

**UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION**

In the Matter of)	
)	
)	Docket No. 05-16
LYLE E. CRAKER, PH.D.)	
)	

RESPONDENT’S SUPPLEMENTAL PRE-HEARING STATEMENT

In response to the ALJ’s Order of May 23, 2005, Respondent respectfully submits his Supplemental pre-hearing statement.

1. ISSUE

As the ALJ has ruled, the issue is: Whether a preponderance of the evidence established that granting Respondent’s application for registration as a manufacturer of the Schedule I controlled substance marijuana would be in the public interest as that term is used in 21 USC § 823(a).

2. PROPOSED STIPULATIONS AND ADMISSIONS OF FACT

See ALJ Order for Admissions and Stipulations.

3. PROPOSED WITNESSES.

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4. SUMMARY OF TESTIMONY

Proposed Testimony of Dr. Lyle Craker

Dr. Craker will testify about his education, training, and background in plant and soil sciences, about his current position as a professor at the University of Massachusetts. Dr. Craker is editor of the professional, scientific journal, *The Journal of Herbs, Spices and Medicinal Plants*. He is also Chairman of the Medicinal and Aromatic Plant Section in the International Society for Horticultural Science, and the founding organizer of the Herb, Spice, and Medicinal Plant Working Group in the American Society for Horticultural Science. Dr. Craker will testify about plant development research he has conducted, and about his particular interest in the control of mechanisms regulating essential oil synthesis and composition of plants, especially as related to increasing production and quality of plant extracts. He will testify that he has long been involved in researching and growing plants that have medical uses. He will also testify that he has received a variety of funding, including government funding, to support this research.

Dr. Craker will further testify as to why providing him with a DEA license to grow particular strains of cannabis with particular ratios of plant components is in the public interest. First, he will testify that the Multidisciplinary Association for Psychedelic Studies approached him to determine whether he would be able to grow cannabis that would be suitable for use in FDA-approved trials, as part of an attempt to develop cannabis as an FDA-approved drug for particular conditions. In particular, MAPS was interested in developing a strain of cannabis that could be used in conjunction with a vaporizer, so that the therapeutic effects of marijuana could be delivered without smoking, as well as in comparing the efficacy and safety of various delivery systems.

Dr. Craker will further testify that he meets all the criteria for issuing a DEA license. He will testify that he will fully comply with both federal and state law, as he has always done in the past. He will testify that granting the license will promote technical advances, because the cannabis he seeks to grow is for use in the research and development of a vaporization delivery system. Further, that government-approved research may lead to additional discoveries as to

other delivery systems, or other therapeutic benefits available through cannabis. If Dr. Craker does not obtain a license, MAPS researchers are less likely to be able to obtain the type of cannabis they need when they need it, and MAPS will be largely prevented from developing a medical product that could be approved by the FDA. Dr. Craker will further testify that he has never had any criminal convictions, and that he has both researched and grown plants for their potential medical purposes.

Finally, Dr. Craker will testify that issuing the DEA license to him will allow increased research into important public health matters. He will testify that he is willing to provide the same security measures as are currently in place at the University of Mississippi, which holds a similar license. Those measures will protect public safety with respect to any concern about diversion, which can be DEA's only legitimate interest in denying this license.

Proposed Testimony of Irwin G. Martin, Ph.D.

Dr. Martin will testify about his extensive experience in the area of how new drugs are developed, and will offer testimony as to conditions that must be met before a company can begin to develop a particular new drug.

Dr. Martin will discuss the fact that the major developed regions of the world have unified the requirements for the approval of new drugs and biologics. Generally speaking, the US, Europe and Japan have agreed on these requirements through the International Congress on Harmonization (ICH). ICH requirements are grouped into three broad areas: safety, efficacy and quality. Safety includes pre-clinical animal testing while efficacy relates primarily to the results of human clinical studies in patients. Quality, the most relevant to the concern of this case, involves the manufacture and quality control of the product to be tested or consumed.

Dr. Martin will testify that the FDA follows the ICH guidelines for the approval of new drugs and biologics. FDA approval is based on safety and efficacy of new drugs and biologics. Safety, in FDA terminology, includes the quality issues from ICH.

As Dr. Martin will testify, quality means the ability to assure that the drug product is consistent, unadulterated, and manufactured under strict quality standards. Typical assays for testing of product include potency and purity. The ability to control these variables is essential in measuring the dose given during clinical studies and, eventually, the dose that prescribing physicians choose for their patients. To provide proper care of patients, physicians must be able to confidently choose doses based on data derived from carefully controlled clinical studies that used drug product of known potency that delivered a known dose to the patient. Based on these data and the needs of the patient, a physician should then be able to choose a product that delivers a desired dose. Because of the need for consistency between doses, manufacturers of generic versions of branded pharmaceuticals must show that their products deliver a consistent and similar dose of medication to that of the originator's product. The same expectations exist for clinical trial material.

Dr. Martin will also testify that prior to development of a new drug candidate, there are several critical questions that must be answered. One of the first, assuming that further studies support continued development, is the source of the new drug, and whether the company can obtain the amounts they will need at a level of purity that will satisfy the requirements of drug development. One of the biggest delays in drug development is due to change in the drug product, either due to a new formulation or a change in purity. The ability to use data from earlier studies is often lost due to the inability to show equivalence after changes are made in the manufacture of the drug product. Repetition of studies is expensive and costly; as a result, most companies will do everything possible to assure a consistent quality and quantity of product from the beginning of development. Included in these early calculations are the ability to scale up the product to a full manufacturing size without a change in the product's quality or purity as well as the ability to control the cost of goods when doing so. Further, no company would undertake the expensive process of trying to bring a new drug to market without taking steps to assure that if research demonstrates safety and efficacy, they will have sufficient access to the quantity and quality of product that will meet worldwide approval standards and launch the product into the marketplace.

Finally, Dr. Martin will testify that a company developing a new drug must also be free to choose the formulation of the product and control the ratios of active and inert components that the product will contain as well as how the product will be delivered. If there are constraints, the effect is to increase the likelihood the new drug product would be abandoned during development. Where there are significant questions about availability of the new drug product that affect the time required to move from one study to the next, continued development becomes questionable. Thus, a company must be confident that it can manufacture the product when it needs it.

Proposed Testimony of Rick Doblin, Ph.D

Rick Doblin, Ph.D., will testify about his organization's attempts to research both the therapeutic benefits available from cannabis, and the technical advance of providing those benefits through a vaporization technique, which may be a safer delivery system than smoking for many patients. Indeed, it was largely to conduct clinical trials and to research the vaporization technique that Dr. Doblin sponsored Dr. Craker in developing a facility that could produce particular strains of cannabis that appear to be most likely to be successful in the vaporization process. In addition, Dr. Doblin seeks to compare the safety and efficacy of various delivery systems and of various strains of cannabis with differing ratios of components, including not only THC, but also other components of cannabis which research suggests may enhance therapeutic benefits. Dr. Doblin will also testify, as detailed below, about the substantial federal obstruction of his efforts over more than a decade to sponsor a privately-funded, non-profit, FDA-approved drug development effort consisting of a series of scientific studies investigating the safety and efficacy of the cannabis plant for specific medical indications.

Dr. Doblin has a Ph.D. in Public Policy from the Kennedy School of Government at Harvard University. He works to develop cannabis and other substances into FDA-approved prescription medicines and is the founder and director of a non-profit research and educational organization,

the Multidisciplinary Association for Psychedelic Studies (MAPS). MAPS holds the only Orphan Drug designation granted by the FDA for any medical use of cannabis, for the AIDS Wasting Syndrome. MAPS promotes scientific research into the risks and benefits of Schedule I substances in treating various medical and psychological conditions. MAPS provides financial, regulatory and scientific assistance to researchers who MAPS helps to design, fund and obtain the necessary approvals to conduct their studies, as well as providing support during the research and evaluation process.

Unlike other Schedule I drugs, such as MDMA, LSD, and psilocybin, for which private suppliers for research exist, the federal government through the National Institute on Drug Abuse (NIDA) has a monopoly on the supply of marijuana that can legally be used in research. NIDA has its marijuana grown at the University of Mississippi under the direction of Prof. Mahmoud El-Sohly.

As Dr. Doblin will testify, based on substantial evidence demonstrating that cannabis offers therapeutic benefits to patients with a variety of conditions, MAPS seeks to develop cannabis as an FDA-approved medication. To that end, it seeks to further research the possibility of delivering cannabis through vaporization, and comparing those results with those obtained through smoking or other delivery methods. Although it stands ready to sponsor research, and has made arrangements for that research to take place, MAPS cannot obtain the cannabis it needs from the one currently existing cannabis provider. Moreover, even if it could obtain what it needs for testing purposes from the one currently existing cannabis provider, neither MAPS nor any rational drug developer could enter into an expensive research and development phase for a product that is not available for, and that may not meet FDA standards for, prescription use. In addition, no new drug developer can develop a product when it cannot be confident it has access to the product it requires. Thus, it has sponsored Dr. Craker in his efforts to establish a cannabis farm at which the kinds of cannabis MAPS needs for these purposes can be grown under the conditions necessary to assure the availability and consistency of product necessary to pursue FDA approval.

Dr. Doblin will also testify about MAPS' experiences in assisting Dr. Donald Abrams, Dr. Ethan Russo, and Chemic Labs with their attempts to conduct cannabis research sponsored by MAPS, about MAPS' efforts to assist Professor Lyle Craker of the University of Massachusetts at Amherst in developing a research cannabis farm to be sponsored by MAPS, and about MAPS' interaction with NIDA, DEA, the FDA, and NIH surrounding these processes.

MAPS-sponsored researchers are currently unable to purchase marijuana from NIDA, import marijuana from the Dutch Office of Medicinal Cannabis, contract with Dr. El-Sohly to grow marijuana, or obtain permission to grow their own marijuana. MAPS' privately-funded therapeutic drug development effort is fundamentally compromised by NIDA's monopoly on supply.

MAPS' Experience Assisting Dr. Donald Abrams with his Cannabis Research

Dr. Doblin will testify that he and MAPS approached Dr. Donald Abrams in 1992 and offered him support for becoming involved in conducting research into the risks and benefits of the medical use of cannabis in treating the AIDS wasting syndrome. He will testify that the

research protocol for this study was approved by the FDA in the summer of 1994, but that when Dr. Abrams submitted an application to NIDA for the research cannabis, NIDA summarily rejected this request, after failing to communicate with him to offer either critiques or assistance for nine months.

In May 1995, MAPS tried to contract with Prof. Mahmoud El-Sohly, Director of NIDA's University of Mississippi cannabis farm, to provide cannabis for Dr. Abrams' FDA-approved study, but Prof. El-Sohly would not provide MAPS with the cannabis. Dr. Doblin will testify that Dr. Abrams submitted a revised protocol to NIH in May 1996, after NIDA began requiring that medical cannabis proposals be submitted to NIH for peer review. This protocol was formally rejected in August 1996. Dr. Doblin will testify that Dr. Abrams submitted a revised protocol to NIH in May 1997. In the revised protocol, Dr. Abrams changed his focus from a study on the safety and efficacy of medical cannabis to treat AIDS wasting syndrome to a study assessing the risks of cannabis in HIV patients who did not suffer from the AIDS wasting syndrome. On September 18, 1997, Dr. Abrams finally received a NIDA grant of \$978,000 to conduct his research along with the marijuana required to conduct the study.

Dr. Doblin will testify that the results of Dr. Abrams' study demonstrate that HIV patients taking protease inhibitors do not experience adverse short-term effects from using cannabinoids. In addition, while all three groups in the study (placebo, the group receiving oral dronabinol, and the group receiving smoked cannabis) gained weight, the smoked cannabis group gained an average of 3.51 kilograms, as compared to 3.18 kilograms with oral dronabinol, and 1.30 kilograms in the placebo group.

Dr. Doblin will testify that NIDA's refusal to sell marijuana for Dr. Abrams' FDA-approved protocol convinced him that until MAPS could obtain permission to establish its own source of supply, that the federal resistance to research created so much uncertainty over supply that it would be practically impossible for MAPS to initiate its drug development program.

MAPS' Experience Assisting Dr. Ethan Russo with his Cannabis Research

Dr. Doblin will testify that MAPS also provided assistance to Dr. Ethan Russo in obtaining FDA approval for a study on the use of cannabis in the treatment of migraines. Dr. Russo was not able to obtain cannabis with which to perform the FDA-approved study, due to NIDA's refusal to supply cannabis for his independently-funded research.

In 1999, MAPS helped Dr. Russo to submit a research proposal to the Food and Drug Administration (FDA) to study the effects of smoked cannabis in treating migraine headaches. This study aimed to compare the treatment efficacy of smoked cannabis as compared to that of oral dronabinol (Marinol) and of injected sumatriptan (Imitrex – the most effective of non-cannabis treatments for migraine used at the time the study was submitted). On May 14, 1999, the FDA formally critiqued Dr. Russo's proposal, and on October 1, 1999, the FDA approved the study.

Dr. Doblin will testify that following FDA approval, Dr. Russo's study needed to undergo a Public Health Service (PHS) review in association with the National Institute on Drug Abuse (NIDA), in order to obtain a cannabis supply from NIDA to perform the study. No substance

other than cannabis, including cocaine, heroin, and MDMA, requires a PHS review in addition to FDA approval. As a result, any study approved by the FDA with the exception of those involving cannabis can proceed directly from FDA approval to clinical trials.

Dr. Doblin will testify that in February of 2000, NIDA responded to Dr. Russo, explaining that the PHS review committee had criticisms of his research design, and therefore would not allow him to purchase cannabis from NIDA for his privately-funded study. Dr. Doblin will testify that NIDA's refusal to supply cannabis for this study has effectively prevented it from going forward.

Dr. Doblin will also testify that NIDA's refusal to provide Dr. Russo with marijuana for his study further convinced him that MAPS needed to obtain its own independent source of supply prior to initiating a drug development program for marijuana.

MAPS' Experience Assisting Chemic Labs in Performing Vaporizer Research

A study by Chemic Laboratories, funded by MAPS and CaNORML, requiring 10 grams of cannabis to analyze the contents of the vapor stream from a cannabis vaporizer, has also been stalled by executive branch obstructionism. Dr. Doblin will testify about MAPS' experience working with Chemic to enable this study to go forward.

On June 24, 2003, Chemic submitted separate applications to the U.S. Department of Health and Human Services (HHS) and to the Drug Enforcement Administration (DEA), in order to obtain the marijuana that was required to perform the study. Chemic applied to HHS to approve its research protocol so that it could purchase 10 grams of cannabis from NIDA. Chemic also applied to DEA to register to import 10 grams of medical cannabis from the Dutch Office of Medical Cannabis (DOMC), part of the Dutch Ministry of Health, as the DOMC offers a quality of cannabis that is required for part of the study but is unavailable from NIDA.

Regarding the DEA application, Dr. Doblin will testify that DEA advised MAPS and Chemic that it would not process the application until after HHS determined the merit of the protocol, and that DEA did not publish a notice in the Federal Register upon the filing of the application as required by law. Regarding the HHS application, Dr. Doblin will testify that HHS has failed to decide on the scientific merit for 25 months (as of July 2005). Chemic did not receive any communication from HHS until October 2003, more than three months after the initial application. At that time HHS indicated that there was insufficient information in the application, although MAPS and Chemic had filed according to HHS specifications. MAPS and Chemic refilled a revised protocol on January 29, 2004. Despite numerous inquiries, HHS did not give any answer or further information about the status of the application, with the exception of one email in March 2004, stating that the application was awaiting PHS review.

Dr. Doblin will testify that on June 9, 2004, he received a letter from NIDA rejecting his request for help in this process, on the basis that NIDA's mission is not to study the medical uses of marijuana and that NIDA has no control over the PHS review. On July 14, 2004, MAPS, along with others, filed a lawsuit against HHS and DEA alleging unreasonable delay in processing Chemic and Prof. Lyle Craker's applications (see below). The lawsuit was dismissed without prejudice. However, following the lawsuit, DEA announced in December 2004 that Chemic needed a research license in addition to its analytical lab license, although the criteria required to

receive each license are identical. Chemic applied immediately for the license but did not hear until early March 2005 that its research license was being processed. HHS also notified Chemic in early March that its protocol was finally being reviewed.

Chemic has thus been blocked for over two years from conducting any MAPS-sponsored vaporizer research, fundamentally obstructing MAPS' drug development plan. Chemic has been unable to purchase or import marijuana for its proposed research.

Dr. Doblin will testify that Chemic's inability to purchase or import 10 grams of convinced him that so long as NIDA retained a monopoly on the supply of marijuana that is legal for research, no drug development effort for marijuana would take place.

MAPS' Experience Attempting with Prof. Lyle Craker to Arrange for an Independent Supply of Research Cannabis

MAPS is sponsoring Prof. Lyle Craker, Director of the Medicinal Plant Program in the Department of Plant and Soil Sciences at the University of Massachusetts at Amherst, in developing a cannabis farm to supply cannabis exclusively for FDA- and DEA-approved research into the medical uses of the cannabis plant. Dr. Doblin will testify that in June 2001, Prof. Craker applied to DEA for a license to establish this facility. He will testify about the several years of delay tactics that DEA used in the processing of this application. The first direct response to the application did not come until March 4, 2003, more than 20 months after the initial application was submitted, at which time DEA required that Prof. Craker demonstrate that research needs were not adequately met by NIDA's supply of cannabis. Prof. Craker responded to this request on June 2, 2003.

DEA also failed to publish a notice of Prof. Craker's application in the Federal Register until July 2003, more than two years after the initial application. Dr. Doblin will testify that there was no comment during the sixty-day comment period required by law other than an objection by Prof. Mahmoud El-Sohly, Director of NIDA's cannabis farm. In order to help expedite the processing of Prof. Craker's application, MA Senators Kennedy and Kerry wrote a letter to DEA Administrator Karen Tandy on Oct. 20, 2003, expressing their strong support for the UMass Amherst marijuana production facility.

Prof. Craker and MAPS filed a lawsuit against DEA on July 21, 2004, alleging unreasonable delay in processing Prof. Craker's application. After the court issued a show cause order, DEA rejected Prof. Craker's application on December 10, 2004. Dr. Craker challenges that denial in this proceeding.

Proposed Testimony of Irvin Henry Rosenfeld

Mr. Rosenfeld is one of the seven remaining living participants in an FDA Compassionate Investigational New Drug (IND) Program, closed to new entrants in 1992, that provides NIDA marijuana for free to people who demonstrated that nothing else worked for relief of their symptoms and a qualified physician believed that marijuana did. Irv Rosenfeld suffers from a rare bone disorder called multiple congenital cartilaginous exostoses, which is marked by bony

protrusions that cause chronic pain. Mr. Rosenfeld will testify about his condition, and how marijuana provides him relief.

Mr. Rosenfeld will testify that he has been in the program since November, 1982, and every month receives at his pharmacy about 300 marijuana cigarettes, with a THC level less than 4%. He will testify that in 2001, he was one of four of the seven official patients who participated in Dr. Ethan Russo's privately-funded "Chronic Cannabis Use in the Compassionate Investigational New Drug Program Study." That study showed "very few adverse effects in the patients" and documented reported medical benefits.

Mr. Rosenfeld will testify that neither the FDA nor NIDA showed the slightest interest in studying his case in 22 years and that Dr. Russo's study generated important information. He will testify that there is a compelling public interest in further research into the potential medical uses of marijuana, both smoked and vaporized, as well as marijuana extracts and other forms of delivery.

Proposed Testimony of Angel Raich

Ms. Raich is a patient whose board-certified doctor has recommended the use of cannabis to relieve painful symptoms of several chronic diseases, and to suppress the wasting syndrome that threatens her life. In fact, her doctor has testified that it is his opinion that without medical cannabis, Ms. Raich will likely die. Ms. Raich will testify as to how medical cannabis has helped her when all other medications failed. She will testify that it is in the public interest to increase research into the medical effects of cannabis, and to research various means of delivering the medication. Ms. Raich will also testify that she has a federal court injunction precluding the federal government from prosecuting her for her medical use of cannabis.

Proposed Testimony of Valerie Corral

Ms. Valerie Corral is a medical marijuana patient who will testify that marijuana has been helpful to her for the treatment of brain damage, epilepsy and migraines. She will testify that she founded The Wo/Men's Alliance for Medical Marijuana (WAMM), a collective of seriously ill patients who work to educate the general public regarding the medical benefits of marijuana, and to insure that patients, who have a recommendation from their physician, have safe access to legal under California law, and natural supply of Marijuana for the treatment of terminal and debilitating illness. WAMM works closely with local law enforcement and the legal community.

Ms. Corral will testify that, although the WAMM marijuana was grown legally under California law, on September 5, 2002, the DEA raided the WAMM garden and, using chainsaws, destroyed the medicine belonging to 250 patients, 85% of them terminally ill. WAMM has since filed charges against the Federal Government and has obtained an injunction, permitting the WAMM garden to operate pending the resolution of the *Raich v. Ashcroft* case.

Ms. Corral will testify that it is in the public interest for there to be more research into the risks and benefits of the medical use of marijuana, both smoked and vaporized, and that the UMass Amherst facility will facilitate privately-funded research.

Proposed Testimony of Phillip T. Alden

Mr. Alden will testify that he is a person living with AIDS. He will testify that he has used medical marijuana for the past eight years to combat nerve pain from Peripheral Neuropathy and to boost his appetite and calm the nausea resulting from his Antiretroviral Therapy. He usually gets his medicine from one of the California medical cannabis distribution facilities in San Francisco.

Mr. Alden will testify that his physician, Dennis Isrealski of the Edison Clinic in San Mateo, wanted to do a clinical study involving medical marijuana, and that Mr. Alden was the first patient to qualify for the study. The study used marijuana obtained from the federal government. According to the pharmacist Mr. Alden was working with, the marijuana was freeze-dried before it came into his possession, and he had to thaw it out for twenty-four hours before Mr. Alden could obtain it.

Mr. Alden will testify that when he first received the government-grown marijuana, he noticed it was rolled with cigarette paper. The product tasted terrible upon lighting up, and was very harsh on his throat and lungs. In addition, the government-rolled product contained stems and seeds. The seeds popped when ignited and made the marijuana taste much, much worse.

Mr. Alden will testify he was required to smoke a lot of the government-grown marijuana every day for the study. At the request of the study coordinator, Dr. Israelski, he stopped using the medical cannabis he had previously obtained.

Mr. Alden will testify that he was forced to drop out of the study two weeks early because the harshness of the government marijuana gave him bronchitis. Its THC content was very low, and as such, it did not work very well. Once off the government-grown product, his bronchitis cleared up and he went back to using the effective medical cannabis from the medical cannabis distributors in San Francisco.

Proposed Testimony of Dr. Donald Abrams

Dr. Donald Abrams, a researcher into the medical benefits of cannabis, will testify about the process of getting approval to conduct a pilot study on the use of cannabis to treat AIDS wasting syndrome. He will testify that he submitted to the FDA, with MAPS' assistance, an initial protocol design, which the FDA approved in the summer of 1994. Dr. Abrams then submitted an application to NIDA to obtain the cannabis needed to conduct the study. NIDA took no action on this application for nine months and did not contact Dr. Abrams with any suggested modifications to his proposal. Dr. Abrams received a letter dated April 19, 1995 from NIDA's Director, Alan Leshner, summarily rejecting his request. Dr. Abrams replied nine days later, on

April 28, 1995, to Dr. Leshner, criticizing NIDA for its failure to communicate with him for nine months or to offer him any opportunity to revise his proposal into one that NIDA would approve. Dr. Abrams submitted a revised protocol to NIH in May 1996. This protocol was formally rejected in August 1996.

Dr. Abrams will testify that he changed his protocol from a study on the safety and efficacy of medical cannabis to treat AIDS wasting syndrome to a study assessing the risks of cannabis in HIV patients who did not suffer from AIDS wasting syndrome. Dr. Abrams submitted that revised protocol to NIH in May 1997. On September 18, 1997, Dr. Abrams finally received a NIDA grant of \$978,000 to conduct his research.

Dr. Abrams will testify that the results of his study demonstrate that HIV patients taking protease inhibitors do not experience adverse short-term effects from using cannabinoids. Dr. Abrams will also testify about his research with marijuana vaporizers as compared with smoking marijuana, evaluating the potential use of vaporizers as a non-smoking delivery system.

Proposed Testimony of Dr. Lester Grinspoon

Dr. Lester Grinspoon is a faculty member (emeritus) of the Harvard Medical School in the Department of Psychiatry. He will testify that he has been studying cannabis since 1967 and has published two books on the subject. In 1971, *Marihuana Reconsidered* was published by Harvard University Press. *Marihuana, the Forbidden Medicine*, coauthored with James B. Bakalar, was published in 1993 by Yale University Press; the revised and expanded edition appeared in 1997. Dr. Grinspoon will testify generally about the history of cannabis as medicine; whether there is “accepted medical use” of cannabis; and the difficulties caused by NIDA having the monopoly on marijuana for research purposes, for example, NIDA's refusal to sell marijuana to Dr. Donald Abrams for his FDA-approved study of marijuana and AIDS wasting syndrome or to Dr. Ethan Russo for his FDA-approved study of marijuana and migraines, and Chemic Laboratories' inability, after waiting for more than two years, to purchase 10 grams from NIDA for marijuana vaporizer research.

Proposed Testimony of Former California State Senator John Vasconcellos

John Vasconcellos will testify about his position in the California State Senate prior to, during, and after the passage of Proposition 215, the medical marijuana voter initiative that California voters passed in 1996. He will testify about how shortly after the passage of Prop. 215, on December 30, 1996, federal officials (the Secretary of Health and Human Services, the US Attorney General, and the Director of the Office of National Drug Control Policy) made threats to revoke the licenses of physicians who made recommendations in accordance with Prop. 215. He will testify that these threats and other factors helped influence him to work to obtain funds from the State of California to conduct scientific research into the potential medical uses of marijuana. He will testify that he was eventually successful in these efforts and that the California Legislature passed, and the Governor signed, a bill to provide \$3 million a year for three years to conduct FDA-approved research into the risks and benefits of the medical use of

marijuana. He will testify about how this funding resulted in the creation of California's Center for Medicinal Cannabis Research (CMCR), located at UC San Diego.

He will further testify about how he viewed the progress of CMCR in conducting research, and about CMCR's relationship with NIDA, which provided the marijuana for the research, and DEA, which licensed the researchers who conducted the studies. He will testify about the political context that has resulted in no additional allocations for CMCR from the California State Legislature.

He will testify about his view that CMCR has conducted important pioneering research but that CMCR does not have the resources or the mission to develop marijuana into an FDA-approved prescription medicine. He will testify that he believes that it is in the public interest for DEA to license Prof. Craker's UMass Amherst facility, in order to facilitate privately-funded research to build on CMCR-funded studies.

Proposed Testimony from Barbara Roberts, Ph.D.

Dr. Roberts will testify, based on her years of experience working in the area of drug policy, that it is in the public interest for DEA to issue a license to Prof. Craker to establish a facility to produce marijuana exclusively for federally-approved research. Dr. Roberts served for 10 years in the White House Office of National Drug Control Policy. She served as senior policy analyst and Acting Deputy Director for demand reduction, and paid close attention to the developing issue of the medical use of marijuana. During her tenure, she specifically recommended that the National Academy of Sciences be commissioned to undertake a review of the scientific evidence regarding therapeutic applications of marijuana. Dr. Roberts will testify that the controversy over the medical use of marijuana is best resolved through scientific research, rather than through political methods that seek either to suppress or bypass research. Dr. Roberts will testify that the UMass Amherst production facility planned by Dr. Craker will facilitate privately-funded efforts to conduct FDA-approved research aimed at evaluating the safety and efficacy of the medical uses of marijuana, and is therefore in the public interest.

Dr. Roberts will testify that in her view, drug abuse prevention educational programs that discuss marijuana should be based on an accurate, honest evaluation of marijuana's properties and that in the long-run, educational efforts that are based on either exaggerating the risks and/or denying the benefits of marijuana will not be seen as credible and can become counter-productive. Dr. Roberts will testify that the federal suppression of medical marijuana research is not a necessary part of any effective strategy to reduce the costs of drug abuse, and that a special survey of marijuana use in California and Arizona, funded by ONDCP after the passages of the first two medical marijuana initiatives in 1996, did not find that the initiatives resulted in increased use of marijuana by young people or by people of any age.

Proposed Testimony of Dale Gieringer, Ph.D.

Dr. Gieringer is on the National Advisory Council of the California Center for Medicinal Cannabis Research (CMCR) located at UC San Diego. He is also the California state coordinator of the National Organization for Reform of Marijuana Laws (NORML), a co-founder of the California Drug Policy Reform Coalition and of Californians for Compassionate Use, and on the advisory board of MAPS. He received his doctorate from the Department of Engineering-Economic Systems at Stanford University in California. He will testify that the intent of the CMCR program, as described in its enabling legislation, is to scientifically study the therapeutic benefits and risks of medical marijuana, not to sponsor any version of it for FDA approval. At no time has the CMCR board proposed or discussed the idea of applying for an NDA or even conducting Phase 3 studies, and there are no plans for CMCR to move on to Phase 3 studies after its current studies are complete. The CMCR was set up in 2000 with a three-year legislative appropriation of \$3 million per year, all of which has been committed to ongoing studies, and no new funding is expected from the state. Had the CMCR intended to develop marijuana as an FDA-approved drug, it would have needed to establish its own independent supply of cannabis for R&D purposes. The idea of establishing a state medical marijuana garden was discussed but rejected during the drafting of the CMCR's enabling legislation, and it was decided to specifically require that the CMCR obtain marijuana from NIDA, rather than other sources.

Proposed Testimony of Rodney Skager, Ph.D.

Dr. Skager is a Professor Emeritus at the Graduate School of Education and Information Studies, University of California, Los Angeles, and is also co-director of the biennial California Attorney General's survey of drug use among secondary school students (the California Student Survey or CSS), and the Co-Chair of the California Senate Task Force on Alcohol and Other Drug Abuse Prevention Education in Schools. He received his Ph.D. in psychology from the University of California, Los Angeles, and his doctoral dissertation was entitled "Consumer Choice and FDA Drug Regulation." Dr. Skager will testify as to his experience conducting and reporting on a study as to the effects on drug use among teenagers of California's Proposition 215, the Medical Marijuana Initiative. The study does not support the idea that public awareness of and support for the medical use of marijuana "sends the wrong message" and is against the public interest. The federal Substance Abuse and Mental Health Administration provided funds to the California Department of Alcohol and Drug Programs for a 1996 study, as part of CSS, of the effects on teenagers of ads supporting Proposition 215 and of its approval by the voters. The grant provided funding for a considerably larger sample for the 1996-97 survey as well as the addition of questions assessing reactions to the 215 initiative and its promotional messages. The pre- and post-Proposition 215 California data could then be contrasted with 12th grade results for the MTF national and eastern regional samples. Results of the study are summarized in Exhibit 48, Percentage of California 11th Grade Students Reporting Use of Marijuana in the Previous Six Months vs. Previous Year for the National MTF Survey of 12th Grade Students, Biennially for 1991-92 through 1997-98. The study did not show the expected correlation between the publicity attendant upon Proposition 215, and marijuana use among teenagers. On the contrary, after voters approved Proposition 215 (1997-98 results), marijuana use by California 11th graders leveled off, and even slightly decreased, in opposition to national trends. Responses to questions about Proposition 215 revealed that about two thirds of 9th and three quarters of 11th

graders had read or heard something about the proposition. Regardless of grade level, only one in 10 or fewer believed that “a lot more” of their peers would try marijuana as a result of passage. Only 30% of current users in grade 11 believed that more of their peers would try the drug. A much smaller minority of non-users thought the same. On whether or not passage of Proposition 215 was a “good” or “bad” thing, both 9th and 11th grade students varied considerably in their perceptions of the medical value of marijuana. Sixty four percent of 9th and 58% of 11th graders were either “not sure” or thought Proposition 215 was a “bad” thing. Dr. Skager and his co-author submitted three versions of the report over the next three years to the California Department of Alcohol and Drug Programs, which rejected or refused to accept each version.

Proposed Testimony of John Lewin, M.D., as Representative of the California Medical Association, and of Representatives of Other Medical Associations

Dr. John Lewin, CEO and Executive Vice President of the California Medical Association or other representative(s) of the California Medical Association and possibly other medical associations will testify that their associations have reviewed the relevant literature and studies relating to the medical effects of marijuana on sick patients, and that they strongly support continuing scientific studies relating to the medical benefits of marijuana. They will testify further that marijuana should be studied under the same conditions as any other substance is studied, with private development of cannabis-based medicines being the most likely path to approved medicines and new discoveries.

5. DOCUMENTS

1. “Marijuana and Medicine,” Institute of Medicine, the National Academy of Sciences, 1999.
2. Single Convention on Narcotic Drugs, United Nations, 1961 (as amended by the 1972 Protocol)
3. Curriculum Vitae of Lyle E. Craker, as published on the website of UMass Amherst: Department of Plant, Soil, and Insect Sciences
4. Email from Matt Strait to Mahmoud A. ElSohly dated July 25, 2003, attaching Federal Register application of Dr. Lyle Craker to cultivate marijuana for research
5. Email from Mahmoud A. ElSohly to Steve Gust, Hari Singh, Walt Chambliss and Larry Walker dated August 29, 2003, attaching draft response to Federal Register notice
6. Email from Mahmoud A. ElSohly to Walt Chambliss, Steve Gust, Larry Walker and Hari Singh dated September 1, 2003, attaching second draft of proposed response to UMass-Amherst’s application for manufacturer’s license to cultivate marijuana

7. Email from Hari Singh to Mahmoud A. ElSohly, Walt Chambliss, Steve Gust and Larry Walker dated September 2, 2003, suggesting small revision to second draft of DEA response
8. Email from Mahmoud A. ElSohly to Walt Chambliss, Steve Gust, Hari Singh and Larry Walker dated September 9, 2003, regarding second draft
9. Third draft of DEA response to Federal Register notice, dated September 9, 2003
10. Curriculum Vitae of Lester Grinspoon, M.D.
11. Curriculum Vitae of Irwin G. Martin, Ph.D.
12. Letter from Department of Health & Human Services, to Rick Doblin, President, Multidisciplinary Association for Psychedelic Studies, Inc., dated May 25, 1999, regarding qualification of marijuana as orphan drug
13. Letter from Nora D. Volkow, M.D., Director, Department of Health & Human Services, to Rick Doblin, President, Multidisciplinary Association for Psychedelic Studies, Inc., dated June 9, 2004, regarding Dr. Doblin's concerns about HHS review process
14. Letter from Rick Doblin, Ph.D., MAPS President, to Dr. Nora Volkow, NIDA Director, dated May 19, 2004, regarding marijuana's potential use as FDA-approved medication
15. Letter from Donald I. Abrams, M.D., Assistant Director, AIDS Program, San Francisco General Hospital, to Alan I. Leshner, Ph.D., Director, National Institute on Drug Abuse, dated April 28, 1995, regarding use of marijuana by patients with HIV-related wasting syndrome
16. Martin, Basic Mechanisms of Cannabinoid - Induced Analgesia, International Association for the Study of Pain
17. Bouke C. de Jong, M.D., Marijuana Use and Its Association with Adherence to Antiretroviral Therapy Among HIV-Infected Persons With Moderate to Severe Nausea, *Acquir Immune Defic Syndr*, Volume 38, Number 1, January 1 2005
18. Donald I. Abrams, MD, *Short-Term Effects of Cannabinoids in Patients with HIV-1 Infection*, 139 *Ann Intern Med* 258-266 (2003)
19. Ethan Russo, *Chronic Cannabis Use in the Compassionate Investigational New Drug Program: An Examination of Benefits and Adverse Effects of Legal Clinical Cannabis*, *Journal of Cannabis Therapeutics*, Vol. 2(1) (2002)

20. New York State Journal of Medicine, October 1988, Volume 88, Number 10
21. Lester Grinspoon, M.D., Marijuana, The Forbidden Medicine
22. Doblin & Kleiman, *Marijuana as Antiemetic Medicine: A Survey of Oncologists' Experiences and Attitudes*, 9 J. Clin. Oncol. 1314-1319 (1991).
23. American Medical Association, Report 10 of the Council on Scientific Affairs (I-97) (presented 1997)
24. American Medical Association, Featured CSA Report: Medical Marijuana (A-01) (presented 2001)
25. Wade, Makela, Robson, House, Bateman, *Do Cannabis-Based Medicinal Extracts Have General Or Specific Effects On Symptoms In Multiple Sclerosis? A Double-Blind, Randomized, Placebo-Controlled Study on 160 Patients*, Multiple Sclerosis Journal, May 2004.
26. United Kingdom National Cannabis Agency: Protocol.
27. Baker, Pryce, Croxford, Brown, Pertwee, Huffman, & Layward, *Cannabinoids Control Spasticity and Tremor in a Multiple Sclerosis Model*, Nature, Vol. 404, (2 March 2000)
28. Letter dated 5/10/95 from Dr. Doblin to Professor Mahmoud El Souly
29. Memorandum dated 5/12/95 from Dr. Doblin to Professor Mahmoud El Souly
30. Memorandum dated 5/15/95 from Dr. Doblin to Dr. Donald Abrams
31. Memorandum dated 5/24/95 from Dr. Doblin to Donald Abrams
32. Memorandum dated 5/25/95 from Dr. Doblin to Dr. El Souly
33. Memorandum dated 6/1/95 from Dr. Doblin to Lester Grinspoon
34. 64 Fed. Register 29358 (6/1/1999)
35. 65 Fed. Reg. 54067 (9/6/2000)
36. 68 Fed. Reg. 61699 (10/29/2003)
37. 69 Fed. Reg. 42068 (7/13/2004)
38. 70 Fed. Reg. 24455 (5/9/2005)

39. 68 Fed. Reg. 35919 (6/17/2003)
40. 69 Fed. Reg. 12180 (3/15/2004)
41. 69 Fed. Reg. 11662 (3/11/2004)
42. 70 Fed. Reg. 10681 (3/4/2005)
43. Show Cause Order (dated 12/10/2004)
44. Letter to Administrator Karen Tandy from Senators Edward M. Kennedy and John F. Kerry (dated 10/20/2003)
45. Letter to Administrator Karen Tandy from California Medical Association (dated June 29, 2005)
46. *Cannabis: The Scientific and Medical Evidence*, The United Kingdom Parliament House of Lords, Select Committee on Science & Technology, Ninth Report, November 4, 1998
47. Curriculum Vitae of Rodney Skager, Ph.D.
48. Graph: Percentage of California 11th Grade Students Reporting Use of Marijuana in the Previous Six Months vs. Previous Year for the National MTF Survey of 12th Grade Students, Biennially for 1991-92 through 1997-98, from R. Skager, *Revisoning Youth Policy on Marijuana and Other Drug Use: Alternatives to Zero Tolerance*, in NEW DIRECTIONS IN MARIJUANA POLICY, 5-9 (Earleywine, M, Ed., New York: Oxford University Press. In press)
49. Letter to Rick Doblin from Chemic Laboratories showing timeline of application for 10 mg of marijuana (dated July 25, 2005)
50. Letter to Administrator Karen Tandy from Congresspersons John W. Oliver and Michael E. Capuno (dated July 26, 2005)
51. Letter to Brian Bayley from Patients Out Of Time (dated May 24, 2005)

Any documents received from NIDA or DEA in the course of this proceeding (currently requested but not received under the Freedom of Information Act)

Any documents received from the United Kingdom Home Office relating to a license to cultivate cannabis (currently requested but not received under UK Freedom of Information Act)

6. OTHER MATTERS

Respondent is aware of no other matters at this time.

7. DESIRED LOCATION

Respondents have no objection to the hearing being held in Arlington, Virginia.

8. BEST ESTIMATE AS TO TIME

Per the Court's Order, the Hearing Dates are already scheduled, and Respondent will comply with those dates.

Respectfully submitted,
Lyle E. Craker

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Dated: July 26, 2005

CERTIFICATE OF SERVICE

I hereby certify that on July 26, 2005, I caused a copy of the foregoing Respondent's Supplementary Pre-Hearing Statement and attached Exhibits to be served on the following by hand-delivery:

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