

**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 TO EXCLUDE EVIDENCE

On September 16, 2005,¹ counsel for Respondent filed a motion to exclude certain testimony and exhibits that the Government intends to offer in the above-captioned proceeding. Counsel for Respondent asserts, in substance, that this evidence is inadmissible under 21 C.F.R. § 1316.59(a) and the Memorandum to Counsel and Ruling on Motion in Limine that I issued on August 12.

On October 20, counsel for the Government filed a response to Respondent's motion, agreeing that certain evidence should be excluded, and contending that other evidence at issue is admissible as rebuttal or as relevant to issues in the proceeding.

The Parties' Contentions

Section 1316.59(a) requires me to "admit only evidence that is competent, relevant, material and not unduly repetitious." In the August 12 memorandum and ruling, I held that evidence pertaining to any of the factors listed in 21 U.S.C. § 823(a) is relevant but that evidence pertaining to marijuana's therapeutic uses is not.

Respondent objects to: (1) the Government's proposed exhibits 46 and 60, documents from the American Medical Association and a letter from the Iowa Board of Pharmacy Examiners, respectively, and a portion of the proposed testimony of Eric Voth, M.D., all pertaining to the stance of certain medical organizations concerning medical marijuana; (2) Dr. Voth's testimony about whether there is a need for an additional registered manufacturer of marijuana; and (3) the Government's proposed exhibits 41, 48, 49, and 50, as well as testimony from Dr. Voth concerning the potential harms of using marijuana.

¹ All dates herein are 2005.

Respondent asserts that the Government's proposed exhibits 46 and 60 and the referenced portions of Dr. Voth's testimony pertain to whether the benefits and risks of marijuana use should be the subject of further research and are thus excluded pursuant to the August 12 memorandum and ruling. Respondent further contends that a witness he intended to call on this issue was unable to attend the hearing and therefore Respondent has not introduced evidence that would justify admitting the Government's evidence in rebuttal. Finally, on this point, Respondent contends that permitting this evidence would open the door to evidence on Respondent's behalf concerning medical organizations that support further research into marijuana's medical benefits.

With respect Dr. Voth's proposed testimony about Respondent's contention that a pharmaceutical manufacturer would not develop a marijuana product unless it was assured of a reliable supply, Respondent asserts that 21 C.F.R. § 1316.59(b) permits Dr. Voth to express an opinion only if he is qualified to do so, and because Dr. Voth does not have experience in developing new drugs or bringing them to market he therefore does not possess the requisite qualifications.

Respondent contends that the Government's proposed exhibits 41, 48, 49, and 50, as well as Dr. Voth's proposed testimony about whether marijuana is medicine and the adverse results of inhaling or smoking it, should be excluded because they are precluded by the August 12 memorandum and ruling. Respondent further contends that insofar as the Government seeks to use this evidence to show the dangers of marijuana use in general, such evidence is not relevant to the factors listed in 21 U.S.C. § 823(a), and to the extent the Government seeks to use this evidence to show its concern for diversion, the evidence is irrelevant because the possibility of diversion is established by the statute and Respondent is willing to stipulate that there is a public interest in maintaining effective controls against diversion.

The Government asserts, in response, that its proposed exhibits 46 and 60 go beyond the premises Respondent references and are admissible as rebuttal to Dr. Doblin's testimony that there are qualified experts who accept marijuana as medicine. The Government further asserts that on cross examination, Dr. Doblin was asked about Respondent's exhibit 24, an American Medical Association report on medical marijuana, and therefore it would be inappropriate to exclude the Government's proposed exhibit 46.

In addition, the Government asserts that it withdrew its anticipated exhibit 42, a 1997 medical journal article co-authored by Dr. Voth, because in the August 12 memorandum and ruling I excluded Respondent's exhibit 22, a 1991 article co-authored by Dr. Doblin. The Government asserts that inasmuch as Dr. Doblin testified about the subject matter of Respondent's exhibit 22, and also testified that there are experts who accept marijuana as medicine, Dr. Voth should be permitted to testify about whether there is substantial expert support for this proposition. With respect to proposed Government exhibit 60, the Government notes that the exhibit mentions Respondent's exhibit 22 and sources that critique the article.

With respect to Dr. Voth's testimony, the Government agrees with Respondent that there should not be any testimony about whether organizations agree or disagree that the health benefits and risks of medical marijuana should be the subject of further research. The Government contends, however, that Dr. Voth should be permitted to testify that he disagrees with Dr. Doblin's characterization that qualified experts have accepted marijuana as a medicinal drug.

The Government also agrees with Respondent that Dr. Voth's anticipated testimony about the need for another manufacturer should be excluded, but asserts that the basis for such exclusion is the August 12 memorandum and ruling, not Dr. Voth's lack of qualifications. The Government asserts that as a medical practitioner, Dr. Voth is at least as qualified as Dr. Doblin to testify about marijuana and is an expert on the drug. The Government asserts that it will introduce evidence as to Dr. Voth's qualifications at the hearing and that he should be permitted to testify to rebut Dr. Doblin's testimony about marijuana's chemistry and the availability of scientific evidence about marijuana.

With respect to Respondent's contention that the Government's proposed exhibits 41, 48, 49, and 50, as well as Dr. Voth's anticipated testimony about marijuana as medicine and the harmful effects of smoking or inhaling it, should be excluded, the Government agrees that the costs and benefits of marijuana as medicine are not relevant issues. The Government asserts, however, that Respondent goes beyond the August 12 memorandum and ruling by arguing that the possibility of diversion is established by 21 U.S.C. § 823(a)(1). The Government contends that evidence about abuse of marijuana and the potential for diverting it, whether at the point of cultivation or downstream, is

relevant. The Government notes that 21 U.S.C. § 823(a)(1) requires maintaining controls against diversion by limiting the number of manufacturers of a Schedule I or II controlled substance to that which will ensure an adequate and uninterrupted supply under adequately competitive conditions, and asserts that adding another manufacturer will increase the illicit as well as the licit supply of marijuana. The Government quotes *Johnson Matthey, Inc.*, 60 Fed. Reg. 26,050 (1995), for the proposition that the DEA considers the consequences of downstream diversion when assessing Section 823(a)(1).

Discussion

Proposed Government exhibit 46 appears to be copies of resolutions from the American Medical Association stating the organization's positions on medical marijuana, health aspects of marijuana use, legalization of marijuana, and alcohol and drug abuse education. The document is not dated. As noted, the Government asserts that this document rebuts Dr. Doblin's testimony. Dr. Doblin, testifying on cross examination about the factors to be considered in determining whether a drug has an accepted medical use, stated, "The drug must be accepted by qualified experts. I would say there are qualified experts who accept marijuana as medicine."² Providing evidence that there are experts who do not accept a proposition does not contradict testimony that there are experts who do. I therefore find that proposed Government exhibit 46 does not rebut Dr. Doblin's testimony and that it is covered by the August 12 memorandum and ruling.

The Government further asserts that proposed exhibit 46 is admissible because on cross examination Dr. Doblin referred to Respondent's exhibit 24, a report by the American Medical Association's Council on Scientific Affairs in June 2001. However, Dr. Doblin's testimony was limited to a reference to a statement in the document about the number of chemical compounds in marijuana, and I find that this testimony does not render exhibit 46 admissible as rebuttal evidence. I will therefore exclude the Government's proposed exhibit 46.

Proposed Government exhibit 60 is a letter dated March 10, 1995, from the Iowa Board of Pharmacy Examiners to Iowa Senator Elaine Szymoniak, expressing the Board's belief that pertinent medical literature supported its opposition to marijuana for

² Transcript p. 622.

therapeutic purposes. For the same reasons expressed above, I find that this document does not rebut Dr. Doblin's testimony and I will therefore exclude it.

Inasmuch as the parties agree that Dr. Voth's testimony about the need for another manufacturer of marijuana because no pharmaceutical company would develop a product without a marijuana supply to ensure consistency of dose should be excluded, I will exclude it. The parties disagree as to Dr. Voth's qualifications to testify about research or drug development. It appears from Dr. Voth's curriculum vitae, the Government's proposed exhibit 36, that he has authored or co-authored a number of journal articles on marijuana, but it is not clear whether he has expertise in drug development. I will therefore allow the Government to question Dr. Voth on this issue and rule on whether he is qualified to testify about it if it becomes necessary.

With respect to Dr. Voth's anticipated testimony as to whether marijuana's chemistry is known and reproducible and whether scientific evidence about marijuana is widely available, it appears that Dr. Voth is an expert on marijuana and that his testimony would rebut Dr. Doblin's testimony. I therefore will not exclude it.

The parties agree that Dr. Voth's proposed testimony as to whether marijuana is viable medicine and concerning the deleterious effects of smoking or inhaling it should be excluded, and I therefore will.

Finally, Respondent apparently views some of Dr. Voth's testimony as going to the possibility that marijuana may be diverted. I do not read the summary of Dr. Voth's testimony as including this issue, but if it does, I will allow the testimony. I note, as the Government asserts, that 21 U.S.C. § 823(a)(1) refers to controlling diversion by limiting the number of manufacturers to that which can produce an adequate and uninterrupted supply under adequately competitive conditions, and evidence concerning diversion generally is admissible in proceedings such as this. *See, e.g., Noramco of Delaware, Inc. v. DEA*, 375 F.3d 1148 (D.C. Cir. 2004).

Proposed Government exhibit 41 discusses both the risks of smoking marijuana and the extent of use; I shall not exclude the article, but to the extent it discusses risks, I conclude that it pertains to whether marijuana has the potential for use as medicine and shall not consider it. Proposed Government exhibits 48 and 50 discuss the consequences of using marijuana. I conclude that these exhibits also pertain to whether marijuana has


the potential for use as medicine and shall therefore exclude them. Proposed Government exhibit 49 discusses the risk of becoming cannabis-dependent; I conclude that this article pertains to diversion generally and shall therefore not exclude it.

Dated: November 8, 2005


Mary Ellen Bittner
Administrative Law Judge

CERTIFICATE OF SERVICE

This is to certify that the undersigned on November 8, 2005, caused a copy of the foregoing to be faxed and delivered via interoffice mail 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 Thirteenth Street, N.W., Suite 1200 South, Washington, D.C. 20005.


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