DRUGS AND THE LAW COMMITTEE

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By Regular Mail

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DEA Administrator Karen P. Tandy
Mailstop AXS
2401 Jefferson Davis Highway
Alexandria VA 22301

Re: In the Matter of Lyle E. Craker, Ph.D.,
Drug Enforcement Administration Docket No. 05-16

Dear Administrator Tandy:

The Drugs and the Law Committee (the "Committee") of the Association of the Bar of the City of New York respectfully submits this letter in support of the position of Lyle E. Craker, Ph.D. ("Dr. Craker") that registration of Dr. Craker by the Drug Enforcement Administration ("DEA") as a bulk manufacturer of marijuana would be consistent with "the public interest," as that term is used in 21 U.S.C. 823(a).

Summary

The Committee proposes that such registration, in the absence of any indication in the record that Dr. Craker is not qualified to be registered as a bulk manufacturer, would be consistent with the public interest because (1) the statutory scheme established by Congress, in the Controlled Substances Act, contemplates that controlled substances may be, through research, shown to have medicinal uses and (2) such registration is necessary to break an impasse in the application of the regulatory system that thwarts the development of marijuana as a pharmacotherapy for various adverse medical conditions, requires that medical patients who use marijuana to relieve adverse medical conditions to violate the laws of the United States, leaves unresolved a controversy that has resulted in extensive litigation and will likely continue to do so unless resolved through the conduct of clinical research, and potentially undermines public trust in the integrity of the government agencies entrusted with supervising the regulatory system.

Summary of underlying factual assumptions

As set forth in the various statements filed by the DEA and Dr. Craker prior to the hearings before Administrative Law Judge Mary Ellen Bittner in August and December of 2005 and in the testimony offered in those hearings, Dr. Craker applied to the DEA in June of 2001 to

be registered as a bulk manufacturer of marijuana for the purposes of cultivating marijuana for use in research preliminary to and necessary for the development of marijuana as a prescription medication. After the commencement of litigation, the DEA rejected Dr. Craker's application in 2004 on the grounds that the application is not consistent with the public interest.

Since 1974, as the successor to the Drug Supply Program of the National Institute of Mental Health ("NIMH")[1], the National Institute on Drug Abuse ("NIDA") has been the only entity that may legally provide marijuana for use in FDA-approved research in the United States into the use of marijuana in humans. The University of Mississippi has been since the inception of the Drug Supply Program in 1968 the only person authorized to manufacture marijuana, first on behalf of NIMH and then on behalf of NIDA.

Any person who seeks to obtain marijuana from NIDA for FDA-approved research must submit its research protocol to an additional round of review by the Public Health Service for safety and efficacy, a process that does not apply to research with any other controlled substance, including the substances other than marijuana in Schedule I of the Controlled Substances Act, such as heroin and LSD.

The testimony of various witnesses, including Dr. Irwin Martin, Dr. Dale Gieringer, Dr. Rick Doblin, and, on cross-examination, Dr. David Auslander established that a significant concern of any person (a "sponsor") seeking to submit a New Drug Application ("NDA") to the FDA is to ensure consistency in the drug in question (including botanical products) since a sponsor must demonstrate to the FDA at the conclusion of the process that the drug material tested in the clinical trials will be the same material distributed to the consumer public as prescription medicine. Accordingly, any sponsor of an attempt to develop marijuana as an FDA-approved prescription medicine must have assurance of access to and control over its source of the material to be used in clinical trials.

However, there is at present only one source of marijuana for research purposes in the Untied States: NIDA, a government entity charged with preventing and treating drug abuse, not fostering research into therapeutic uses of marijuana as a prescription medication. According to the testimony of Dr. Doblin, the president of a non-profit pharmaceutical company ("MAPS") dedicated to developing certain Schedule I substances as prescription medicines, MAPS sought to obtain an independent source of marijuana due to five years of non-cooperation by NIDA and DEA with its attempts to secure a reliable source of marijuana of uniform consistency. MAPS expressly seeks to sponsor the development of marijuana as a prescription medicine and has obtained FDA approval of certain research protocols into the vaporization of marijuana as an alternative to ingestion by smoking. Dr. Craker submitted his application for registration as a bulk manufacturer of marijuana for use in research sponsored by MAPS as a last resort at the end of a process in which MAPS could not obtain an adequate and uninterrupted supply of marijuana for legitimate medical, scientific, research, and industrial purposes through any other legal

[1] See http://www.drugabuse.gov/about/organization/nacda/marijuanastatement.html.

channel.

I. In the absence of any conflict with the "public interest," the Controlled Substances Act mandates registration of an applicant to be a bulk manufacturer of marijuana

Title 21 of the United States Code provides in relevant part at Section 823(a):

> 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. In determining the public interest the following factors shall be considered:
>
> (1) maintenance of effective controls against diversion of any controlled substance in schedule I into other than legitimate medical, scientific, research or industrial channels by limiting the bulk manufacture of such controlled substances to a number of channels which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes; [and]
>
> (6) such other factors as may be relevant to and consistent with the public health and safety.

A plain reading of the statute suggests that it favors registration of manufacturers. By its terms the statute affirmatively mandates that the Attorney General register a person who applies to be a bulk manufacture of a schedule I substance (discussed infra) if such registration would be consistent with the public interest. (The Committee notes that the statute does not require that the applicant demonstrate that registration would further the public interest, but only that registration be consistent with the public interest.)

In defining the public interest, the statute first requires that the Attorney General ensure "an adequate and uninterrupted supply" of the controlled substance for the purposes of conducting research; the statute then invites consideration of a broad array of factors – or perhaps any factor whatsoever – relevant to public health and safety.

II. Since the statutory scheme contemplates the rescheduling of marijuana, the United States Government should not preclude attempts to develop marijuana for medical purposes

A. The Controlled Substances Act contemplates that research may lead to the rescheduling of Schedule I substances, including marijuana

The Controlled Substances Act classifies marijuana in Schedule I. The three criteria for classification in Schedule I are:

> (A) The drug or other substance has a high potential for abuse.
>
> (B) The drug or other substance has no currently accepted medical use in treatment in the

United States.

(C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.[2]

The classification of a controlled substance in Schedule I means that there is no legal use of the substance for any purposes by a medical patient. The only way by which a Schedule I substance may be made available to patients as a prescription medication would be if the Attorney General were to transfer that substance to one of Schedules II through V. Accordingly, no person may legally use marijuana for any therapeutic benefits, notwithstanding the strength or extent of anecdotal evidence of medicinal use – or even a patient's subjective experience, if the Attorney General has not transferred marijuana to a different schedule such that a physician could prescribe marijuana.

The statutory scheme for controlled substances clearly contemplates that the Attorney General may reschedule a controlled substance based on scientific research. See 21 U.S.C. 811(a) and 812(b). The Committee sees no provision of the Controlled Substances Act precluding the relocation of marijuana out of Schedule I into a schedule which would permit the prescription of marijuana in the event that scientific research establishes a medicinal use. The testimony presented before Judge Bittner described the process of obtaining FDA approval of a substance for medicinal use, including the filing of a Investigational New Drug Application, conduct of three phases of clinical trials, and the filing of an NDA. FDA approval of marijuana for a medical purpose is the event that would establish "an accepted medical use in the United States" and would provide the basis for rescheduling marijuana. Dr. Doblin testified that FDA has approved proposed research protocols for marijuana and has awarded marijuana "orphan drug" status, which, inter alia, provides tax benefits for a sponsor of drug development to treat diseases with small patient populations, as a treatment for HIV-wasting syndrome.

B. The DEA's position appears to rest on the assumption that there can not be a medical use of marijuana

In the instant matter the DEA has presented an extremely narrow reading of the public interest, apparently premised on the conclusion that it is not in the public interest to register as a bulk manufacturer a person who proposes to manufacture marijuana to be used as a medicine since as a matter of law there can be no medical use of marijuana. The DEA appears to conclude that, there can be no medicinal use of marijuana and that, by logical extension, since research to establish a medicinal use of marijuana is futile, there is no basis for registering a person as a bulk manufacturer of marijuana for use in research for that purpose.

Paragraph 8 of the DEA's Order to Show Cause, dated December 10, 2004, sets forth the DEA's position as to why MAPS has not shown that registration of Dr. Craker as a bulk manufacturer of marijuana would be consistent with the public interest because, inter alia, "current research must utilize smoked marijuana, which ultimately cannot be the permitted delivery system for any potential marijuana medication due to the deleterious effects and the

[2] 21 U.S.C. 812(b).

difficulty in monitoring the efficaciousness of smoked marijuana." This proffered basis strongly suggests that the DEA has concluded that (a) there cannot be a medicinal use of marijuana and therefore (b) there should not be any research oriented towards proving a medicinal use, even privately-funded research, notwithstanding the statutory scheme that contemplates that research may provide a basis for transferring a controlled substance, including marijuana, from one schedule to another.

The preceding statement in the Order to Show Cause corresponds to a public statement appearing on the internet site of the DEA entitled "Exposing the Myth of Medical Marijuana" ("Myth of Medical Marijuana"),[3] which explains why smoked marijuana is not a viable medicine due to (a) the purported health risks of marijuana and (b) the existence of purported safer alternatives to marijuana.

Paragraph 9 of the Order to Show Cause proceeds to state that "[I]n compliance with 21 USC 823(a) and the Single Convention,[4] DEA must limit the number of producers of research-grade marijuana to that which can provide an adequate and uninterrupted supply under adequately competitive conditions." As a factual matter, in light of the various rejections by NIDA of applications for marijuana for use in research into medicinal uses thereof – even those that did not expressly indicate an intention to develop marijuana as a prescription medication – described in the testimony of Dr. Doblin, exclusive control by NIDA over the source of marijuana for research in the United States has not heretofore been shown to provide an "uninterrupted" supply of marijuana for research; the testimony indicates that NIDA's control has prevented the commencement of any supply of marijuana to certain proposed research protocols.

Further, the uncontradicted testimony established that an "adequate" supply of marijuana for use in research to develop marijuana as a medicine in compliance with the requirements of the FDA would be a supply subject to the control of the sponsor such that a sponsor could ensure that the marijuana tested throughout the clinical trials would be the same as that proposed to the FDA for use by patients as prescription medicine. The Committee proposes, therefore, that "adequate," as that term appears in 21 U.S.C. 823(a) be construed to mean, in the context of proposed research to test the medicinal use of a Schedule I substance, "adequate to permit timely cost-effective compliance with FDA regulatory requirements." A contrary construction would, as a practical matter of the economics of the pharmaceutical industry, preclude research to find medicinal uses of marijuana – research which is contemplated under the statutory scheme.

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[3] See http://www.usdoj.gov/dea/ongoing/marijuanap.html.

[4] The Single Convention on Narcotic Drugs, March 30, 1961, 18 U.S.T. 1407. Government witness Matt Strait of the DEA stated on cross-examination that he was not aware of any particular issues related to international treaties with regard to the Craker application (Tr. August 25, 1096:3-8) and that a schedule I researcher could cultivate marijuana (Id. 1096:12 - 1098:12). Accordingly, the Committee understands that in and of itself the Single Convention does not require that the DEA deny Dr. Craker's application to be registered as a bulk manufacturer of marijuana.

The Committee respectfully submits that the above-quoted statements in the Order to Show Cause and the "Myth of Medical Marijuana" page from the DEA website strongly indicate that the DEA has determined that there should not be any research conducted for the purposes of developing marijuana as a prescription medicine so that there will never be an occasion to reschedule marijuana. By extension, it appears that the DEA has concluded that research conducted for the purposes of developing marijuana in its plant form as a prescription medication can not be in the public interest and therefore registration of a bulk manufacturer for that purpose can not be in the public interest.

This apparent position on potential medical uses of marijuana is consistent with the DEA's "Proposed Stipulations and Admissions of Fact" in the Prehearing Statement dated February 28, 2005. Item number three in the list recites that "marijuana has no currently accepted medical use in treatment in the United States," a statement that is simply a paraphrase of the definition of a Schedule I substance. Whether there is or is not a currently accepted medical use of marijuana has no relevance to the question of whether or not the DEA should register a bulk manufacturer of marijuana to facilitate FDA-compliant research – unless the DEA reads the Controlled Substances Act to mean that there cannot and should not be acceptance of medical uses of marijuana.

The DEA's position therefore appears to pervert the intention of the Controlled Substances Act, and suggests that the DEA understands its role is to abort any research that might lead to the acceptance of a medicinal use for marijuana in the United States and that the agency construes its mandate as one to circumscribe the content of medical knowledge.

The Committee submits that such a position directly contradicts the first factor for determining the public interest as set forth at 21 U.S.C. 823(a)(1), which requires that there be an adequate and uninterrupted supply of marijuana for scientific, medical, [and] research purposes.

III. In contrast to the current position of the DEA, the public interest requires that the DEA facilitate research into medical uses of marijuana and DEA should register bulk manufacturers in order to facilitate this research

As discussed above, 21 U.S.C. 823(a)(6) states that consideration of whether registration of an applicant to be a bulk manufacturer of a Schedule I controlled substance is consistent with the public interest includes "such other factors as may be relevant and consistent with the public health and safety." This broad language invites consideration of numerous societal concerns and conditions.

The Committee proposes that review of the following factors establishes that registration of Dr. Craker as a bulk manufacturer of marijuana for use in FDA-compliant clinical trials of medicinal uses of marijuana, whether sponsored by MAPS or by another person, is consistent with the public interest.

Gonzales v. Raich decision

As background, the Committee notes that the Supreme Court of the United States in Gonzales v. Raich, 545 U.S. __, 125 S. Ct. 2195, 162 L.Ed.2d 1 (2005), on June 6, 2005, reversed an order of the Court of Appeals for the Ninth Circuit that had reversed an order of the United States District Court for the Northern District of California denying a preliminary injunction seeking injunctive and declaratory relief prohibiting the enforcement of the Controlled Substances Act to the extent it prevents the plaintiffs from possessing, obtaining, or manufacturing cannabis for their personal medical use, which use was legal under the law of the State of California. The issue decided by the Supreme Court was whether application of the Controlled Substances Act to the plaintiffs was a valid exercise of federal authority under the United States Constitution. The Court expressly disclaimed any assessment of the medical potential of marijuana. Id. at 2201.

In explaining that it did not address substantive due process claims by the plaintiffs (because the Court of Appeals did not reach these theories), the Court said "We do note, however, the presence of another avenue of relief. As the Solicitor General confirmed during oral argument, the statute authorizes procedures for the reclassification of Schedule I drugs." Id. at 2215. Accordingly, a plain reading of the Raich decision indicates that the Supreme Court of the United States assumed that the statutory scheme provides a viable process for conducting the research that could result in the approval of marijuana for use as a prescription medicine, thereby establishing an accepted medical use of marijuana in treatment in the United States and supporting transfer of marijuana to a schedule that would permit prescription use. Unfortunately, the documents and testimony suggest that the DEA and NIDA have determined that a priori there is no need to permit such research; it would seem, then, that the Supreme Court was misinformed in that, while the statute authorizes procedures for the reclassification of Schedule I drugs, the agencies charged with administering the statute do not intend to allow the conduct that might lead to reclassification.

Proposed factors

Development of new medical treatments

It seems axiomatic to the Committee that the development of new medical treatments for adverse medical conditions is consistent with the public health. The testimony of Senator John Vasconcellos, Dr. Barbara Roberts, and Dr. Doblin all addressed the extensive anecdotal evidence that marijuana has a wide array of potential medical uses. Likewise, the Supreme Court in footnote 37 of the Gonzales decision likewise acknowledged the allegations of effective medical uses of marijuana.

The Committee would have assumed that when seriously ill citizens allege that a substance, controlled or otherwise, yield significant health benefits, government agencies would take every action and spare no expense to facilitate research in the hope of finding new treatments. Counterintuitively, however, documents and testimony in the instant proceeding indicate that DEA and NIDA have taken the diametrically opposed position. (Any argument that the research currently conducted by the Center for Medicinal Cannabis Research in California is

adequate and therefore makes unnecessary any additional research is foreclosed by the testimony before Judge Bittner by former Senator Vasconcellos that that research is limited in scope and that its public funding from the State of California will expire shortly with no indication that the State of California has the means to renew the funding.)

Reduction of criminality by eliminating inappropriate criminal penalties for an activity that should not be criminal

Due to the location of marijuana in Schedule I of the Controlled Substances Act, marijuana has no legitimate medical use as a matter of law and may not used as a medicine. In essence, the Controlled Substances Act is a narrow filter, excluding any use of controlled substances except under a permitted exception, that exception being prescription use after the federal Government concludes on the basis of rigorously-tested evidence that there is a medicinal use.

For Schedule I substances, there is no hole in the filter through which to permit any use in the absence of the rigorously-tested evidence. Any person who on the basis of personal experience asserts that marijuana has health-protective (even life-saving) effects nonetheless becomes a criminal by using marijuana for such health-protective or life-saving purposes.[5] The Committee proposes that the population of persons who use marijuana for medicinal purposes is not one appropriately required to enter into the illegal market for marijuana in order to obtain their choice of medicine or subjected to the risk of criminal prosecution. The only way to evaluate the anecdotal claims under the system established by Congress for regulating drugs is to permit FDA-approved clinical trials of marijuana: in the event that research establishes medical uses of marijuana, then the persons who subject themselves to the risks inherent in participating in an illegal market will no longer need to do so. The testimony indicated that researchers need to be independent of NIDA in order to conduct such FDA-approved research; the only way to do so is for the DEA to register a bulk manufacturer without the involvement of NIDA.

Accordingly, the Committee proposes that registration of Dr. Craker as a bulk manufacturer, in the absence of any other defect in his application, would not only be consistent with the public safety but would affirmatively further it.

In addition the Committee proposes two factors which are plausibly outside the statute but nonetheless merit consideration.

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[5] The Committee notes that Philip Alden, a proposed witness for respondent Dr. Craker, who allegedly was a participant in research conducted by the Center for Medicinal Cannabis Research until he contracted bronchitis from using the NIDA-supplied marijuana, declined to testify after consulting with his attorney.

Removal of medical marijuana litigation from the courts

As is apparent merely from a review of the Raich decision, persistent demand for marijuana as a medical intervention has led to legislative efforts to facilitate access to marijuana as a medicine for medical patients, such efforts consisting largely of the various state initiatives such as the California Compassionate Use Act of 1996. In addition, as set forth in Raich, there have been thirty years of litigation before administrative tribunals and the United States District Courts challenging the classification of marijuana in Schedule I. Based on the degree of public interest in testing medical uses of marijuana, as evidenced both by the state initiatives and the history of litigation, the Committee concludes that there will likely be additional attempts to argue the medical uses of marijuana in courts of law if not administrative proceedings with no foreseeable end.

The Committee proposes that action by the DEA could help remove the question of marijuana's purported medical utility from the courtroom to the more appropriate forum, that being the laboratory in the context of research intended to test marijuana's viability as a prescription medicine. The DEA could do so by registering an applicant, such as Dr. Craker, as bulk manufacturer of marijuana in order to break NIDA's monopoly and thereby facilitate FDA-approved research into medical uses of marijuana.

Ensuring continued public trust in the integrity of government

To the extent that NIDA exercises a monopoly over the legitimate manufacture of marijuana and by restricting the supply thereof discourages research into medical uses of marijuana, and to the extent that the DEA is complicit in this monopoly and alleged attendant inhibition of research, NIDA and DEA have abused the trust of the taxpaying citizenry of the United States. Should the public come to believe in the position expressed by the witnesses for Dr. Craker, the Committee anticipates a further decline in the public trust in and respect for the regulatory process and the integrity of the government agencies charged with implementing the laws of the United States.

The matter of "medical marijuana" is a high-profile controversy in United States drug control policy that plays out in the courts and in the popular press. It is arguably a controversial matter of societal conflict, one that will not likely go away. The operative question appears to the Committee to be whether DEA will take action to help resolve this controversy. Accordingly, the Committee proposes that it is in the public interest for the DEA to do whatever it can to facilitate the maximum amount of research; registering Dr. Craker as a bulk manufacturer of marijuana is ultimately a very small step for the DEA to take in terms of resolving the controversy over the alleged medical uses of marijuana. It is a step which the DEA should take forthwith in the absence of any defect in Dr. Craker's application. The Committee assumes that the DEA is capable of working with Dr. Craker, or any other qualified applicant to arrive at an acceptable plan for establishing a manufacturing facility subject to the necessary safeguards.

Conclusion

For the foregoing reasons, the Committee respectfully proposes that registration of Dr. Craker as a bulk manufacturer, in the absence of any indication in the record that Dr. Craker is not qualified to be registered as a bulk manufacturer, would be consistent with the public interest as that term is used in 21 U.S.C. 823(a).

Very truly yours,

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