U.S. Department of Justice

Drug Enforcement Administration
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FAX TRANSMISSION

Date: August 12, 2005

To: Julie M. Carpenter, Esq.
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Re: *In the Matter of Lyle E. Craker Docket No. 05-16*

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

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Please see attached Memorandum to Counsel and Ruling on Motion in Limine.

Attachment

UNITED STATES DEPARTMENT OF JUSTICE
Drug Enforcement Administration

In the Matter of

Lyle E. Craker, Ph.D.

Docket No. 05-16

MEMORANDUM TO COUNSEL AND RULING ON MOTION IN LIMINE

On July 22, 2005,[1] counsel for the Government filed a motion in limine to exclude certain testimony and exhibits that Respondent intends to offer in the above-captioned proceeding. The Government asserts, in substance, that the Administrative Procedure Act, at 5 U.S.C. § 556(d), requires me to exclude evidence that is "irrelevant, immaterial, or unduly repetitious," that regulations implementing the Controlled Substances Act, at 21 C.F.R. § 1316.59(a), require me to admit "only evidence that is competent, relevant, material and not unduly repetitious," and that reviewing courts have routinely upheld agencies' decision to exclude such irrelevant, immaterial, or unduly repetitious evidence.

The Government contends that the primary factual issues in this case are whether the University of Mississippi produces an adequate quantity of marijuana of acceptable quality for research purposes and whether another cultivator is necessary to supply marijuana for scientific investigations and new drug products. The Government asserts that various testimony and exhibits listed in Respondent's prehearing statement are not relevant to 21 U.S.C. §823(a)(1), and that this subsection specifies that the Drug Enforcement Administration (DEA) "must register a manufacturer of Schedule I controlled substances only if the current manufacturer cannot '...produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes.'"[2] The Government contends that this provision specifies a threshold issue, and that if the University of Mississippi produces an "adequate and uninterrupted supply under adequately competitive conditions," Respondent's registration would be at most a contingency registration, which would contravene DEA policy.

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[1] All dates herein are 2005 unless otherwise indicated.

[2] Government's Motion in Limine to Exclude Respondent's Proposed Testimony and Listed Exhibits Pursuant to 5 U.S.C. §556(d) and 21 C.F.R. §1316.59(a), July 22, 2005, p. 3.

The Government asserts that proposed Respondent exhibits 16, 22, 20, 19, 17, and 18 should be excluded because they concern research on the potential benefits and risks of using marijuana as medicine, but do not address any of the factors listed in 21 U.S.C. § 823(a).

The Government further contends that the proposed testimony of Respondent witness Angel Raich contains anecdotal evidence of the benefits of using marijuana as medicine; the testimony of Valerie Corral contains pleas for further research into such use; the testimony of Dr. Irwin Martin does not address the threshold issue under 21 U.S.C. § 823(a)(1) noted above; and the testimony of Dr. Grinspoon and the book *Marijuana, the Forbidden Medicine*, relate to anecdotal evidence as to the efficacy of marijuana in treating various medical conditions. The Government also notes that some of this evidence was rejected in *Alliance for Cannabis Therapeutics v. DEA*, 930 F.2d 936 (D.C. Cir. 1991), *affirmed after remand*, 15 F.3d 1131 (D.C. Cir. 1994).

On August 8, Respondent filed an opposition to the Government's motion. Respondent asserts that all of his proposed witnesses and exhibits are relevant to the issues in this proceeding, that relevant evidence is that which has "'any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence,'"[3] and that in an administrative hearing the administrative law judge has a duty to err on the side of inclusion when determining relevance.[4]

Respondent contends that the issue in this case is whether Respondent's registration would be in the public interest, that all the factors listed in 21 U.S.C. § 823(a) must be considered in making that determination, and that even if some of his witnesses and exhibits are not relevant to the first five factors, they are relevant to the sixth, "such other factors as may be relevant to and consistent with the public health and safety."[5]

With respect to the exhibits that the Government seeks to exclude, Respondent asserts that articles concerning past research on medical marijuana are relevant under 21 U.S.C. § 823(a)(3); evidence of existing research on marijuana's benefits and risk is relevant to whether Respondent's proposal to cultivate it is for legitimate scientific, medical, or research purposes; and the articles are relevant to the question of whether there is adequate competition given that the current registered cultivator can grow marijuana only subject to contractual constraints. With respect to the witnesses, Respondent asserts that Ms. Raich's and Ms. Corral's testimony will be relevant to the first and sixth factors listed in § 823(a); Dr. Martin's testimony will be relevant to the first, third, and sixth factors; and Dr. Grinspoon's testimony and book are relevant to the first factor.

Discussion

The Controlled Substances Act specifies:

> The Attorney General shall register an applicant to manufacture controlled substances in schedule I or II if he determines that such registration is consistent with the public interest and with United States obligations under international

[3] Quoting Fed. R. Evid. 401.
[4] Citing *Underwood v. Elkay Mining*, 105 F.3d 946, 951 (4th Cir. 1997).
[5] 21 U.S.C. § 823(a)(6).

treaties, convention, or protocols in effect on May 1, 1971. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such 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;
(2) compliance with applicable State and local law;
(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;
(4) prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;
(5) past experience in the manufacture of controlled substances and the existence in the establishment of effective control against diversion; and
(6) such other factors as may be relevant to and consistent with the public health and safety.[6]

At the outset, I note that the Deputy Administrator has consistently held that the factors in 21 U.S.C. § 823(a) are to be considered in the disjunctive and that she may properly rely on any one or a combination of these factors, giving each the weight she considers appropriate in determining whether a registration would be in the public interest.[7] I further note that DEA's implementing regulations specifically provide that

> 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.[8]

In light of DEA precedent and the agency's own regulations, I conclude, in agreement with Respondent, that 21 U.S.C. § 823(a)(1) does not specify a threshold condition, i.e., that if there are a number of establishments that can produce an adequate and uninterrupted supply of the controlled substance at issue under adequately competitive conditions, no other manufacturers should be registered. Accordingly, I further conclude that Respondent may offer evidence that is relevant to any of the factors listed in 21 U.S.C. § 823(a).

The issue remains whether evidence of marijuana's claimed therapeutic benefits should be excluded in this proceeding. As noted above, Respondent asserts that such evidence is relevant under § 823(a)(6), "such other factors as may be relevant to and consistent with the public health and safety," because it addresses whether the research for which Respondent proposes to grow marijuana meets the statutory requirement of manufacture for a legitimate purpose. But the parties stipulated that research into the therapeutic use of cannabis is ongoing, § 823(f) specifically provides for research with

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[6] 21 U.S.C. § 823(a).

[7] *Penick Corporation*, 68 Fed. Reg. 6947 (DEA 2003), affd. sub nom. *Noramco of Delaware, Inc. v. DEA*, 375 F.3d 1148 (DC Cir. 2004).

[8] 21 C.F.R. § 1301.33(b).

Schedule I controlled substances, and there is no contention that Respondent intends to cultivate marijuana for other than legitimate research purposes. In these circumstances, I find that evidence pertaining to marijuana's therapeutic uses is irrelevant to the issue of whether Respondent's registration would be consistent with the public interest.

Conclusions

In light of the foregoing, I grant the Government's motion with respect to Respondent's exhibits 16, 22, 20, 19 (except with respect to discussion of the quality or supply of cannabis provided for research), 17, and 18; the proposed testimony of Ms. Raich, Ms. Corral, and Dr. Grinspoon (except that I deny the motion with respect to Dr. Grinspoon's testimony on difficulties resulting from the National Institute of Drug Abuse holding a monopoly on cultivation of marijuana for research purposes); and Dr. Grinspoon's book. I deny the Government's motion with respect to Dr. Martin's proposed testimony.

Dated: August 12, 2005

Mary Ellen Bittner
Administrative Law Judge

Certificate of Service

This is to certify that the undersigned on August 12, 2005, caused a copy of the foregoing to be faxed and delivered to counsel for the Government, Brian Bayly, Esq., Office of Chief Counsel, Drug Enforcement Administration, Washington, D.C. 20537, and a copy to be faxed and mailed, postage paid to counsel for Respondent, Julie M. Carpenter, Esq., Jenner & Block, 601 13th Street, N.W., Washington, D.C. 20005.

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