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UNITED STATES DEPARTMENT OF JUSTICE  
Drug Enforcement Administration

In the Matter of

Lyle E. Craker, Ph.D.

Docket No. 05-16

**OPINION AND RECOMMENDED RULING, FINDINGS OF FACT,  
CONCLUSIONS OF LAW, AND DECISION OF THE  
ADMINISTRATIVE LAW JUDGE**

MARY ELLEN BITTNER, ADMINISTRATIVE LAW JUDGE

APPEARANCES:

Brian Bayly, Esq.  
for the Government

Julie M. Carpenter, Esq.  
for Respondent

Dated: February 12, 2007

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### I. The Single Convention

As discussed above, the Single Convention specifies that signatory parties have certain responsibilities with respect to marijuana and that such parties are to establish a single government agency to discharge those responsibilities. As Respondent asserts in his brief, it is not clear whether the DEA or NIDA is that agency.<sup>138</sup> The DEA, through its registration process, performs the licensing function, and, through its quota-setting process, determines the total amount of marijuana the National Center is permitted to produce, but NIDA determines how much marijuana the National Center produces for it. It is noteworthy that no government agency takes physical possession of the National Center's crop; it appears, however, from the United Kingdom's regulatory scheme described above that the parties to the Single Convention are free to construe the term "physical possession" as they see fit.

It also appears, although it is not entirely clear, that the marijuana grown by the National Center or by any other registrant for utilization in research would qualify as either "medicinal" within the meaning of Article 1, Paragraph (1)(o),<sup>139</sup> or as "special stocks" within the meaning of Article 1, Paragraph (1)(x),<sup>140</sup> and that therefore the government monopoly on importing, exporting, wholesale trading, and maintaining stocks would not apply. I therefore find that the Single Convention does not preclude registering Respondent.

### II. The Statutory Factors

#### A. Section 823(a)(1)

21 U.S.C. § 823(a)(1) requires consideration of maintaining effective controls against diversion by limiting the manufacturing of Schedule I or II controlled substances "to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research and industrial purposes." Respondent emphasizes that in *Noramco of Delaware v. DEA*, 375 F.3d 1148 (D.C. Cir. 2004), the United States Court of Appeals for the District of Columbia Circuit found that "The stated purpose of section 823(a)(1) is

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<sup>138</sup> Respondent's Proposed Findings of Fact, Conclusions of Law and Argument, p. 66.

<sup>139</sup> Single Convention, art. 1, para. 1(o).

<sup>140</sup> Single Convention, art. 1, para. 1(x).

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to effectively control against diversion and it expressly directs the DEA to limit competition only as a means to achieve ‘maintenance’ of such control.”<sup>141</sup> I note, however, that in the same opinion the court apparently found that it was not improper for the Deputy Administrator to consider the adequacy of competition;<sup>142</sup> I therefore address both issues.

### 1. Controls Against Diversion

Respondent testified that he would grow marijuana in a climate-controlled room that had one wall in the earth and had only one door, that the drying area would be connected to the cultivation room, and that the DEA personnel who visited the University of Massachusetts to inspect the proposed cultivation and drying area said that they thought the area could be made secure. There is no evidence or contention that either Respondent or anyone working with him would be likely to divert the marijuana from the growing or drying or storage areas. I also note that in his August 2002 answers to the DEA’s questions, Respondent stated that he intended to grow about twenty-five pounds (dry weight) of marijuana in the first year of cultivation if his application is granted, and there is no evidence – nor does the Government contend – that his intentions are otherwise. I therefore find that it is unlikely that the marijuana that Respondent would grow would be diverted from the University of Massachusetts’ facility.

There remains the question of whether marijuana would be diverted after it left the University of Massachusetts. In this respect, the Government emphasizes that Dr. Doblin believes that marijuana should be available as medicine and for non-medical purposes as well, and that the incident in which Dr. Doblin arranged for marijuana from a user in the compassionate use program to be sent to the Drug Detection Laboratory and then to Chemic demonstrates that he would not be averse to operating outside of the DEA’s regulatory framework.

The record in this proceeding demonstrates that Dr. Doblin disagrees with the DEA’s position on the dangers of marijuana use, and it also demonstrates, as the Government asserts, that Dr. Doblin and MAPS are the sponsors of Respondent’s application and would determine the recipients of the marijuana that Respondent would

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<sup>141</sup> *Noramco*, 375 F.3d at 1153.

<sup>142</sup> *Id.* at 1154, 1157.

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grow if he becomes registered to do so. However, the record also establishes that MAPS and Dr. Doblin would not at any time have physical possession of that marijuana and, perhaps most importantly, that Respondent would send marijuana only to researchers who hold DEA registrations and, therefore, have the requisite approval from the Department of Health and Human Services, including findings that the researcher is qualified and competent, that the research protocol is meritorious, and that the research project has procedures in place to adequately protect against diversion of the marijuana. In these circumstances, I conclude that there is minimal risk that the marijuana that Respondent would cultivate would be diverted.

### **2. Competition**

#### **a. Adequacy of Supply**

Although the record contains evidence that there have been some problems with the marijuana that the National Center produces, I find that a preponderance of the record establishes that the quality is generally adequate. I further find that there is no evidence that researchers whom NIDA approves to obtain marijuana have experienced difficulties in obtaining marijuana from the National Center when they need it.

The record does establish, however, that NIDA's system for evaluating requests for marijuana for research has resulted in some researchers who hold DEA registrations and requisite approval from the Department of Health and Human Services being unable to conduct their research because NIDA has refused to provide them with marijuana. I therefore find that the existing supply of marijuana is not adequate.

#### **b. The Policy Against "Shelf Registrations"**

As discussed above, the Government contends that registering Respondent would violate the DEA's policy against contingent registrations because Respondent has not shown that his registration would result in a pharmaceutical company developing a drug product from plant marijuana.

I disagree. Respondent is not obligated to show that his registration will lead to a pharmaceutical product but, rather, that he will use his registration to produce marijuana that will be used in legitimate research. That, Respondent has done.

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

The Government also asserts that the process by which NIDA awards the contract to grow marijuana for research provides adequate competition inasmuch as the demand for licit marijuana is extremely limited and marijuana is the most commonly abused drug in the United States. The question is not, however, whether the NIDA process addresses that agency's needs, but whether marijuana is made available to all researchers who have a legitimate need for it in their research. As discussed above, I answer that question in the negative.

It is also undisputed that the NIDA contract requires the contractor to analyze samples of marijuana supplied by law enforcement agencies, a separate activity from cultivating marijuana for research purposes and a requirement that a qualified cultivator may not be able to fulfill.

I find that the NIDA contractual process does not, in the context of this case, render competition in the manufacture of marijuana adequate.

**3. Conclusions with respect to Section 823(a)(1)**

I find that if Respondent's application is granted, the risk that the marijuana that he would cultivate would be diverted is minimal and that competition in the manufacture of marijuana for research purposes is inadequate. I therefore find that this factor weighs in favor of granting Respondent's application.

**B. Section 823(a)(2)**

Section 823(a)(2) requires consideration of the applicant's compliance with applicable law. There is neither evidence nor contention that Respondent has not complied with applicable laws and I therefore find that this factor weighs in favor of granting Respondent's application.

**C. Section 823(a)(3)**

Section 823(a)(3) calls for consideration of the promotion of technical advances in the art of manufacturing controlled substances and in developing new substances. It is undisputed that Respondent has no experience in manufacturing or otherwise handling controlled substances. He does have considerable experience in cultivating medicinal plants, which might promote technical advances in the cultivation of marijuana or in

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developing new medications from it. I find, however, that there is not sufficient evidence in the record on which to base a finding as to whether granting Respondent's registration would promote technical advances.

### **D. Section 823(a)(4)**

Section 823(a)(4) requires consideration of the applicant's prior conviction record under laws relating to the manufacture, distribution, or dispensing of controlled substances. It is undisputed that Respondent has never been convicted of any violation of any law pertaining to controlled substances, and I therefore find that this factor weighs in favor of granting the application.

### **E. Section 823(a)(5)**

Section 823(a)(5) requires consideration of the applicant's past experience in manufacturing controlled substances and the existence of effective controls against diversion. As discussed above, Respondent has no experience in manufacturing controlled substances, but does have experience in growing medicinal plants. As also discussed above, I find that the risk of diversion that would result from granting Respondent's application is minimal. I therefore find that this factor weighs in favor of granting the application.

### **F. Section 823(a)(6)**

Section 823(a)(6) requires consideration of other factors relevant to public health and safety. I have discussed Dr. Doblin's use of marijuana and his attitude toward the regulation of marijuana above, and need not repeat that discussion here.

The Government contends that granting Respondent's application would amount to circumventing the Department of Health and Human Services' policy with respect to providing marijuana to researchers, and that the DEA has no legal authority to do so. But as quoted above, the NIH Guidance by its own terms applies to marijuana that the Department of Health and Human Services makes available, not marijuana that might be available from some other legitimate source. I therefore find that the NIH Guidance is not a factor in determining whether Respondent's application should be granted.

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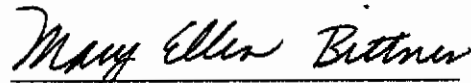
### CONCLUSIONS

I conclude that granting Respondent's application would not be inconsistent with the Single Convention, that there would be minimal risk of diversion of marijuana resulting from Respondent's registration, that there is currently an inadequate supply of marijuana available for research purposes, that competition in the provision of marijuana for such purposes is inadequate, and that Respondent has complied with applicable laws and has never been convicted of any violation of any law pertaining to controlled substances. I therefore find that Respondent's registration to cultivate marijuana would be in the public interest.

### RECOMMENDED DECISION

I recommend that Respondent's application be granted.

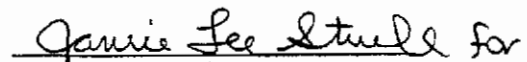
Dated: February 12, 2007



Mary Ellen Bittner  
Administrative Law Judge

### CERTIFICATE OF SERVICE

<sup>JLS</sup>  
This is to <sup>hand</sup>certify that the undersigned on February 12, 2007, caused a copy of the foregoing to be delivered ~~via interoffice mail~~ <sup>hand delivered</sup> to counsel for the Government, Brian Bayly, Esq., Office of Chief Counsel, Drug Enforcement Administration, Washington, D.C. 20537, and a copy to be mailed, ~~postage paid,~~ <sup>hand delivered</sup> to counsel for Respondent, Julie M. Carpenter, Esq., Jenner & Block, 601 Thirteenth Street, N.W., Suite 1200 South, Washington, D.C. 20005. JLS

  
Patricia A. Medico  
Secretary to Mary Ellen Bittner  
Administrative Law Judge