930 F.2d 936 (1991)

ALLIANCE FOR CANNABIS THERAPEUTICS, Petitioner,
v.
DRUG ENFORCEMENT ADMINISTRATION, Respondent.
The NATIONAL ORGANIZATION FOR the REFORM OF MARIJUANA LAWS, Petitioner,
v.
DRUG ENFORCEMENT ADMINISTRATION, Respondent.

Nos. 90-1019, 90-1020.

United States Court of Appeals, District of Columbia Circuit.

Argued March 4, 1991.
Decided April 26, 1991.

937 *937 Thomas C. Collier, Jr., with whom Steven K. Davidson and Amy W. Lustig were on the brief, for petitioner Alliance for Cannabis Therapeutics in 90-1019.

Kevin B. Zeese was on the brief, for petitioner The Nat. Organization for the Reform of Marijuana Laws in 90-1020.

Charlotte J. Mapes, Atty., Dept. of Justice, with whom Margaret A. Grove, Atty., Dept. of Justice, and Stephen E. Stone, Associate Chief Counsel, Dept. of Justice, were on the brief, for respondent in 90-1019 and 90-1020. Madeline R. Shirley, Atty., Dept. of Justice, also entered an appearance, for respondent.

Before SILBERMAN, BUCKLEY, and HENDERSON, Circuit Judges.

Opinion for the Court filed by Circuit Judge SILBERMAN.

SILBERMAN, Circuit Judge:

This is a petition for review of a final order of the Administrator of the Drug Enforcement Administration (DEA). The order maintains the classification of marijuana as a narcotic drug under Schedule I of the Controlled Substances Act, see 21 U.S.C. §§ 811-812. Petitioners, Alliance for Cannabis Therapeutics (ACT) and National Organization for the Reform of Marijuana Laws (NORML), who claim that marijuana should be reclassified in Schedule II, argue that the DEA Administrator's decision rests on an improper application of the statutory standards and an incorrect determination that petitioners failed to meet them. We think that the Administrator's interpretation of the statute was in the main acceptable, but he appears to have relied on several factors that are unreasonable because logically impossible to satisfy; therefore, we remand.

I.

The Controlled Substances Act (CSA) is a comprehensive regulatory measure that divides the universe of hazardous drugs into five different categories of substances (so-called schedules), which determine the severity of restrictions on doctors' and patients' access to controlled drugs.[1] Drugs can be "re-scheduled"

or "de-scheduled" only if the DEA makes certain statutorily-mandated findings. Schedule I drugs are subject to the most severe controls and give rise to the harshest penalties for violations of these controls; they are deemed to be the most dangerous substances, possessing no redeeming value as medicines. The Act sets forth statutory criteria to be used in determining whether a drug should be placed in Schedule I:

> (A) The drug or other substance has a high potential for abuse.
>
> (B) The drug or other substance has no currently accepted medical use in treatment in the United States.
>
> (C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.

21 U.S.C. § 812(b)(1).

The Act contains a somewhat different set of criteria for Schedule II:

938 *938 (A) The drug or other substance has a high potential for abuse.

> (B) The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.
>
> (C) Abuse of the drug or other substance may lead to severe psychological or physical dependence.

21 U.S.C. § 812(b)(2).

As is apparent, one salient concept distinguishing the two schedules is whether a drug has "no currently accepted medical use in treatment in the United States." This case turns on the appropriate definition and application of that phrase.

The Administrator is guided by a set of statutory factors in making a classification decision as to which schedule is appropriate. *See* 21 U.S.C. § 811. And two of those factors bear on the Administrator's definition of generally accepted medical use — the "scientific evidence of [the drug's] pharmacological effect, if known" and "the state of current scientific knowledge regarding the drug or other substance." 21 U.S.C. § 811(c)(2), (3).

Petitioners argued below that marijuana has medical uses for the treatment of cancer, glaucoma, and other diseases and therefore it cannot properly be maintained in Schedule I. The ALJ agreed with petitioners and found, based on testimony of a number of physicians and patients, that a "respectable minority" of American physicians accept those uses, which was sufficient, according to the ALJ, to say that marijuana had a currently accepted medical use. The Administrator rejected the ALJ's recommendation, however, determining that the phrase "currently accepted medical use" required a greater showing than that a minority — even a respectable minority — of physicians accept the usefulness of a given drug.

In a prior proceeding, the Administrator had employed an additional eight factor test to further elaborate the characteristics of a drug that he thought had a "currently accepted medical use":

> (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 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 (1988).

The Administrator, in his opinion in this proceeding, reaffirmed this eight factor test. *See* 54 Fed.Reg. 53,783. He stated that "these characteristics rely heavily on verifiable scientific data and acceptance by the medical community," which he thought went "hand in hand" because "[m]ost physicians ... rely on scientific data in formulating their opinions regarding the safety and effectiveness of a drug...." 54 Fed.Reg. 53,783 (1988).

Most important to the Administrator was his conclusion that "the chemistry, toxicology, and pharmacology of marijuana is not established" and its effectiveness has not been documented in humans with scientifically-designed clinical trials (such as double-blind studies where neither the patient nor the observer knows who received the placebo and who received the actual substance). *Id.* at 53,784. Therefore, "[t]he vast majority of physicians do not accept marijuana as having a medical use" and it is "not recognized as medicine in generally accepted pharmacopoeia, medical references, journals, or textbooks." *Id.* The Administrator exercised with a vengeance his prerogative under *Universal Camera Corp. v. NLRB,* 340 U.S. 474, 477, 71 S.Ct. 456, 459, 95 L.Ed. 456 (1951), to *939 reject the ALJ's recommended decision, labelling the ALJ's standard for "currently accepted medical use" as use by a "respectable minority" of physicians as "preposterous."[2] 54 Fed.Reg. 53,784.

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II.

The petitioners renew their argument that the Administrator unreasonably rejected the evidence they presented (largely anecdotal) that a number of physicians believe marijuana is medically useful and, instead, improperly predicated his determination on the absence of demonstrated scientific evidence that the drug is medically useful and safe. The difficulty we find in petitioners' argument is that neither the statute nor its legislative history precisely defines the term "currently accepted medical use"; therefore, we are obliged to defer to the Administrator's interpretation of that phrase if reasonable. *See NLRB v. United Food & Commercial Workers Union,* 484 U.S. 112, 123, 108 S.Ct. 413, 420, 98 L.Ed.2d 429 (1987); *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843-45, 104 S.Ct. 2778, 2781-83, 81 L.Ed.2d 694 (1984). And since Congress required the Administrator, in making scheduling determinations with respect to any drug, to consider the "scientific evidence of [the drug's] pharmacological effect" and the "state of current scientific knowledge regarding the drug," 21 U.S.C. § 811(c)(2), (3), we do not see how it can be thought an unreasonable application of the statutory phrase to emphasize the lack of exact scientific knowledge as to the chemical effects of the drug's elements. Perhaps if virtually all doctors in the United

States were vociferous in their espousal of marijuana for medical treatment — notwithstanding scientific uncertainties — the Administrator's position would be more vulnerable. But that is not the case; the ALJ's finding (not contested by the petitioners) is only that a "respectable minority" take that position. The determination as to how much weight to place on scientific uncertainties as opposed to anecdotal evidence in applying the statutory phrase "currently accepted medical uses," then, is very much a policy judgment which we have no authority to challenge. *See generally Chevron.* We certainly have no grounds, on this record, to dispute the Administrator's premise that without much more complete scientific data American physicians will not "accept" marijuana.

Petitioners, however, mount something of a flanking attack on that premise. They assert that the Administrator's eight factor test, which emphasizes, in factors 1, 2 and 3, scientific knowledge of the chemistry of the drug and its effectiveness in humans established through scientifically-designed clinical trials, is improperly drawn from the Food, Drug and Cosmetic Act (administered by the Food and Drug Administration) and not the Controlled Substances Act which the Administrator is authorized to apply. The First Circuit in *Grinspoon v. Drug Enforcement Administration,* 828 F.2d 881, 891-92 (1st Cir.1987), upon which petitioners rely, had held that earlier criteria the Administrator had employed to define "currently accepted medical use" were contrary to the statute because they were a carbon copy of those used by the FDA in licensing new drugs. The present criteria, it is argued, duplicate a number of those original criteria. But the criteria challenged in *Grinspoon* included several elements, such as the availability of patent information or FDA-required labelling, which were necessary only to market the drug in interstate commerce. These criteria are clearly relevant to the FDA's mission, but not to the DEA's, *see Grinspoon,* 828 F.2d at 887. The First Circuit never suggested the DEA Administrator was foreclosed from incorporating and relying on those standards employed by the FDA that are relevant to the pharmaceutical qualities of the drug. The court merely held that while FDA approval is sufficient to establish the existence of an accepted medical use, the converse is not true — that absent FDA approval, commonly accepted medical use cannot
940 be proven. *940 *Id.* at 890. Nor can we conceive of a reason the Administrator should be barred from employing notions developed by a sister agency insofar as those notions serve the missions of both agencies.[3]

Which brings us to the most troubling part of the Administrator's decision — the part which we think obliges us to order a remand. Petitioners, almost in passing, point out that three of the factors in the Administrator's eight-factor test appear impossible to fulfill and thus must be regarded as arbitrary and capricious. Impossible requirements imposed by an agency are perforce unreasonable: "Conditions imposed by [the] order are ... unreasonable by virtue of being impossible to meet." *D.C. Transit Sys., Inc. v. Washington Metropolitan Area Transit Comm'n,* 466 F.2d 394, 402 (D.C.Cir.), *cert. denied,* 409 U.S. 1086, 93 S.Ct. 688, 34 L.Ed.2d 673 (1972). These three factors are:

> (4) General availability of the substance and information regarding the substance and its use;
>
> (5) Recognition of its clinical use in generally accepted pharmacopeia, medical references, journals or textbooks;
>
> (8) Recognition and use of the substance by a substantial segment of the medical practitioners in the United States.

Petitioners argue that one cannot logically show that a drug enjoys general "availability" or "use" by a substantial segment of medical practitioners if the drug remains in Schedule I. One of the very purposes in placing a drug in Schedule I is to raise significant barriers to prevent doctors from obtaining the drugs too

easily. DEA regulations require doctors who wish to use such drugs to submit a scientific research protocol to the FDA for approval and permit use only in accordance with the protocol. And the FDA insists that a developed scientific study program be presented in order to gain approval of the protocol. *See* 21 C.F.R. § 1301.33(b) (requiring compliance with 21 C.F.R. § 130.3). The DEA regulations further impose mandatory registration with the DEA and mandatory record-keeping and safe-keeping requirements, presenting additional barriers to widespread use, *see* 21 C.F.R. § 1301.33, 1301.42. We are therefore hard-pressed to understand how one could show that *any* Schedule I drug was in general use or generally available. We are also concerned that the fifth factor "recognition of [a drug's] clinical use in generally accepted pharmacopeia, medical references, journals, or textbooks" might be subject to the same objection. Petitioners assert that if a drug is not widely prescribed — regardless of its safety or use — it will not appear in a pharmaceutical listing of medically useful drugs. Since the government did not respond clearly to the argument, we are left in doubt as to the argument's validity. Under these circumstances, we think the appropriate course is to remand to the agency for an explanation as to how all three of these factors were utilized by the Administrator in reaching his decision.[4]

To be sure, the Administrator did not explicitly rely on factors (4) and (8) in the analytical portion of his opinion (he did say "marijuana is not recognized as a medicine in generally accepted pharmacopeia, medical references, and textbooks," indicating his reliance on factor (5)). But since he did reaffirm the eight criteria's applicability to this case, we simply cannot be certain what role, if any, factors (4) and (8) played in
941 his *941 decision. Under our governing cases, we must remand for the requisite explanation. *See* *MCI Telecommunications Corp. v. FCC,* 917 F.2d 30, 39-40 (D.C.Cir.1990); *City of Vernon v. FERC,* 845 F.2d 1042, 1046-49 (D.C.Cir.1988).

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For the foregoing reasons, the case is remanded.

It is so ordered.

[1] When it enacted the CSA in 1970, Congress placed marijuana in Schedule I. From that time, petitioners have indefatigably sought to obtain a change in marijuana's classification. The long and checkered history of this proceeding and an explanation of the complex statutory scheme are detailed in *National Org. for the Reform of Marijuana Laws v. Ingersoll,* 497 F.2d 654 (D.C.Cir.1974); *National Org. for the Reform of Marijuana Laws v. Drug Enforcement Admin.*, 559 F.2d 735 (D.C.Cir.1977).

[2] The Administrator further described the ALJ as relying on "irresponsible and irrational statements," and thought some of his findings "appalling." 54 Fed.Reg. 53,783.

[3] Petitioners insist that the prior decision of this court in this case, *National Org. for the Reform of Marijuana Laws (NORML) v. Drug Enforcement Administration,* 559 F.2d 735, 750 n. 65 (D.C.Cir.1977), also implies that the agency was in error by relying on the FDA standards. But this court merely insisted on the *distinct* nature of the FDA and the DEA proceedings without as much as hinting that the tests for compliance with the two statutes must be mutually exclusive. *See NORML,* 559 F.2d at 750.

[4] Petitioners also quarrel with the Administrator's decision that marijuana lacks "accepted safety for use." Since the Administrator based this determination on his decision that no medical uses are possible (and thus any use lacks "accepted safety"), we do not see that "safety" issue as raising a separate analytical question.