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COMMENTS:

Re: Lyle Craker, Ph.D, Docket No. 05-16

Julie- Per our discussion, here is the Government's latest response. Thanks- Brian Bayly BB

UNITED STATES DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

IN THE MATTER OF	)	
	)	
	)	**Docket No. 05-16**
LYLE CRAKER, PH.D.	)	
	)	
	)	

GOVERNMENT'S RESPONSE TO 'RESPONDENT'S SECOND SUPPLEMENTAL BRIEF IN SUPPORT OF MOTION FOR RECONSIDERATION'

The Government, by and through the undersigned attorney, pursuant to the Deputy Administrator's December 2, 2010 Order, responds to 'Respondent's Second Supplemental Brief in Support of Motion for Reconsideration,' which was filed on March 7, 2011. ("Resp Supp Brief March 2011")

I. Post Final Order Procedural History

The final order, *Lyle E. Craker; Denial of Application*, 74 Fed. Reg. 2101 (2009), took official notice of a number of facts, which resulted in the following post final order pleadings and orders:

1. January 30, 2009- Respondent's "Request of Opportunity under 5 U.S.C. § 556(e) to Respond to New Officially Noticed Evidence and Motion for Reconsideration"
2. February 9, 2009- Deputy Administrator's *Lyle E. Craker; Denial of Application; Change in Effective Date*, 74 Fed. Reg. 7264 (2009) (This Order changed the effective date of the final order to April 1, 2009, so that the Deputy Administrator

could consider Respondent's January 30, 2009 response to the final order. The effective date of the final order since then has been extended to incorporate all the post-final order pleadings.)

3. March 11, 2009- "Respondent's Supplemental Brief in Support of Request under 5 U.S.C. § 556(e) to Respond to New Officially Noticed Evidence and Motion for Reconsideration"
4. April 13, 2009- "Government's Response to Respondent's Post-Final Order Motions" (This pleading responded both to Respondent's January 13, 2009 request to respond to officially noticed new evidence and motion for reconsideration and Respondent's March 11, 2009 supplemental brief.)
5. May 18, 2009- Deputy Administrator's interim order directing Respondent to submit a witness list if the hearing were re-opened
6. June 5, 2009- "Respondent's Witness List and Document List"
7. December 2, 2010- Deputy Administrator's "Lyle E. Craker, Ph D., Order Regarding Respondent's Request under 5 U.S.C. § 556(e) to Respond to Officially Noticed Evidence and Motion for Reconsideration" (This Order denied Respondent's motion to re-open the hearing to call additional witnesses but allowed Respondent to submit into the record some additional exhibits. The Order also allowed Respondent to file another brief in support of his motion for reconsideration.)
8. March 7, 2011- "Respondent's Second Supplemental Brief in Support of Motion for Reconsideration"

This present response answers Respondent's latest pleading, the March 7, 2011 supplemental brief. This response, however, does not re-hash all previous arguments. The Government will incorporate all its previous arguments made in its briefs, exceptions and post-final order filings into this response without repeating such arguments. Nevertheless, the Government would submit the following:

II. Motion to Strike Respondent's Appended Exhibits A, B, E, F, G and H

The Deputy Administrator's December 2, 2010 Order ("Dec. 2010 Order") invited Respondent to submit "all of the correspondence between Chemic and HHS (or any of its components) relating to the application he has in his possession … ." (Dec. 2010 Order 26) Exhibit A is a "Revised Final Report" submitted by Chemic but not submitted to HHS. Exhibits B and H are study protocols related to the Chemic research, but the exhibits do not indicate that these protocols were part of the correspondence between Chemic and HHS. Exhibits E, F and G are critiques of the Chemic study from three persons, but these critiques were sent to Chemic. Such exhibits are not "correspondence." Furthermore, Respondent has not laid any foundation to demonstrate that these exhibits were provided to HHS by Chemic.

In any event, even if Respondent timely submitted these exhibits, the Deputy Administrator should find that DEA does not have the jurisdiction and expertise to evaluate the Chemic protocol. Any such expert evaluation by law must be conducted by HHS.

III. Respondent's argument that the current marijuana supplier does not produce an adequate supply under 21 U.S.C. § 823(a)(1)

Respondent's initial argument was that the University of Mississippi's National Center for Natural Products Research ("National Center") could not "produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical ... purposes" as set forth in 21 U.S.C. § 823(a)(1). These arguments were totally refuted as a matter of fact; the National Center has produced an adequate supply both in terms of quality and quantity. Respondent has not pressed this argument because it has been amply refuted.

But Respondent's alternative argument is that there is an "inadequate supply" for purposes of Section 823(a)(1) because HHS has not, under its law, approved all the protocols for researchers who apply to HHS (through NIDA) to obtain marijuana from the National Center. This interpretation of Section 823(a)(1) is untenable to put it charitably. DEA cannot interpret Section 823(a)(1) based upon its subjective and unauthorized evaluation of whether it believes HHS improperly withheld marijuana from a researcher.

If Respondent believes that the HHS system unlawfully prevents research, its remedy is with HHS and only HHS. Indeed 21 U.S.C. § 823(f) explicitly states that those who seek to conduct research with Schedule I controlled substances "shall be referred to the Secretary [of HHS], who shall determine the qualifications and competency of each practitioner requesting registration, as well as the merits of the research protocol." Yet Respondent's interpretation would not just ignore this mandate in Section 823(f), it

would, in effect, change the wording of the statute to have DEA, and not HHS, evaluate research protocols for marijuana. Moreover, Respondent seeks to carve out this exception for just one Schedule I controlled substance, marijuana.

The final order, *Lyle E. Craker; Denial of Application*, 74 Fed. Reg. 2101 (2009), recognized this issue by noting that if Chemic, one of the researchers who had its protocol rejected by HHS, "... had a valid basis to challenge HHS's denial of its request for marijuana, it presumably had remedies available to challenge that agency action either within HHS or in the courts. ..." 74 Fed. Reg. at 2109.[1] Nowhere does Respondent ever cite any authority that one agency has the authority to overrule the policy of another agency.

Respondent tries to craft together several anecdotes to demonstrate that the HHS marijuana policy has resulted in limiting research because NIDA refuses to provide marijuana to such researchers.[2] The final order noted that: "As of April 2004, HHS had approved at least 17 pre-clinical or clinical studies of marijuana, which were sponsored by the California Center for Medicinal Cannabis Research (CMCR)." 74 Fed. Reg. at 2105.

Chemic, highlighted by Respondent as one example of a researcher that could not obtain NIDA marijuana and as mentioned previously herein, continues to seek review with HHS. (Resp Supp Brief March 2011 12-13) Indeed, Respondent's Exhibit K,

[1] Indeed, Exhibit K to Respondent's Supplemental Brief is a letter, from HHS to Chemic, inviting Chemic to alter its protocol so that HHS can reevaluate its protocol.

[2] The third researcher whose protocol was initially denied by HHS was Dr. Donald Abrams. His protocol was eventually approved by HHS. The Government addressed this issue in its "Government's Response to Respondent's Post-Final Order Motions" at pages 4-5.

which is a response letter to Chemic from HHS, informs Chemic of its concerns resulting in the initial rejection of Chemic's vaporizer, but invites Chemic to address its concerns. The HHS letter to Chemic concludes: "Once you provide this information the committee will evaluate your responses and provide a timely decision... Please contact me if you need additional information or have questions." Resp Supp Brief March 2011, Exhibit K.

In the December 2, 2010 Order, the Deputy Administrator allowed Respondent to put into evidence a February 1, 2000 letter to Ethan Russo, M.D., from HHS. (Dec. 2010 Order 25) The purpose in allowing such new evidence was to clarify Dr. Doblin's testimony when he testified that HHS denied Dr. Russo's protocol in 1999, i.e., the record was unclear whether HHS denied this protocol under its old policy or under the new policy that was published on May 21, 1999. (Dec. 2010 Order 23-25; G- 24) As such, Respondent now features this February 1, 2000 letter as evidence that HHS unduly denied Dr. Russo's protocol even under its more liberal policy promulgated under the May 21, 1999 policy statement.

First, Dr. Gust testified that Dr. Russo did have a grant denied by HHS in 1999 (or more precisely on February 1, 2000 as noted in the aforementioned letter) but that Dr. Russo received alternative funding and did not resubmit his protocol to HHS under the May 21, 1999 protocol. (Gov. FCA 69, ¶ 302) [3] Second, even if Dr. Russo would have re-submited his protocol to HHS instead of seeking alternative funding, again DEA has no part in the HHS process.

[3] "Gov. FCA" refers to the Government's Proposed Findings of Fact, Conclusions of Law and Argument.

In support of its main argument that DEA should by-pass HHS's marijuana policy, Respondent argues that NIDA's mission is not to promote research but is related to drug abuse issues. (Resp Supp Brief March 2011 6) This argument is just another substantive complaint that Respondent has about the HHS process; again, DEA does not have any authority to second-guess and overrule HHS's policy. Moreover, this argument is refuted as a matter of fact. The NIDA representative, Steve Gust, Ph. D., testified that NIDA's review of protocols was accomplished by panels of experts from specialty institutes of the NIH. (Gov. FCA 67, ¶ 293;Gov. FCA 68-69, ¶ 298) *See also,* 74 Fed. Reg. at 2105

Respondent argues that the National Center ("Dr. El Sohly") "might have a market interest in blocking the development of medicinal marijuana; he acknowledged that he worked with certain 'pharmaceutical partners' … seeking to develop 'pharmaceutical products that are based on naturally-occurring THC.'" (Resp Supp Brief March 2011 13) However, the National Center has no say whatsoever in either granting or denying research protocols or setting any prices.

IV. Respondent's arguments pertaining to the Single Convention on Narcotic Drugs[4]

First, Respondent argues that DEA should have applied the "relaxed requirements for medical marijuana equivalent to the exemption for medical opium." (March 2010 Supp Brief 15) The December 2 Order clearly refuted this argument by noting the Commentary to the Single Convention clearly made the

[4] March 30, 1961, 18 U.S.T. 1407.

distinction between medicinal marijuana and plant or whole-grown marijuana that had to be "procured from the national opium agency." [Emphasis in original] (Dec. 2010 Order 11-12) The clear wording of Article 2 (e)[5]- "The Agency shall ... have the exclusive right of ... wholesale trading and maintaining stocks other than those held by manufacturers of ... medicinal opium [marijuana]"- makes Respondent's interpretation untenable.

Article 2(e) concludes: "Parties need not extend this exclusive right to medicinal opium [marijuana] ... ." This part of Article 2(e) again makes clear the distinction of wholesale marijuana, which falls under the Government's exclusive right to handle marijuana, as opposed to medicinal marijuana, which can be exempted from the Government's exclusive right to regulate wholesale trading of marijuana.

The December 2 Order also clearly explained that a manufacturer potentially could develop a derivative of cannabis into a "medicinal cannabis" product that would be exempt from the Single Convention's wholesale requirements. (Dec. 2010 Order 12-13) Thus, Respondent's argument is also refuted in this regard.

In a related argument, Respondent argues that he will cultivate marijuana that eventually will be made into medicinal marijuana, and thus the Government's "exclusive right" would not apply. (March 2010 Supp Brief 16) This argument

[5] Although Article 23 applies to the control of opium, Article 28 states that if a Party permits the production of cannabis, then the opium restrictions under Article 23 also apply to cannabis.

has the exemption "swallow the rule" and would completely vitiate the language of Article 23(e)(2).

Finally, Respondent argues that since there is no Government agency that actually takes physical possession of any marijuana produced and since it is DEA, and not NIDA, that is "responsible" for carrying out the requirements of the Single Convention, then DEA should register Respondent. March 2010 Supp Brief 16-21)

In regard to the fact that no Government agency actually takes physical possession of the marijuana, the final order explained:

> As for the argument that the Single Convention does not require that the Government take physical possession, the argument provides no comfort to Respondent for two reasons. First, the argument ignores that taking possession and engaging in wholesale distribution are two separate activities under the Convention.

74 Fed. Reg. at 2114. In other words, the "two separate activities" are governed by two distinct sections of Article 23. Article 23(2)(d) pertains to the a government taking physical possession, which is not the section that the final order is interpreting. The final order is interpreting Section (2)(e), which pertains to the "wholesale trading" requirement.

Respondent's second contention is that DEA, and not NIDA, is responsible for effectuating the Single Convention; therefore, Respondent should be registered because he, as well as the National Center, would be under DEA control. Again, the final order, in quoting from the following Single Convention's Commentary excerpt, clearly refuted this argument:

> [T]he acquisition of the crops and the wholesale and international trade in these agricultural products cannot be entrusted to private traders, but must be undertaken by governmental authorities in the producing countries. Article 23 * * * and article 28 * * * therefore require a government monopoly of the wholesale and international trade in the agricultural product in question in the country which authorizes its production. Commentary at 278.

74 Fed. Reg. at 2114-2115.

In Respondent's scheme, anyone who meets minimal requirements under DEA laws will be eligible to manufacture whole plant marijuana and distribute it to anyone who submits an approved FDA Initial New Drug Application (IND). And under this scenario, it would not be just Respondent that could take advantage of Respondent's scheme; many other marijuana manufacturers could be registered as well. But the above quoted portion of the Commentary and the express language of Article 23(2)(e) are totally at odds with Respondent's inapposite interpretation. The intent of the Single Convention is in harmony with the existing system and not at all with what Respondent envisions.

Conclusion

For the foregoing reasons, the Government respectfully requests the Administrator to deny "Respondent's Second Supplemental Brief in Support of Motion for Reconsideration" and to deny all previous post-final motions submitted by Respondent.

Respectfully submitted,

Brian Bayly
Attorney, Office of Chief Counsel

Dated: April 1, 2011

CERTIFICATE OF SERVICE

On April 1, 2011, I sent a copy of the foregoing by facsimile, (202) 661-4810, to Counsel for Respondent, Julie M. Carpenter, Esq., Jenner & Block, 601 Thirteenth Street, NW, Washington, D.C. 20005. In addition, on April 1, 2011, I hand delivered the original with attachments and two copies of the foregoing to the DEA Office of the Administrator.

Brian Bayly