UNITED STATES COURT OF APPEALS

FOR THE DISTRICT OF COLUMBIA CIRCUIT

September Term, 2004

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

Consolidated with:

MULTIDISCIPLINARY ASSOCIATION FOR PSYCHEDELIC STUDIES and VALERIE CORRAL,

Petitioners,

vs. **No. 04-1247**

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

ALL PETITIONERS' MOTION FOR RECONSIDERATION

All petitioners in this case move pursuant to Fed. R.App.P. 27 and Local Rule 27(l), for reconsideration of the panel orders (Sentelle, Henderson and Tatel, dated November 22, 2004) that the petition (No. 04-1247) requesting a writ of mandamus regarding HHS delay of 17 and 1/2 months in acting on a research protocol and application to purchase 10 grams of marijuana for laboratory studies of marijuana vaporization be dismissed without prejudice, and that the petition (No. 04-1246) requesting a writ of mandamus regarding DEA delay of 17 and 1/2 months in acting on an application for registration to import 10 grams of marijuana for laboratory studies of marijuana vaporization be dismissed without prejudice, (as to which applications, the consolidated mandamus petition claims that the agencies' actions have been unreasonably delayed). The panel did direct the DEA to file a response to the petition seeking to compel DEA to act on an application filed almost 3 and 1/2 years ago for registration to manufacture marijuana.

A. Grounds

As grounds therefore, the petitioners state that the panel's dismissal actions appear inconsistent with the controlling legal standard for mandamus relief, cited by the panel's order. Those standards are, from *Telecom. Research and Action Center v. FCC*, 750 F.2d 70, 80 (D.C. Cir. 1984) [the *TRAC* standards hereafter]:

(1) the time agencies take to make decisions must be governed by a 'rule of reason ["a reasonable time encompassing months, occasionally a year or two, but not several years," *MCI Telecom. Corp. v. FCC* 627 F.2d 322, 340 (D.C. Cir. 1980)];

(2) where Congress has provided a timetable or other indication of the speed with which it expects the agency to

proceed in the enabling statute, that statutory scheme may supply content for this rule of reason;

(3) delays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake;

(4) the court should consider the effect of expediting delayed action on agency activities of a higher or competing priority;

(5) the court should also take into account the nature and extent of the interests prejudiced by delay; and

(6) the court nature and extent of the interests prejudiced by delay need not 'find any impropriety lurking behind agency lassitude in order to hold that agency action is "unreasonably delayed."

B. Legal Argument

The Delayed Permits. Both cases are brought by petitioner Multidisciplinary Association for Psychedelic Studies (MAPS) as part of its comprehensive effort to sponsor research in the medical efficacy and safety of the controlled substance marijuana, using a vaporizer delivery system as compared to the smoke of burned marijuana. MAPS' effort involves applications by its contractors (petitioner Craker and Chemic, an analytical testing laboratory) for several federal permits: One (filed June 25, 2001 by Craker) seeks authorization from the respondent Drug Enforcement Administration (DEA) to manufacture marijuana for research purposes; another (filed June 24, 2003 by Chemic) requests DEA permission to import 10 grams of marijuana for research into the health benefits of vaporizers as compared to smoking; a further permit request (filed June 24, 2003 by Chemic) seeks to purchase 10 grams of marijuana for research (into the health benefits of vaporizers as compared to smoking) from the respondent

National Institute of Drug Abuse ([NIDA] an agency within the Department of Health and Human Services [HHS]).

The USSC's Medical Marijuana Case. On November 29, 2004, *Ashcroft v. Raich, et al.* (No. 03-1454) was argued, in which the federal government has appealed a Ninth Circuit decision, invalidating the Controlled Substances Act (as beyond the federal jurisdictional definition of interstate commerce) as applied to patients using medical marijuana in compliance with one of the ten states' (California) laws allowing such use with a doctor's approval. One of these patients (Raich) will die, according to her attending physician, if denied marijuana. During the argument, Justice Breyer questioned the patients' resort to a jurisdictional exemption from federal law, instead of using federal administrative law or the FDA-approved research process to seek marijuana's reclassification based on scientifically proven medical benefit. Patients' counsel referred the Court to MAPS' amicus curiae brief in *Raich* detailing federal obstruction of medical marijuana research.

At least one U.S. Supreme Court justice appears poised to overturn the 9th Circuit's decision in *Raich* on the grounds that FDA-approved research can be undertaken to establish the medical safety and efficacy of marijuana necessary to attain rescheduling. In fact, as petitioner has pointed out in his briefing before this Court, such research has been obstructed by the HHS' and DEA's unreasonable refusal to act on petitioner's properly filed applications. This Court should reconsider in light of the fact that seriously ill patients like Angel Raich are in life-threatening danger, and the U.S. Supreme Court may be under the misapprehension that the responsible agencies are acting promptly and properly to facilitate the legitimate research process.

That case and this case do not exist in a vacuum: For more than thirty years, the federal government has methodically obstructed medical marijuana research, while citing the

lack of research results as a rationale for preventing the meaningful consideration of rescheduling and potential legal access as an FDA-approved prescription medicine. This case presents another example of federal obstruction.

At stake here in this request to reconsider the denial of mandamus relief is the award of permits to enable non-human testing of the effectiveness of vaporizers in reducing or eliminating the potentially harmful constituents of smoked marijuana by heating, but not burning, the marijuana plant material. During the *Raich* argument, government counsel attributed Congress's rejection of marijuana's medicinal benefits to its concern that "smoking is harmful." Ironically, the research the respondents are blocking (by delaying action on the application to purchase 10 grams and on the application to import 10 grams) would determine whether the use of vaporizers reduces or eliminates the supposed dangers of smoking marijuana. If the research could go forward (facilitated by the relief requested here), preliminary evidence suggests that vaporization produces a far healthier method for obtaining marijuana's therapeutic benefit as compared to smoking. Government counsel's expression before the Supreme Court of Congressional concern for the health risks of smoking implies its (and FDA) interest in the medical use of vaporized marijuana if it were proven significantly safer than smoked marijuana. Accordingly, the respondents' obstruction of vaporizer research appears to conflict with the government's position before the U.S. Supreme Court.

The TRAC standards and the Permits.

(1) Rule of Reason. Relief ought not be denied simply because the permit applications have been delayed only 17 and 1/2 months rather than 41+ months. Every day of delay lengthens a patient's suffering from the deprivation of potentially legal effective medicine, or from the risk of being both in pain and under criminal prosecution or detention.

(2) Statutory or regulatory timetables.

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 publicly-funded 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."

As specified above, FDA is required to review much more complicated protocols involving clinical applications within 30 days: 21 C.F.R. ‘ 312.20(c).

(3) Less delay tolerated when human health at stake. MAPS’ interest is in sponsoring research aimed at developing marijuana into an FDA-approved prescription medicine. Petitioner Corral’s interest in the research concerns her quality of life and the ability to be autonomous which only medicinal marijuana appears to provide. For her sake and other similarly situated patients, their health should render ordinary delay intolerable.

Furthermore, American federal research obstruction stands in vivid contrast to extensive government funded or authorized privately-funded medical marijuana research underway for several years in Britain, Canada, Spain and Israel. Other sovereigns care just as much for their nations’ public health as American regulators, but apparently they care more for the suffering of patients amenable to palliative marijuana treatment than American

regulators. This court ought not countenance such apparent and unreasonable governmental discrimination among international researchers.

(4) Effect of expediting delayed action on agency activities of a higher or competing priority. Because the agency action necessary to evaluate the delayed applications requires a very small amount of time, expediting the delayed action will have no impact on competing agency obligations. Evaluating the scientific merit of Chemic's protocol for the vaporizer research could be accomplished in a day's work or less for one person because the protocol is simple, has been submitted by a firm that regularly conducts research for the pharmaceutical industry and has DEA licenses to conduct research with other Schedule I and II drugs, and is accompanied by a peer review statement confirming the high quality of its design. The action the petition seeks from DEA, its filing in the federal register of the application to import, is a non-discretionary ministerial action required by regulation to be done "upon the filing" of the application for a license to import. Such perfunctory action cannot reasonably be deemed to distract significant agency resources from competing tasks.

(5) Nature and extent of the interests prejudiced by delay. Delay prejudices the large number of potential patients in states that have not allowed the medical use of marijuana, whose ailments are either less ably treated by existing prescription medicine or for whom alternative medicine is unaffordable, and places at risk of federal arrest thousands of patients in the states already registering medical marijuana users. Financial harm is borne by MAPS, which seeks to market marijuana as an FDA-approved prescription medicine, and by patients and health care providers who are prevented the possibility of obtaining access to affordable and less expensive health care in the form of a potential non-patented herbal medication, of

special benefit for the growing class of uninsured and working poor.

(6) Delay "impropriety" unnecessary to relief from delay. Notwithstanding the federal government's thirty year record of delay, a finding of intransigence or obstruction is not necessary to the relief requested here, simply a reply to the mandamus action by the slow moving agencies. At the risk of repetition, the scope of the permits and research to be done thereunder is simple and basic, while the potential benefit to seriously ill patients is substantial. This reconsideration motion does not seek the ultimate petition relief, an order to act on the applications within a time certain. The motion only seeks an order that the agencies respond to the petition and explain their delay.

Conclusion

In summary, this Court should grant reconsideration of the order summarily denying the petitions claims on the grounds that, 1) HHS time limits for the review of protocols in other very similar contexts are 21 days, 2) Some medical marijuana patients' lives are literally endangered if they are denied marijuana, for example Angel Raich, and Jonathan Magbie, who died in a DC jail while serving a 10 day jail sentence for marijuana possession after his medical marijuana claim was denied, 3) DEA and HHS have already had 17 1/2 months to evaluate these applications, 4) these delays highlight the government's obstruction of medical marijuana research and contradict the impression of U.S. Supreme Court Justice Breyer that the FDA drug development approval process is actually a viable alternative to state legislative and initiative processes. The federal government is cynical in that it is calling for more research on the one hand and preventing that research from taking place on the other, for purely political reasons. All the petitioners are seeking in the mandamus petition is for the agencies to be directed to respond to the applications so that if the applications are denied, petitioners can avail themselves of administrative review

provisions set out in the Administrative Procedures Act. All the petitioners are seeking in this reconsideration motion is that the agencies reply to the allegations in the petition and provide an explanation for their delay.

C. The Relief Sought

WHEREFORE, the petitioners seek reconsideration of the panel's November 22, 2004 order, and further orders compelling all respondents to file a response to the mandamus petition within thirty days, or such other relief as deemed proper.

D. The Movant's Statement of Consent or Opposition.

Local Rule 27(a)(5) requires the movant to discuss the other parties' intended replies to the motion (consent, opposition or no response) and report those replies herein. This rule appears to be inapplicable here. All respondents are federal agencies which certainly will be represented by counsel in both cases, rather than appearing in this court pro se as the named respondent administrator, secretary or director. No respondent counsel has contacted undersigned petitioners' counsel, petitioner has not been informed who will be or is counsel for respondents, and it would be unethical for counsel to contact an individual party where he knows or reasonably expects that the party will be represented by counsel. Accordingly, the movant has not discussed this motion and the respondents' intended responses with the party respondent(s) in this case.

E. Corporate Disclosure Statement, Pursuant to Fed. R.App.P. and D.C. Cir. Ct. L.R. 26.1

Pursuant to the foregoing rules, the petitioner MULTIDISCIPLINARY ASSOCIATION FOR PSYCHEDELIC STUDIES (MAPS) hereby discloses any parent corporation and any publicly held corporation that owns 10% or more of its stock, and its general nature and purpose: MAPS is an IRS-approved non-profit medical research and educational organization (EID #59-2751953), and a not-for-profit

corporation organized and chartered under Florida state law, with its principal place of business located at 2105 Robinson Avenue, Sarasota, Florida. MAPS has issued no stock or partnership shares, has no corporate or other parent, and neither it nor its members have issued shares or debt securities to the public.

THE PETITIONERS

By Their Attorney:

Michael D. Cutler, Esq.
(Mass. BBO No. 110940)
46 Kenwood Street
Brookline MA 02446-2413
Telephone: (617) 816-6056

Attorney for the Consolidated Petitioners, Multidisciplinary Assoc. for Psychedelic Studies, Valerie Corral and Lyle E. Craker

Certificate of Service: I hereby certify that on this date, I mailed copies of this motion and a cover letter (giving notice of the eight day reply deadline) to the following addressees and addresses, being all respondents in the consolidated case.

Dated:

Michael D. Cutler

DRUG ENFORCEMENT ADMINISTRATION
DEA Administrator Karen Tandy
2401 Jefferson Davis Hwy.
Alexandria, VA 22301-1055

DEPARTMENT OF HEALTH AND HUMAN SERVICES
The Honorable Tommy G. Thompson
200 Independence Ave., S.W.
Humphrey Bldg., Room 713-F
Washington, DC 20201-0004

NATIONAL INSTITUTE ON DRUG ABUSE
Director Nora D. Volkow M.D.
NIH Neuroscience Ctr, Rm 5274
6001 Executive Boulevard
Bethesda, MD 20892-0001

NATIONAL INSTITUTES OF HEALTH
Director Elias A. Zerhouni MD
MSC 0148 (Rm 126)
1 Center Drive
Bethesda, MD 20892-0148