U. S. Department of Justice
Drug Enforcement Administration
Office of Chief Counsel

July 26, 2005

Julie M. Carpenter, Esq.
Jenner & Block
601 Thirteenth Street, N.W.
Suite 1200 South
Washington, D.C. 20005
(202) 639-6000

Dear Ms. Carpenter:

Enclosed is the Government's Supplemental Prehearing Statement with the attachments. The attachments include all of the University of Mississipi's DEA registrations. I am sorry I didn't get these to you sooner, but I had trouble locating all the different registrations. I believe now you have all of the applicable registrations.

If any exhibits are incomplete or illegible, please let me know. If you have any other questions about these document copies provided to you or the supplemental prehearing statement, please call me at (202) 307-8092.

Sincerely,

Brian Bayly

Enclosures

UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

IN THE MATTER OF	)	
	)	**Docket No. 05-16**
	)	
	)	
Lyle E. Craker, Ph.D.	)	
	)	

GOVERNMENT'S FIRST SUPPLEMENTAL
PREHEARING STATEMENT

Pursuant to the May 23, 2005 Prehearing Ruling of the Administrative Law Judge, the United States Department of Justice, Drug Enforcement Administration, by and through the undersigned attorney, hereby submits the following supplemental prehearing statement.

ADDITIONAL PROPOSED STIPULATIONS AND ADMISSIONS OF FACT

ADDITIONAL PROPOSED WITNESSES

Eric A. Voth, M.D., FACP
Chairman
The Institute on Global Drug Policy
901 Garfield
Topeka, Kansas 66606

Eric A. Voth, M.D., FACP (NEW WITNESS)

Eric A. Voth, M.D., FACP, (Dr. Voth) will present and testify about his curriculum vitae. He will testify about his background pertaining to the potential uses and abuses of medical marijuana and his experience at The Institute on Global Drug Policy. Dr. Voth will testify why he believes that marijuana, particularly plant material and particularly through smoking devices, is not viable medicine. Dr. Voth also will testify about his participation in and familiarity with the I.O.M. publication, Marijuana and Medicine: Assessing the Science Base, Joy, Janet, et al., Ed., (National Academy Press, Washington, D.C. 1999). Dr. Voth will

testify why he believes this publication does not support any form of smoked marijuana as potential "medicine."

Dr. Voth will testify about the various adverse health effects that can result from smoking or inhaling the marijuana plant material. Dr. Voth will testify about the alternatives to using the marijuana plant material in research. Dr. Voth will distinguish GW's product Sativex from what Rick Doblin is proposing to do with the plant material and the vaporizer. Dr. Voth will testify about alternative medications for marijuana in light of the professed medical uses claimed by marijuana proponents.

Dr. Voth will testify about what medical associations or other similar associations endorse or do not endorse marijuana as medicine.

Dr. Voth will testify about the need for the a manufacturer of marijuana in light of the University of Massachusetts' contention that a marijuana manufacturer is needed because no pharmaceutical company would develop a marijuana medical product without a marijuana supply to insure consistency of dose.

Dr. Voth will endorse and testify about some or all of the following documents, articles or publications listed in Government Exhibits 23, 25, 31, 37-53, 56-61, 63, 80-81 and 84. He will also review and may testify about articles, documents or publications submitted by Respondent.

Dr. Voth's testimony would refute the testimony of the University of Massachusetts' witness, Lester Grinspoon, M.D., who has published two books, which endorse the use of marijuana as medicine. One of these publications, Grinspoon, Bakalar, Marihuana Reconsidered (Yale University Press, rev. 1997).

Mr. Kenneth H. Davis, Jr. (NEW WITNESS)
Senior Program Director
Bioanalytical Chemistry Center
Research Triangle Institute
East Institute Drive
Hermann Building
P.O. Box 12194
Research Triangle Park, NC 27709

Mr. Davis is a Senior Program Director, Bioanalytical Chemistry Center, at the Research Triangle Institute (RTI). He will testify regarding his job, experience, training, and education relative to his employment with RTI. Mr. Davis will testify to the summarized testimony on pages 5 through 7, and pages 27 through 29, of the Government's Prehearing Statement [Initial] dated February 28, 2005.

Mr. Joel Egertson (NEW WITNESS)
Formerly: Senior Drug Policy Advisor
Office of Public Health and Science
Office of the Secretary of Health and Human Services

Mr. Egertson was a Senior Drug Policy Advisor with the Office of Public Health and Science, Office of the Secretary of Health and Human Services (HHS) until he retired from federal employment. Mr. Egertson will testify that, as part of duties, he convened and coordinated the Public Health Services (PHS) Committee. He will testify regarding his previous employment with HHS, and his experience, training, and education relative to his role as the PHS Committee coordinator. A summary of his testimony is contained on pages 26 through 27 of the Government's Prehearing Statement [Initial] dated February 28, 2005. Mr. Egertson will not testify to the summary outlined on page 27, lines 1 through 5, of the Government's Prehearing Statement [Initial].

Dr. Mahmoud Elsohly **(ADDITIONAL TESTIMONY; CLARIFICATION OF INITIAL PROFFER)**

Dr. Elsohly will also testify that, since the submission of the Government's Prehearing Statement [Initial] on February 28, 2005, NIDA awarded a contract to University of Mississippi to be the sole provider of research-grade marijuana to authorized researchers. The previous contract expired on November 8, 2004, and was extended to March 15, 2005. The new contract award was effective March 15, 2005. Dr. ElSohly will testify regarding the terms of the new contract.

Dr. ElSohly will also testify that all direct requests to the University of Mississippi for marijuana materials are re-directed to NIDA for review and/or approval. The University of Mississippi then must wait for NIDA to direct the University of Mississippi to send specific marijuana materials, in specific quantities, to the approved researcher. Dr. ElSohly does not recall MAPS directly requesting marijuana materials from the University of Mississippi.

In response to the Administrative Law Judge's Prehearing Ruling dated May 23, 2005, regarding "more information about Dr. ElSohly's comments and objections to Respondent's application, as referenced on page 8 of the Government's prehearing statement," the following information is provided. Dr. ElSohly's comments are outlined in Government's proposed exhibit 5, and in the summary of Dr. ElSohly's testimony.

Dr. ElSohly will also testify regarding the patents held, and patents pending, of which the University of Mississippi is the assignee, and of which he is an Inventor, with regard to marijuana and marijuana extracts. He will also discuss the manufacturing registration that allows the University of Mississippi to develop an extract product as noted in Government Exhibits 78 and 79.

Dr. Steven Gust (ADDITIONAL TESTIMONY)

Clarification/modification of Government's Prehearing Statement [Initial], p. 12, lines 10-18: A new contract was awarded on March 15, 2005, and expires on March 15, 2010. The University of Mississippi was the successful bidder for the new contract, however, it should be noted that procurement was open to any and all bidders. Dr. Gust will testify that he specifically asked for notice of the bidding for this contract be sent to Dr. Craker, who did not submit a contract bid. There are three requirements for a researcher to obtain marijuana from the NIDA contractor. These requirements include an approval of an investigational new drug application, or IND, from the FDA; successfully registering for a Schedule I license from the DEA; and being reviewed for scientific merit (peer review). Prior to 1999, scientific review was provided either by an NIH peer review committee or by consultants to NIDA.

In 1999, HHS created a PHS Committee. The PHS Committee reviews requests from non-NIH funded researchers (i.e., privately funded research) to study possible medical uses of marijuana (research which involves the use of marijuana with a medical effect upon human beings). The PHS Committee is comprised of individual experts in the various medical fields under investigation and includes NIH staff members and other health agencies such as the FDA.

NIDA administers the nation's drug supply program and distributes a variety of Schedule I controlled substances to researchers. The vast majority of requests have been for MDMA, opiates such as heroin and synthetics, and marijuana. A few requests have been made for mescaline, LSD, ibogaine, and cannabinoids other than THC. In order to receive any Schedule I controlled substance, NIDA requires the research project to be

approved through scientific peer review. This scientific peer review can be achieved in one of three methods: (1) NIH peer review; (2) expert consultant reviews; or (3) PHS Committee review. NIH-supported researchers receive approved scientific review via the usual process of peer review of the project within the NIH system. For researchers without NIH funding, NIDA must rely upon expert consultant peer reviews, unless the research proposal involves the study of marijuana upon human beings, or the study has potential medical applications of marijuana upon human beings. In that case, HHS requires the PHS Committee to conduct the scientific peer review.

Omit the sentence on page 13 of the Government's Prehearing Statement [Initial] beginning with "Furthermore, when an IND . . ."

Helen Kaupang (NEW TESTIMONY)

Helen Kaupang will testify that she received Government Exhibit 80 from Keith Kamita, Chief of the Narcotics Enforcement Division, Department of Public Safety, State of Hawaii. This report explained Hawaii's marijuana laws to ONDCP Director John Walters.

Ms. Kaupang will explain she received the following information from Mr. Kamita about this report. Under Hawaii law, physicians are not authorized to administer or dispense marijuana to their patients. It is up to the patient to obtain or grow his/her marijuana; the physician under State law can not get involved in the administering or dispensing. All of these patients listed on the third page of the report who are listed as participating in the medical marijuana program have addresses that correspond to the island, e.g., there are 312 "medical marijuana" patient listed for Oahu, which means these patients have listed their addresses on the Island of Oahu.

Under State law a physician can not prescribe marijuana (Schedule I controlled Substance) all the medical use of marijuana certificate does is acts as his written certification that in the physician's professional opinion that the potential benefits of the medical use of marijuana would likely outweigh the health risk for that particular qualifying patient. (Chapter 329-122 Hawaii Revised Statutes) Under the Hawaii law, the physician is required to note the reason the "patient" is receiving a marijuana recommendation from the physician. All these marijuana recommendations pertain to plant material as opposed to extracts. Under Hawaii law a patient and his caregiver may jointly possess not more than three mature marijuana plants, four immature marijuana plants and one ounce of usable marijuana per each mature plants. It is unlawful for a physician to distribute to his patients marijuana.

Ms. Kaupang will testify that three physicians that are participating in the Hawaii marijuana program are under criminal investigation for either supplying marijuana seeds or plants directly to the patient in violation of State law or, in one, case issuing recommendations for patients to use marijuana without establishing a medical need and/or without examining the patient.

Ms. Kaupang, based upon her experience and training at DEA and particularly while working at DEA Headquarters at the DEA Registration Unit, will testify about the difference between an analytical registration and a chemical registration and why DEA has these two separate registration categories. She will testify that an analytical registration is limited to identifying drug samples while a chemical registration entails hypotheses, variables and comparisons, which go beyond just identifying a certain drug.

David Auslander, Ph. D. (NEW WITNESS)
Pharmaceutical Development & Validation expert
c/o Teltech Expert Research
Minneapolis, MN

David Auslander, Ph. D., (Dr. Auslander) will testify about his education, experience and expertise in drug development and the process for commencing and bringing a launching a pharmaceutical drug product on the market. He will testify as to the latter based on his C.V. as set forth in Government Exhibit 83.

Dr. Auslander would testify about the feasibility or possibility of a pharmaceutical company developing a marijuana pharmaceutical product from plant material as opposed to developing a marijuana pharmaceutical product from extracts. And the testimony would include the necessity of having a ready source of supply of marijuana before **any** pharmaceutical company would develop a marijuana pharmaceutical drug product from plant material.

DEA Diversion Group Supervisor Lisa Young
DEA Diversion Investigator Violeta Willmott
DEA Riverside District Office
4470 Olivewood Ave.
Riverside, CA 9250

DEA Diversion Group Supervisor Lisa Young or DEA Diversion Investigator Violeta Willmott will testify about their education, training, duties and experience with DEA. One or both of these witnesses will testify about the following.

Since around March 2005, the DEA Riverside Diversion Group joined an investigation by the San Bernardino Sheriff's Office (SBSO) of the California Alternative Care Givers Christian Alliance (CACGCA), 40927 Big Bear Blvd., Big Bear, California. Prior to the investigation commencing, CACGCA had posted flyers advertising medical marijuana organically grown with physicians available for consultation at the clinic. The

investigation was commenced because law enforcement personnel had received several complaints about CACGCA. Law enforcement personnel made several undercover visits to CACGCA and obtained marijuana from the clinic without obtaining any physical exams or seeing a physician. The undercover officers received pre-signed recommendations from a physician assistant, and these recommendations were pre-signed by DEA registered physician JoAnne Benzor, M.D. Based upon these recommendations, the undercover operatives then received marijuana from CACGCA inserted into brownies, Rice Krispies, cookies or prescription vials.

As a result, a state search warrant was obtained and executed at CACGCA on June 8, 2005. During the execution of the search warrant, law enforcement personnel found and seized 343 chocolate bars containing 1.6 to 2.2 ounces each, 139 prescription bottles with marijuana plant material and 67 vials of marijuana.

DEA Policy Expert (To be named at a later date)

A DEA policy expert will testify that, while DEA has grave concerns about marijuana in general, DEA is particularly concerned about the plant material since that is the form in which marijuana is diverted and abused. The expert will explain that DEA analogizes marijuana to raw opium, which under current DEA policy is not allowed to be cultivated domestically but only imported. The expert will explain that DEA does not consider raw opium a pharmaceutical drug but only extracts from opium are considered pharmaceutical drugs for use in treatment. By analogy, the plant material from marijuana cannot be considered a pharmaceutical drug.

ADDITIONAL DOCUMENTARY EVIDENCE

36. Copy of Dr. Voth's C.V. (unknown pages)

37. Copy of Voth, Eric, A., M.D., and Schwartz, Richard H., M.D., *Medical Applications of Delta-9-Tetrahydrocannabinol and Marijuana*, Annals of Internal Medicine, Vol. 126, No. 10, May 15, 1997 (8 pages)

38. Copy of Voth, Eric A., M.D., *A Peek into Pandora's Box: The Medical Excuse Marijuana Controversy*, Journal of Addictive Diseases, Vol. 22(4), 2003 (20 pages)

39. Copy of Schwartz, Richard H., M.D., and Voth, Eric, A., M.D., *Marijuana as Medicine: Making a Silk Purse out of a Sow's Ear*, Journal of Addictive Diseases, Vol. 14(1), 1995 (7 pages)

40. Copy of Schwartz, Richard H., M.D., Cooper, Meghan N., B.A., Oria, Marife, M.D., Sheridan, Michael J., Sc. D., *Medical Marijuana: A Survey of Teenagers and Their Parents*, Clinical Pediatrics, July/August 2003 (6 pages)

41. Copy of Advances in Pediatrics, (Royal Society of Medicine Press, London), "The Use and Toxicity of Cannabis in Teenagers," pg. 131-144, Schwartz, Richard H., M.D., and Voth, Eric, A., M.D. (14 pages)

42. Copy of Schwartz, Richard H., M.D., and Voth, Eric, A., M.D., Sheridan, Michael J., Sc. D., *Marijuana to Prevent Nausea and Vomiting in Cancer Patients: A Survey of Clinical Oncologists*, Southern Medical Journal, Vol. 90, No. 2, February 1997 (6 pages)

43. Copy of National Institute on Drug Abuse, Office of Rare Diseases Reports, *Report on the Rare Diseases Research Activities at the National Institutes of Health*, (FY 2003) (10 pages)

44. Copy of *Drug Enforcement Administration, Notice of Denial of Petition*, 66 Federal Register 20,038 (2001) (39 pages)

45. Copy of National Institute on Drug Abuse, National Drug Intelligence Center, *National Drug Threat Assessment 2005*, February 2005 (32 pages)

46. Copy of American Medical Association, H-95-952 Medical Marijuana; H-95.995 Health Aspects of Marijuana, H-95.998 AMA Policy Statement on Cannabis (Marijuana), and H-170.992 Alcohol and Drug Abuse Education (4 pages)

47. Copy of National Multiple Sclerosis Society, *National MS Society Information Sourcebook, Marijuana (Cannabis)* (2005) (4 pages)

48. Copy of Stelow, Edward B., M.D., et al., *Bong Lung: Regular Smokers of Cannabis show Relatively Distinctive Histologic Changes that Predispose to Pneumthorax*, Am. J. Surg. Pathol, Vol 29, No. 7, (July 2005), pg. 980-982 (3 pages)

49. Copy of Chen, Chuan-Yu, et al., *Who becomes cannabis dependent soon after onset of Use? Epidemiological Evidence from the United States: 2000-2001*, Drug and Alcohol Dependence 79, (2005) pg. 11-22 (7 pages)

50. Copy of Matochik, John A., et al, *Altered Brain Tissue Composition in Heavy Marijuana Users*, Drug and Alcohol Dependence 77, (2005) pg. 23-30 (8 pages)

51. Copy of Teare, Laura, and Zajicek, John, *The Use of Cannabinoids in Multiple Sclerosis*, Expert Opin. Investig. Drugs, 14(7) (2005), pg. 859-869 (11 pages)

52. Copy of Health Canada notice announcing the approval of Sativex® as a prescription medication (4 pages)

53. Copy of an April 13, 2005 letter from GW to the U.S. Department of Health and Human Services (5 pages)

54. Copy of a letter, dated June 6, 2002, from Hon. John W. Olver, et al, to then-DEA Administrator Asa Hutchinson (1 page)

55. Copy of a response letter, dated July 1, 2001, from then-DEA Administrator Asa Hutchinson to Hon. John W. Olver, et al (3 pages)

56. Copy of Complaint and Notice of Proposed Disciplinary Action by the Board of Medical Examiners, State of Oregon, In the Matter of Phillip Edwin Leveque, D.O., dated February 12, 2002 (5 pages)

57. Copy of Stipulated Order by the Board of Medical Examiners, State of Oregon, In the Matter of Phillip Edwin Leveque, D.O., dated April 10, 2002 (5 pages)

58. Copy of Order of Emergency Suspension by the Board of Medical Examiners, State of Oregon, In the Matter of Phillip Edwin Leveque, D.O., dated March 12, 2004 (6 pages)

59. Copy of Complaint and Notice of Proposed Disciplinary Action by the Board of Medical Examiners, State of Oregon, In the Matter of Phillip Edwin Leveque, D.O., dated March 16, 2004 (8 pages)

60. Copy of letter from the State of Iowa, Board of Pharmacy Examiners, to Senator Elaine Szymoniak, The Iowa Senate, dated March 10, 1995 (7 pages)

61. Copy of *The Church of the Living Tree; Denial of Application*, 68 Fed. Reg. 17,403 (2003) (3 pages)

62. Copy of *United States v. Oakland Cannabis Buyers' Cooperative and Jeffrey Jones*, 532 U.S. 483 (2001)

63. Copy of *Marion "Molly" Fry, M.D., Revocation of Registration*, 67 Fed. Reg. 78,015 (2002) (8 pages)

64. Copy of M2 Presswire, "United Nations' World Drug Report 2004 presents in-depth look into global drug trends," June 28, 2004 (3 pages)

65. Copy of a patent related to the University of Mississippi's DEA registration (23 pages)

66. Copy of a patent related to the University of Mississippi's DEA registration (11 pages)

67. Copy of a patent related to the University of Mississippi's DEA registration (6 pages)

68. Copy of a patent related to the University of Mississippi's DEA registration (10 pages)

69. Copy of a patent related to the University of Mississippi's DEA registration (9 pages)

70. Copy of a patent related to the University of Mississippi's DEA registration (6 pages)

71. Copy of a patent related to the University of Mississippi's DEA registration (13 pages)

72. Copy of a patent related to the University of Mississippi's DEA registration (20 pages)

73. Copy of a patent related to the University of Mississippi's DEA registration (10 pages)

74. Copy of a DEA researcher registration for the University of Mississippi (1 page)

75. Copy of a DEA manufacturing registration for the University of Mississippi (1 page)

76. Copy of a DEA manufacturing registration for the University of Mississippi (1 page)

77. Copy of a DEA analytical lab registration for the University of Mississippi (1 page)

78. Copy of a Memorandum of Agreement, October 1999, between DEA and the University of Mississippi (9 pages)

79. Copy of a letter, dated June 15, 2005, from DEA to the University of Mississippi and agreement by the University of the Mississippi to the terms of the letter (4 pages)

80. Copy of "Hawaii's Medical Use of Marijuana Program" report from the State of Hawaii, Department of Public Safety, Narcotics Enforcement Division, to ONDCP (5 pages)

81. Copy of Hawaii Statutes related to marijuana (10 pages)

82. Copy of "National Survey on Drug Use and Health" (NSDUH) (4 pages)

83. Copy of Curriculum Vitae for David Auslander, Ph. D. (4 pages)

84. Copy of *Marijuana Scheduling Petition: Denial of Petition; Remand*, 57 Fed. Reg. 10,499 (1992) (19 pages)

Respectfully submitted,

Brian Bayly
Senior Attorney
Office of Chief Counsel

Dated: July 26, 2005

CERTIFICATE OF SERVICE

On July 26, 2005, I sent, via Federal Express, postage prepaid, a copy of the foregoing to Julie M. Carpenter, Esq., Jenner & Block, 601 13th St., NW, Suite 1200 South, Washington, D.C. 20005, Amherst, Massachusetts 01003, and filed the original and two copies of the foregoing at the DEA Office of Administrative Law Judges by hand delivery.

Brian Bayly