send the marijuana, and Dr. Doblin would find researchers who would use the marijuana. (Tr.- 721, l. 15-21; 740-741, l. 10-22, 1-9) Indeed, the Final Order chronicled all the steps that Dr. Doblin made to set up this system. (F.O. pg. 91-92)

And the Final Order noted that Dr. Doblin has regularly abused the substance, which is “the very substance the applicant seeks to produce.” (F.O. pg. 93) Under these circumstances, there is no question that DEA should consider Dr. Doblin’s habitual marijuana abuse. To arbitrarily rule that such evidence is “irrelevant” would not only be a miscarriage of justice for this particular case, but would create undue problems for future adjudications.

Issue 10

Respondent has appended two documents that pertain to general policy and goals of the new administration under President Obama. (Supp. Brief Exhibits A and B) Respondent uses these exhibits to critique DEA's policy pertaining to marijuana. (Supp. Brief pg. 3) Although it is not clear if Respondent seeks to introduce these exhibits into evidence, out of an abundance of caution, the Government objects to the admission of these exhibits or any discussion related to them.

Under *Robert M. Golden, M.D., Revocation of Registration*, 61 Fed. Reg. 24,808, 24,812 (1996), the newly discovered evidence must be relevant to the dispute. These exhibits are not even tangentially relevant to the issues and certainly should not be admitted under the *Golden* standard.

Respectfully submitted,

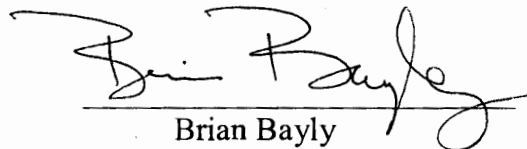


Brian Bayly
Attorney, Office of Chief Counsel

Dated: April 13, 2009

CERTIFICATE OF SERVICE

On April 13, 2009, I sent a copy of the foregoing by scan e-mail, to Counsel for Respondent, Julie M. Carpenter, Esq., Jenner & Block, 601 Thirteenth Street, NW, Washington, D.C. 20005. In addition, on March 24, 2009, I delivered the original with attachments and two copies of the foregoing to the DEA Office of the Deputy Administrator.



Brian Bayly