UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

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

RESPONDENT'S PRE-HEARING STATEMENT [INITIAL]

In response to the ALJ's Order of Feb. 8, 2005, Respondent respectfully submits his initial pre-hearing statement.

1. ISSUE

Whether granting Dr. Craker's application to cultivate cannabis for use in researching and developing a pharmaceutical product whose therapeutic properties could be available to patients is in the public interest, as defined by 21 U.S.C. § 823(a).

Whether DEA's denial of the application properly concluded that issuing a license to Dr. Craker would not be in the public interest for the reasons stated in its denial.

2. PROPOSED STIPULATIONS AND ADMISSIONS OF FACT

1. Numerous studies have concluded that cannabis offers therapeutic benefits to some patients.

2. Research continues about how cannabis may be of therapeutic benefit to patients.

3. It is in the public interest to research both already identified therapeutic benefits and as-yet-unidentified therapeutic benefits available from cannabis.

4. It is in the public interest to research different systems for delivering therapeutic benefits from cannabis to patients.

5. Because THC (one of the components of cannabis) offers therapeutic benefits to some patients, the FDA has approved a synthetic version of THC, called dronabinol, in the form of a pill for use as therapeutic drug.

6. Some patients are unable to use dronabinal (brand name Marinol); many patients are prescribed Marinol for nausea and because of the nausea, they cannot keep a pill down.

7. NIDA and the FDA have approved numerous Phase II studies involving cannabis.

8. Ten states have adopted laws that permit, under state law, the use of medical cannabis in some circumstances. Those states are Alaska, California, Colorado, Hawaii, Maine, Montana, Nevada, Oregon, Vermont, and Washington.

9. Thirty states have classified cannabis to recognize its therapeutic potential, or immunized patients from prosecution if they are participating in statutorily-authorized therapeutic research program.

10. There is currently in effect a federal injunction prohibiting the United States from prosecuting some patients in California who grow and use marijuana for medical purposes.

11. The federal government has established and maintained a compassionate use program under which it provides marijuana cigarettes to some patients for their medical use.

12. GW Pharmaceuticals, operating in England, currently holds a United Kingdom license to grow, and does grow, cannabis for medical research and development.

13. England is a signatory to the Single Convention [insert full name].

14. GW Pharmaceuticals has developed a cannabis-based oral spray, trademarked and patented as "Sativex," as a means of delivering the therapeutic benefits of cannabis to patients. As of April, 2005, that product has been approved for marketing in Canada.

15. Until 1941, cannabis was listed in the United States Pharmacopoeia and National Formulary, the official US compendia of acceptable standards for strength, quality, purity, packaging, labeling and storage for drugs and excipients

16. Until 1970, it was not illegal, as a matter of federal law, to possess or use cannabis for medical purposes.

3. PROPOSED WITNESSES.

Lyle E. Craker, Ph.D.
University of Massachusetts
Department of Plant and Soil Science
Amherst, Massachusetts

Richard Doblin, Ph.D.
Multidisciplinary Association for Psychedelic Studies
3 Francis Street
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Irwin G. Martin, Ph.D.
Ann Arbor, MI

Angel Raich
3708 Victor Ave
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Valerie Corral
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Irvin Henry Rosenfeld
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Philip Alden
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Dr. Donald Abrams
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Lester Grinspoon
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One or more Drug Policy Experts

(Respondent has discussed testimony with several potential experts, but has not yet determined which will testify. Respondent will supplement this Pre-Hearing Statement to identify such witnesses as soon as possible.)

Representative From One Or More Medical Associations

(Respondent has communicated with a group of medical associations, but has not yet confirmed which ones will give the proffered testimony. Respondent will supplement this Pre-Hearing Statement to identify such witnesses as soon as possible.)

Researchers interviewed by DEA/NIDA whose names appear on the reports of telephone interviews conducted by the government.

(Respondent has just this week received copies of those interviews and has not yet had an opportunity to speak with these just-identified researchers. Respondent will supplement this statement as soon as it determines which, if any, of those researchers it will call.)

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 from any concern with diversion, which can be DEA's only legitimate interest in denying this license.

Proposed Testimony of Dr. 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 the 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 quantify 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 led Dr. Doblin to sponsor 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 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 research with other Schedule I drugs, such as MDMA, LSD, and psilocybin, for which private suppliers 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 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 its own marijuana. MAPS' privately-funded 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 MAPS-funded and CaNORML-funded study by Chemic Laboratories, 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 22 months (as of April, 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 21 months 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 10 grams of marijuana or to import 10 grams convinced him that as long as NIDA retained a monopoly on the supply of marijuana that is legal for research, that 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 Irv 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 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 tesified 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 doctor, Dennis Isrealski, at 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, 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 (emeritus) of the Harvard Medical School in the Department of Psychiatry. He will testify that he has been studying cannabis since 1967 and have 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; the difficulties caused by NIDA having the monopoly on marijuana for research purposes, and the role of various entities in furthering medical marijuana research and development.

Proposed Testimony from One or More Drug Policy Experts

One or more drug policy experts will discuss how the public interest is served by facilitating scientific research into the potential risks and benefits of the medical uses of marijuana, either smoked, vaporized or in other delivery systems. As DEA Administrator Robert Bonner stated, "Those who insist that marijuana has medical uses would serve society better by promoting or sponsoring more legitimate scientific research, rather than throwing their time, money and rhetoric into lobbying, public relations campaigns and perennial litigation." -(Federal Register Vol. 57, No. 59 / Thursday March 26, 1992, p. 10503).

The person or persons will testify about how the federal monopoly on the supply of marijuana for research acts to inhibit privately-funded research and how the licensing of the UMass Amherst facility would help to catalyze privately-funded research on the important public health issue of medical marijuana. The testimony will emphasize the strong public interest in having questions of medical drug policy resolved as a matter of science.

Proposed Testimony from Representative of One of More Medical Associations

Representatives from one of more 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

Marijuana And Medicine: Assessing The Science Base, Janet E. Joy, Stanley J. Watson, Jr., and John A. Benson, Jr., Editors, Division of Neuroscience and Behavioral Health, Institutes Of Medicine, National Academy Press Washington, D.C. 1999

Transcript of argument before the United States Supreme Court in
Raich v. Ashcroft, No. 03-1454

U.N. Single Convention on Narcotic Drugs (1961) (as amended)

Dr. Craker's Curriculum Vitae

Various drafts of Dr. Mahmood El-Sohly's comments in response to Dr. Craker's application for a DEA license, and e-mail correspondence relating to those drafts:

Email dated 9/2/03 from Hari Singh to Mahmoud ElSohly

Email dated 9/8/2003 from Steve Gust to Mahmoud A. ElSohly (with draft)

Email dated 9/9/03 from Mahmoud A. ElSohly to Walt Chambliss and others (with draft)

DRAFT #3 of letter dated 9/9/03 to DEA from Mahmoud A. ElSohly

Email dated 9/11/03 from Mahmoud ElSohly to Walt Chambliss and others (with draft attached)

Email dated 8/29/03 from Mahmoud ElSohly to Steve Gust and others (with draft attached)

Letter dated 5/25/99 from The Department of Health and Human Services/FDA to Rick Doblin, granting "orphan drug" designation for marijuana.

Letter dated June 9, 2004 from Nora Volkow, Director, NIDA to Rick Doblin.

Letter dated May 25, 2004 to Nora Volkow from Rick Doblin.

Letter dated April 28, 1995 from Dr. Donald Abrams to Alan Leshner, Director, NIDA

Federal Register Vol. 57, No. 59 / Thursday, March 26, 1992, p. 10503

Lester Grinspoon, Marihuana, the Forbidden Medicine (Harvard University Press 1971)

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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)

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David Baker et al., Cannabinoids Control Spasticity and Tremor in a Multiple Sclerosis Model, 404 Nature 84 (2000) (finding therapeutic potential in the use of cannabis to control the debilitating symptoms of MS)

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Richard E. Doblin & Mark A.R. Kleiman, Marijuana as Antiemetic Medicine: A Survey of Oncologists' Experiences and Attitudes, 9 J. Clinical Oncology 1314 (1991) (reporting that a majority of oncologists surveyed thought marijuana should be available by prescription)

H.M. Meinck et al., Effect of Cannabinoids on Spasticity and Ataxia in Multiple Sclerosis, 236 J. Neurology 120 (1989) (concluding from a neurological study that herbal cannabis provided relief from both muscle spasms and ataxia, a combined benefit not found in other available medications)

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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

Depending in part on what additional documents and information Respondent obtains from DEA, and depending on whether Respondent and DEA can come to agreement on stipulations, Respondent's initial estimate as to the time required to present its case is 3 to 5 days.

Respectfully submitted,
Lyle E. Craker

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Dated: April 22, 2005

CERTIFICATE OF SERVICE

I hereby certify that on April 22, 2005, I caused a copy of the foregoing Respondent's Pre-Hearing Statement [Initial] to be served on the following by U.S. Mail, first-class postage prepaid:

Brian Bayley, Esq.
Office of the Chief Counsel
Drug Enforcement Administration
Washington, DC 20537

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Julie M. Carpenter