ALLIANCE FOR CANNABIS THERAPEUTICS, PETITIONER v. DRUG ENFORCEMENT ADMINISTRATION, RESPONDENT PHYSICIANS ASSOCIATION FOR AIDS CARE AND THE LYMPHOMA FOUNDATION OF AMERICA, INTERVENORS;
DRUG POLICY FOUNDATION AND THE NATIONAL ORGANIZATION FOR THE REFORM OF MARIJUANA LAWS, PETITIONERS v. DRUG ENFORCEMENT ADMINISTRATION, RESPONDENT

No. 92-1168, No. 92-1179

UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

15 F.3d 1131; 1994 U.S. App. LEXIS 2684; 304 U.S. App. D.C. 400

October 1, 1993, Argued

February 18, 1994, Decided

PRIOR HISTORY: [**1] Petitions for Review of an Order of the Drug Enforcement Administration.

COUNSEL: Steven K. Davidson argued the cause for petitioners. With him on the briefs were Amy W. Lustig and Kevin B. Zeese. Thomas C. Collier, Jr. entered an appearance for petitioner Alliance for Cannabis Therapeutics and intervenors in No. 92-1168.

Lena D. Mitchell, Attorney, U. S. Department of Justice, argued the cause for respondent. With her on the brief was John C. Keeney, Acting Assistant Attorney General. Eumi L. Choi entered an appearance for respondent.

Steven K. Davidson and Amy W. Lustig were also on the brief for intervenors.

JUDGES: Before MIKVA, Chief Judge, and BUCKLEY and GINSBURG, Circuit Judges. Opinion for the court filed by Circuit Judge BUCKLEY.

OPINION BY: BUCKLEY

OPINION: **[*1132]** BUCKLEY, Circuit Judge:

The Alliance for Cannabis Therapeutics, the Drug Policy Foundation, and the National Organization for the Reform of Marijuana **[*1133]** Laws petition for review of a final order of the Administrator of the Drug Enforcement Administration declining to reschedule marijuana from Schedule I to Schedule II of the Controlled Substances Act. Rescheduling to Schedule II would permit doctors to prescribe marijuana **[**2]** for therapeutic purposes. Petitioners' central claim is that the Administrator's order rests on an unreasonable interpretation of the statute. Because our previous disposition of this matter in *Alliance for Cannabis Therapeutics v. DEA, 289 U.S. app. D.C. 214, 930 F.2d 936 (D.C. Cir. 1991)* ("ACT") constitutes the law of the case, we decline to reconsider this claim. We also find that the Administrator satisfied ACT's mandate on remand and that petitioners' other claims lack merit.

I. BACKGROUND

A. Statutory Scheme

The Controlled Substances Act ("CSA places hazardous drugs in five categories, or schedules, which impose varying restrictions on access to the drugs. See *21 U.S.C. § 812* (1988). Marijuana is assigned by statute to Schedule I, the most restrictive of these. See id. Schedule I drugs may be obtained and used lawfully only by doctors who submit a detailed research protocol for approval by the Food and Drug Administration and who agree to abide by strict record-keeping and storage rules. See 21C.F.R. §§ 1301.33, 1301.42.

The CSA allows the Attorney General to reschedule a drug if he finds that it does not [**3] meet the criteria for the schedule to which it has been assigned. *21 U.S.C. § 811(a).* The Attorney General has delegated this authority to the Administrator. See 28 C.F.R. § 0.100(b). In rescheduling a drug, the Administrator must consider, inter alia, "scientific evidence of [the drug's] pharmacological effect, if known," and "the state of current scientific knowledge

regarding the drug or other substance" in determining whether to reschedule the drug. *21 U.S.C. § 811(c)(2), (3).*

A drug is placed in Schedule I if (1) it "has a high potential for abuse," (2) it has "no currently accepted medical use in treatment in the United States," and (3) "there is a lack of accepted safety for use of the drug...under medical supervision." *21 U.S.C. § 812(b)(f)* (1988) (emphasis added). The Schedule II criteria are somewhat different: (1) the drug "has a high potential for abuse." (2) it "has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions," and (3) "abuse of the drug...may lead to severe psychological **[**4]** or physical dependence." *21 U.S.C. § 812(b)(2)* (1988) (emphasis added). Petitioners' central claim is that the Administrator misinterpreted the language italicized above.

B. Procedural History

This is the latest chapter in petitioners' efforts to move marijuana into a less restrictive CSA schedule. They claim that marijuana is misclassified because it has been shown to serve various medicinal purposes. Specifically, they content that marijuana alleviates some side effects of chemotherapy in cancer patients, aids in the treatment of glaucoma, an eye disease, and reduces muscle spasticity in patients suffering from multiple sclerosis and other maladies of the central nervous system. In support of these contentions, they introduced affidavits and testimony for a number of patients and practicing physicians who insist that, in their experience, marijuana has proven safe and effective.

The petition to reschedule marijuana was first filed in 1972 and has been before this court on four prior occasions--*National Org. for the Reform of Marijuana Laws v. Ingersoll, 162 U.S. App. D.C. 67, 497 F.2d 654 (D.C. Cir. 1974); National Org. for the Reform of Marijuana Laws v. Drug Enforcement Admin., 182 U.S. App D.C. 114, 559 F.2d 735 (D.C. Cir. 1977);* **[**5]** National

Org. for the Reform of Marijuana Laws v. Drug Enforcement Admin. & Dept. of Health, Education & Welfare, No. 79-1660 (D.C. Cir. Oct. 16, 1980); and most recently, *ACT, 289 U.S. App. D.C. 214, 930 F.2d 936 (D.C. Cir. 1991)*. ACT is the only part of this history we need recount.

In ACT, the Alliance for Cannabis Therapeutics ("Alliance") and the National Organization for the Reform of Marijuana Laws ("NORML") argued that the Administrator's refusal to reschedule marijuana rested on an unreasonable interpretation of the statutory phase, "currently accepted medical use," **[*1134]** *930 F.2d at 939; see 21 U.S.C. §§ 812*(b)(1)(B), (2)(B). In a scheduling proceeding involving another drug, the Administrator determined that "the characteristics of a drug or other substance with an accepted medical use include:

(1) scientifically determined and accepted knowledge of its chemistry;

(2) the toxicology and pharmacology of the substance in animals;

(3) establishment of its effectiveness in humans through scientifically designed clinical trials;

(4) general availability of the substance **[**6]** and information regarding the substance and its use;

(5) recognition of its clinical use in generally accepted pharmacopeia, medical references, journals or textbooks;

(6) specific indications for the treatment of recognized disorders;

(7) recognition of the use of the substance by organizations or associations of physicians; and

(8) recognition and use of the substance by a substantial segment of the medical practitioners in the United States.

53 Fed. Reg. 5,156, 5,157-58 (Feb. 22, 1988).

Applying these criteria to the petition to reschedule marijuana, the Administrator found on December 29, 1989, that marijuana had no currently accepted medical use and thus had to remain in Schedule I. *54 Fed. Reg. 53,767, 53,768 (1989).* The eight-factor test had been published in the Federal Register on February 22, 1988, 17 days after the close of the evidence but before the oral arguments to the administrative law judge in the marijuana rescheduling proceedings.

On reviewing the Administrator's decision, we found the eight-factor test for determining whether a drug had a "currently accepted medical use" to be **[**7]** "in the main acceptable." *ACT, 930 F.2d at 937.* We noted the ambiguity of the phrase and dearth of legislative history on point and deferred to the Administrator's interpretation as reasonable. Id, at 939 (citing *Chevron U.S. A. Inc. v. Natural Resources Defense Council, 467 U.S. 387, 843-45, 81 L. Ed. 2d 694, 104 S. Ct. 2778 (*1984) (court may not substitute its own construction of ambiguous statutory provision for reasonable interpretation by agency of statute entrusted to its administration)). We were troubled, however, by three of the eight criteria and remanded the case "for an explanation as to how [these] had been utilized by the Administrator in reaching his decision." *930 F.2d at 940.* In particular, we were concerned over the apparent impossibility of meeting the fourth, fifth, and eighth criteria, all of which assumed an availability of marijuana for medical purposes that was prohibited by

Schedule I.

On March 26, 1992, the current Administrator issued the order that is the subject of this appeal. See *57 Fed. Reg. 10,499* (Mar. 26, 1992) ("Final Order"). He concluded, on remand, that **[**8]** his predecessor had not in fact relied on two of the three "impossible" criteria; he explained the third; and, after applying new criteria, he again denied the petition to reschedule marijuana. *Id. at 10,508.*

II. DISCUSSION

A. Law of the Case

We held, in ACT, that the Administrator's interpretation of the CSA was reasonable. Under the "law of the case" doctrine, appellate courts do not reconsider matters resolved on a prior appeal in the same proceeding.

18 Wright & Miller, Federal Practice & Procedure 4478 at 788 (1981). The doctrine is not a jurisdictional limitation; rather, it "merely expresses the practice of courts generally to refuse to reopen what has been decided...."*Meseight criteria and remanded the case "for an explanation as to how [these] had been utilized by the Administrator in reaching his decision." 930 F.2d at 940.* In particular, we were concerned over the apparent impossibility of meeting the fourth, fifth, and eighth criteria, all of which assumed an availability of marijuana for medical purposes that was prohibited by

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Petitioners do not contend that any of these exceptions apply here. Instead, they assert **[**9]** that in ACT we gave only cursory attention the statutory interpretation argument whereas, in their view, the law of the **[*1135]** case doctrine applies only where the prior appeal has analyzed an issue at length. We disagree on both counts. First, our treatment of the statutory interpretation question was entirely adequate. Second, even summarily treated issues become the law of the case. In *Christianson v. Colt Industries Operating Corp., 486 U.S. 800, 817, 100 L. Ed. 2d 811, 108 S. Ct. 2166 (1988),* the Supreme Court noted: " That the Federal Circuit did not explicate its rationale is irrelevant, for the law of the case turns on whether a court previously 'decided upon a rule of law'--which the Federal Circuit necessarily did--not on whether, or how well, it explained the decision." In ACT, we decided that it was not "an unreasonable application of the statutory phrase [for the Administrator] to emphasize the lack of exact scientific knowledge as to the chemical effects of the drug's elements." *930 F.2d at 939.*

As noted above, our only concern, in ACT, was with three of the standards adopted by the Administrator and his possible reliance on them. As a consequence, **[**10]** in remanding the case, we asked him to explain how his decision had been affected by those standards. In the Final Order, the present Administrator found that two of these criteria--the "general availability of the substance" and the "use of the substance by a

substantial segment of ... medical practitioners"--played no role in his predecessor's decision. See *57 Fed. Reg. at 10,507.*

Further, the Administrator found that his predecessor's conclusion that marijuana failed to meet the third of the questioned criteria--"recognition of [the drug's] clinical use in generally accepted pharmacopeia"--rested on a determination that marijuana lacked a known, reproducible chemistry. See id. We had objected to the "recognition of clinical use" standard only because it seemed to require widespread therapeutic use of the drug--an impossibility for Schedule I substances. See *ACT, 930 F.2d at 940*. The Administrator's interpretation of that criterion meets our objection.

The Final Order discards the earlier formulation and applies a new five-part test for determining whether a drug is in "currently accepted medical use":

(1) The **[**II]** drug's chemistry must be known and reproducible

(2) there must be adequate safety studies;

(3) there must be adequate and well-controlled studies proving efficacy;

(4) the drug must be accepted by qualified experts; and

(5) the scientific evidence must be widely available.

57 Fed. Reg. at 10,506. None of these criteria is impossible for a Schedule I drug to meet; in fact, petitioners concede in their briefs that the new standard has corrected the flaws we identified in ACT.

B. Petitioners' Other Arguments

Petitioners make two additional arguments: (1) They assert that they were deprived of the opportunity to confirm their evidentiary submissions to the governing legal standard because the previous Administrator had

failed to publish the eight-factor test on which he relied, as required by the Freedom of Information Act ("FOIA"), *5 U.S.C. § 552(a)(I)(D)*, until two weeks after the close of the evidence in the rescheduling proceeding; and (2) they claim that the Administrator's ruling was not the produce of reasoned decisionmaking because he was biased and ignored the record.

While **[**12]** Alliance and NORML had apparently raised these issues in ACT, we did not expressly address them; nor did we decide them by necessary implication because our limited remand in ACT could have reflected a decision to postpone consideration of these remaining arguments. Accordingly, we conclude that ACT did not establish the law of the case as to these issues. See *Bouchet v. Nat'l Urban League, 235 U.S. App. D.C. 37, 730 F.2d 799, 806 (D.C. Cir. 1984)* (" Only when an issue not expressly addressed must have been decided by 'necessary implication' will the [law of the case] doctrine be applied ...").

1. The FOIA Claim

Section 552(a)(1) of FOIA provides in relevant part:

[*1136] Each agency shall separately state and currently published in the Federal Register for the guidance of the public--

...

(D) ... statements of general policy or interpretations of general applicability formulated and adopted by the agency...

...

Except to the extent that a person has actual and timely notice of the terms thereof, a person may not in any manner ... be adversely affected by [] a matter required to be published in the Federal Register and not so published. **[**13]**

5 U.S.C. § 552(a)(1) (emphasis added). This provision requires agencies to set out in advance the legal standards that will be applied so that "actions can be guided, and strategies planned." *Northern Calif. Pwr.Agency v. Morton, 396 F. Supp. 1187, 1191* (D.D.C.), aff'd mem. sub. nom. *Northern Calif. Pwr. Agency v. Kleppe, 176 U.S. App. D.C. 241, 539 F.2d 243 (D.C. Cir. 1976).* To establish a claim under the statute, however, the litigant must show that "he was adversely affected by a lack of publication or that he would have been able to pursue an alterative course of conduct" had the information been published. *Zaharakis v. Heckler, 744 F.2d 711, 714 (9th Cir. 1984).*

Petitioners argue that the Administrator violated the statute by using the eight-factor test to evaluate the evidence presented in the marijuana rescheduling petition. As the test was not published until 17 days after the close of the evidence, they contend that they were "adversely affected" by the Administrator's reliance on the test because they had no opportunity to tailor their evidence to meet its requirements. **[**14]** Accordingly, they ask us to remand the case to the Administrator with instructions to reopen the record for the submission of new evidence.

We decline to do so because petitioners have failed to demonstrate that they have in fact been adversely affected by the lack of notice. During the nearly two years between the publication of the eight-factor test on February 22, 1988, and the Administrator's ruling on December 29, 1989, petitioners never sought to reopen the record. As parties to an important controversy, they had a responsibility to proffer any evidence that was made newly relevant by the adoption of the criteria. Their failure to do so suggests either that they were satisfied that the evidence already presented would meet the test or that they had no further evidence to offer.

Thus, we have no reason to believe that petitioners would have pursued an "alternative course of conduct" had the test been published earlier. *Zaharakis, 744 F.2d at 714.*

Furthermore, we do not agree that *McLouth Steel Products v. Thomas, 267 U.S. App. D.C. 367, 838 F.2d 1317 (D.C. Cir. 1988)* supports their position. That case is distinguishable. McLouth arose **[**15]** in the context of a rulemaking in which an agency failed to identify adequately a key standard in its notice of proposed rulemaking in violation of *5 U.S.C. § 553*. Unlike petitioners, the McLouth challengers knew the governing legal standard by the time they were called on to submit evidence; their complaint was that they had not had a chance to challenge the standard at the time it was adopted. *838 F.2d at 1322-23*. We held that the challengers were not required to demonstrate that the failure of notice had caused "specific prejudice" because "we cannot say with certainty whether petitioners' comments would have had some effect [on the adoption of the standard] if they had been considered when the issue was open." Id, at 1323-24. Here, petitioners' challenge is not to the standard but to their claimed inability to respond to it.

2. The Reasoned Decisionmaking Claim

In ACT, Alliance and NORMAL argued that the prior Administrator had been biased and ignored the record. On this appeal, petitioners repeat these claims and accuse his successor of the same errors. We need not consider **[**16]** whether the previous Administrator's ruling stemmed from reasoned decisionmaking, however, because we remanded it to the agency. We thus confine our review to the current Administrator's treatment of the record in the Final Order.

In support of their bias claim, petitioners point to what they describe as a long history of the Drug Enforcement Administration's **[*1137]** anti-marijuana prejudice as evidenced by this court's need to remand their petition on four occasions and what they describe as the prior Administrator's "unusually strident decision" rejecting the administrative law judge's recommendation that the drug be rescheduled. They also cite various statements by the present Administrator in the Final Order as evidence of a lack of objectivity. See, e.g., *57 Fed. Reg. at 10,502* ("The only favorable

evidence that could be found by [petitioners] consists of stories by marijuana users"); id. ("sick people are not objective scientific observers, especially when it comes to their own health."); *id. at 10,503* ("sick men, women, and children can be fooled by these claims and experiment with the drug....It is a cruel hoax to offer **[**17]** false hope to desperately ill people.")

We are not impressed. The need to remand a case several times is not evidence per se of agency prejudice. Nor do we think the statements cited by petitioners show that the Administrator was unfair, especially when considered in the context of a reasonable preference for rigorous scientific proof over anecdotal evidence, even when reported by respected physicians.

Moreover, our review of the record convinces us that the Administrator's findings are supported by substantial evidence. See *21 U.S.C. § 877*(1988) (substantial evidence standard applies to findings of fact in rescheduling proceedings). The Final Order canvasses the record at length. It recites the testimony of numerous experts that marijuana's medicinal value has never been proven in sound scientific studies. The Administrator reasonably accorded more weight to the opinions of these experts than to the anecdotal testimony of laymen and doctors on which petitioners relied. The Administrator noted that with one exception, none of [these doctors] could identify under oath the scientific studies they swore they relied on. Only one had enough **[**18]** knowledge to discuss the scientific technicalities involved. Eventually, each one admitted he was basing his opinion on anecdotal evidence, on stories he heard from patients and on his impression about the drug.

Final order, *57 Fed. Reg. at 10,502-03*. These findings are consistent with the view that only rigorous scientific proof can satisfy the CSA's "currently accepted medical use" requirement. *Id at 10,500.*

III. CONCLUSION For the foregoing reasons, the petitions for review are Denied.