UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

MULTIDISCIPLINARY ASSOCIATION FOR PSYCHEDELIC STUDIES and VALERIE CORRAL, **Petitioners,** **vs.** **THE UNITED STATES OF AMERICA; THE HONORABLE TOMMY G. THOMPSON, Secretary of the DEPARTMENT OF HEALTH AND HUMAN SERVICES; NORA D. VOLKOW M.D., Director of the NATIONAL INSTITUTE ON DRUG ABUSE; and ELIAS A. ZERHOUNI M.D., Director of the NATIONAL INSTITUTES OF HEALTH,** **Respondents**	**PETITION FOR REVIEW** **No. _____**

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

PETITION FOR REVIEW TO COMPEL AGENCY ACTIONS UNLAWFULLY WITHHELD OR UNREASONABLY DELAYED

A. Nature of Relief Requested and Identity of the Parties

1. This petition for review of federal agency action unlawfully withheld or unreasonably delayed, seeks declaratory relief (regarding petitioners' entitlement to prompt action by the respondents) and an order compelling the respondents to:

   a. Approve or deny the application of Chemic Laboratories Inc. (an analytical laboratory in Canton, Massachusetts [Chemic hereafter]), licensed by the respondent Drug Enforcement Administration of the Department of Justice (DEA hereafter) to work with controlled substances including marijuana, submitted on June 24, 2003, seeking permission to purchase ten grams of marijuana from the respondent National Institute of Drug Abuse (an institute within HHS; NIDA hereafter), to fulfill a research contract with petitioner MAPS; and,

b. Compel respondent the Department of Health and Human Services (HHS hereafter) to approve or reject the scientific merit of the vaporizer research protocol Chemic submitted to HHS with its foregoing application to purchase ten grams of marijuana from NIDA.

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 Valerie Corral is a California-licensed medical marijuana patient and caregiver, founder of the Wo/Men’s Alliance for Medical Marijuana, with an office at

4. Respondent HHS is an agency of the federal government.

a. HHS' Secretary is respondent Tommy G. Thompson; and,

b. Its headquarters are located at 200 Independence Ave., S.W., Washington, D.C.

5. Respondent National Institutes of Health (NIH hereafter) is an institute within HHS.

a. NIH's director is respondent Elias A. Zerhouni M.D., and

b. Its headquarters are located at 1 Center Drive (MSC 0148, Room 126), Bethesda, Maryland.

6. Respondent NIDA is an institute within HHS.

a. NIDA's director is respondent Nora D. Volkow M.D.

b. Its headquarters are located at NIH Neuroscience Center (Room 5274), 6001 Executive Boulevard Bethesda, Maryland.

B. Jurisdiction and Venue

7. 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).

8. Venue is proper in this Court because at least one of the respondent agencies is headquartered in Washington, D.C.

C. Petitioners' Standing

9. MAPS' 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 prescription medicines approved by the Food and Drug Administration (a government agency within HHS; FDA hereafter), for use by doctors and patients.

a. Much of MAPS' work is done with contractors and scientists who have expertise in research with controlled substances. Such research partners include Chemic, a contract research laboratory working for the pharmaceutical industry with existing permits from DEA to work with marijuana and other controlled substances.

b. 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.

c. Chemic's application to purchase marijuana from NIDA, and its vaporizer research protocol (for use with the purchased marijuana) were designed in partnership and under contract with MAPS.

d. The research (for which the delayed permits seek federal authorization) when approved will

be funded by MAPS and California NORML (a nonprofit membership organization dedicated to marijuana policy reform).

e. MAPS seeks to obtain a source of high-potency marijuana that can be delivered in the non-smoking delivery system known as the 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.

f. 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).

g. 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 other disease treatments.

10. MAPS has suffered, and continues to suffer, adverse effects from HHS' failure to act and unreasonable delay in acting on Chemic's application to purchase marijuana from NIDA (among other effects listed below, without limitation).

    a. MAPS has an economic interest in conducting research to explore the development of the whole marijuana plant as a FDA-approved prescription medicine, to help treat a substantial number of patients who may require marijuana for their health and safety.

    b. MAPS' interest is rendered worthless by HHS' inaction because legitimate research, such as the Chemic protocol which is part of MAPS' drug development plan, cannot proceed given the current monopoly of marijuana supply held by

NIDA and NIDA's failure to provide marijuana to Chemic or even to review its protocol;

c. HHS' 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 applications submitted in full compliance with the procedures promulgated by HHS.

d. MAPS and Chemic cannot proceed with their vaporizer research that will be used to supply data to FDA regarding the constituents of the vapor stream, information that FDA will likely deem material to its decision on whether to approve marijuana for prescription use if administered through the use of a vaporizer.

e. MAPS' interest in medical marijuana research is within the zone of interests intended to be

protected or regulated under relevant statutes enabling good faith medical research in the use of controlled substances (many of which, some even with toxic dose levels, have been proven to be medically useful after testing similar to the research which the petitioners seek to conduct).

f. DEA also has failed to decide, after more than one year, on Chemic's application (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), seeking registration to import ten grams of marijuana from the Dutch Office of Medicinal Cannabis (DOMC hereafter). This DEA failure to act is the subject of another petition for review filed here simultaneously with this action (a motion to consolidate both petitions shall be filed promptly);

g. DEA also has failed to decide, after more than three years, on a MAPS-sponsored application

from Prof. Lyle Craker, Director of the Medicinal Plant Program of the Department of Plant and Soil Sciences at the University of Massachusetts at Amherst, 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, seeking registration to manufacture marijuana[1], to supply to researchers approved by FDA and/or DEA. This DEA failure to act also is the subject of another petition for review filed simultaneously here with this action (a motion to consolidate both petitions shall be filed promptly);

[1] The relevant statutes and regulations cited in this petition refer to "manufacture" of a controlled substance; as relevant here, to "manufacture" marijuana means to grow marijuana plants; *see* 21 U.S.C. § 802[15].

h. Thus, government obstruction has prevented MAPS from obtaining access to marijuana legal for research by either growing its own, importing it, or purchasing it from NIDA, effectively halting MAPS' drug development effort.

11. 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 state (but not federally) licensed private facility for growing treatment grade marijuana (exclusively for its members' personal medical use) was destroyed by DEA despite approvals for its operation from state and municipal authorities.

b. Corral is a patient with a serious illness; before using whole marijuana, she was subject to frequent gran mal seizures (after an auto accident) and addicted to stupor-inducing anti-

seizure patent medication.

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

d. Every day HHS delays consideration of the Chemic research application 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 medication.

D. Background for Chemic's Vaporizer Research Protocol Application

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

a. MAPS has its own independent sources of other Schedule 1 drugs, such as 3,4-methylenedioxymethamphetamine (MDMA) and psilocybin,

b. and thus has been able to sponsor ongoing FDA-approved research into the use of MDMA-assisted psychotherapy in the treatment of posttraumatic stress disorder (PTSD)(IND # 63,384), and has also been able to cosponsor ongoing FDA-approved research into the use of psilocybin in the treatment of obsessive-compulsive disorder

(OCD) (IND # 56,530).

13. On May 21, 1999, HHS and NIH promulgated an announcement of new procedures governing applications by researchers to obtain marijuana from NIDA (hereafter "the announcement"). The announcement was promulgated pursuant to 42 U.S.C. §§ 241(a) and 282(c), to further the statutory schemes of 21 U.S.C. § 801 et. seq. (the Controlled Substances Act); 21 U.S.C. § 823(f) (governing DEA registration of research with controlled substances); 21 U.S.C. § 321 et. seq. (the "drug" and "new drug" provisions of the Federal Food, Drug, and Cosmetic Act); and, 21 CFR 312.22(a) (setting out the general principles of investigational new drug applications to FDA).

14. With the promulgation of the announcement, HHS created procedures through which non-NIH funded research protocols will be eligible to obtain NIDA marijuana on a cost-reimbursed basis.

15. The announcement was published on-line at the NIH website in the "NIH Guide for Grants and Contracts," which is "the official publication for NIH medical and behavioral research grant policies, guidelines and funding opportunities."

16. The Guide is published on a weekly basis. It is used by NIH contracting offices and other HHS agencies to announce their funding opportunities.

17. According to the NIH website, the NIH Guide serves, "in lieu of the Federal Register, in compliance with the Administrative Procedures Act."

18. The announcement was published on the NIH website as NOT99-091, entitled, "Announcement Of The Department Of Health And Human Services' Guidance On Procedures For The Provision Of Marijuana For Medical Research."

19. The announcement states that its intent is to provide guidance to the biomedical research community, for the study of marijuana in scientifically valid investigations and well-

controlled clinical trials, using HHS procedures for providing research-grade marijuana to research applicants.

20. The announcement further described HHS' purpose in issuing it, being to facilitate the research needed to evaluate public health questions about the medical efficacy of marijuana in treating serious human diseases, by establishing a procedure for making research-grade marijuana available for well-designed studies on a cost-reimbursable basis.

    a. The announcement also identified HHS' purposes in issuing these procedures for researchers' access to marijuana, as being to support quality research for the development of clinically meaningful data on the medical efficacy of marijuana; and, to make available a sufficient amount of research-grade marijuana to support studies most likely to yield usable, essential data, including protocols submitted by non-NIH funded sources.

21. The announcement further stated that after submission, the scientific merits of each protocol would be evaluated through a Public Health Service (PHS) interdisciplinary review process. This process would consider a number of factors, including the scientific quality of the proposed study, the quality of the organization's peer-review process, and the objectives of the proposed research.

22. Pursuant to 21 C.F.R. §1301.32, strict time limits apply to HHS review of applications and protocols submitted to it by DEA, in the case of an application for registration to conduct research with Schedule I controlled substances. Pursuant to §1301.32(a), "The Secretary shall determine the qualifications and competency of the applicant, as well as the merits of the protocol (and shall notify the Administrator of his/her determination) within 21 days after receipt of the application and complete protocol, except that in the case of a

clinical investigation, the Secretary shall have 30 days to make such determination and notify the Administrator." While Chemic's protocol (which is not a clinical investigation) was submitted directly to HHS in accordance with procedures as described in the announcement (and not DEA), the limits imposed by §1301.32(a) are nevertheless instructive as to a time period deemed reasonable for the evaluation of the scientific merit of privately-funded Schedule I research protocols.

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

    a. The research protocol does not involve 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 contract with Chemic as follows: "This protocol is intended to provide guidance on the completion of an extraction evaluation of emissions produced when marijuana is vaporized using the [vaporizer]; 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

vaporized marijuana, and to meet the requirements of 21 C.F.R. Part 160.

24. On June 24, 2003 Chemic submitted an application and the vaporizer research protocol to HHS, seeking permission to purchase ten grams of marijuana with which to conduct its vaporizer study.

    a. Chemic's application complied with all of the requirements specified in the announcement.

    b. The protocol was designated, "Protocol #2696; Evaluation of Volcano Vaporizer for the efficient emission of THC, CBD, and CBN and the significant reduction and/or elimination of total particulate matter (TPM) and tar components (various organic compounds in TPM that absorb UV radiation.)"

    c. MAPS and California NORML are prepared to adequately fund Chemic's research.

25. Chemic also submitted a separate but related application to the DEA on June 24, 2003, seeking registration under 21 U.S.C. § 958 and 21 C.F.R. §§

1301.11, 1301.13, 1301.14 and 1301.34, to import ten grams of marijuana from DOMC, as an additional source of marijuana needed to undertake its research.

a. The marijuana that Chemic seeks registration to import is of a higher THC content (potency) and purity than the supply produced by NIDA.

b. Access to marijuana from DOMC and NIDA is essential to Chemic's research under contract with MAPS and California NORML, and necessary for the later stages of the research protocol submitted to HHS pursuant to the announcement.

c. DEA informed petitioners that it refuses to process Chemic's application for registration to import the marijuana from DOMC, until HHS rules upon the scientific merit of the research protocol Chemic submitted to HHS pursuant to the announcement.

d. This DEA refusal is the subject of a separate petition for review filed simultaneously here

with this action (a motion to consolidate both petitions shall be filed promptly), seeking to compel the DEA to act on Chemic's application for import registration.

E. The Agencies' Inaction on Chemic's Vaporizer Research Protocol

26. Chemic and MAPS inquired of HHS and NIDA several times over the past year, seeking information on the progress of the evaluation of their vaporizer protocol.

27. On October 10, 2003 (more than three months after the initial submission), Chemic and MAPS received the first communication from NIDA and HHS regarding the protocol, in the form of a letter from Joel Egertson, Senior Drug Policy Advisor, Office of Secretary of HHS. Egertson stated, "It has been determined that there is insufficient information in the application to judge the merits of the protocol."

a. While the information submitted initially was sufficient to fully comply with the procedures specified in the announcement, Chemic submitted an expanded and revised protocol on January 29, 2004, to Rear Admiral Arthur J. Lawrence, Assistant Surgeon General, Deputy Assistant Secretary for Health (Operations), as instructed by Egertson.

b. Egerston advised MAPS and Chemic Laboratories that Dr. Lawrence would be taking over responsibility for reviewing the protocol upon Egertson's retirement in late 2003.

28. On March 17, 2004, Willem Scholten, Director of DOMC, wrote to Dr. Lawrence to inquire about the status of the review of Chemic's protocol.

29. On March 17, 2004, Dr. Lawrence wrote to Scholten and said, "The responsibility for conducting the reviews is being transferred to a different unit of the Department. At the moment, I don't have the ability to specify where this particular protocol

is in the process."

30. Also on March 17, 2004, MAPS wrote to Dr. Lawrence offering to do whatever was necessary to expedite the review process. MAPS has not yet received a reply from Dr. Lawrence.

31. On May 6, 2004, Chemic President Joseph P. St. Laurent wrote to Dr. Lawrence inquiring about the status of the review, noting that "As I am sure you can understand, a contract laboratory facility needs to be monitored closely in order to meet all of our clients needs. Chemic Laboratories is currently predicting laboratory schedules for the summer months and would very much like to include this protocoled study on the schedule. Therefore, any information regarding the protocol review status is appreciated. I look forward to your response." No response has been received.

32. On May 24, 2004, MAPS wrote to NIDA Director and respondent Dr. Nora Volkow requesting assistance in facilitating the review of the Chemic protocol.

33. On June 9, 2004, Dr. Volkow replied to MAPS that, "As you know, NIDA is just one of the participants on the HHS review panel. ... Therefore, I am sorry but I do not believe that we can be of help to you in resolving these concerns."

34. A NIDA official has told Chemic verbally that NIDA has available sufficient marijuana for the submitted protocol, that such marijuana will cost approximately $70.00, and that the only remaining step (as specified in the announcement) is for HHS to evaluate the scientific merits of the protocol through a PHS interdisciplinary review process. The official, however, could not say when that evaluation would take place.

35. Chemic and MAPS have been ready to begin the vaporizer research for over a year, awaiting only HHS action to approve or deny the protocol and the government-authorized supply of marijuana, which has been unreasonably delayed or denied without a legitimate or otherwise legally sufficient excuse.

F. Unreasonable Delay on the Chemic Application

36. The announcement provides the only procedures by which a non-government funded researcher may obtain otherwise illegal marijuana from NIDA for legally authorized testing, as an alternative to the import application.

a. The announcement was published on the NIH website in section entitled the "NIH Guide for Grants and Contracts," which is the official publication for NIH medical and behavioral research grant policies, guidelines and funding opportunities.

b. According to NIH, this Guide serves, "in lieu of the Federal Register, in compliance with the Administrative Procedures Act."

c. Under these circumstances, the announcement is legally binding upon HHS and NIH.

37. The delay of more than one year in evaluating the scientific merits of Chemic's vaporizer research protocol is unreasonable and in violation of the

HHS procedures promulgated in the announcement, which have the force of law, because (among other reasons, without limitation):

a. Processing protocols submitted in compliance with HHS and NIH procedures, and designed to facilitate research in an area of treatment for which a growing number of patients and States have expressed a critical need, is a reasonable and appropriate priority within HHS' other responsibilities;

b. The consequences of HHS' delay upon patients whose health and safety require marijuana-related treatment (to either suffer otherwise treatable symptoms, or risk arrest to obtain treatment deemed illegal by the federal government) 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;

d. In contrast, FDA is required to review much more complicated protocols within 30 days. See 21 C.F.R. § 312.20[c]).

e. In further contrast, pursuant to 21 C.F.R. §1301.32(a), HHS review of applications and protocols submitted to it by DEA in the case of an application for registration to conduct non-clinical research (such as Chemic's protocol), must be completed 21 days after receipt of the application and complete protocol.

38. 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).

G. **Relief Requested**

WHEREFORE, the petitioners request that this Court:

1. Grant a declaration that the agencies' delay has been unreasonable and a violation of the petitioners' rights to a prompt determination of Chemic's permit applications; and,
2. Order HHS (including its sub-divisions NIH and NIDA) to promptly (not more than twenty days after issuance of this Order) issue a final ruling on the adequacy of Chemic's vaporizer protocol, and its entitlement to purchase marijuana from NIDA sufficient to carry out the research described in the pending protocol; and,
3. Grant such further relief as the Court deems just and equitable, including an award of 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 Petitioners
Multidisciplinary Association for
Psychedelic Studies and
Valerie Corral

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