UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

IN THE MATTER OF	)	
	)	Docket No. 05-16
LYLE E. CRAKER, PHD.	)	
	)	

GOVERNMENT'S EXCEPTION TO OPINION AND RECOMMENDED RULING, FINDINGS OF FACT, CONCLUSIONS OF LAW, AND DECISION OF THE ADMINISTRATIVE LAW JUDGE

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Pursuant to 21 C.F.R. § 1316.66(a), the Government files its Exceptions to the Administrative Law Judge's (ALJ) Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law and Decision (recommendation), issued February 12, 2007. The Government respectfully requests that the Deputy Administrator not to adopt the ALJ's ultimate recommendation and requests the Deputy Administrator to deny the application based on the arguments submitted in the Government's Proposed Findings of Fact, Conclusions of Law and Argument (Government's brief) and based upon the arguments presented in these Exceptions as follows.

I. The Single Convention

The Government takes exception to the ALJ's finding "that the Single Convention (treaty) does not preclude registering Respondent." (ALJ 82)[1] The correct determination is not whether the treaty precludes registration, but whether any "such registration is consistent ... with United States obligations under [the treaty] ..." 21 U.S.C. § 823(a). Respondent has failed to meet his burden of proving that his registration would be consistent with the treaty.

The Government takes exception to the ALJ's reliance on how another signatory, the United Kingdom, chooses to interpret or implement its treaty obligations. *Id.* It is for the United States government to interpret its responsibilities under the treaty and implement it in a manner consistent with domestic law. The United States has chosen to fulfill its obligations under the treaty by establishing a system of controls wherein the Drug Enforcement Administration (DEA) exercises certain designated responsibilities

[1] "ALJ- " refers to page numbers in the ALJ's recommendation. "R.- " refers to page numbers in the hearing transcript. "Gov. FCA- " refers to page numbers in the Government's brief with paragraph numbers where applicable. "G.- " refers to Government exhibits. "Resp. FCA-" refers to page numbers in the Respondent's brief. "Resp.- " refers to Respondent's exhibits

and the Secretary of Health and Human Services (HHS) exercises other designated responsibilities.

Among the specific HHS responsibilities is the Controlled Substances Act requirement that "Registration applications by practitioners wishing to conduct research with controlled substances in schedule I shall be referred to the Secretary [of Health and Human Services], who shall determine the qualifications and competency of each practitioner requesting registration, as well as the merits of the research protocol." 21 U.S.C. § 823(f). The Secretary of HHS has established a review process which mandates that, in addition to Food and Drug Administration (FDA) approval, such a determination will include the review and approval of the Public Health Service (PHS) and National Institute on Drug Abuse (NIDA). The current system of having one supplier bid on a contract every five years is a reasonable interpretation of the treaty and a reasonable accommodation of the treaty with the existing laws and Government agencies that regulate the manufacture and cultivation of marijuana. (G-24; Gov. FCA 136-137).

The general intent of the treaty is to limit the propagation and dissemination of controlled substances. The treaty requires a Party's government to purchase and acquire all cannabis and to maintain a monopoly over the cannabis trade. Article 23, Paragraph 2(a)-(e). The treaty further mandates that the Party has "the exclusive right of importing, exporting, wholesale trading and maintaining stocks [of marijuana]." Id. Article 1, paragraph x (iv) and (v) excludes from the definition of "stocks," and thus by extension excludes from the monopoly requirement, stocks held by "retail pharmacists or other authorized retail distributors and by institutions or qualified persons in the duly authorized exercise of therapeutic or scientific functions" and "special stocks," which are

defined as "... the amounts of drugs held in a country ... by the Government of such country ... for special government purposes and to meet exceptional circumstances; ... " [Article 1, paragraph w].

The Government takes exception to the ALJ's finding that the marijuana proposed to be grown by Respondent qualifies under either exception to the "stocks" monopoly requirement. (ALJ 82). It is clearly not being held as "retail" stock. The ALJ's conclusion that it would be held as "medicinal" stock has no legal or factual underpinning. The definition that the recommendation references [Article 1, paragraph 1(o)], defines it as that "which has undergone the processes necessary to adapt it for medicinal use." Marijuana has no currently accepted medicinal use, which is why it is a schedule I controlled substance. Therefore, any marijuana cultivated by Respondent cannot possibly have "undergone the processes necessary to adapt it for medicinal use." The absurdity of the ALJ's conclusion is evident if one substitutes opium for marijuana, then the ALJ's conclusion would be that all opium cultivated qualifies as "medicinal" stock, a result contrary to reality.

The ALJ's conclusion that it would be held as "special" stock, as defined in Article 1, paragraph (w), likewise has no legal or factual underpinning. *Id.* The marijuana proposed to be cultivated by Respondent will not "be held . . by the government . . for special government purposes and to meet exceptional circumstances." [Article 1, paragraph 1(w)]. Indeed, under Respondent's scheme it will be under the control of MAPS and Doblin.

Furthermore, the ALJ's conclusion is qualified ("although it is not entirely clear") and, thus, should have been that the Respondent had not met his burden of establishing that his proposed cultivation of marijuana met either Article 23 exception and Respondent has failed to meet his burden of proving that his registration would be consistent with the treaty.

II. The Statutory Factors.

A. Section 823(a)(1)

1. Controls Against Diversion.

The Government takes exception to the ALJ's finding that "it is unlikely" that any marijuana would be diverted from Respondent's facility. (ALJ 83). The correct analysis should be whether Respondent has carried his burden of proving that he will be able to "maintain effective controls against diversion." Respondent candidly admitted that he has no experience in the control against diversion (R. 79) and what distinguishes his experience with other medicinal plants from handling controlled substances are the security requirements. (R. 36). Other than giving general assurances that the facility will have whatever locks or fences deemed necessary to prevent theft, Respondent did not offer any evidence of what procedures he would implement to prevent diversion from the facility. For example, there was no evidence of how persons having direct access to the material would be properly vetted (including appropriate background checks), how accountability for every part of every plant (down to individual seeds) would be implemented through inventory controls and recordkeeping, how quota would be maintained, how shipping and handling would be implemented, how they would handle and report any in-transit losses, etc. Maintenance of effective controls means more than

simply "locking it up," and Respondent has failed to carry his burden as to such controls at his facility.

Moreover, the Government takes exception to ALJ's minimization of the risk of diversion presented by the extensive control and involvement of Doblin. Only after his attempts to procure a source of supply from overseas or domestically seized marijuana failed, did Doblin turn to the legally authorized source of domestic marijuana. (R. 503-522; Gov. FCA 41-42, ¶¶ 175-176) Doblin stated that "once a product was produced that we [MAPS] would then indicate where is should be used." (R. 583). Doblin stated that Respondent would "manufacture the drug according to our [MAPS] requests . . then MAPS would allocate it to government approved projects, first projects that MAPS was sponsoring." (R. 589). The ALJ's conclusion that because Doblin and MAPS would not have physical possession of the marijuana, that there was little risk of diversion, ignores not only every theory of agency, but the explicit statements that Doblin was in charge of who received the marijuana. It is akin to concluding that Pablo Escobar had no control over cocaine distributed by the Medellin Cartel because he never touched the drugs.

A clear example of how Doblin can, and will, divert marijuana without actual physical possession was the diversion of compassionate use marijuana to Chemic. First, Doblin publicly solicited a companionate use patient to send NIDA provided compassionate use marijuana to Drug Detection Lab for analysis (R. 674). He "sort of put the word out through others to try and reach patients to see if anyone would be interested in doing that." (R. 682). Second, Doblin arranged with Drug Detection Lab to send some of this marijuana to Chemic for use in their research that was beyond the scope of their DEA registration. (R. 669; Gov. FCA 78, 82, 85).

The Government takes exception to ALJ's refusal to consider Doblin's specific unlawful activities with marijuana (R. 717). Doblin admitted to smoking marijuana for recreational purposes on a weekly basis and admitted that his source was not NIDA, the only lawful source in the country, and therefore by implication that he procures it illegally (R. 720). The ALJ erroneously prohibited the Government from inquiring further of Doblin as to his source of supply (R. 719). Coupled with the Chemic diversion incident, Doblin's own cavalier disregard for DEA regulations intended to prevent diversion and contempt for the criminal laws of the United States regarding marijuana should be considered when evaluating the effectiveness of controls against diversion by the person who will direct the supply of marijuana produced by Respondent.

The Government takes exception to the ALJ's finding that Respondent will only send marijuana to researchers who have the requisite approval from the "Department of Health and Human Services." (ALJ 84). Doblin continually refers to "FDA approval" while ignoring "HHS approval." Doblin stated several times that MAPS desired its "own independent source of supply" (R. 579, 581, 584) and that "what we're trying to do is get the Public Health Service and NIDA out of the picture." (R. 666). The Recommendation appears to incorrectly equate FDA approval with HHS approval.

The Government takes exception to the ALJ's finding that the risk of diversion under these circumstances is minimal. (ALJ 84) The correct finding should have been that Respondent has failed to meet his burden of proving that he could maintain effective controls against diversion.

2. Competition.

a. Adequacy of Supply.

While the Government agrees, in part, with the ALJ's finding that the quality is "generally" adequate (the Government contends that it is adequate, not "generally" adequate), the Government takes exception to the methodology used to reach that result. *Id.* As in other parts of the Recommendation, the ALJ incorrectly places the burden of proof on the Government. The finding that "a preponderance of the evidence establishes that the quality is generally adequate" should have been satisfied at a much lower level that the Respondent had failed to meet its burden of proof to establish that the current supply is inadequate. Although the Government agrees with the Recommendation's finding that there was no evidence that a NIDA approved researcher experienced any difficulties in receiving marijuana when they needed it, the Government takes exception to the lack of clarity that it was the Respondent's failure to produce any evidence that resulted in this finding. *Id.*

A finding that the Respondent has failed to establish that the current supply of marijuana is inadequate in terms of its quality, quantity and timeliness should have ended the discussion on this point. The Government takes exception to the Recommendation's finding that NIDA's system for evaluating requests for marijuana renders the supply inadequate. *Id.* First, the Government takes exception to the finding that any DEA registrant with "requisite approval from the Department of Health and Human Service" has been unable to receive marijuana from NIDA. *Id.* Again, the Recommendation appears to incorrectly equate FDA approval with HHS approval.

The Controlled Substances Act states that "Registration applications by practitioners wishing to conduct research with controlled substances in schedule I shall be referred to the Secretary [of Health and Human Services], who shall determine the qualifications and competency of each practitioner requesting registration, as well as the merits of the research protocol." 21 U.S.C. § 823(f). DEA has no authority to overrule the HHS determination on the qualifications and competency of the research applicant or the merits of the research protocol. The Secretary of HHS has established a review process which mandates that, in addition to FDA approval, such a determination will include the review and approval of the PHS and NIDA. The ALJ's finding that an adverse determination on the qualifications and competency of the research applicant or the merits of the research protocol under the system mandated by HHS resulted in an inadequate supply is illogical. The inability of unqualified or incompetent applicants with unscientific and unapproved protocols, as determined by HHS, to receive marijuana has absolutely no bearing on the adequacy of the supply to HHS approved researchers. The Government takes exception to the ALJ's blatant usurpation of the authority of the Secretary of HHS.

b. The Policy Against "Shelf Registrations."

The Government takes exception to the ALJ's finding that Respondent has met his burden of establishing that his registration would not violate DEA policy against "shelf registrations." *Id.* The finding that Respondent would produce marijuana "that will be used in legitimate research" has no factual basis in the record. The operative word is "legitimate" research. Respondent failed to produce evidence that any HHS approved researcher, to include legitimate pharmaceutical companies, intend to acquire

marijuana from Respondent. A "build it and they will come" expectation does not satisfy the burden of proof on this point. Indeed, the system that Respondent and Doblin intend to implement would provide marijuana to researchers who had FDA approval, even if they did not have HHS approval. The Government considers any researcher who does not have HHS approval to be illegitimate.

c. Competition via the Process for Awarding NIDA's Contract.

The Government takes exception to the ALJ's conclusion that marijuana is not made available to all researches who have a "legitimate" need for it. (ALJ 85). As discussed in section 2a, above, "legitimacy" is only possible for those researchers that have HHS approval. All HHS approved researchers receive an adequate and uninterrupted supply from NIDA.

The Government also takes exception with the ALJ's finding that the NIDA contracting process requires an analytical activity that a cultivator "may not be able to fulfill." Nothing in the NIDA contracting process precludes a successful bidder from sub-contracting components that they do not have the in-house capacity to fulfill. Indeed, the current contract holder, the National Center, does exactly that when, for example, it sub-contracts to Research Triangle Institute to roll the marijuana cigarettes. Respondent recognized that he may need assistance from other components of the University of Massachusetts or a commercial company to analyze the THC content of his harvested crop. (R. 207-208)

The Government takes exception to the ALJ's finding that the government contracting process does not render competition adequate and to her failure to clearly state that the applicant bears the burden of proving that competition is inadequate. (ALJ

85). In addition to the normal Federal Register notice process, Respondent received a personal notice of the request for bids in connection with the contract that was open during the pendency of its application. (Gov. FCA 71, ¶ 71; 72, ¶ 314). Respondent chose not to compete because, in his words, he had no interest in the contract, had no experience in controls against diversion, recognized the extensive experience of the current contract holder, had no interest in the analyses part of the contract, and believed that he had little chance of being the successful bidder. (Gov. FCA 88-89, ¶¶ 386-387, 389). The government contracting process, which the ALJ completely eschews, is the essence of full and open competition where any individual or company that believes it can provide a better product, at a better price, in a timelier manner, or under better conditions is able to compete. It is illogical that the ALJ could find that Respondent successfully met his burden of establishing inadequately competitive conditions by affirmatively refusing to engage in the open competition provided by the contracting process. The fact that the Government has chosen to fulfill its statutory and treaty obligations by limiting the supply of this schedule I controlled substance to a single successful bidder, after giving all interested parties the same full and fair opportunity to compete, hardly renders the conditions inadequately competitive. Respondent did not avail himself of the competition because he did not want to comply with the HHS mandated system for determining the competency and qualifications of the researchers or the scientific merit of their protocols. Moreover, DEA cannot dictate to HHS how it fulfills its mandate and the Government refuses to be complicit in Doblin's scheme to substitute himself for the HHS.

3. Conclusion

Title 21 C.F.R. 1301.55(a) clearly assigns to the applicant the burden to prove the statutory requirements for registration as a manufacturer. For the reasons stated above, the Government takes exception to the ALJ's unsubstantiated findings that Respondent has met his burden of proving that he could maintain effective controls against diversion and that there was not an adequate and uninterrupted supply under adequately competitive conditions under 21 U.S.C. § 823(a)(1).

B. Section 823(a)(2).

This factor considers Respondent's compliance with applicable state and local law. This factor is most often relevant in controlled substance cases involving practitioners who have had their state medical license or state controlled substance license revoked or denied. In *Genesis 1:29 Corporation: Denial of Application*, 68 FR 15225 (2003), the Deputy Administrator held that "[s]ection 823(a) contains no express threshold requirement of state authorization. Nonetheless, DEA has previously determined that where as here state law requires manufacturers of controlled substances to obtain a state license, it would be pointless to grant a Federal registration when the Respondent lacked state authority." While the failure to have a required state or local license would prove fatal to an application, the actual possession of any required state or local license, which would infer that some responsible state or local government official had passed judgment on the suitability of the applicant, may weigh in Respondent's favor. However, an expectation by Respondent that the required state license will ineluctably follow the granting of a DEA registration and a promise to comply with state and local law in the future simply renders this factor irrelevant and does not weigh in

favor of either party. Thus, the Government takes exception to the ALJ weighing this factor in favor of Respondent.

C. Section 823(a)(3).

While the Government concurs with the ALJ's conclusion that "it is undisputed that Respondent has no experience in manufacturing or otherwise handling controlled substances," the Government takes exception to the unsubstantiated speculation that Respondent's experience in cultivating medicinal plants "might promote technical advances in the cultivation of marijuana or in developing new medications from it." (ALJ 85-86). Respondent clearly and unequivocally testified that he would be using currently existing methodologies, technologies, processes and equipment. (R. 40, 79, 185-205). Respondent holds no patents and has no patent applications pending or envisioned concerning the cultivation of marijuana. (R. 238). The complete lack of any evidence that Respondent will promote technical advances in the art of manufacturing the controlled substance (i.e., marijuana) stands in stark contrast to other applicants who have presented specific and measurable evidence of how their registration would promote technical advances.

In *Roxanne Laboratories, Inc*, 63 FR 55891, 55899 (1998), Roxanne applied for a registration as an importer of Schedule II substances. Roxane put on uncontested evidence that it was the first manufacturer to market cocaine in a premixed topical solution. This was sufficient for the applicant to carry its burden with respect to this factor. In *Johnson Mathey*, 67 FR 39041, 39044 (2002), Johnson Mathey had developed a patent that permitted the manufacture of hydrocodone in a one-step process and had four other patent applications pending. It had also filed a patent application in Europe

for the production of thebaine, a precursor to oxycodone. This was sufficient for that applicant to carry its burden with respect to this factor. In *Penick Corporation, Inc.*, 68 FR 6947, 6950-51 (2003), Penick had patented processes to produce oxycodone and narcotic antagonists from morphine or codeine instead of thebaine, had invented a process to produce hydrocodone and hydromorphone, and had a more efficient process to produce oxycodone from thebaine. The Deputy Administrator found that Penick's patents and development of manufacturing processes promoted technical advances in the manufacture of controlled substances.

Respondent's lack of evidence is even less than that found in *Chattem Chemicals, Inc,* 71 FR 9834, 9838 (2006). Chattem averred that it had produced advances in the art of manufacturing those controlled substances that it had already registered to produce and that it intended to develop a process to produce thebaine from poppy straw concentrate if registered as an importer. The Deputy Administrator found that "[t]here was little evidence, however, that Chattem has achieved any noteworthy success in technical advances in the manufacturing of controlled substances, or in the development of new substances or patents. Accordingly, the Deputy Administrator finds that this factor weighs against granting Chattem's application."

The Government takes further exception to the lack of a finding as to this factor. Respondent had the burden of proof and the ALJ's conclusion that "there is not sufficient evidence in the record on which to base a finding" should have instead been a conclusion that as Respondent failed to meet his burden, this factor weighs against granting the application. (ALJ 86)

D. Section 823(a)(4).

While the Government concurs with the ALJ's conclusion that "[i]t is undisputed that Respondent has never been convicted of any law pertaining to controlled substances," the Government takes exception that scope of the inquiry is limited to Respondent. (ALJ 86)

In *Market Street Market*, 67 FR 11142, 11143 (2002), the Deputy Administrator stated that "[a]s a preliminary matter, DEA has consistently held that a retail store operates under the control of its owners, stockholders, or other employees, and therefore the conduct of these individuals is relevant in evaluating the fitness of an applicant for registration." See also *Prices Power International*, 67 FR 2910, 2911 (2002). In evaluating this factor in other Final Orders, the Deputy Administrator has considered the applicant "or any person affiliated with it," *Planet Trading, Inc., d/b/a/ United Wholesale Distributors, Inc.*, 71 FR 11055, 11057 (2007); *Georgia Convenience Wholesale, Inc.*, 72 FR 9969, 9970 (2007) and "any of its officers, agents, or key employees." *Chattem*, 71 FR at 9838. *Penick*, 68 FR at 6951.

The ALJ's Recommendation clearly ignores the obvious reality that MAPS, an organization which supports the legalization of drugs of abuse for recreational use, is seeking to set up the University of Massachusetts program as a front organization to gain control over, in Doblin's own words, an "independent source of supply." (R. 473-474, 477-478, 583-584, 604, 633-634, 639). Doblin initiated contact with Respondent, prepared a one-page Memorandum of Understanding for MAPS and Respondent, assisted in filling out the registration application, helped in answering all of DEA's questions to Respondent, sued on behalf of Respondent, will provide all of the funding, will seek out

all of the customers, will determine the quality that is to be produced, and will act in the place of NIDA and the PHS in deciding who receives the marijuana. (R. 39-40, 351-353, 382-384, 603-604, 647-648; Resp. FCA 1-2). In effect, MAPS will do everything except water the plants. By limiting the inquiry to the proxy, the ALJ ignored the real party in interest.

This factor usually is limited to considering past "convictions." This normally is sufficient since a prior conviction is an established adjudication of criminal activity relating to controlled substances and avoids having the administrative hearing becoming side-tracked into a contest of whether the applicant, its officers, agents, key employees or any person affiliated with it has engaged in such criminal activity. In the present case, however, there is equally compelling evidence of criminal activity relating to the very controlled substance at issue. Doblin's boastful admissions under oath during the hearing that he has a long, continuing and unabated history of unlawfully procuring and using marijuana for recreational use establishes the past criminal activity relevant to this factor as much as any "conviction" would. Doblin's unwarranted luck in avoiding any conviction for his admitted unlawful activity does not diminish the relevance of his conduct to this factor.

Thus, based on the conduct of the real party in interest to the application, the Government takes exception to the conclusion that this factor weighs in favor of granting the Respondent's application.

E. Section 823(a)(5).

While the Government concurs with the ALJ's conclusion that "Respondent has no experience in manufacturing controlled substances," the Government takes exception to the relevance of Respondent's "experience in growing medicinal plants" to this factor. (ALJ 86).

It is patently clear that the "prior experience" contemplated by factor 5 is experience with controlled substances, not other products. In no case involving applications to handle controlled substances, has "prior experience" with non-controlled substances ever been considered as support for granting an application.

In cases where the applicant had favorable past experience handling controlled substances, it formed the basis for weighing this factor in favor of the applicant. In *Chattem*, the Deputy Administrator found that Chattem had experience in manufacturing controlled substances, other than narcotics produced from narcotics raw material (but possessed the necessary technology to do so) and had maintained effective controls against diversion and, thus, weighed this factor in favor of granting the registration (71 FR at 9838). In *Penick*, the evidence showed that Penick had manufactured narcotics from 1947 until sometime in the 1990s. (68 FR at 6947). Although the objectors, Mallinckrodt and Noramco, "asserted that the regulatory requirements have changed since Penick exited the market, they adduced no evidence that Penick would be unable to comply with current or future requirements." The Deputy Administrator thus concluded that this factor weighs in favor of granting the application.

In *Johnson Mathey*, the Deputy Administrator found that the applicant's 17 year history as a DEA registrant manufacturer of controlled substances with successful record

keeping and security practices was sufficient to find this factor in favor of the applicant (67 FR at 39044). In *Roxane*, the applicant had been in the business of manufacturing controlled substances for years and had "an exceptional record for maintaining controls against diversion of these substances, above and beyond what is required by law" (63 FR 55899). The Deputy Administrator found that Roxane had met its burden with respect to this factor "despite Mallinckrodt's argument that Roxane had no experience in handling the international shipment of bulk cocaine." Id.

In other cases, where an applicant's past experience handling controlled substances was either inconsequential or detrimental, it formed the basis for weighing this factor against the applicant. In *Prodim Denial of Application*, 64 FR 15809, 15810 (1999), the Deputy Administrator found that even though the controlled substance exporter applicant had "handled controlled substances as a paramedic and a Navy corpsman, there is no evidence that he has any experience in exporting controlled substances, nor in the responsibilities of a DEA registrant in preventing the diversion of controlled substances." In *Johnson Mathey, Inc.*, 60 FR 26050, 26052 (1995), the ALJ found that while Johnson Mathey's successful handling of fentanyl was in its favor, it's less satisfactory past experience with methylphenidate provided sufficient grounds to deny the application.

Analogous to this factor is the "past experience" considered in applications for registration to distribute list chemical products. [21 U.S.C. § 823(h)(4)]. These applicants often have ample experience in distributing sundry items, including over-the-counter drug products, to local convenience stores and gas stations. As the Deputy Administrator stated in *Taby Enterprises of Oscenola, Inc.*, 71 FR 71557, 71558 (2006),

however, "[n]umerous DEA final orders have made clear that because of the potential for diversion, an applicant's (and its controlling person's) lack of experience in distributing List I chemicals is a factor which weighs heavily against granting an application for a registration. *Tri-County Bait Distributors*, 71 FR 52160, 52163 (2006); *Jay Enterprises*, 70 FR 24620, 24621 (2005); *ANM Wholesale*, 69 FR 11652, 11653 (2004)."

Even when an applicant had past experience in distributing listed chemicals in his retail outlet, but neither the owner nor employees had experience selling listed chemicals at the wholesale level, "Judge Bittner therefore found this factor weighed in favor of a finding that [the] registration would be inconsistent with the public interest. The Deputy Administrator agrees with that conclusion." *H&R Corporation*, 71 FR 30168, 30171 (2006).

The rationale for limiting "past experience" to controlled substances is obvious. It would give some basis for the Deputy Administrator to determine if the applicant has a familiarity with the DEA policies and procedures relative to handling controlled substances and demonstrated an ability and willingness to comply with them. That is why a good track record with controlled substances has consistently been weighed favorably to an applicant and a poor or non-existent track record with controlled substances has consistently been weighed against an applicant. Because a track record handling other products, whether they are sundry items, over-the-counter drugs, or medicinal plants, is not informative of the applicant's ability, aptitude or willingness to handle controlled substances in conformity with the myriad of DEA requirements, it cannot form the basis for weighing his factor in favor of the applicant. This is especially valid when the applicant has the burden of proof.

The Government further takes exception to the ALJ's conclusion that the risk of diversion is "minimal." (ALJ 86). Respondent has the burden of proving the "existence in the establishment of effective control against diversion." This requirement is in addition to the more general "maintenance of effective controls against diversion" contained in factor 1, discussed above. Good, poor or non-existent "past experience" in having "effective controls against diversion" must be considered as an integral part of Factor 5. Since the applicant has no prior experience in the establishment of effective controls, the ALJ has no factual basis to conclude that the risk is "minimal." Again, this is especially valid when the applicant has the burden of proof. Thus, the Government takes exception to the conclusion that this factor weighs in favor of granting the Respondent's application.

F. Section 823(a)(6).

The Government takes exception to the ALJ making no finding as to the relevance of Doblin's pivotal role in evaluating "such other factors as may be relevant to and consistent with the public health and safety." MAPS focuses on the development of beneficial, socially-sanctioned uses of psychedelic drugs and marijuana including for spiritual exploration. It is apparent that socially-sanctioned is not synonymous with legally-sanctioned and spiritual exploration means recreational use. But as Dr. Voth credibly testified, marijuana legalization advocates use "medical marijuana" as a "stalking horse." (R. 1966-1967). This conclusion is consistent with Doblin's own personal unlawful marijuana experience. (R. 712, 715). Doblin's self-serving pronouncement that MAPS is a not-for profit pharmaceutical company is refuted by his acknowledgement that they have no facilities, no capacity, no prospective products, no

prospective customers, and no budget to produce any pharmaceutical product. (Gov. FCA 82, ¶ 361)

The Government takes exception to the ALJ's refusal to consider the HHS system for determining which researchers will receive research grade marijuana. This amounts to a complete usurpation of the statutory authority of the Secretary of HHS. As discussed above, the Secretary of HHS has established a review process which mandates that, in addition to FDA approval, such a determination will include the review and approval of the PHS and NIDA. As noted above, Doblin stated several times that MAPS desired its "own independent source of supply" (R. 579, 581, 584) and "what we're trying to do is get the Public Health Service and NIDA out of the picture." (R. 666). DEA will not register any researcher in this class who does not have the requisite HHS approval. Although Respondent and his sponsor stated that they will only give marijuana to DEA registrants, this assertion is repeatedly undercut by their acknowledgment that they will give marijuana to any researcher who only has FDA approval and DEA registration, even if they do not have HHS approval. This is either patently deceptive or oxymoronic since no DEA registrant researcher in this class will ever exist without the statutorily required HHS approval.

The Government takes exception to the failure of the ALJ to find that Respondent has failed to meet his burden of proving that this factor, which considers matters relevant to and consistent with the public health and safety, should be weighed in his favor. Thus, this factor should be weighed in favor of denial of the application.

Conclusions

For all of the reasons set forth above, the Government takes exception to each and every finding and conclusion set forth by the ALJ.

Recommended Decision

For all of the reasons set forth above, the Government takes exception to the Recommended Decision of the ALJ and requests the Deputy Administrator to deny Respondent's application.

Respectfully submitted,

Charles E. Trant

Charles E. Trant
Attorney
Office of Chief Counsel

DATED: March 26, 2007

CERTIFICATE OF SERVICE

On March 26, 2007, I caused a copy of the foregoing to be mailed by Federal Express or courier, postage prepaid, to counsel for Respondent, Julie Carpenter, Esq., Jenner & Block, LLP, 601 13th Street, N.W., Washington, D.C. 20005. This is to further certify that the original and two copies were delivered by hand to the DEA Office of Administrative Law Judges on March 26, 2007.

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