UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

MULTIDISCIPLINARY ASSOCIATION FOR PSYCHEDELIC STUDIES; LYLE CRAKER and VALERIE CORRAL,

Petitioners,

vs. **No. 04-1246**

THE UNITED STATES OF AMERICA; THE HONORABLE KAREN TANDY, Administrator of the DRUG ENFORCEMENT ADMINISTRATION,

Respondents.

AMENDED PETITION FOR REVIEW TO COMPEL AGENCY ACTION UNLAWFULLY WITHHELD OR UNREASONABLY DELAYED

The petition has been amended to reduce the number of pages as required by Fed. R.App.P. 21(d); and divided into two sections. The first section (I) describes the issues to be addressed pursuant to Rule 21(a)(2) (immediately following). The second section (II) begins with a statement of the nature of the claim presented by this action in averment 1, followed by a detailed factual history of the petitioners' claims.

I. FED. R.APP.P. 21(a)(2) STATEMENT

A. THE RELIEF SOUGHT:

1. A declaration that the petitioners are entitled to prompt action by the respondent Drug Enforcement Administration (the agency) on petitioner Cracker's manufacturing application (described in section II infra at averments 19-29; averment) and Chemic Laboratories Inc. of Canton, Massachusetts (Chemic's) import application (averments 47-51), and that the respondent's failures to act on those applications thus far constitute violations of their rights to prompt actions.

2. An order compelling the agency to act within twenty days on petitioner Craker's pending application for registration to manufacture marijuana for medical research purposes, to either approve or deny the application;

3. If the agency does not approve Craker's manufacturing application, this Court shall order the agency to issue an Order to Show Cause as required by 21 C.F.R. §§ 1301.35 and 1301.37 within twenty days of the application's denial, affording Craker or other petitioners an opportunity for administrative hearings pursuant to 21 C.F.R. § 1341-46 and 1316.41-68.

4. Order the agency to publish notice immediately in the Federal Register, and comply in all other manners with 21 C.F.R. § 1301.34(a) concerning Chemic's pending application for

registration to import ten grams of marijuana from the Dutch Office of Medicinal Cannabis for medical research purposes;

5. Order the agency to act within twenty days of the expiration of the thirty day comment specified in 21 C.F.R. § 1301.34(a), to either approve or deny Chemic's import application;

6. If the agency does not approve Chemic's import application, this Court shall order the agency to issue an Order to Show Cause as required by 21 C.F.R. §§ 1301.35 and 1301.37 within twenty days of the application's denial, affording Chemic or any of the petitioners an opportunity for administrative hearings pursuant to 21 C.F.R. § 1341-46 and 1316.41-68.

7. Grant such further relief as the Court deems just and proper, including an award of the petitioners' attorneys fees and costs.

B. THE ISSUES PRESENTED

1. Does the agency's consideration of the foregoing applications constitute discrete agency actions, as to which the respondent is legally required to act?

2. Must the time period, during which these applications have been complete (or supplemented) and pending without resolution by the agency, be deemed unreasonable or egregious as a matter of law, considering: The length of time elapsed since the agency came under a duty to act; the statute authorizing the

agency's action; the consequences of the agency's delay; and, any plea of administrative convenience or limited resources?

C. FACTS NECESSARY TO UNDERSTAND THE ISSUES PRESENTED

Craker's Manufacturing Application:

1. On June 25, 2001, petitioner Craker filed a manufacturing application with the agency (averments 29-34).

2. On August 20, 2002 (more than a year after the initial filing), Craker resubmitted his application to the agency (averments 35-36).

3. On June 20, 2003 (two years after the initial filing), at the agency's request Craker submitted addition information on his application (averment 37).

4. On July 24, 2003, the agency published notice of the application in Federal Register, soliciting comments on the application (averment 39). On September 23, 2003, the public comment period expired (averment 41).

5. Today, almost a year has passed since the expiration of the public comment period on the application, which was filed more than three years ago. The agency has failed or refused to act on the application.

Chemic's Import Application

6. On June 24, 2003, Chemic filed an import application with the agency (averment 48).

7. On the same date, Chemic filed a research protocol with federal Department of Health and Human Services (HHS) for its approval (as to the protocol's scientific merit) regarding the use of the imported research material (marijuana) (averment 51). HHS' year-long failure or refusal to evaluate the protocol's merit is the subject of a separate action in this court filed herewith (consolidation of these actions shall be sought promptly).

8. Today, more than a year after Chemic's application was filed with the agency, it has failed or refused to act on it.

D. REASONS WHY THE WRIT SHOULD ISSUE:

1. There appears to be no reasonable basis for disputing that the grant or denial of the pending applications constitute discrete agency actions, rather than the exercise of systemic policy-making discretion.

2. There appears to be no reasonable basis for disputing that the times elapsed since the applications' filings are far, far longer than the time that reasonably could be deemed to be consumed by the tasks inherent in each application's consideration, particularly with reference to time periods set on similar tasks throughout the statutory process for similar applications and similar actions in other nations.

3. There appears to be no reasonable basis for disputing the severe human harm endured by petitioner Corral (and similarly

situated seriously ill patients), and the depreciation and frustration of the other petitioners' substantial financial interests, directly caused by the agency's undue delay in disposing of the foregoing applications.

4. There appears to be no reasonable basis for a claim that swifter action on the agency's application decisions is prohibited by considerations of administrative convenience or limited resources.

5. The lack of an explicit time limit for application decision-making does not authorize the agency to ignore its legal obligation to act on pending non-frivolous applications within a reasonable period of time.

II. DETAILED FACTUAL HISTORY OF THE PETITIONERS' CLAIMS

A. Nature of the Petition

1. This petition for review, of federal agency action unlawfully withheld or unreasonably delayed, seeks declaratory relief and an order compelling the Drug Enforcement Administration (DEA hereafter) to approve or deny the following two related applications for registration, pending before it pursuant to 21 U.S.C. §§ 823 and 958, and 21 C.F.R. §§ 1301.01 et. seq.:

   a. The application of petitioner Prof. Lyle E. Craker (Craker hereafter), Director of the Medicinal Plant Program, Department of Plant and Soil Sciences, of the University of Massachusetts at Amherst (UMass Amherst hereafter) submitted on June 25, 2001 pursuant to 21 U.S.C. § 823 and 21 C.F.R. §§ 1301.11, 1301.13, 1301.14 and 1301.33 seeks DEA registration to manufacture marijuana [the relevant statutes and regulations cited in this petition refer to an applicant's or resource's "manufacture" of a controlled substance; as relevant here, to "manufacture" marijuana means to grow marijuana plants; *see* 21 U.S.C. § 802(15)] to supply to researchers approved by the Food and Drug Administration (FDA hereafter) and/or DEA.

   b. The application of Chemic Laboratories, an analytical laboratory in Canton, Massachusetts (Chemic, hereafter), working for the pharmaceutical industry with existing permits from DEA to conduct research

with marijuana and other controlled substances, submitted on June 24, 2003 under 21 U.S.C. § 958 and 21 C.F.R. §§ 1301.11, 1301.13, 1301.14 and 1301.34, seeks DEA registration to import ten grams of marijuana from the Dutch Office of Medicinal Cannabis (DOMC hereafter) for use in a medical marijuana research project investigating the safety advantages of a non-smoking delivery device for marijuana known as the Volcano vaporizer.

B. Parties

2. Petitioner Multidisciplinary Association for Psychedelic Studies (MAPS hereafter) is an IRS-approved non-profit research and educational organization (EID #59-2751953) with its principal place of business located at 2105 Robinson Avenue, Sarasota, Florida.

3. Petitioner Craker has an office located at the Stockbridge Hall-Room 12A, 80 Campus Center Way at UMass Amherst.

4. Petitioner Valerie Corral is a California-licensed medical marijuana patient and caregiver, and founder of the Wo/Men's Alliance for Medical Marijuana, with an office at 230 Swanton Road, Davenport, California.

5. Respondent DEA is a government agency within the U.S. Department of Justice, the headquarters of which are located at 950 Pennsylvania Avenue N.W., Washington, D.C.

   a. The DEA Administrator is Karen Tandy.

b. The DEA headquarters are located at 2401 Jefferson Davis Highway, Alexandria, Virginia.

C. Jurisdiction and Venue

6. This Court has jurisdiction pursuant to 5 U.S.C. § 706(1), 21 U.S.C. §§ 877 and 965, and 28 U.S.C. §§ 1361, 2201 and 2202. *See* *Cobell v. Norton*, 240 F.3d 1081, 1095 (D.C. Cir. 2001) and *Telecommunications Research and Action Center ["TRAC"] v. F.C.C.*, 750 F.2d 70, 78-81 (D.C. Cir. 1984), as clarified in *In re GTE Service Corp.*, 762 F.2d 1024, 1026 n. 5 (D.C. Cir. 1985) (the court which has jurisdiction to review a final agency order also has exclusive jurisdiction to review a claim of failure to act or unreasonable delay by means of a petition for review).

7. Venue is proper in this Court pursuant to Title 21 U.S.C. §§ 877 and 965, because the respondent's parent agency is headquartered in Washington, D.C.

D. Petitioners' Standing

8. MAPS' corporate mission is to design, obtain approval for, fund and conduct scientific research with the goal of developing Controlled Substances Act Schedule I substances such as marijuana into FDA-approved prescription medicines.

9. MAPS has expertise in designing comprehensive FDA-approved drug development plans, identifying contractors with expertise in research with which to partner in seeking government permits, obtaining government permits for

research, and funding or obtaining funding for the research.

10. Much of MAPS' work is done with contractors and scientists who have expertise in research with plants and/or controlled substances. Such research partners include Craker and Chemic.

11. MAPS seeks to work with Craker to obtain a source of high-potency marijuana that can be delivered in the non-smoking delivery system (vaporizer), which Chemic is researching. MAPS seeks to sponsor the research necessary to determine whether high potency marijuana, either smoked or vaporized, can be accepted by the FDA as safe and efficacious for multiple medical applications.

12. MAPS successfully obtained Orphan Drug designation (Application 97-1053) from the FDA for marijuana as a treatment for the HIV-associated wasting syndrome, under a program created by Congress to facilitate the development of drugs for rare diseases (fewer than 200,000 patients per year). MAPS thus has a clear economic interest in conducting research into the risks and benefits of the medical use of marijuana for HIV-associated wasting syndrome, as well as for other human diseases.

13. MAPS' interest in medical marijuana research is within the zone of interests intended to be protected or regulated under relevant statutes governing medical research with controlled substances (many of which, even some with toxic

dose levels, have been proven to be medically useful after testing similar to the research for which petitioners seek government permission, with the applications pending before DEA which are the subject of this petition).

14. Research under Craker's application when approved will be funded by MAPS; research under Chemic's application when approved will be funded by MAPS and California NORML (a nonprofit membership organization dedicated to marijuana policy reform). This research has been unreasonably delayed because DEA has taken no action to approve or deny the Craker and Chemic applications pending before it.

15. MAPS has suffered, and continues to suffer, adverse effects from DEA's failure to act and unreasonable delay in acting in among other effects, without limitation, that:

    a. MAPS has an economic interest in conducting research to explore the development of marijuana as a FDA-approved prescription medicine, to help treat a substantial number of patients who may require marijuana for their health and safety, which interest is rendered worthless by DEA's inaction because MAPS can neither grow nor import marijuana for use in legal research, such as the Chemic research protocol (the application for which is one of the subjects of this petition), and cannot proceed with any research using marijuana;

b. MAPS cannot implement its drug development research plans given the monopoly of the National Institute on Drug Abuse (NIDA) over the supply of research marijuana acceptable to FDA, in part due to NIDA's failure to sell marijuana in a timely and reasonable manner to Chemic (the subject of a petition for review filed simultaneously here with this action; a motion to consolidate both petitions shall be filed promptly);

c. Unless MAPS can obtain an independent source of research grade marijuana, it cannot raise the funds required to conduct the necessary FDA-approved clinical trials into the risks and benefits of the use of marijuana, either smoked or vaporized, thus preventing MAPS from initiating a drug development program which is an integral part of its mission;

d. DEA's refusal to act promptly also constitutes an adverse impact on MAPS in that such inaction violates MAPS' and its members' expectation and entitlement that the federal government and its sub-divisions will act promptly, in compliance with relevant regulations and statutes, and in good faith on non-frivolous registration applications.

16. Petitioner Valerie Corral is a California state-licensed medical marijuana patient and caregiver, and founder of the Wo/Men's Alliance for Medical Marijuana (WAMM).

a. WAMM is a medical marijuana co-op, whose unlicensed private facility for growing treatment grade marijuana exclusively for its members' personal medical use was destroyed by the DEA, despite approvals to operate from state and local authorities.

b. Corral is a patient with a severely debilitating illness; before using whole marijuana, she was subject to frequent grand mal seizures (from injuries in an auto accident) and addicted to stupor-inducing anti-seizure patent medication;

c. Corral and similarly situated patients (whose serious illnesses and resulting quality of life respond only to plant marijuana smoke, and not to the marijuana-derivative patent medicine Marinol) have an incalculable interest in the development of a supply of research-grade marijuana, sufficient to enable patient access to marijuana delivery systems free of virtually all harmful and non-treatment related contaminants within smoked marijuana.

d. Every day DEA delays consideration of the Craker and Chemic research applications is another day that Corral and other patients must either suffer otherwise remediable pain, or risk arrest to use marijuana as medicine.

e. These patients (for whom plant marijuana is a superior treatment to other forms of treatment) rely on MAPS, a

non-profit entity, to seek government permission to conduct research on the development of plant marijuana into an FDA-approved prescription medicine.

17. Petitioner Craker is Director of the Medicinal Plant Program of the Department of Plant and Soil Sciences at UMass Amherst, and his DEA application for registration to manufacture marijuana is the subject of this petition.

18. Craker has suffered, and continues to suffer, adverse effects from DEA's failure to act and unreasonable delay in acting, including but not limited to his:

    a. Inability to proceed with his plan to grow marijuana to facilitate federal government-approved research;

    b. Inability to proceed with any of his own research into the production of marijuana; and,

    c. Inability to obtain funding for UMass Amherst regarding the production facility.

E. <u>Background to Chemic and Craker's DEA Applications</u>

19. The federal government currently maintains a legally-enforced monopoly on the supply of marijuana (but no other Schedule 1 drug), under the exclusive control of NIDA; NIDA's consent to any research involving marijuana, and its supply of NIDA-grown marijuana to the researchers, are required before any marijuana-related research can begin.

20. MAPS has its own independent sources of other Schedule 1 drugs, such as 3,4-methylenedioxy-methamphetamine (MDMA) and psilocybin, and thus has sponsored ongoing FDA-approved

research into the use of MDMA-assisted psychotherapy in the treatment of posttraumatic stress disorder (PTSD)(IND# 63,384), and also has cosponsored ongoing FDA-approved research into the use of psilocybin in the treatment of obsessive-compulsive disorder (OCD) (IND# 56,530).

21. NIDA-supplied marijuana can be used legally for research, but not for individual patient prescription. No pharmaceutical company would freely choose to use NIDA marijuana for research aimed at the licensing of marijuana as a prescription medicine.

22. NIDA has twice recently refused to provide marijuana to FDA-approved and MAPS-sponsored protocols:

    a. A protocol by Donald Abrams M.D. (IND# 43,542) for the use of marijuana on subjects with HIV-related wasting; and,

    b. A protocol by Ethan Russo M.D. (IND# 58,177) for the use of marijuana on subjects with migraines.

23. Craker's proposed program at UMass Amherst, to be funded by MAPS, is intended to provide a source other than NIDA for MAPS' government-approved research with marijuana.

24. Title 21 U.S.C. § 823 and 21 C.F.R. § 1301.35(a) require DEA to register applicants to manufacture marijuana, if such manufacture is consistent with United States Treaty Obligations and the public interest.

25. Title 21 U.S.C. § 958 and 21 C.F.R. §§ 1301.34(b) and 1301.35(a) require DEA to register applicants to import

marijuana, if such importation is consistent with United States Treaty Obligations and the public interest.

26. DEA is required to apply criteria specified in 21 U.S.C. § 823 and 21 C.F.R. §§ 1301.32 and 1301.33 (governing registration to manufacture), and 21 U.S.C. § 958 and § 1301.34(b) (governing registration to import), to determine whether granting registration is consistent with the public interest.

27. Among the relevant criteria set by 21 U.S.C. § 823(a)(1) and 21 C.F.R. § 1301.33(b) for DEA's decision-making on the public interest in manufacturing or import applications for schedule one drugs are the objectives that the application process result in DEA authorizing sufficient numbers of manufacturers to assure "adequately competitive conditions" for the production of these drugs, to ensure an "adequate and uninterrupted supply of these substances … for legitimate medical, scientific research and industrial purposes ..."

> "In order to provide adequate competition, the Administrator shall not be required to limit the number of manufacturers in any basic class to a number less than that consistent with maintenance of effective controls against diversion solely because a smaller number is capable of producing an adequate and uninterrupted supply." 21 C.F.R. 1301.33(b).

28. DEA created a form, denoted "DEA form 225," by which applicants must submit registration applications to manufacture or import controlled substances (*see* 21 C.F.R. §§ 1301.11, 1301.13 and 1301.14).

F. Craker's Manufacturing Application

29. On June 25, 2001, petitioner Craker submitted a properly-completed DEA Form 225 to DEA in compliance with 21 C.F.R. §§ 1301.11, 1301.13 and 1301.14, seeking registration to manufacture marijuana.

30. On December 5, 2001, Cari Robertson, Group Supervisor, DEA Diversion Control, claimed in a phone conversation with Rick Doblin, Ph.D, President of MAPS, that DEA had no record of Craker's application.

31. On December 21, 2001, Doblin subsequently faxed a photocopy of the original application to Robertson at DEA. In early February 2002, Robertson notified Doblin that DEA lost the original application, and that a photocopied application was invalid without an original signature.

32. On June 6, 2002 five Massachusetts Congressional Representatives (Reps. Barney Frank, James P. McGovern, Michael E. Capuana, William Delahunt, and John Olver, whose district includes UMass Amherst) sent a letter to DEA Administrator Asa Hutchinson, urging him to "license privately-funded sources of marijuana for use in federally-approved studies, in order to substantially facilitate the conduct of scientific research into the risks and benefits of the potential medical uses of marijuana."

33. On July 1, 2002, DEA Administrator Asa Hutchinson wrote to Rep. Barney Frank that "it is essential" for NIDA to retain its monopoly, claiming that US international treaty

obligations prohibit "cultivation of marijuana by private growers not under the oversight of a national government agency."

34. In July 2002, DEA returned to Craker his original application unprocessed, with a DEA date stamp showing it had been received on June 25, 2001.

    a. The original application was returned to Craker in an envelope without a cover letter (using a return address for DEA), without identifying information about who at DEA returned the application.

    b. DEA did not, however, declare the application "defective" pursuant to 21 C.F.R. § 1301.13.

35. Craker resubmitted the original application to DEA on August 20, 2002, along with a legal analysis prepared by the ACLU Drug Policy Litigation Project and the Washington D.C. law firm of Covington & Burling, demonstrating that the requested registration of the UMass Amherst facility would be consistent with United States treaty obligations.

    a. The analysis noted that in 1998 the British Home Office, also party to the same international drug control treaties as the US, licensed a privately-funded producer of marijuana (GW Pharmaceuticals) to cultivate marijuana for medical research.

    b. The International Narcotic Control Board, which oversees treaty compliance, has never objected to

British licensing of private marijuana manufacture for medical research purposes.

36. On March 4, 2003, Frank Sapienza, Chief, DEA Drug and Chemical Evaluation Section, sent a letter to Craker requesting additional information (*see* 21 C.F.R. § 1301.15), stating that DEA was "currently reviewing" Craker's "pending application."

    a. DEA maintained that there was insufficient evidence that NIDA was unable to provide marijuana in quantities and qualities sufficient to meet the needs of the research community.

    b. DEA's desire for the testimony of researchers, about whether NIDA reliably can supply adequate quality of research grade marijuana, raises questions about the agency's good faith. Because DEA can revoke, delay or refuse to license researchers to engage in government-authorized studies, researchers are intimidated from complaining to DEA about NIDA as the sole source of marijuana.

    c. The primary justification for Craker's application was MAPS' need for a consistent, timely and reliable source of higher potency material under its control, and available both for research and prescription use, as any other pharmaceutical company would require, just as MAPS has secured for its MDMA and psilocybin research projects.

d. The letter from DEA stated, "to further consider your application, please provide this office with any credible evidence to support your assessment of this issue."

37. On June 2, 2003, Craker responded to DEA's March 4, 2003 request for additional information. Other members of the research community also sent DEA letters concerning the issue addressed in DEA's March 4, 2003 request for additional information, including a March 11, 2003 letter from Dr. Ethan Russo; a March 25, 2003 letter to DEA from the Marijuana Policy Project; a May 2, 2003 letter to DEA from Drug Policy Alliance; and, a July 10, 2003 letter to DEA from petitioner MAPS.

38. 21 C.F.R. § 1301.33(a) requires DEA to publish a notice in the Federal Register "upon the filing" of an application for registration to manufacture a controlled substance.

39. On July 24, 2003, more than two years after Craker originally filed his application, and nearly five months after DEA's March 2003 letter stated that it was "currently" processing Craker's "pending" application, DEA finally published the required notice of Craker's application in the Federal Register (68 Fed.Reg. 43755). The notice stated that Craker's application was submitted to DEA on June 25, 2001.

40. 21 C.F.R. § 1301.33(a) provides for a sixty-day comment period during which any other manufacturing applicant, and

any person who is presently registered with DEA to manufacture such substances, may file comments or objections to this notice of application.

41. That sixty-day period ended on September 23, 2003.

42. On or shortly after September 9, 2003, DEA received the only comment in response to its publication of the notice in the Federal Register concerning Craker's manufacturing application. The comment from Professor Mahmoud El-Sohly, Director of NIDA's marijuana farm at the University of Mississippi, opposed DEA licensing of Craker's UMass Amherst facility.

43. On October 23, 2003, Massachusetts' United States Senators, John Kerry and Edward Kennedy, sent a letter to DEA, expressing their strong support for DEA registration of the UMass Amherst medical marijuana research production facility.

44. The letter stated:

> We believe that the National Institute on Drug Abuse facility at the University of Mississippi has an unjustifiable monopoly on the production of marijuana for legitimate medical and research purposes in the United States.
>
> Federal law makes clear that the importation and bulk manufacture of Schedule I and II substances must be provided "under adequately competitive conditions." (21 U.S.C. 823(a)(1).)
>
> Federal regulations also provide: "In order to provide adequate competition, the Administrator shall not be required to limit the number of manufacturers in any basic class to a number less than that consistent with maintenance of effective controls against diversion solely because a smaller number is

capable of producing an adequate and uninterrupted supply." (21 C.F.R. 1301.33(b).)

Federal law clearly requires adequate competition in the manufacture of Schedule I and II substances. The current lack of such competition may well result in the production of lower-quality research-grade marijuana, which in turn jeopardizes important research into the therapeutic effects of marijuana for patients undergoing chemotherapy or suffering from AIDS, glaucoma, or other diseases.

45. 21 C.F.R. §§ 1301.33, 1301.35, 1301.37, 1301.41 and 1301.43 require DEA to either approve or deny an application to manufacture a controlled substance, and provide that before DEA can deny such an application it must issue an Order to Show Cause, giving the applicant an opportunity to request an administrative hearing to present evidence and argument as to why the application should be granted.

46. DEA has not issued an Order to Show cause nor taken any further action whatsoever on Craker's June 2001 application for registration to manufacture marijuana, since the publication of notice in the Federal Register on July 24, 2003.

G. <u>Chemic's Import Application</u>

47. On January 21, 2003, petitioner MAPS and California NORML contracted with Chemic for a $25,000 study to evaluate the contents of the vapor stream from a marijuana vaporizer.

a. The study does not involve any human subjects nor require FDA approval.

b. The protocol investigates the efficacy of vaporizers as an alternative non-smoking delivery system for marijuana,

in response to concerns expressed by the National Academy of Science's Institute of Medicine's medical marijuana report ("Marijuana and Medicine: Assessing the Science Base," Institute of Medicine, March 17, 1999, funded by the White House Office of National Drug Control Policy), about the health risks associated with the traditional smoking methods of ingesting marijuana.

c. The purpose of the study is stated in the Chemic contract as follows:

> "This protocol is intended to provide guidance on the completion of an extraction evaluation of emissions produced when marijuana is vaporized ... to provide evidence of product efficiency to MAPS, which would subsequently design and seek agency [FDA] approval for the protocol development and initiation of a Phase I clinical investigation, comparing cannabinoid blood levels in subjects smoking (i.e., pyrolysis) marijuana versus marijuana vaporized with the Volcano, and to meet the requirements of 21 C.F.R. Part 160."

48. On June 24, 2003, Chemic submitted a properly-completed DEA Form 225 to DEA in compliance with 21 C.F.R. §§ 1301.11, 1301.13 and 1301.14, seeking registration to import ten grams of marijuana from DOMC, for use in the above-described research.

49. DOMC marijuana is of a potency and mix of cannabinoids unavailable to NIDA,

a. superior to the quality of NIDA's marijuana, and;

b. required for the later phases of the vaporizer study.

50. DOMC is part of the Dutch Ministry of Health, Welfare and Sport.

a. The DOMC operates in compliance with all international treaty obligations, and sells pharmaceutical quality marijuana to pharmacies that can deliver it as a prescription-only drug under the Dutch controlled substances legislation.

b. DOMC is authorized to export marijuana to fully-licensed research projects.

51. DEA verbally advised Chemic that it will not process the application to import until after HHS determines whether the vaporizer protocol is scientifically meritorious.

a. Chemic submitted the protocol to HHS on June 24, 2003 with a separate application to HHS for NIDA-supplied marijuana to carry out the first phases of the vaporizer study. The HHS application was submitted pursuant to and in full compliance with procedures promulgated by HHS.

b. HHS has failed to act on the application and has failed to make a determination concerning whether the protocol is scientifically meritorious. The failure of HHS to act is the subject of another petition for review filed simultaneously herewith (a motion shall be filed to consolidate both petitions).

52. 21 C.F.R. § 1301.34(a) requires DEA to publish a notice in the Federal Register "upon the filing" of an application for registration to import a controlled substance, to be

followed by a thirty-day comment period in which interested parties may submit comments concerning the application.

53. DEA has not filed the notice in the Federal Register as required by 21 C.F.R. § 1301.34(a).

54. 21 C.F.R. §§ 1301.34, 1301.35, 1301.37, 1301.41 and 1301.43 require DEA to either approve or deny an application to import a controlled substance, and provide that before DEA can deny such an application, it must issue an Order to Show Cause giving the applicant an opportunity to request an administrative hearing to present evidence and argument as to why the application should be granted.

H. DEA's Unreasonable Delay

55. Nothing in the relevant statutes or regulations requires or permits the DEA to withhold action upon a properly-submitted application for registration to import a controlled substance for research purposes, pending a finding by HHS that the research protocol is scientifically meritorious.

56. DEA's more than two-year delay in publishing the required notice in the Federal Register and over three-year delay in acting to approve Craker's application to manufacture marijuana, or to issue an Order to Show Cause regarding that application, constitute a failure to act and/or unreasonable delay under the governing statutes and regulations. DEA's inaction constitutes unreasonable delay because (among other reasons, without limitation):

a. Approving applications such as Craker's, designed to facilitate research in an area of treatment for which a substantial number of patients and States have expressed a critical need, is a reasonable and appropriate priority among DEA's other responsibilities;

b. The consequences of DEA's delay upon patients whose health and safety require treatment with legally-available marijuana is unconscionable; and,

c. No reasonable basis exists for an allegation of administrative inconvenience, practical difficulty in carrying out the permit processing, or a need to further delay this research due to limited administrative resources.

57. DEA's delay in processing Craker's manufacturing application also constitutes the agency's violation of its express statutory mandate to ensure the provision of "an adequate and uninterrupted supply … for legitimate medical" research purposes.

58. DEA has not issued an Order to Show cause, nor taken any action whatsoever on Chemic's June 24, 2003 application for registration to import marijuana.

59. DEA's more-than-one-year delay in publishing the required notice in the Federal Register, and failure to act to approve Chemic's application to import marijuana or issue an Order to Show Cause regarding that application,

constitute a failure to act and/or unreasonable delay under the governing statutes and regulations which have the force of law.

60. Had DEA complied with the governing statutes and regulations by acting promptly on the pending application, it would have either granted the application or issued an Order to Show Cause, entitling the petitioners under 21 C.F.R. §§ 1301.41-46 and 1316.41-68 to administrative hearings with all attendant substantive and procedural rights including the right to judicial review under 21 U.S.C. §§ 877 and 965 of final DEA action.

a. DEA's failure to act and unreasonable delay has the effect of precluding petitioners from exercising these rights, as there has been no "final agency action."

b. Under these circumstances, this Court has jurisdiction to review petitioners' claims of unreasonable delay. "Were it otherwise, agencies could effectively prevent judicial review of their policy determinations by simply refusing to take final action." *Cobell v. Norton*, 240 F.3d 1081, 1095 (D.C. Cir. 2001).

I. Relief Requested

WHEREFORE, petitioners request that this Court:

I. Grant petitioners a declaration that they are entitled to prompt action on Cracker's UMass Amherst manufacturing application and Chemic's import application, and that the

respondent's failures to act thus far constitute violations of those rights to prompt actions.

II. Order DEA to promptly (not more than twenty days after issuance of this Order) approve or deny petitioner Craker's pending application for registration to manufacture marijuana at UMass Amherst.

A. If DEA does not approve Craker's manufacturing application, this Court shall order the agency to promptly (within twenty days) issue an Order to Show Cause as required by 21 C.F.R. §§ 1301.35 and 1301.37,

B. affording Craker an opportunity for administrative hearings pursuant to 21 C.F.R. § 1341-46 and 1316.41-68;

III. Order DEA to publish notice immediately in the Federal Register, and comply in all other manners with 21 C.F.R. § 1301.34(a) concerning Chemic's pending application for registration to import ten grams of marijuana from the Dutch Office of Medicinal Cannabis; and,

A. After the thirty-day comment period specified in 21 C.F.R. § 1301.34(a), order the DEA to act promptly (within twenty days of the end of such comment period) to either approve or deny Chemic's import application;

B. If DEA does not approve Chemic's import application, the Court shall order DEA to promptly (within twenty days) issue an Order to Show Cause as required by 21

C.F.R. §§ 1301.35 and 1301.37, affording Chemic an opportunity for administrative hearings pursuant to 21 C.F.R. § 1341-46 and 1316.41-68;

IV. Grant such further relief as the Court deems just and proper, including an award of the petitioners' attorneys fees and costs.

Respectfully Submitted,

THE PETITIONERS

By Their Attorney:

Michael D. Cutler, Esq.
Massachusetts BBO#: 110940
46 Kenwood Street
Brookline MA 02446-2413
Telephone: (617) 816-6056

Attorney for the Petitioners,
Multidisciplinary Association
for Psychedelic Studies,
Valerie Corral and
Lyle E. Craker, Ph.D.

Certificate of Service: I hereby certify that on this date, I mailed a copy of this document and cover-letter to the respondent Tandy at the DEA headquarters, 2401 Jefferson Davis Highway, Alexandria, Virginia.

DATED:

Michael D. Cutler