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Legal Brief Bank

GETTMAN V. DEA

The Rescheduling of Marijuana Under Federal Law
Petitioner's Brief
Case # 01-1182

In the United States Court of Appeals
for the District of Columbia Circuit
Jon Gettman and High Times Magazine, Petitioners
against
Drug Enforcement Administration, Respondent
Petition for Review of an Order of the Drug Enforcement Administration,

Dated March 20, 2001

Brief for Petitioners [filed December 18, 2001]

THIS CASE HAS BEEN SCHEDULED FOR ORAL ARGUMENT ON MARCH 19, 2002

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JURISDICTIONAL STATEMENT

The Controlled Substances Act of 1970 (CSA) places drugs in five categories, or schedules, which impose varying restrictions on access to the drugs. See 21 U.S.C. §811, 812 (1994). Under the CSA, drugs may be transferred between, or removed from the schedules. *Id.* On July 10, 1995, pursuant to 21 U.S.C. §811(a), Jon Gettman petitioned the Drug Enforcement Agency (DEA) to initiate rulemaking proceedings that would amend the scheduling of marijuana, tetrahydrocannabinols, Dronabinol and Nabilone. (1) (A4). On December 17, 1997, the DEA forwarded the Petition to the Secretary of Health and Human Resources (HHS) for its evaluation and recommendation, as required by 21 U.S.C. §811(b). (A293). The DEA denied the petition to reschedule marijuana on March 20, 2001. See Drug Enforcement Agency Notice of Denial of Petition, 66 Fed. Reg. 20038 (April 18, 2001) at A416. Gettman timely filed a Petition for Review in this Court on April 19, 2001, pursuant to 21 U.S.C. §877. (A422). The Petition review of the DEA's final order denying Gettman's petition to reschedule marijuana. (2)

STATEMENT OF ISSUES

1. Whether the DEA's determination that marijuana has a "high" potential for abuse was without any factual scientific support and flawed by its failure to evaluate marijuana's relative potential for abuse as compared to other scheduled substances.
2. Whether the DEA erroneously concluded that a "high" potential for abuse is not required for Schedule I status so long as it determined that marijuana has no currently accepted medical use in treatment in the United States and lacks safety for use under medical supervision.
3. Whether the DEA's determination that marijuana should remain in Schedule I was flawed by the failure to consider all eight factors determinative of control as required by 21 U.S.C. §811(c).
4. Whether the DEA improperly relied on marijuana's lack of FDA approval to establish that it has no currently accepted medical use in treatment in the United States and lacks safety for use under medical supervision.
5. Whether the petition was unreasonably denied without the opportunity for a hearing.

STATUTES AND REGULATIONS

21 U.S.C. § 811 (1994). Authority and criteria for classification of substances

(a) Rules and regulations of Attorney General; hearing

The Attorney General shall apply the provisions of this subchapter to the controlled substances listed in the schedules established by section 812 of this title and to any other drug or other substance added to such schedules under this subchapter. Except as provided in subsections (d) and (e) of this section, the Attorney General may by rule -

(1) add to such a schedule or transfer between such schedules any drug or other substances if he -

(A) finds that such drug or other substance has a potential for abuse, and

(B) makes with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of this title for the schedule in which such drug is to be placed; or

(2) remove any drug or other substance from the schedules if he finds that the drug or other substance does not meet the requirements for inclusion in any schedule.

Rules of the Attorney General under this subsection shall be made on the record after opportunity for a hearing pursuant to the rulemaking procedures prescribed by subchapter II of chapter 5 of Title 5. Proceedings for the issuance, amendment, or repeal of such rules may be initiated by the Attorney General (1) on his own motion, (2) at the request of the Secretary, or (3) on the petition of any interested party.

(b) Evaluation of drugs and other substances

The Attorney General shall, before initiating proceedings under subsection (a) of this section to control a drug or other substance or to remove a drug or other substance entirely from the schedules, and after gathering the necessary data, request from the Secretary a scientific and medical evaluation, and his recommendations, as to whether such drug or other substance should be so controlled or removed as a controlled substance. In making such evaluation and recommendations, the Secretary shall consider the factors listed in paragraphs (2), (3), (6), (7), and (8) of subsection (c) of this section and any scientific or medical considerations involved in paragraphs (1), (4), and (5) of such subsection. The recommendations of the Secretary shall include recommendations with respect to the appropriate schedule, if any, under which such drug or other substance should be listed. The evaluation and the recommendation of the Secretary shall be made in writing and submitted to the Attorney General within a reasonable time. The recommendations of the Secretary to the Attorney General shall be binding on the Attorney General as to such scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance. If the Attorney General determines that these facts and all other relevant data constitute substantial evidence of potential for abuse such as to warrant control or substantial evidence that the drug or other substance should be removed entirely from the schedules, he shall initiate proceedings for control or removal, as the case may be, under subsection (a) of this section.

(c) Factors determinative of control or removal from schedules

In making any finding under subsection (a) of this section or under subsection (b) of section 812 of this title, the Attorney General shall consider the following factors with respect to each drug or other substance proposed to be controlled or removed from the schedules:

- (1) Its actual or relative potential for abuse.
- (2) Scientific evidence of its pharmacological effect, if known.
- (3) The state of current scientific knowledge regarding the drug or other substance.
- (4) Its history and current pattern of abuse.
- (5) The scope, duration, and significance of abuse.
- (6) What, if any, risk there is to the public health.
- (7) Its psychic or physiological dependence liability.
- (8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.

21 U.S.C. § 812 (1994). Schedules of controlled substances

(a) Establishment

There are established five schedules of controlled substances, to be known as schedules I, II, III, IV, and V. Such schedules shall initially consist of the substances listed in this section. The schedules established by this section shall be updated and republished on a semiannual basis during the two-year period beginning one year after October 27, 1970 and shall be updated and republished on an annual basis thereafter.

(b) Placement on schedules; findings required

Except where control is required by United States obligations under an international treaty, convention, or protocol, in effect on October 27, 1970, and except in the case of an immediate precursor, a drug or other substance may not be placed in any schedule unless the findings required for such schedule are made with respect to such drug or other substance. The findings required for each of the schedules are as follows:

(1) 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.

(2) Schedule II.

(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 substances may lead to severe psychological or physical dependence.

(3) Schedule III.

(A) The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.

(4) Schedule IV.

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule III.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.

(5) Schedule V.

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule IV.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV.

STATEMENT OF THE CASE

On July 10, 1995, Jon Gettman petitioned the DEA to initiate proceedings for the repeal of rules placing marijuana in Schedule I, tetrahydrocannabinols in Schedule I, Dronabinol in Schedule II, and Nabilone in Schedule II. (A4). The Petition was accepted for filing on July 27, 1995. (A291). On December 17, 1997, the DEA forwarded the Petition to the Department of Health and Human Resources (HHS), stating in part:

"The DEA's initial review of the petition indicates that Mr. Gettman raises issues of science and medicine which have not been evaluated by the Department of Health and Human Resources as part of a scheduling action to date. The relevance of some of the new scientific findings cited by Mr. Gettman has not been established. Some of the issues are (1) the newly identified cannabinoid receptor in the brain, (2) the discovery of an endogenous anandemine ligand for the cannabis receptor, and (3) the development of a cannabinoid receptor antagonist."

"In light of the above and in accordance with the provisions of Title 21 U.S.C., Section 811(b), of the CSA, the DEA requests that you provide a scientific and medical evaluation of the available data and a scheduling recommendation for these substances. The DEA will continue to collect and review data regarding the trafficking and abuse of these substances." (A293) (emphasis added).

After more than five years without a response, Gettman wrote to HHS requesting, inter alia, a status report and an opportunity for a hearing on HHS' proposed findings. (A296). Gettman's request for a hearing was denied on December 22, 2000. (A300). On January 17, 2001, HHS recommended that marijuana remain in schedule I of the CSA. (A302). Based on HHS's recommendation and the DEA's consideration of additional scientific data, the Administrator denied Gettman's Petition to reschedule marijuana on March 20, 2001. See Drug Enforcement Agency Notice of Denial of Petition, 66 Fed. Reg. 20038 (April 18, 2001) at A421. On the same date, the DEA indicated that Gettman would receive separate responses for the other substances at issue in his Petition. Id. To date, no separate responses have been received.

STATEMENT OF FACTS

As grounds to reschedule marijuana, tetrahydrocannabinols, Dronabinol, and Nabilone Gettman asserted that "there is no scientific evidence that they have sufficient abuse potential to warrant schedule I or II status under the Controlled Substances Act." (A4). (3) In support of his petition, Gettman submitted eight abstracts corresponding to the eight factors determinative of control under 21 U.S.C. §811(c). (A5-A40). Gettman also provided a summary of relevant scientific evidence, and the opinions of qualified experts published since or not included in the record of a prior marijuana rescheduling proceeding (i.e. the "NORML Petition"). (A41-A290). (4)

As set forth in Gettman's petition, the DEA's previous findings during the NORML litigation have been challenged by recent scientific discoveries, and now a great deal more is known about the precise chemistry and pharmacology of cannabinoids. (A8-A12). The discovery of a cannabinoid

receptor system in the human body began a scientific revolution that discredited previous hypotheses and radically altered contemporary knowledge about marijuana's effects on the body and brain. Id. Of greatest significance, the existence of the cannabinoid receptor system accounts for the substance's low toxicity, explains why marijuana has never been proven to cause brain damage, and supports the assertion that tolerance does not contribute to a dangerous dependence liability. (A13-A18). Gettman argued that the dependence liability of marijuana is, at least, significantly lower than well-known drugs of abuse, such as heroin, cocaine, and amphetamines. (A5-A7).

On December 17, 1997, the DEA forwarded Gettman's petition and "necessary data" to HHS for a scientific and medical evaluation and scheduling recommendation. (A293). In a letter to the DEA dated January 17, 2001, HHS recommended that marijuana continue to be subject to control under schedule I. (A302). Notably, HHS conceded that marijuana has low toxicity, a low dependence liability and that it contains a medically beneficial drug. (A28, A331). Notwithstanding these concessions, HHS concluded that marijuana "has a high potential for abuse, has no currently accepted medical use in treatment in the United States, and has a lack of accepted safety for use under medical supervision." (A302). After reviewing additional data, the DEA concluded that there was no substantial evidence that marijuana should be removed from Schedule I and denied Gettman's petition to reschedule marijuana on March 20, 2001. (A416).

According to the DEA, the denial of Gettman's petition was based "exclusively on the scientific and medical findings of HHS, with which the DEA concurs, that lead to the conclusion that marijuana has a high potential for abuse." (A419). In support of its conclusion, HHS provided various statistics regarding the prevalence of marijuana use, emergency room episodes related to marijuana, deaths related to marijuana use, and treatment of marijuana users. (A331). HHS reasoned that "the large number of individuals using marijuana on a regular basis and the vast amount of marijuana that is available for illicit use are indicative of widespread use." (A331) (emphasis added). While the HHS may have established widespread use of marijuana and some potential for abuse, a point Gettman concedes, they failed to address Gettman's assertion that marijuana is no more dangerous than alcohol, caffeine, and nicotine, other drugs whose use is far more prevalent in the United States than marijuana. (A19-A23).

More importantly, the DEA and HHS did not address Gettman's principal argument that marijuana does not have a high potential for abuse as compared to other scheduled substances. The only comparative assessment performed by HHS and DEA was to other cannabinoid substances. (A309, A352). Specifically, HHS concluded that marijuana is structurally related to Dronabinol (i.e. Marinol), a Schedule III drug; Nabilone, a Schedule II drug, and "all other cannabinoid compounds," which are listed as Schedule I. (A309); See also A352 (DEA comparing marijuana's abuse liability to that of Dronabinol). In finding these similarities, the DEA and HHS provided no rationale as to why marijuana should be placed in Schedule I with THC, rather than Schedule III with Dronabinol or Schedule II with Nabilone. Gettman had requested rescheduling of all four substances and argued that there was no scientific basis for an assertion that marijuana or any cannabinoid had a greater dependence liability or potential for abuse than Dronabinol, which is presently a Schedule III substance. (A38-A40).

As an alternative ground to deny the petition, the DEA asserted that marijuana can only be placed in Schedule I, regardless of its level of abuse potential, because it is "undisputed that such drug has no currently accepted medical use in treatment in the United States and a lack of accepted

safety for use under medical supervision." (A421). According to the DEA, Schedule I is the only classification for substances without medical use and safety. (A419). In reaching its conclusion that marijuana lacks medical utility and safety, the DEA and HHS relied on the views of experts at the 1997 "NIH Workshop on the Medical Utility of Marijuana," (A321, A377), and the fact that the FDA has not approved marijuana. (A331-32, A420). Nowhere in their reviews do the DEA or HHS address Gettman's arguments regarding the impact of marijuana's Schedule I status on state law enforcement agencies or individuals most affected by the regulation, including patients who use medical marijuana, physicians and the young. (A19-A29).

SUMMARY OF ARGUMENT

Under the CSA, a substance cannot be classified under Schedule I unless it meets three criteria: it must have (1) a "high" potential for abuse, (2) no currently accepted medical use in treatment in the United States, and (3) lack of safety for use under medical supervision. See 21 U.S.C. §812(b)(1). In determining whether the three criteria are met, all of which are essential to Schedule I status, the DEA and HHS must consider eight factors determinative of control which are set forth at 21 U.S.C. §811(c). The duty to consider all eight factors is not qualified in any way.

In denying Gettman's petition to remove marijuana from Schedule I, the DEA and HHS's fundamental error was their failure to evaluate marijuana's relative abuse potential as compared to other scheduled substances, as required by 21 U.S.C. §812(b). The only structural and pharmacological similarities noted by the DEA and HHS were between marijuana and other cannabinoid substances, including Dronabinol (a Schedule III substance). (A309, A352). At most, HHS established that marijuana is widely used and has some potential for abuse, but not enough to justify Schedule I classification. Indeed, HHS conceded that marijuana has a low toxicity and dependence liability. HHS' determination that marijuana has a "high" potential for abuse is further flawed by its failure to consider all eight factors determinative of control as required by 21 U.S.C. §811(c). Specifically, the DEA and HHS failed to consider the impact of Schedule I status on state law enforcement agencies, the young, and patients who use marijuana to treat their illnesses.

As an alternative ground to deny the petition, the DEA asserted that Schedule I status is required for marijuana — regardless of its level of potential for abuse — because it has no currently accepted medical use in treatment in the United States and lacks safety for use under medical supervision. (419-421). This very argument, however, was explicitly rejected by this Court in *NORML v. DEA*, 559 F.2d 735 (1977), where it was held that all three criteria under §812(b) must be established to justify schedule I status. Moreover, the DEA's conclusions regarding marijuana's lack of medical utility and safety ignores the current medical and scientific record. Indeed, since the petition was filed eight states have passed laws affording legal protection to patients who use marijuana to treat illness. Although these laws recognize the benefits of medical marijuana and have put into practice the safety of the substance, neither HHS nor the DEA addressed them.

During the DEA's six year delay in deciding the petition, there has been a sea change in medical and scientific knowledge concerning marijuana's uses and effects, which the DEA has failed to consider. Such a failure, coupled with the denial of Gettman's request for a hearing, (A299), has precluded a meaningful and reliable determination of the appropriate scheduling of marijuana. Accordingly, a hearing is required to resolve the factual contradictions and disputes apparent

from the scientific record, and to protect the interests of other parties, including state governments and individuals impacted by Schedule I control.

ARGUMENT

I STANDARD OF REVIEW

As set forth below, this Petition for Review challenges the legal standards employed by the DEA and HHS in deciding Gettman's petition, as well as the sufficiency of evidence underlying the DEA's conclusions. With respect to the legal applications, the relevant standard of review is articulated in *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). In *Chevron*, the Court explained that a court reviewing an agency decision must employ a two-step analysis that focuses initially on the intentions of Congress:

"First, always, is the question whether Congress had directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Id.* at 842-43.

In the absence of congressional intent, however, the court must proceed to a second inquiry:

"If . . . the court determines Congress has not directly addressed the precise question at issue, the court does not simply impose its own construction on the statute, as would be necessary in the absence of an administrative interpretation. Rather, if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute." *Id.* at 843 (footnote omitted).

Should this Court determine that the DEA and HHS employed the correct legal standards, Gettman nonetheless argues that their conclusions are based on insufficient evidence. In reviewing such conclusions, this Court must determine whether they are based on "substantial evidence," a term the Supreme Court has defined as "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *American Textile Manufacturers Institute, Inc. v. Donovan*, 452 U.S. 490 (1981) (quoting *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 477 (1951)). The Court has further explained that "even if reasonable minds could also go the other way, [a court] must uphold the [agency] if its ultimate finding is supported by substantial evidence in the record as a whole." *NLRB v. J.K. Electronics, Inc.*, 592 F.2d 5, 7 (1st Cir.1979) (emphasis added). See also 21 U.S.C. §877 (1994) (substantial evidence standard applies to findings of fact in rescheduling proceedings).

II. BACKGROUND: THE SCHEDULING OF MARIJUANA UNDER THE CONTROLLED SUBSTANCES ACT

The CSA places controlled substances in five categories, or schedules, which impose varying restrictions on access to the drugs. See 21 U.S.C. §812 (1994). The scheduling classification is also relevant to the criminal penalties prescribed for the manufacture, distribution, dispensation, and possession with intent to distribute controlled substances. *Id.* at §841(b). A drug is placed in Schedule I, the most restrictive category, 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. *Id.* at §812(b)(1) (emphasis added). (5) In determining whether these criteria have been met, the following factors must be considered:

- (1) The drug's actual or relative potential for abuse;
- (2) Scientific evidence of its pharmacological effect, if known;
- (3) The state of current scientific knowledge regarding the drug;
- (4) Its history and current pattern of abuse;
- (5) The scope, duration, and significance of abuse;
- (6) What, if any, risk there is to the public health;
- (7) The drug's psychic or physiological dependence liability; and
- (8) Whether the drug is an immediate precursor of a substance already controlled under the CSA. *Id.* at §811(c).

The CSA allows the Attorney General to transfer a drug between schedules if he finds that it does not meet the criteria for the schedule to which it has been assigned, and the same eight factors must be considered in making such a determination. *Id.* at §811(a)(1).

Despite strong disagreement among lawmakers, physicians and scientists regarding marijuana's uses and effects, it was classified and remains a Schedule I substance. (6) However, Congress and the courts have made clear that marijuana's appropriate scheduling should be assessed according to the evolving scientific and medical record. Months before it enacted the CSA, Congress enacted the "Marihuana and Health reporting Act," Pub. L. No. 91-296, §§ 501-503, 1970 U.S.C.C.A.N. 418, which directed the Secretary of the Department of Health, Education and Welfare ("HEW") to prepare a report within 90 days and annually thereafter, "containing current information on the health consequences of using marihuana" and "containing such recommendations for legislative and administrative action as he may deem appropriate." *Id.* The reason Congress ordered the report was that it had found that "notwithstanding the various studies carried out, and research engaged in, with respect to the use of marihuana, there is a lack of an authoritative source for obtaining information involving the health consequences of using marihuana." *Id.* During debates on the CSA, but before the HEW report was complete, HEW advised Congress as follows:

"Some question has been raised whether the use of the plant itself produces "severe psychological or physical dependence" as required by a schedule I or even schedule II criterion. Since there is still a considerable void in our knowledge of the plant and its effects of the active drug contained in it, our recommendation is that marihuana be retained within schedule I at least until the completion of certain studies now underway to resolve this issue." H.R. Rep. No. 91-1444 (1970), 91st Cong., 2d Sess, reprinted in 1970 U.S.C.C.A.N. at 4579 & 4629.

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Congress also received information from the National Institute of Mental Health, which included the facts that cannabis is not physically addictive and does not necessarily lead to violence or use of other drugs. *Id.* at 4577-78. Acknowledging the controversy, Congress stated that "[t]he extent to which marihuana should be controlled is a subject upon which opinions diverge widely." H.R. Rep. No. 91-1444 (1970), *supra*, reprinted in 1970 U.S.C.C.A.N. 4577.

In response to its uncertainty, Congress placed marijuana only tentatively in Schedule I when it enacted the CSA in 1970. To resolve the uncertainty about whether marijuana belonged in Schedule I, Congress created the bipartisan Commission on Marihuana and Drug Abuse (the "Shafer Commission"), and directed it to prepare a report to guide Congress. See Act of Oct. 14, 1970, Pub. L. No. 91-513, § 601, 1970 U.S.C.C.A.N. (84 Stat.) 1489-90. The Shafer Commission recommended that Congress amend the CSA, and that the states amend their laws, so that possession of marijuana for personal use would not be punished, and "casual distribution of small amounts of marihuana for no remuneration, or insignificant remuneration not involving profit would no longer be an offense." *Marihuana: A Signal of Misunderstanding; First Report of the National Commission on Marihuana and Drug Abuse*, 152-53 (1972). The Commission also confirmed that too little was known about the medical benefits of marijuana and recommended further study. *Id.* at 176.

Not surprisingly, the controversial and tentative scheduling of marijuana led to numerous challenges beginning soon after enactment of the CSA. In 1972, the National Organization for the Reform of Marijuana Laws (NORML) filed a rule-making petition requesting that marijuana either be removed from the CSA entirely or transferred to Schedule V. See *NORML v. Ingersoll*, 497 F.2d 654, 655 (D.C. Cir.1974). Citing United States treaty obligations, this Court rejected NORML's petition in 1972, but remanded the issue to the DEA for further consideration, and recommended that the DEA consider separately rescheduling the leaves of the plant. *Id.* at 656, 660. On remand, the administrative law judge held that cannabis and cannabis resin could be rescheduled to Schedule II; that cannabis leaves could be rescheduled to Schedule V; and that cannabis seeds and synthetic THC could be removed from the Schedule altogether. See *NORML v. DEA*, 559 F.2d at 742. Despite the judge's findings, the DEA refused to remove marijuana from Schedule I based on its view that it had no accepted medical use. *Id.* at 743.

In 1975, NORML filed a Petition for review, *id.* at 743, and this Court held that "placement in Schedule I does not appear to flow inevitably from lack of currently accepted medical use." *Id.* at 749. The court noted that medical use was only one factor which, under the CSA, must be balanced with other considerations including potential for abuse and danger of dependence. *Id.* Of significance, the court recognized possible treatment uses of marijuana and recommended further study of marijuana's medicinal potential. *Id.* The case was remanded once again for further findings from the Secretary. *Id.* at 757. After two years of inaction, the Secretary recommended to the DEA that marijuana remain in Schedule I and the petition was denied ten days later. See, *Annaliese Smith, Marijuana as a Schedule I Substance: Political Ploy or Accepted Science*, 40 Santa Clara L. Rev. 1137, 1154 (2000) (citing 1 *Marijuana, Medicine & the Law* at vi (R.C. Randall ed., 1988)). NORML appealed to this Court once again.

Following NORML's third request for review, this Court ordered the DEA to review the petition in its entirety, for HEW to make scientific and medical findings on all substances at issue, and for both government agencies to file quarterly progress reports with the court. *Id.* Thereafter, in the mid-1980's, the DEA finally called for public hearings on marijuana's proper classification, as

ordered by this Court seven years prior. *Id.* After two years of hearings, the DEA's own administrative law judge, ruled that marijuana should be transferred from Schedule I to Schedule II, based on evidence that a respectable minority of physicians accepted the medical uses of marijuana. *Id.* Notably, Judge Young stated that "it would be unreasonable, arbitrary and capricious for DEA to continue to stand between those sufferers and the benefits of the th[e] substance." See Arleen Hussein, *The Growing Debate on Medical Marijuana: Federal Power vs. States Rights*, 37 Cal. W.L. Rev. 369 (2001) (citing *Cannabis in Medical Practice: A Legal, Historical and Pharmacological Overview of the Therapeutic Use of Marijuana* 51-52 (1997)). However, the DEA once again rejected the judge's recommendation, this time requiring a greater showing to prove currently accepted medical use before approving such a transfer. See *Alliance for Cannabis Therapeutics v. DEA*, 930 F.2d 936, 938 (D.C.Cir. 1991). (7)

In the 1990s, the Alliance for Cannabis Therapeutics (ACT), together with NORML, challenged the DEA's decision by arguing, *inter alia* that three factors of the DEA's new test were impossible to meet due to marijuana's illegal status. *Id.* The petition was again remanded, but the DEA asserted that two of the three factors had not been relied upon, and the third was explained. See *Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131, 1134 (D.C.Cir. 1994). As a result, this Court upheld the DEA's rejection of the petition and application of a new five part test to determine currently accepted medical use:

- (1) the 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.

Id. at 1135. Although marijuana remained in Schedule I after final resolution of the NORML petition, the many decisions by this Court have resulted in greater precision in the statutory guidelines and a running sentiment of the Court that marijuana has medicinal value and should continue to be studied. Whereas the NORML petition was based on marijuana's medical use, Gettman's petition challenged Schedule I status on the ground that marijuana does not have a high potential for abuse. See *Gettman Petition (A4)*. Now, in light of the current scientific and medical record, Gettman also challenges the HHS and DEA findings that marijuana has no currently accepted medical use in treatment in the United States and lacks safety for use under medical supervision. As set forth below, a hearing is particularly critical with respect to these issues.

III. THE DEA'S CONCLUSION THAT MARIJUANA HAS A HIGH POTENTIAL FOR ABUSE WAS LEGALLY ERRONEOUS AND FACTUALLY UNSUPPORTED

A. The DEA Failed to Establish That Marijuana Has a High Potential For Abuse Compared to Other Scheduled Substances

Although the CSA does not provide a definition of "high potential for abuse," the statutory framework and language of §812(b) make clear that a substance must be compared to other scheduled substances in order to determine its level of abuse potential. See 21 U.S.C. 812(b). For example, Schedule I and II substances require a "high" potential for abuse, while Schedule III substances must have a potential for abuse "less than the drugs or other substances in schedules I and II." *Id.* at §812(b)(3) (emphasis added). Similarly, Schedule IV drugs must have "a low potential for abuse relative to the drugs or other substances in Schedule III," and Schedule V drugs must have "a low potential for abuse relative to the drugs or other substances in Schedule IV." *Id.* at §812(b)(4) and (5) (emphasis added). Thus, the statute clearly requires a comparison between scheduled substances in assessing marijuana's level of abuse potential. See *Consumer Product Safety Commission, et. al. v. GTE Sylvania, Inc. et. al.*, 447 U.S. 102, 107 (1980) ("the starting point for interpreting a statute is the language of the statute itself and, absent a clearly expressed legislative intent to the contrary, that language must ordinarily be regarded as conclusive").

Judicial review has confirmed that a comparative assessment of abuse potential is required under the statute. In *Grinspoon v. DEA*, 828 F.2d 881 (1st Cir.1987), the court held that the DEA had established MDMA's high potential for abuse after comparing it to other Schedule I and II substances and finding structural and pharmacological similarities. In so holding, the *Grinspoon* court noted that the CSA provides no definition of the phrase "high potential for abuse," but looked to the legislative history of §811(c)(1) for guidance. *Id.* at 893. The court found that Congress had set forth four alternative standards for determining when a substance possesses a "potential for abuse." *Id.* at 893 (citing Comprehensive Drug Abuse Prevention and Control Act of 1970, H.R. Rep.No.91-1444, 91st Cong., Sess. 1 (1970), reprinted in U.S.C.C.A.N. 4601). However, the court concluded that the passage from the legislative history "provides guidance only as to the minimum needed to show any potential for abuse (i.e. enough to justify a level of CSA control as low as placement in Schedule V)." *Id.*

The DEA argued that placement of MDMA in Schedule I was appropriate because he applied the "abuse potential" standards approved by Congress. *Id.* *Grinspoon* argued that the standards provided no guidance as to whether a substance has a "high" potential for abuse. *Id.* While agreeing with *Grinspoon*, (i.e. that the standards spoke merely to the existence of a minimal potential for abuse required for scheduling under the CSA), the court concluded that one of the four standards "makes it quite clear that the Administrator can permissibly reach a conclusion regarding a substance's level of potential for abuse by comparing the substance to drugs already scheduled under the CSA." *Id.* (emphasis added). The court held that the DEA had made the requisite comparison by

". . . offering several findings concerning the evidence of close structural and pharmacological similarity between MDMA and other substances, such as MDA, which already have been found to have a high potential for abuse and have been placed in Schedule I or II. The administrator also cited animal studies, human behavioral studies, and a survey of MDMA users which suggest that MDMA is related in its effects to Schedule I and II substances such as LSD, cocaine, mescaline, and MDA." *Id.* at 893-94 (internal citations omitted).

After determining that the DEA applied a permissible legal standard, the court held that the record contained substantial evidence of MDMA's high potential for abuse as compared to other scheduled substances. *Id.* (8)

Here, by contrast, the DEA and HHS failed to establish that marijuana has a "high" potential for abuse as compared to other scheduled substances. In fact, HHS conceded that "marijuana has relatively low levels of toxicity and physical dependence as compared to other illicit drugs." HHS Letter to DEA, 1-17-01 at A28. The only structural and pharmacological comparisons made by either agency were to other cannabinoid compounds. (9) First, HHS concluded that marijuana is structurally related to Dronabinol, a Schedule III drug; Nabilone, a Schedule II drug, and "all other cannabinoid compounds, which are listed as Schedule I. (10) Id. at A309. Similarly, the DEA concluded that preclinical and clinical experimental data demonstrate that marijuana and Dronabinol have similar abuse liabilities. See "Additional Scientific Evidence Considered by the DEA" at A352 (finding similarities in drug discrimination, self-administration, and subjective effects between marijuana and Dronabinol). Despite the agencies' common view that marijuana's abuse liability is most similar to Dronabinol (Marinol), neither agency explained why it should remain in Schedule I. Indeed, HHS' and the DEA's conclusions are consistent with Gettman's argument that marijuana does not have a greater dependence liability or potential for abuse than Dronabinol, which presently is a Schedule III substance. See Petition at A39.

Moreover, it should be noted that Gettman's petition requested the rescheduling not only of marijuana, but also of tetrahydrocannabinols, Dronabinol, and Nabilone. Despite the FDA's assurance, one year ago, that its evaluation of all substances was "in the final stages," See FDA Letter to Kennedy, 12-22-00 at A300, Gettman has yet to receive responses concerning the other cannabinoids. The DEA's failure to provide the responses is yet another example of its refusal to consider critical evidence or engage in the required comparative evaluation of marijuana's level of abuse potential. Indeed, a thorough review by HHS of the other cannabinoid substances will demonstrate that marijuana does not have a high potential for abuse as compared to those substances.

Rather than establish that marijuana has a level of abuse potential comparable to other Schedule I or II substances, HHS essentially concluded that it has a "high" potential for abuse because it is widely used, creates a hazard to some users' health, and because people are taking the substance on their own initiative. See HHS Letter to DEA, 1-17-01 at A331 ("the large number of individuals using marijuana on a regular basis and the vast amount of marijuana that is available for illicit use are indicative of widespread use). Not surprisingly, HHS provides no authority for the proposition that widespread use of a controlled substance constitutes a high potential for abuse. At most, the HHS and DEA findings establish that marijuana has a level of abuse potential that may be sufficient for Schedule V under the CSA. See Grinspoon, 828 F.2d at 893. Accordingly, the petition should be remanded for an evaluation of marijuana's abuse potential as compared to other controlled substances.

B. The DEA's Conclusion That Marijuana Has a High Potential for Abuse Was Arbitrary and Capricious Because It Did Not Weigh All Relevant Factors Under 21 U.S.C. 811(c)

In determining whether a substance has a high potential for abuse, the DEA may not select the factors it wishes to consider under §811(c) while ignoring others. As noted by this Court, "(a)side from the criterion of actual or relative potential for abuse, subsection (c) of section 201 lists seven other criteria * * * which must be considered in determining whether a substance meets the specific requirements specified in section 202(b) for inclusion in particular schedules * * *"). See *NORML v. DEA*, 559 F.2d 735 (D.C.Cir.1977) (quoting H.R.Rep.No.91-1444, supra p.14, pt. 1 at

4, reprinted in U.S.C.C.A.N. 1970, p.4602) (emphasis added). Among the factors to be considered is "the scope, duration and significance of abuse." 21 U.S.C. §811(c)(5).

According to the legislative history of §811(c)(5), "in reaching his decision, the Attorney General should consider the economics of regulation and enforcement attendant to such a decision. In addition, he should be aware of the social significance and impact of such a decision upon those people, especially the young, that would be affected by it." H.R. Rep. No.91-1444, supra p.14, pt. 1 at 4, reprinted in U.S.C.C.A.N. 1970, p.4603. However, neither the DEA nor HHS included consideration of the impact of marijuana arrests on specific sub-populations affected by its scheduling decision, including the young and individuals who use marijuana for therapeutic reasons. See Petition at A24-A29. Nor did either agency consider the impact of the scheduling decision on state governments and local jurisdictions who bear the costs of law enforcement, arrests, and corrections related to enforcement of marijuana laws. See Petition at A19-A23 and A24-A29. Finally, neither agency considered any research on the costs and benefits of alternative approaches to effective control of marijuana under the CSA in comparison to retention in Schedule I. Accordingly, the petition should be remanded for consideration of these issues under §811(c)(5).

IV. AS AN ALTERNATIVE GROUND TO DENY THE PETITION, THE DEA ERRONEOUSLY CONCLUDED THAT EVEN IF MARIJUANA DOES NOT HAVE A HIGH POTENTIAL FOR ABUSE, IT MUST REMAIN IN SCHEDULE I BECAUSE IT HAS NO CURRENTLY ACCEPTED MEDICAL USE AND LACKS SAFETY FOR USE UNDER MEDICAL SUPERVISION

A. Congress Expressly Required That All Three Criteria of 21 U.S.C. §812(b)(1) Must be Met To Include a Substance in Schedule I of the CSA

Despite the clear language of section 21 U.S.C. §812(b), which requires that Schedule I substances have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of safety for use under medical supervision, the Administrator concluded as follows:

"Even if one were to assume, theoretically, that your assertions about marijuana's potential for abuse were correct (i.e. that marijuana had some potential for abuse but less than the "high potential for abuse" commensurate with schedules I and II), marijuana would not meet the criteria for placement in schedules III through V since it has no currently accepted medical use in treatment in the United States — a determination that is reaffirmed by HHS in [its] . . . medical and scientific evaluation." DEA Letter to Gettman, 3-20-01 at A421.

In *NORML v. DEA*, 559 F.2d 735, however, this Court explicitly rejected the very same argument. As here, the Acting Administrator in *NORML* argued that placement in Schedule I is automatically required for substances that have no medical use in treatment in the United States. *Id.* at 747. After reviewing the language and legislative history of §§811 and 812, this Court concluded that the Administrator's argument was contrary to Congressional intent:

"Admittedly, Section 202(b), 21 U.S.C. §812(b), which sets forth the criteria for placement in each of the five CSA schedules, established medical use as the factor that distinguishes substances in Schedule II from those in Schedule I. However, placement in Schedule I does not appear to flow

inevitably from lack of a currently accepted medical use. Like that of Section 201(c), the structure of Section 202(b) contemplates balancing of medical usefulness along with several other considerations, including potential for abuse and danger of dependence. To treat medical use as the controlling factor in classification decisions is to render irrelevant the other "findings" required by Section 202(b). The legislative history of the CSA indicates that medical use is but one factor to be considered, and by no means the most important one."

Id. at 748 (emphasis added). Indeed, "a key criterion for controlling a substance, and the one which be used most often, is the substance's potential for abuse." Id. at n.58 (quoting H.R. Rep. No.91-1444, supra at p.14, pt.1, at 34, reprinted in U.S.S.C.A.N. 1970, p.4601).

Further, this Court noted that the "DEA's own scheduling practices support the conclusion that substances lacking medical usefulness need not always be placed in Schedule I." Id. at 748. For example, the Court cited the hearing testimony of the DEA's former Chief Counsel, Donald Miller, where he indicated that several substances listed in Schedule II, including poppy straw, have no currently accepted medical use. Id. (internal citations omitted). Clearly, the Administrator here, in denying Gettman's petition, was not mindful of his agency's prior scheduling practices when he stated:

"Congress established only one schedule û schedule I û for drugs of abuse with 'no currently accepted medical use in treatment in the United States' and 'lack of safety for use . . . under medical supervision.' To be classified in schedules II through V, a drug of abuse must have a 'currently accepted medical use in treatment in the United States.'" DEA Letter to Gettman, 3-20-01 at A4-A5 (internal citations omitted).

Based on this Court's holding in NORML, the DEA's attempt to dispense with a key criterion of 812(b) must be rejected and the petition should be remanded for an assessment of marijuana's level of abuse potential as compared to other scheduled substances.

B. The DEA's Conclusion that Marijuana Has No Currently Accepted Medical Use and Lacks Safety for Use Under Medical Supervision Was Arbitrary and Capricious Because It Did Not Weigh All Relevant Factors Under 21 U.S.C. 811(c)

The DEA's alternative argument is further flawed by its failure to consider all relevant factors under 811(c) in determining whether a substance has no currently accepted medical use in treatment in the United States and lacks safety for use under medical supervision. Among the requisite considerations is the "state of current scientific knowledge regarding the substance." 21 U.S.C. 811(c)(3)(emphasis added). With respect to this factor, Congress intended that "all scientific knowledge" be considered. H.R. Rep. No.91-1444, supra p.14, pt. 1 at 4, reprinted in U.S.C.C.A.N. 1970, p.4602. Despite the clear legislative intent, neither the DEA nor HHS considered the wealth of current scientific knowledge concerning marijuana's medical utility and safety.

Both agencies' assessments of marijuana's medical utility relied almost exclusively on the views exchanged at the 1997 "NIH Workshop on the Medical Utility of Marijuana," which occurred four years prior to the denial of Gettman's petition. See HHS Letter to DEA, 1-17-01, at A321; DEA "Additional Scientific Data" at A377. Citing the workshop, the DEA concluded:

"It has not been established that marijuana is effective in treating any medical condition. At this time, there is no body of knowledge to which a physician can turn to learn which medical condition in which patient will be ameliorated at which dosage schedule of smoked marijuana nor can he/she determine in which patient the benefits will exceed the risks associated with such treatment. The petitioner, therefore, is advocating that individuals become their own physician, a notion that even primitive man found unsatisfactory." DEA "Additional Scientific Data" at A376. (11)

During the past four years, however, there has been a sea change in evidence concerning marijuana's medical utility and safety, which the DEA and HHS have ignored. (12)

Since Gettman's petition was filed in 1995, eight states have passed laws affording legal protection to patients who use marijuana in the treatment of illnesses including arthritis, cachexia, cancer, chronic nervous system disorders, chronic pain, Crohn's disease, epilepsy and other disorders characterized by seizures, glaucoma, HIV and AIDS, multiple sclerosis and other disorders characterized by muscle spasticity, migraines, and nausea. (13) Not surprisingly, the DEA and HHS ignored the medical evidence and patient needs that supported enactment of these state laws.

C. The DEA and HHS Improperly Relied on Lack of FDA Approval to Conclude That Marijuana Has No Currently Accepted Use in Treatment in the United States and Lacks Safety for Use Under Medical Supervision

Rather than consider current evidence in evaluating marijuana's medical use and safety, the DEA and HHS blindly relied on marijuana's lack of FDA approval to maintain its Schedule I status. See HHS Letter to DEA, 1-17-01, at A331-32; DEA "Additional Scientific Data" at A420. However, the lack of FDA approval is not conclusive evidence that a substance has no currently accepted medical use in treatment or that it lacks safety for use under medical supervision. *Grinspoon v. DEA*, 828 F.2d at 886.

In *Grinspoon*, the Administrator issued a Notice of Proposed Rulemaking with regard to placing MDMA into Schedule I of the CSA. *Id.* at 883 (citing 49 Fed.Reg. 30, 210 (1984)). Following hearings, the Administrative Law Judge issued a comprehensive opinion finding that MDMA fit none of the three criteria required for placement in Schedule I. *Id.* at 884. The Administrator refused to accept the reasoning and scheduling recommendation of the ALJ because in his view, the phrases "currently accepted medical use in treatment in the United States" and "accepted safety for use . . . under medical supervision" both meant "that the FDA has evaluated the substance for safety and approved it for interstate marketing in the United States pursuant to the Federal Food, Drug, and Cosmetic Act of 1938 ("FDCA"), 21 U.S.C. §355." *Id.* Accordingly, the Administrator placed MDMA in Schedule I because it lacked FDA approval. *Id.*

Applying the standard of review announced in *Chevron*, *supra*, the *Grinspoon* court noted that Congress had not spoken directly to the proper means of interpreting the second and third criteria of § 812(b)(1). *Id.* However, the absence of express intent did not compel it to proceed to the deferential second step of *Chevron*. *Id.* at 885. After considering the language and structure of the CSA and FDCA, the legislative history of the CSA, and the "subsequent handiwork of Congress in the area of controlled substance regulation," the *Grinspoon* Court held that the Administrator's construction of §812(b)(1) was contrary to Congressional intent. *Id.* at 887. (14)

The court cautioned that "[b]lind reliance on the lack of FDA interstate marketing approval could cause a substance to be placed in Schedule I, even though one or two of the three requirements prescribed by Congress for placement in Schedule I have not been proven." *Id.* at 888.

Although the DEA and HHS here purport to have considered the eight factors of section 811(c) in determining that marijuana lacks medical use and safety, an examination of their findings and conclusions reveals that, in fact, they relied almost exclusively on lack of FDA approval to support their desired outcome. (15) Turning first to the HHS "findings and recommendations," the agency found that marijuana does not have a currently accepted medical use because "[t]he FDA has not approved a new drug application for marijuana," and lacks safety for use under medical supervision because "[t]here are no FDA-approved marijuana products." See HHS Letter to DEA, 1-17-01, at A331-32. Similarly, the DEA cited a statutory provision entitled "NOT LEGALIZING MARIJUANA FOR MEDICINAL PURPOSES" and took prominent note of its final declaration that "marijuana and other Schedule I drugs have not been approved by the Food and Drug Administration to treat and disease or condition." DEA "Additional Scientific Data" at A420 (citing Pub. L. No. 105-277, Div. F, 112 Stat. 2681-760 to 2681-761 (1998) (emphasis added by the Administrator). Such blind reliance on lack of FDA approval as a substitute for current scientific evidence should be rejected and the petition remanded for a proper consideration of the factors required by §811(c).

V. A HEARING IS REQUIRED TO RESOLVE FACTUAL CONTRADICTIONS IN THE RECORD AND TO AFFORD PETITIONERS THE OPPORTUNITY TO PRESENT CURRENT SCIENTIFIC AND MEDICAL EVIDENCE IGNORED BY THE DEA AND HHS

After more than five years without a response to their petition, Gettman and High Times Magazine wrote to HHS and requested the opportunity to comment on HHS' evaluation and to present evidence for its review. (A299). In light of the factual contradictions in the record, petitioners were "specifically interested that individuals who use marijuana medically be allowed to provide testimony for consideration and review by advisory panels." *Id.* In denying Gettman's petition without the opportunity for a hearing or a public notice and comment period, HHS stated:

"I note that the petitioner had the opportunity to submit any evidence he believed to be relevant when he submitted his petition. He appears to have availed himself of this opportunity since his petition exceeds 275 pages. In addition, the CSA requires that a rule by the DEA that adds a substance to a schedule, transfers a substance to a different schedule, or removes a substance from control must be made on the record after an opportunity for a hearing (see 21 U.S.C. 811(a)). Furthermore, FDA is not bound to consider only the evidence contained in the petition, but rather considers all relevant evidence in its medical and scientific evaluation. Thus, in developing a medical and scientific evaluation for the substances identified in Mr. Gettman's petition, the Agency is taking into account studies, reports and data that have become available since Mr. Gettman filed his petition with the DEA." See HHS Letter to Kennedy, 12-22-00 at A301.

HHS' view that Gettman had the opportunity to present all relevant evidence in 1995 ignores the fact that considerable medical and scientific evidence has been become available during its unreasonable delay in deciding the petition. Although Congress expressly provided that "[t]he evaluation and recommendations of the Secretary shall be . . . submitted to the Attorney General within a reasonable time," see 21 U.S.C. §811(b) (emphasis added), HHS did not make its

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recommendations to the DEA until five and one half years after the petition was filed. By denying petitioners a hearing after such unreasonable delay, HHS has effectively deprived petitioners of a meaningful opportunity to present current evidence relevant to the petition, particularly with respect to marijuana's medical use and safety, and to resolve factual contradictions in the record. This unfair result is exacerbated by HHS' own failure to consider the current medical and scientific records as well as the impact of Schedule I classification on other interested parties. See Arguments III.B and IV.B, supra.

Furthermore, HHS' response incorrectly suggests that hearings are limited to actual rulemaking proceedings. See HHS letter to Kennedy, 12-22-00 at A301(citing 21 U.S.C. 811(a)) (requiring that rule by the DEA that adds a substance to a schedule, transfers a substance to a different schedule, or removes a substance from control must be made on the record after an opportunity for a hearing). Such a limitation, however, is contrary to precedent established during the NORML litigation, where hearings were ordered after HHS recommended that marijuana remain in Schedule I. See Hearing on Petition to Reschedule Marijuana and Its Components, 51 Fed. Reg. 22946 (June 24, 1986) (codified at 21 C.F.R. pt 1308). There is no reason to treat this case differently, especially in light of the recent medical developments concerning marijuana, the great number of individuals impacted by marijuana's Schedule I status, and the rights of states governments to enact medical marijuana laws. Indeed, it has been fifteen years since hearings were held with respect to marijuana's proper scheduling.

CONCLUSION

Wherefore the reasons stated, petitioners respectfully request that the petition be remanded for an evaluation of marijuana's relative abuse potential as compared to other scheduled substances, and for meaningful consideration of all factors under section 811(c) in determining whether marijuana meets the three criteria of 812(b). Following a proper evaluation by HHS, petitioners request a public notice and comment period and hearings before an administrative law judge, which should include testimony from HHS and DEA officials, marijuana researchers, state government officials, patients, physicians, and other interested parties.

DATED: December 18, 2001 Respectfully Submitted,

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Footnotes:

(1) Subsequent to the filing of Gettman's petition, High Times Magazine was added as a petitioner. All references to Gettman throughout this brief should be deemed references to both Gettman and High Times Magazine as co-petitioners.

(2) To date, no responses have been received regarding Gettman's petition to reschedule tetrahydrocannabinols, Dronabinol and Nabilone.

(3) Since the petition was filed in 1995, Dronabinol has been rescheduled to Schedule III in a different proceeding initiated by its manufacturer. See Rescheduling of the Food and Drug Administration Approved Product Containing Synthetic Dronabinol, 64 Fed.Reg. 35928-30, (July 2, 1999) (to be codified at 21 C.F.R., pts. 1308).

(4) The prior marijuana rescheduling petition referred to throughout this brief was filed by the National Organization for Reform of Marijuana Laws (NORML) in 1972. The NORML Petition was ultimately resolved in 1994 following this Court's decision in Alliance for Cannabis Therapeutics v. DEA, 15 F.3d 1131 (D.C.Cir. 1994)

(5) Schedule II substances must have a high potential for abuse, a currently accepted medical use with severe restrictions, and abuse leading to severe psychological or physical dependence.

Schedule III substances must have a potential for abuse less than the drugs in Schedule I and II, a currently accepted medical use, and abuse of the drug leading to only moderate or low physical dependence or high psychological dependence.

Schedule IV substances must have a low potential for abuse relative to the drugs in Schedule III, a currently accepted medical use in treatment in the United States, and abuse leading to limited physical dependence or psychological dependence relative to the drugs in Schedule III.

Schedule V drugs contain low potential for abuse relative to the Schedule IV drugs, a currently accepted medical use in the United States, and abuse leading to limited physical dependence or psychological dependence relative to the Schedule IV substances. *Id.* at *812(b)(1)-(4).

(6) This classification is significant because Schedule I drugs may only be used for research purposes under strict guidelines. See 21 U.S.C. §823.

(7) The DEA's standard required that the following eight factors be met: (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. *Id.* (citing Schedules of Controlled Substances, 53 Fed. Reg. 5156 (1988) (codified at 21 C.F.R. pt. 1308)).

(8) Specifically, the Administrator made "46 numbered findings related to MDMA's similarity to other drugs with a high potential for abuse" which "were based on scientific evidence concerning the chemical structural similarity between MDMA and other Schedule I and II drugs; the pharmacological effects of MDMA and these other drugs; animal drug discrimination studies; animal self-administration studies; and recent studies of the neuro-toxic effects of MDMA and related drugs on rats." *Id.* (emphasis added).

(9) In addition, HHS desperately attempted to establish a similarity between marijuana and other drugs (cocaine, heroin, phencyclidine, and methamphetamine) by asserting that "marijuana abusers prefer inhalation, intravenous or intranasal routes rather than oral routes of administration." See HHS Letter to DEA, 1-17-01 at A309. Certainly, HHS would be hard pressed to provide any evidence that individuals snort or inject marijuana.

(10) As explained by HHS, Dronabinol is another name for Marinol. See HHS Letter to DEA, 1-17-01 at A309.

(11) The HHS also cited the Institute of Medicine's 1999 Report for the proposition that marijuana should continue to be studied for medical purposes, see HHS Letter to DEA, 1-17-01 at A321, but failed to note the Report's findings that cannabinoid drugs had therapeutic value for pain relief, control of nausea and vomiting, and appetite stimulation. See Institute of Medicine, *Marijuana and Medicine: Assessing The Science Base* at 2 (Janet E. Joy et al. eds., National Academy Press 1999).

(12) Given the DEA's six year delay in deciding the petition, Gettman has been unable to address the current scientific record, and requires a hearing to do so. See Argument IV, below.

(13) See Alaska Stat. $\text{\textcircled{0}}$ 17.37.010-17.37.080 & 11.71.090 (1999); Cal. Health & Safety Code $\text{\textcircled{0}}$ 11362.5(b)(1)(A) and (d); Colo. Const., Art. XVIII, $\text{\textcircled{0}}$ 14; Haw. S.B. 862, 20th Legis. (1999) (signed into law on July 12, 2000); Me. Rev. Stat. Ann., Tit. 22, $\text{\textcircled{0}}$ 2383-B(5) (2000); Nev. Const., Art. 4, $\text{\textcircled{0}}$ 38; Ore. Rev. Stat. $\text{\textcircled{0}}$ 475.300-475.346 (1999); Wash. Rev. Code $\text{\textcircled{0}}$ 69.51.010-69.51.080 (1997). In addition, pro-medical marijuana initiatives are underway in Arizona, Iowa, Maryland, Massachusetts, Minnesota, New Hampshire and New York.

(14) In holding that lack of FDA approval did not establish MDMA's lack of currently accepted medical use and safety, the Grinspoon court noted that a substance may fail to obtain FDA interstate marketing approval for any of seven specific reasons, only two of which are related to "safety" and "efficacy." *Id.* (citing 21 U.S.C. $\text{\textcircled{0}}$ 355(d)(1)-(7)).

(15) The remainder of HHS' and the DEA's support is derived from outdated data. See Argument III.B, *supra*. 1