United States Court of Appeals
For the First Circuit

No. 86-2007

LESTER GRINSPOON, M.D.,

Petitioner,

v.

DRUG ENFORCEMENT ADMINISTRATION,

Respondent.

PETITION FOR REVIEW OF ORDER OF
THE DRUG ENFORCEMENT ADMINISTRATION

Before

Coffin and Torruella, Circuit Judges,

and Pettine,*, Senior District Judge

Richard Cotton for petitioner.

Harry S. Harbin with whom William F. Weld, Assistant Attorney General, Criminal Division, Charles S. Sapho, Chief, Narcotic and Dangerous Drug Section, Dennis F. Hoffman, Chief Counsel, Drug Enforcement Administration, Stephen E. Stone, Associate Chief Counsel, Drug Enforcement Administration, and Charlotte A. Johnson, were on brief for respondent.

September 18, 1987

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*Of the District of Rhode Island, sitting by designation.

COFFIN, Circuit Judge. On November 13, 1986, the Administrator of the Drug Enforcement Administration ("DEA") issued a final rule placing the substance 3,4-methylenedioxymethamphetamine ("MDMA") into Schedule I of the Controlled Substances Act ("CSA"), 21 U.S.C. §§ 811, 812 (1987).[1] 51 Fed. Reg. 36,552 (1986). In reaching this decision, the Administrator found that MDMA met all three of the statutory requirements for classification as a Schedule I substance, namely,

> (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).

Dr. Lester Grinspoon, a psychiatrist and faculty member of the Harvard Medical School, petitions this court to review the final rule. Dr. Grinspoon seeks to conduct research on the therapeutic use of MDMA and believes that the imposition of Schedule I controls will effectively foreclose such research. He cites four reasons for vacating the Administrator's scheduling determination. The first

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1. The Act established five categories of substances whose manufacture and distribution are subject to federal control. The Act's initial scheduling of substances can be found in 21 U.S.C. § 811. These listings are subject to amendments and additions pursuant to 21 U.S.C. § 811. Substances placed into Schedule I are subject to the most severe controls and penalties imposed by the Act.

reason advanced is that the Administrator applied the wrong legal standards for "currently accepted medical use in treatment in the United States" and for "accepted safety for use . . . under medical supervision" in 21 U.S.C. § 812(b)(1). The other three reasons contained in Dr. Grinspoon's petition challenge the scheduling determination as arbitrary and capricious because (a) the Administrator's determination that MDMA had a "high" potential for abuse was flawed by his failure to articulate a legal standard and his reliance on insufficient record evidence; (b) the Administrator failed to give adequate weight to the evidence showing that placing MDMA into Schedule I would create a barrier to medical research on the drug; and (c) the rule is based upon incomplete and arbitrary recommendations from the Secretary of Health and Human Services. Petitioner urges this court to remand the case to the DEA with instructions to place the substance MDMA into Schedule III.

Although we are satisfied that these final three claims do not require us to overturn the rule, we believe that Dr. Grinspoon's first claim has considerable merit and requires us to remand the scheduling determination for reconsideration by the Administrator. After describing the administrative history of the rule, we shall consider each of petitioner's claims in turn.

I. Administrative History.

In January of 1984, the DEA prepared a document entitled "Schedule I Control Recommendation Under the CSA for 3,4-Methylenedioxymethamphetamine (MDMA)." The control recommendation, which was based upon information compiled from various DEA data

sources and scientific and medical literature, considered all three Schedule I criteria listed in section 812(b)(1) and concluded that (1) MDMA has a high potential for abuse; (2) MDMA has no known legitimate medical use for treatment in the United States; and (3) there is a lack of accepted safety for the use of MDMA under medical supervision. Based upon these findings, the DEA recommended that MDMA be placed into Schedule I of the CSA.

In March of 1984, pursuant to the procedures set out in the CSA, 28 U.S.C. 811(b),[2] the Administrator submitted the DEA's control recommendation to the Assistant Secretary for Health of the Department of Health and Human Services ("HHS") for scientific and medical evaluation and for an HHS recommendation as to whether MDMA should be controlled. The HHS evaluation was conducted by Dr. Charles Tocus, Chief of the Drug Abuse Staff of the Food and Drug Administration ("FDA"). Dr. Tocus stated in his affidavit that he searched the FDA files and found no reference to MDMA. Based upon this absence of information in the FDA files and a review of the information contained in the DEA control recommendation carried out by Dr. Tocus, HHS responded by making minor (typographical)

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2. 21 U.S.C. § 811(b) provides that

> The Attorney General shall, before initiating proceedings under subsection (a) of this section to control a drug or other substance . . . , 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.

corrections in the DEA's eight-factor analysis[3] and concurring in the recommendation that MDMA be placed into Schedule I.

Upon receiving the HHS evaluation and recommendation, the Administrator issued a Notice of Proposed Rulemaking with regard to placing MDMA into Schedule I of the CSA. 49 Fed. Reg. 30,210 (1984). Later, following the receipt of several comments and requests for a hearing, the Administrator referred the matter to an Administrative Law Judge ("ALJ") with instructions to "conduct a hearing for the purpose of receiving factual evidence and expert opinion regarding the proposed scheduling of MDMA." 51 Fed. Reg. 36,552 (1986). During the course of the hearing, the ALJ heard 33 witnesses and received 95 exhibits into evidence.[4] On May 22, 1986, the ALJ issued a comprehensive opinion finding that MDMA fit none of the three criteria

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3. Section 811(c) requires the Administrator to consider the following eight factors for each drug proposed to be controlled under the CSA:

> (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 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. § 811(c).

4. On July 1, 1985, while the hearing was proceeding, the Administrator placed MDMA into Schedule I of the Controlled Substances Act pursuant to the emergency scheduling provisions of the Act, 21 U.S.C. § 811(h)(1). 50 Fed. Reg. 23,118 (1985). The Administrator determined that this action was necessary to avoid an imminent hazard to the public safety. Id.

prerequisite to placement in Schedule I. Relying on the hearing testimony of experts in the health care community, the ALJ concluded that MDMA had an accepted medical use for treatment in the United States, 21 U.S.C. § 812(b)(1)(B), and an accepted safety for use under medical supervision, 21 U.S.C. § 812(b)(1)(C). The ALJ also found that the record did not establish that MDMA had a "high" potential for abuse. 21 U.S.C. § 812(b)(1)(A). The ALJ therefore recommended that MDMA be placed into Schedule III of the CSA.

The Administrator, however, declined to accept the reasoning and scheduling recommendation of the ALJ. In his October 13, 1986, decision, the Administrator held that the phrases "currently accepted medical use in treatment in the United States" and "accepted safety for use . . . under medical supervision" as used in the CSA, 21 U.S.C. § 812(b)(1), both mean 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. From these premises, the Administrator reasoned that because the FDA has not approved a new drug application ("NDA") or investigational new drug application ("IND") authorizing interstate marketing of MDMA under the FDCA, MDMA cannot be lawfully marketed and has neither a currently accepted medical use in treatment in the United States nor an accepted safety for use under medical supervision. Finally, the Administrator found that the DEA had sustained its burden of proving that MDMA has a high potential for abuse. The Administrator's final rule, effective November 13, 1986,

placed MDMA into Schedule I. Dr. Grinspoon appeals from this final rule under the CSA, 21 U.S.C. § 877.

II. Accepted Medical Use And Safety Under The CSA.

We turn first to petitioner's claim that the Administrator erred in interpreting the phrases "accepted medical use in treatment in the United States" and "accepted safety for use . . . under medical supervision" in section 812(b)(1) to mean, in essence, "approved for interstate marketing by the FDA under the FDCA." Before embarking on an analysis of that issue, however, we begin by explaining the appropriate standard of review in a case, such as this, where a court must assess an agency's interpretation of a statute it administers.

A. Standard of Review.

The Administrator argues correctly that we must review his interpretation of the CSA in light of the guidelines set forth by the Supreme Court in Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984). In Chevron the Court explained that a reviewing court 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 (emphasis supplied). 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; emphasis supplied).

It is undisputed that Congress has not directly spoken to the question at issue here, namely, the proper means of interpreting the second and third criteria of section 812(b)(1). The absence of express intent, however, does not compel us to proceed to the deferential second step of the Chevron scheme. As the Supreme Court indicated in a footnote to its Chevron opinion, "[i]f a court, employing traditional tools of statutory construction, ascertains that Congress had an intention on the precise question at issue, that intention is law and must be given effect." Id. at 843 n.9. Recently the Supreme Court has reaffirmed this proposition, holding in INS v. Cardozo-Fonseca, 107 S. Ct. 1207 (1987), that a court faced with a "pure question of statutory interpretation" should rely upon traditional methods of statutory construction in an attempt to determine the intent of Congress. Id. at 1221; International Union, UAW v. Brock, 816 F.2d 761, 764-65 (D.C. Cir. 1987) (applying "traditional tools" of statutory construction to invalidate agency's interpretation of statutory language as conflicting with intent of Congress).

The Administrator contends that congressional intent favoring his interpretation of the CSA can be gleaned from the language of

the statute, its legislative history, and the language and history of subsequent legislative enactments designed to enhance the regulatory system established by the CSA in 1970. In the alternative, he argues that if the intent of Congress is ambiguous, then his construction of the statute is permissible in view of the statutory scheme.[5] Our review of the sources identified by the litigants convinces us that Congress neither expressed nor implied an affirmative intent regarding how the second and third Schedule I criteria should be interpreted. Nevertheless, these same sources -- 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 -- lead us to conclude that the Administrator's construction of subsections 'B) and (C) of 21 U.S.C. § 812(b)(1) is contrary to congressional intent.[6]

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5. Contrary to the assertions of the Administrator, this is not a situation in which Congress has expressly vested the Administrator with authority to define general statutory criteria by issuing regulations. Were this such a case, such regulations would be controlling unless they were "arbitrary, capricious, or manifestly contrary to the statute." Chevron, 467 U.S. at 843-44. Here, the CSA expressly delegates to the Attorney General only the authority to make "the findings prescribed by subsection (b) of section 812 of this title for the schedule in which [a] drug is to be placed." 21 U.S.C. § 811(a)(1)(B) (emphasis supplied). This explicit delegation of authority to apply prescribed statutory criteria is not equivalent to an explicit delegation of authority to define those criteria.

6. Our review of the legislative sources below also convinces us that the Administrator's interpretation is unreasonable and would be invalid even under the second prong of the Chevron test. See International Union, UAW v. Brock, 816 F.2d at 765 n.6.

B. Statutory Language and Structure.

The Administrator begins by arguing that the language of the CSA itself is evidence of congressional intent favoring his construction of the statute. His argument is based on the definitions of terms chosen by Congress in drafting the relevant provisions of the CSA. He first cites the definition of the term "United States" as used in "accepted medical use in treatment in the United States." 21 U.S.C. § 812(b)(1)(B). This term is the only portion of the Schedule I criteria that Congress has expressly defined in the CSA, providing that "[t]he term 'United States,' when used in a geographic sense, means all places . . . subject to the jurisdiction of the United States." 21 U.S.C. § 802(28) (emphasis supplied). Coupling this statutory definition of "United States" with the dictionary definition of "accepted" -- which means "generally approved" or "generally agreed upon" -- the Administrator argues that the phrase "accepted medical use in treatment in the United States," 21 U.S.C. § 812(b)(1)(B), must contemplate an administrative determination that the substance has been "generally approved" for use in treatment in "all places" subject to United States jurisdiction. In other words, FDA interstate marketing approval is necessary to satisfy this criterion because, otherwise, the substance could not be deemed to be "generally approved" everywhere in the United States.[7]

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7. The Administrator does not confine this argument to section 812(b)(1)(B), but also states that "accepted safety for use . . . under medical supervision, 21 U.S.C. § 812(b)(1)(C), is equivalent to FDA approval because, otherwise, the safety of the substance could never be "generally agreed upon."

We find this argument to be strained and unpersuasive. The CSA's definition of "United States" plainly does not require the conclusion asserted by the Administrator simply because section 802(28) defines "United States" as "all places subject to the jurisdiction of the United States." 21 U.S.C. § 802(28) (emphasis supplied). Congress surely intended the reference to "all places" in section 802(28) to delineate the broad jurisdictional scope of the CSA and to clarify that the CSA regulates conduct occurring any place, as opposed to every place, within the United States. As petitioner aptly notes, a defendant charged with violating the CSA by selling controlled substances in only two states would not have a defense based on section 802(28) if he contended that his activity had not occurred in "all places" subject to United States jurisdiction. We add, moreover, that the Administrator's clever argument conveniently omits any reference to the fact that the pertinent phrase in section 812(b)(1)(B) reads "in the United States," (emphasis supplied). We find this language to be further evidence that the Congress did not intend "accepted medical use in treatment in the United States" to require a finding of recognized medical use in every state or, as the Administrator contends, approval for interstate marketing of the substance.

Nor does the dictionary definition of "accepted" offered by the Administrator convince us that Congress intended FDA approval to be the equivalent of the second and third Schedule I criteria. Use of the term "accepted" in sections 812(b)(1)(B) and 812(b)(1)(C) may indicate that Congress intended the medical use or safety of the

substance to be "generally agreed upon," but this alone does not inform us as to who must generally be in agreement. The Administrator reads "accepted" to mean that the FDA must have approved the drug for interstate marketing. Dr. Grinspoon, on the other hand, prefers to interpret "accepted" as meaning that the the medical community generally agrees that the drug in question has a medical use and can be used safely under medical supervision. Our conclusion is that the term "accepted" does not cure the statute's ambiguity. We are simply unable to extrapolate from the drafters' choice of the word "accepted" and thereby ascertain a general congressional intention favoring the interpretation advanced by the Administrator.

In another argument focusing upon the language of the statute, the Administrator urges us to adopt his interpretation of the CSA because it is entirely consistent with the interpretation of the phrase "accepted medical use in treatment in the United States" employed in the Commissioners' Notes to the Uniform Controlled Substances Act, §§ 203-12, 9 U.L.A. 221-35 (1979) ("Uniform CSA").[8] At first glance, this argument appears to have considerable merit. The Uniform CSA, like its federal counterpart, creates five schedules

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8. The Commissioners' Notes provide:

> Experimental substances found to have a potential for abuse in early testing will also be included in Schedule I. When those substances are accepted by the Federal Food and Drug Administration as being safe and effective, they will then be considered to have an accepted medical use for treatment in the United States, and thus, will be eligible to be shifted to an appropriate schedule based upon the criteria set out in Sections 205, 207, 209, and 211.

9 U.L.A. at 221.

of controlled substances and, indeed, was modeled on the federal CSA. 9 U.L.A. 187, 188 (1979).[9] But, while we agree that the Uniform CSA offers an interesting comparison, we fail to see how the interpretation of the Uniform CSA offered by the Commissioners has any bearing at all on the intent of Congress, which enacted the federal CSA prior to the creation of the Uniform CSA. We can only conclude, therefore, that this argument, despite its facial appeal, has no bearing on the claim that the language of the federal CSA evidences congressional intent to adopt the construction of the statute favored by the Administrator.

While the Administrator's arguments fail to persuade us that Congress affirmatively intended his construction of the CSA, we believe nevertheless that the language and structure of the two relevant statutes, the CSA and the FDCA, are helpful in determining whether the Administrator's interpretation squares with congressional intent. Although, as the District of Columbia Circuit has stated,"[t]he interrelationship between the two Acts [CSA and FDCA] is far from clear," National Organization for Reform of Marijuana Laws (NORML) v. DEA, 559 F.2d 735, 750 (D.C. Cir. 1977), we are persuaded that this interrelationship precludes the Administrator's reliance on the absence of FDA approval as a substitute for the second and third Schedule I criteria under the CSA.

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9. The Uniform CSA was approved for adoption by the states in 1970. To date, 48 states, the District of Columbia, Guam, and the Virgin Islands have adopted the Uniform CSA. 9 U.L.A. Supp. 123-24 (1986).

The CSA clearly provides that a substance may not be placed in Schedule I unless it lacks both a "currently accepted medical use in treatment in the United States" and "accepted safety for use . . . under medical supervision." The FDCA, on the other hand, provides that a substance may fail to obtain FDA interstate marketing approval (or exemption) for any of seven specific reasons. 21 U.S.C. § 355(d)(1)-(7). Although approval may be withheld because the substance lacks both "safety", 21 U.S.C. § 355(d)(2), and "efficacy" for a particular use, 21 U.S.C. § 355(d)(5), it is equally possible for a substance to be disapproved for interstate marketing because it lacks only one of these attributes, or because the application fails to contain relevant patent information, 21 U.S.C. § 355(d)(6), or even because the labeling proposed for the drug "is false or misleading in any particular." 21 U.S.C. § 355(d)(7). Thus, we find no necessary linkage between failure to obtain FDA interstate marketing approval and a determination that the substance in question is unsafe and has no medical use. Indeed, the FDCA does not even mention the term "medical use." In short, it is plainly possible that a substance may fail to obtain interstate marketing approval even if it has an accepted medical use.

Another possible reason for failure to obtain FDA new drug approval is that the manufacture, distribution, and use of a substance might not involve interstate marketing.[10] Unlike the CSA scheduling

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10. Indeed, Dr. Grinspoon argues that MDMA is a drug that has been legally manufactured and used only within a particular state. Petitioner's brief at 20.

restrictions, the FDCA interstate marketing provisions do not apply to drugs manufactured and marketed wholly intrastate. Compare 21 U.S.C. § 801(5) with 21 U.S.C. § 321(b), 331, 355(a). Thus, it is possible that a substance may have both an accepted medical use and safety for use under medical supervision, even though no one has deemed it necessary to seek approval for interstate marketing. Indeed, as Dr. Grinspoon argues, there is no economic or other incentive to seek interstate marketing approval for a drug like MDMA because it cannot be patented and exploited commercially. The prospect of commercial development, of course, is irrelevant to one who, like Grinspoon, seeks only to do research.

These considerations tend to indicate that the absence of FDA approval for interstate commerce does not foreclose the possibility that a substance might still possess an accepted medical use or even be considered safe for use under medical supervision. It appears, instead, that blind 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 of a drug in Schedule I have not been proven. Based solely on the language of the CSA and the FDCA, therefore, we find it unlikely that substituting the lack of FDA interstate marketing approval for the statutory requirements that a substance lack both an "accepted medical use" and "accepted safety for use . . . under medical supervision" is consistent with the intent of Congress in enacting the CSA. We turn now to consider whether the legislative history of the CSA confirms or rebuts this tentative conclusion.

C. Legislative History.

The Administrator purports to have identified portions of the CSA's legislative history that support his construction of the statutory language. First, he cites a passage from the House Committee Report that states:

> Under Reorganization Plan No. 1 of 1968 [reprinted in 1968 U.S. Code Cong. & Ad. News 4734] a Bureau of Narcotics and Dangerous Drugs has been established in the Department of Justice to regulate all these drugs (including legitimate importation, exportation, manufacture, and distribution) to prevent diversion from legitimate channels. Safety and efficacy will continue to be regulated under the Federal Food, Drug, and Cosmetic Act by [HHS].

H.R. Rep. No. 1444, 91st Cong., 2d Sess. (1970), reprinted in 1970 U.S. Code Cong. & Ad. News 4566, 4584 (hereinafter cited as "House Commitee Report"). From this, the Administrator draws the proposition that "Congress clearly intended that the 'safety and efficacy' of narcotic and dangerous drugs (e.g., whether such drugs are acceptable for medical use and safe for such use) be determined by [HHS] under the [FDCA]." Respondent's Brief at 17-18 (emphasis deleted). The Administrator's conclusion is objectionable, however, because his parenthetical comment -- equating a finding of "safety and efficacy" by the FDA with a finding of "accepted medical use" and "accepted safety for use . . . under medical supervision" -- is totally unsupported by the quoted passage from the House Committee Report. Nowhere does Congress equate "safety and efficacy" under the FDCA with the second and third Schedule I criteria contained in section 812(b)(1). This, indeed, is the point at issue in this litigation, and we are loath to accept such a disingenuous argument.

Second, the Administrator looks to the history underlying the legislative scheduling of the drug alphacetylmethadol in Schedule I for support. With regard to the scheduling of this substance, there is evidence that the Director of the Bureau of Narcotics and Dangerous Drugs represented to Congress that the FDA had not issued an NDA or an IND for alphacetylmethadol, and claimed that this lack of FDA approval settled the issue whether alphacetylmethadol had a "currently accepted medical use." Because Congress eventually did schedule alphacetylmethadol in Schedule I of the CSA, see 21 U.S.C. § 812, Schedule I(a)(3), the Administrator contends that it directly approved the statutory interpretation he advances today. We are unpersuaded, however, that this isolated instance -- with no indication of express congressional approval or even tacit reliance on the Director's statement -- is reason enough to defer to the Administrator's construction of the statute. Indeed, the impermissibility of substituting FDCA standards for CSA scheduling criteria becomes even more apparent when we compare the dearth of support in the legislative history for such an interpretation with the language and history of several subsequent legislative enactments in the controlled substance field.

D. Subsequent Legislation.

The Administrator has cited three subsequent legislative enactments as support for his position that Congress has approved his construction of the second and third criteria for Schedule I substances. Our review of these legislative enactments, however, leads us to find that the subsequent legislation tends to weaken,

not strengthen, the position espoused by the Administrator in this litigation. We can only conclude, despite the Administrator's claim that Congress has repeatedly approved his construction of the CSA, that Congress has never expressly or implicitly approved an interpretation of section 812(b)(1) that would direct findings of "no currently accepted medical use" and "lack of accepted safety for use . . . under medical supervision" whenever a substance lacked FDA interstate marketing approval. Rather, we are persuaded to the contrary that the subsequent enactments by Congress buttress our conclusion that the Administrator's construction of the CSA conflicts with congressional intent. To demonstrate why this is so, we shall review each of the three pieces of subsequently enacted legislation relevant to the current dispute in the paragraphs that follow.

First, in 1984, Congress amended the CSA to include an "emergency scheduling" provision. See 21 U.S.C. § 811(h). This provision allows the Attorney General to place certain substances into Schedule I on a temporary basis without regard to the regular scheduling criteria and procedures if such emergency scheduling is "necessary to avoid an imminent hazard to the public safety." 21 U.S.C. § 811(h)(1). This amendment to the CSA, however, expressly states that the Attorney General's authority to schedule substances in this expedited manner does not apply where an "exemption or approval is in effect for the substance under section 355 of this title,"[11] i.e.,

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11. 21 U.S C. § 355 is the section of the FDCA describing the standards and procedures for FDA interstate marketing approvals and exemptions.

where the FDA has permitted the substance to be marketed in interstate commerce. Id. The fact that Congress expressly authorized the Attorney General to use expedited procedures and rely upon the absence of FDA interstate marketing approval, rather than the usual Schedule I criteria, only in temporary emergency situations suggests to us that these shorthand methods are not appropriate in routine (i.e., nonemergency) situations such as the one before us in the instant case. We do not interpret the explicit reference to FDA approval in the "emergency scheduling" provision to mean, as the Administrator would have us believe, that Congress sought to permit blind reliance on FDA standards as a legitimate shortcut in the general run of cases.

Second, Congress amended the CSA again in 1986 when it enacted the Controlled Substance Analogue Enforcement Act, Pub. L. No. 99-570, §§ 1201-04, 100 Stat. 3207 (codified at 21 U.S.C. §§ 802(32)(A), 813). This amendment defines a "controlled substance analogue" as a substance having a chemical structure and effect on the central nervous system substantially similar to that of a Schedule I or II controlled drug. 21 U.S.C. § 802(32)(A). It provides that analogues of Schedule I and II controlled substances shall, to the extent intended for human consumption, be subject to the same controls and penalties as the controlled substances themselves. 21 U.S.C. § 813. As the Administrator points out, the provision expressly excludes from its definition of "controlled substance analogue," and hence from the scope of the amendment's substantive controls pending final scheduling, any substance for which there is an approved new drug application or an exemption for investigational use under section

355 of the FDCA. 21 U.S.C. § 802(32)(B)(ii), (iii). Again, however, we are unpersuaded by the Administrator's argument that explicit permission to rely on FDA standards in the case of analogues evidences congressional approval of his use of this shorthand method in all scheduling determinations. We believe instead that the authorization to impose Schedule I controls based on the lack of FDA approval, rather than satisfaction of the scheduling criteria set out in section 812(b)(1), in the unique situation of analogues intended for human consumption constitutes a special, and justifiable, exception to the general procedure mandated by section 812(b)(1). We believe, however, that in other cases involving nonanalogues, or analogues intended for uses other than human consumption, absolute reliance on the absence of FDA approval would be inappropriate and, indeed, contrary to the intent of Congress in enacting the CSA.

Third, in 1984, Congress legislatively placed the drug methaqualone in Schedule I. Despite its reputation as a widely abused substance, methaqualone was universally acknowledged to have an accepted medical use and had been approved for interstate marketing by the FDA. The House Committee Report concerning the scheduling of methaqualone stated:

> the [DEA] does not have authority to impose Schedule I controls on a drug which has been approved by the [FDA] for medical use. The statutory findings required for agency scheduling decisions clearly state that the agency may not, in the absence of Congressional action, subject drugs with a currently accepted medical use in the United States to Schedule I controls.

H.R. Rep. No. 534, 98th Cong., 2d Sess. 4 (1984), reprinted in 1984 U.S. Code Cong. & Ad. News 540, 543. The Administrator cites this passage in yet another attempt to demonstrate congressional approval of his position that a substance cannot have an accepted medical use unless the FDA has already approved it for interstate marketing. In fact, however, the actions of Congress with respect to methaqualone demonstrate at most the converse of this proposition: that FDA approval precludes scheduling of a substance in Schedule I. In other words, the methaqualone legislation demonstrates Congress' belief that FDA approval is sufficient to establish the existence of an accepted medical use, but not that the lack of FDA approval -- the issue in this case -- necessarily negates the possibility that the substance in question has an accepted medical use and is safe for use under medical supervision. We therefore do not find the methaqualone legislation to be persuasive authority for the proposition that the Administrator's interpretation of section 812(b)(1) is consistent with congressional intent.

E. Need For A Meaningful Hearing.

We believe there is yet one additional policy reason, no doubt related to some of the other factors already discussed, for rejecting the construction of the CSA advanced by the Administrator as contrary to congressional intent. Under the statutory scheme set up by Congress, the Attorney General may not schedule a substance under the CSA without first obtaining the recommendation of the FDA, through its parent agency, HHS, 21 U.S.C. § 811(b), and providing an "opportunity for a hearing pursuant to the rulemaking procedures

prescribed by [the Administrative Procedure Act]." 21 U.S.C. § 811(a). It is plain, therefore, that while Congress intended the recommendation of HHS to have significant weight in the decisionmaking process, it also intended that there be an opportunity for a meaningful hearing after receipt of the HHS report. It would surely be anomalous if the FDA's recommendation, based solely on the absence of approval for interstate marketing, sufficed to determine the ultimate conclusion prior to the hearing.

If we were to accept the Administrator's construction of section 812(b)(1) in this case, the opportunity for a meaningful hearing would be lost, and satisfaction of the "accepted medical use" and "accepted safety" criteria would turn solely on the existence of FDA approval for interstate marketing. A hearing on issues of the sort required by the statute -- Does the substance have an accepted medical use in treatment in the United States? Is the substance safe for use under medical supervision? -- would be reduced to an empty formality and, for participants like Dr. Grinspoon, would amount to an exercise in futility. We hesitate to interpret the CSA in a manner that would cause its important provision requiring a administrative hearing to be meaningless as to two of the three requirements for scheduling a substance in Schedule I. We believe instead that, for the hearing opportunity to be a significant one on these issues, the agency must remain flexible enough to weigh and consider claims raised at the administrative hearing to the effect that a substance has an accepted use and is accepted as safe even though it is not approved for distribution in interstate commerce.

The importance of a meaningful hearing prior to scheduling can best be appreciated when one considers those situations for which Congress has permitted the Administrator to regulate substances in the absence of a hearing. Neither the emergency scheduling provision, 21 U.S.C. § 811(h), nor the provision for treatment of controlled substance analogues, 21 U.S.C. § 813, requires the Administrator to hold a hearing prior to taking regulatory action. Congress crafted both of these sections to serve as stop-gap measures to be employed pending a final scheduling determination by the DEA, following a full evidentiary hearing, for the substance in question. Significantly, it is only in these provisions for temporary controls pending final scheduling that Congress has emphasized the absence of FDA interstate marketing approval, 21 U.S.C. § 811(h)(1) (emergency scheduling provision); 21 U.S.C. § 802(32)(B)(ii), (iii) (controlled substance analogue act). In the case of emergency scheduling, it appears that Congress has already done the balancing and determined that the risk of ongoing abuse amounting to an "imminent hazard to the public safety" justifies temporary scheduling without a hearing in the absence of FDA approval. Likewise in the latter case, Congress has responded to the need for expedited investigation and prosecution of "clandestine chemists who develop subtle chemical variations of controlled substances (called analogues or 'designer drugs') for illicit distribution and use," H.R. Rep. No. 848, 99th Cong., 2d Sess., pt. 1, 2 (1986), and permitted Schedule I controls to take effect without first requiring a hearing so long as FDA approval is lacking. Thus, in both "emergency" situations for which Congress

has seen fit to place particular weight on the absence of FDA interstate marketing approval, it has also determined that a hearing procedure is unwarranted. Clearly, this is not the case in the general administrative scheduling proceedings and the hearing requirement should be given full effect rather than being shortcircuited by blind reliance on the absence of FDA approval.

F. Conclusion.

For the reasons listed above, we conclude that the Administrator erroneously applied an interpretation of the "accepted medical use in treatment in the United States" and "accepted safety for use . . . under medical supervision" criteria of section 812(b)(1) that directly conflicts with congressional intent. We therefore vacate the Administrator's determination that MDMA should be placed in Schedule I of the CSA and remand the rule for further consideration by the DEA. On remand, the Administrator will not be permitted to treat the absence of FDA interstate marketing approval as conclusive evidence that MDMA has no currently accepted medical use and lacks accepted safety for use under medical supervision.

Petitioner Grinspoon has offered his own theory concerning the type of inquiry the Administrator must make under the statute. He urges us to adopt a standard for the second and third criteria that is based upon the opinion of members of the medical community. He contends that Congress drafted the CSA with this type of standard in mind. To support this contention, Grinspoon cites the testimony of two representatives of the Bureau of Narcotics and Dangerous Drugs ("BNDD"), DEA's predecessor agency, during legislative consideration

of Pub. L. No. 91-513, the Comprehensive Drug Abuse Prevention and Control Act of 1970. Michael R. Sonnenreich, Deputy Chief Counsel of the BNDD, testified that drugs in Schedule I would "have no medical use as determined by the medical community," and that "the medical community" would decide "whether or not the drug has [a] medical use . . . ." Hearings on Drug Abuse Control Amendments Before the Subcomm. on Public Health and Welfare of the House Comm. on Interstate and Foreign Commerce, 91st Cong., 2d Sess. 696, 718 (1970) ("House Hearings"). Likewise, John Ingersoll, Director of the BNDD, testified that substances placed in Schedule I would be those drugs that "the medical profession has already determined to have no legitimate medical use in the United States." House Hearings at 678.

While we acknowledge that the statements by the BNDD witnesses before the House Subcommittee tend to support Dr. Grinspoon's position, we do not believe they are entitled to much weight as indicia of congressional intent in fashioning the "accepted medical use" and "accepted safety for use . . . under medical supervision" criteria. See McCaughn v. Hershey Chocolate Co., 283 U.S. 488, 493-94 (1931) ("statements . . . made to committees of Congress . . . are without weight in the interpretation of a statute"). This is especially true where, as here, there is no indication whatsoever in either the legislative history or the history of any subsequent amendments that Congress concurred with the views expressed by the witnesses. In short, we do not find Grinspoon's evidence to be persuasive on the issue of affirmative congressional intent to have certain members of the medical community determine whether a substance

has an "accepted medical use in treatment in the United States" or "accepted safety for use . . . under medical supervision.".

The nature of our review further constrains us from requiring the Administrator to adopt Dr. Grinspoon's proposed construction of section 812(b)(1). Although we find that the Administrator's present interpretation of the second and third Schedule I criteria contravenes congressional intent, we are unable to ascertain with any certainty what Congress intended to be the proper interpretation of subsections (B) and (C). In other words, while we are satisfied that Congress intended to preclude reliance on the absence of FDA approval in assessing whether a substance has an "accepted medical use" and "accepted safety for use . . . under medical supervision," we have found nothing to indicate how Congress affirmatively intended these two ambiguous statutory phrases to be construed and applied. It appears to us that Congress has implicitly delegated to the Administrator the authority to interpret these portions of the CSA, and we must therefore refrain from imposing our own statutory interpretation upon the agency. Chevron, 467 U.S. at 843. Hence, to avoid unduly infringing upon the Administrator's legitimate discretion to develop a legally acceptable standard -- i.e., one that does not conflict with the intentions of Congress, and makes sense in light of the statutory language, the legislative history, and the purposes of the entire legislative scheme -- we remand the rule to the Administrator for reconsideration and for further proceedings not inconsistent with this opinion.

III. Challenges Based on "Arbitrary and Capricious" Standard.

Although a remand is necessary due to our above holding, we nonetheless feel compelled to address the other issues raised in Dr. Grinspoon's petition because they are likely to arise again when the Administrator reconsiders the rule.

A. "High" Potential For Abuse.

In addition to the "accepted medical use" and "accepted safety" criteria discussed above, the CSA also requires substances identified for placement in Schedule I to have a "high potential for abuse." 21 U.S.C. § 812(b)(1)(A). Dr. Grinspoon contends that the Administrator's placement of MDMA in Schedule I is arbitrary and capricious because the Administrator failed to articulate a legal standard for assessing MDMA's potential for abuse and because the evidence in the record is insufficient to support a finding that MDMA has a "high" potential for abuse. While conceding that MDMA has some potential for abuse, and therefore should be scheduled under the CSA, Dr. Grinspoon insists that the Administrator has not proved, as he must for a Schedule I substance, that MDMA's potential for abuse is high.

1. Legal Standard.

The CSA provides no definition of the phrase "high potential for abuse," but both parties agree that the legislative history of the statute provides guidance in this regard. Specifically, the report of the House Committee on Interstate and Foreign Commerce accompanying the bill that eventually became the CSA sets forth four alternative legal standards for determining when a substance

possesses a "potential for abuse." Borrowing from regulations promulgated under the FDCA, the House Committee Report provides that the Administrator may determine a substance has potential for abuse if:

> (1) There is evidence that individuals are taking the drug or drugs containing such a substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or of the community; or
>
> (2) There is significant diversion of the drug or drugs containing such a substance from legitimate drug channels; or
>
> (3) Individuals are taking the drug or drugs containing such a substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs in the course of his professional practice; or
>
> (4) The drug or drugs containing such a substance are new drugs so related in their action to a drug or drugs already listed as having a potential for abuse to make it likely that the drug will have the same potentiality for abuse as such drugs, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.

House Committee Report, supra, at 4601. The Committee Report goes on to state that "potential for abuse" exists only when there is "a substantial potential for the occurrence of significant diversions from legitimate channels, significant use by individuals contrary to professional advice, or substantial capability of creating hazards to the health of the user or the safety of the community." House Committee Report, supra, at 4602.

The Administrator argues that he applied the standards expressly approved by Congress, but Dr. Grinspoon complains that the Administrator articulated no standard for showing that MDMA had a relative potential for abuse sufficient to warrant placement in Schedule I. As Grinspoon notes, the passage from the legislative history quoted above provides guidance only as to the minimum needed to show any potential for abuse, in other words, enough to justify a level of CSA control as low as placement in Scedule V. It offers no guidance for assessing whether a substance should be subject to Schedule I controls, the strictest imposed under the CSA, which require a "high" potential for abuse. For this, argues Grinspoon, the Administrator must prove that MDMA has a high potential for abuse relative to other scheduled substances and must base its proof on existing levels of actual abuse "on the streets."

While we acknowledge that the Administrator's final rule is silent with respect to the legal standard required for a finding of "high" potential for abuse, we do not find the Administrator's action to be arbitrary and capricious. The fourth standard contained in the segment of the Committee Report quoted above 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. Here the Administrator has done just that, offering several findings concerning the evidence of close structural and pharmacological similarity between MDMA and

other substances, such as MDA,[12] which already have been found to have a high potential for abuse and have been placed in Schedule I or II. 51 Fed. Reg. 36,555-57 (1986). 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.[13] We believe this approach to ascertaining MDMA's potential for abuse is entirely consistent with the statutory scheme developed by Congress and therefore hold that the Administrator's method is not arbitrary and capricious.[14] The question remains, of course, whether the evidence

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12. "MDA" is 3,4-methylenedioxyamphetamine and, like MDMA, belongs to a class of compounds known as phenethylamines or, more narrowly defined, phenylisopropylamines or amphetamines.

13. The Administrator also considered that the United Nations Commission on Narcotic Drugs has placed MDMA in Schedule I of the Convention on Psychotropic Substances and that MDMA occupies the same schedule in the Canadian Food and Drug Act as MDA and LSD. 51 Fed. Reg. 36,559 (1986).

14. In addition to the evidence comparing MDMA to other substances with a high potential for abuse, the Administrator also considered evidence related to the "actual" abuse of MDMA and made several findings in this regard. See 51 Fed. Reg. 36,557 - 36,558 (1986). These findings reveal, among other things, that: (1) between 1972 and April 1985, DEA laboratories identified 41 exhibits of MDMA, consisting of 60,000 dosage units; (2) from July 1985, when MDMA was temporarily placed in Schedule I pursuant to the Administrator's emergency scheduling powers, up to the time that the final rule was promulgated, 14 MDMA exhibits, consisting of 35,000 dosage units, had been identified by DEA laboratories; (3) DEA has encountered five laboratories capable of clandestinely producing kilogram quantities of MDMA; (4) the estimate of one DEA witness is that street distribution of MDMA has increased from 10,000 dosage units in 1978 to 30,000 dosage units per month in 1985; (5) according to Dr. Grinspoon himself, MDMA is being taken by a growing number of people, particularly students and young professionals, in a casual and recreational manner; and (6) MDMA is reported to have been associated with two overdose deaths.

Dr. Grinspoon attacks these findings of actual abuse, focusing

collected by the Administrator is sufficient to justify his conclusion that MDMA has a high potential for abuse. Since Dr. Grinspoon has also challenged this aspect of the scheduling determination as arbitrary and capricious, we turn next to a discussion of this issue.

2. Substantial Evidence.

In reviewing the Administrator's conclusion regarding MDMA's potential for abuse, we must determine whether it is 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, 522-23 (1981) (quoting Universal Camera Corp. v. NLRB, 340 U.S. 474, 477 (1951)). The Court has

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(cont.)

on the need to assess the relative level of actual abuse and stressing what he perceives as the current low level of MDMA abuse "on the streets." For example, Grinspoon notes in his brief that the statistics above concerning the 41 evidentiary exhibits identified as MDMA during the period 1972-1985 are insignificant when one considers that MDMA accounted for only one ten-thousandth of all DEA exhibits compiled during this period. Likewise, the five laboratories with the potential to manufacture MDMA account for only a minute fraction of the 2400 laboratories seized by the DEA from 1972-1983. Furthermore, Grinspoon challenges the finding that MDMA has been associated with overdose deaths as "seriously suspect."

While we appreciate Dr. Grinspoon's point that MDMA abuse is low relative to other drugs that seem to be more popular "on the street," we do not believe that this fact precludes the Administrator from finding that MDMA has a high potential for abuse. Grinspoon's argument overlooks the importance of the term "potential" in section 812(b)(1)(A) and runs contrary to the explicit intent of Congress that the Administrator "not be required to wait until a number of lives have been destroyed or substantial problems have already arisen before designating a drug as subject to the controls of the bill." House Committee Report, supra, at 4602. So long as the Administrator can marshal substantial evidence to demonstrate that MDMA is sufficiently similar to scheduled drugs with a "high potential for abuse," we will sustain his determination regardless of existing levels of actual abuse.

further explained this lenient standard of review, stating that "'the possibility of drawing two inconsistent conclusions from the evidence does not prevent an administrative agency's findings from being supported by substantial evidence.'" Id. (quoting Consolo v. Federal Maritime Commission, 383 U.S. 607, 620 (1966)). In other words, "[e]ven if reasonable minds could also go the other way, we 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).

The question before us, therefore, is whether there is substantial evidence in the administrative record to support the Administrator's determination that MDMA is "so related in [its] action to a drug or drugs already listed as having a [high] potential for abuse" that it is likely MDMA "will have the same potentiality for abuse as such drugs." House Commitee Report, supra, at 4601. In support of his conclusion, the Administrator made 46 numbered findings related to MDMA's similarity to other drugs with a high potential for abuse. These findings were based on scientific evidence concerning the chemical structural similarity between MDMA and other Schedule I and II drugs; the similar pharmacological effects of MDMA and these other drugs; animal drug discrimination studies; animal self-administration studies; and recent studies of the neurotoxic effects of MDMA and related drugs on rats. Based on this evidence, the Administrator found, among other things, that (1) MDMA is the N-methyl analogue of MDA and retains the psychomimetic properties of MDA; (2) MDMA produces pharmacological effects in common with

both central nervous system ("CNS") stimulants like amphetamine and hallucinogens like MDA in animals; (3) MDMA and MDA produce the same spectrum of pharmacological effects in mice, dogs, and monkeys when observed during toxicity studies; (4) MDMA, like MDA, amphetamine, and methamphetamine, produces neurotoxic effects when administered to animals; (5) MDMA and MDA may both produce the same neurotoxic effects to serotonergic nerves in humans; (6) in drug discrimination tests, rats trained to recognize amphetamine also recognized MDA and MDMA, and rats trained to recognize MDA also recognized MDMA; (7) based on recent tests involving human subjects, MDMA can be described as maintaining the same potency as MDA, but exhibiting subtle differences in the qualitative nature of the intoxication.

Dr. Grinspoon, in an item-by-item analysis contained in the proposed findings of fact and conclusions of law he submitted to the DEA, calls into question many of the Administrator's findings concerning MDMA's similarity to other drugs with a high potential for abuse. For instance, Grinspoon agrees that MDMA is a member of a family of psychoactive drugs, but disputes the validity of the inference drawn from the similarity by the Administrator. According to Grinspoon, "chemical similarity is not necessarily a good guide to the actual effects of a compound in the human body." Petitioner's Brief at 37. Grinspoon notes that of the 28 known phenethylamines, 17 were not scheduled under the CSA as late as December 1983. Even a subsequent review of these 17 substances by the World Health Organization's Expert Committee on Drug Dependence resulted in a recommendation that only nine of the substances be scheduled by

member nations. Eight were thought harmless enough to remain unscheduled.[15] Also, referring to the Administrator's finding that MDMA, like MDA and amphetamine, is a central nervous system stimulant, Grinspoon asserts that this evidence of pharmacological similarity proves nothing. Several other substances also fit this description, including caffeine and six of the eight phenethylamines that are neither currently controlled nor recommended for control by WHO. Based on this, Grinspoon concludes that the mere fact that a substance is a CNS stimulant does not necessarily imply that it has a high potential for abuse.

In addition, Dr. Grinspoon (1) attacks the Administrator's other findings concerning MDMA's LD-50 rating[16] as being irrelevant to the "potential for abuse" inquiry; (2) discounts the importance of findings that MDMA is neurotoxic when administered to rats; (3) questions the relevancy of the findings related to animal drug discrimination studies; and (4) asserts that the Administrator has incorrectly interpreted the results of two animal self-administration studies. We have reviewed Dr. Grinspoon's item-by-item analysis closely, but find no basis sufficient to overturn the Administrator's decision. Grinspoon's reinterpretation of the scientific evidence before the agency surely demonstrates that the available evidence does not inexorably lead to a conclusion that MDMA is similar to

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15. These eight are clobenzorex, fenbutrazate, furfenorex, morazone, para-oxyamphetamine, 4-bromo-2,5-dimethoxyphenethylamine, N,N-dimethylamphetamine, and N-ethyl-3,4-methylenedioxyamphetamine.

16. "LD-50" signifies the dose of a given drug that will kill 50% of the animals treated with that dose.

drugs possessing a high potential for abuse. But, faced with such uncertainty, we must defer to the conclusion reached by the Administrator, even if we may have favored Dr. Grinspoon's approach had we studied the evidence in a de novo fashion. In reaching this conclusion, we follow the well-established maxim that "[w]here the agency presents scientifically respectable evidence which the petitioner can continually dispute with rival, and we will assume, equally respectable evidence, the court must not second-guess the particular way the agency chooses to weigh the conflicting evidence or resolve the dispute." Asarco, Inc. v. OSHA, 746 F.2d 483, 490 (9th Cir. 1984) (quoting United Steelworkers of America v. Marshall, 647 F.2d 1189, 1263 (D.C. Cir. 1980), cert. denied, 453 U.S. 913 (1981)). We find this maxim to have particular force in a case such as this because, as one court has explained, "[a]ppellate courts have neither the expertise nor the resources to evaluate complex scientific claims." Thompson Medical Co. v. FTC, 791 F.2d 189, 196 (D.C. Cir. 1986), cert. denied, 107 S. Ct. 1289 (1987).

B. Impact Of Scheduling On Research.

Dr. Grinspoon also takes issue with the Administrator's alleged failure to consider evidence tending to show that placement of MDMA in Schedule I would strongly discourage medical research on the drug. Grinspoon contends that failure to consider the impact of a scheduling decision on legitimate research amounts to arbitrary and capricious action on the part of the Administrator because he did not weigh all relevant factors in making his decision. Motor Vehicle Manufacturers Association v. State Farm Mutual Insurance Co., 463 U.S. 29, 42-43

(1983). To buttress his contention, Grinspoon recites a litany of legal, administrative, and practical obstacles that hinder researchers seeking to conduct experiments with Schedule I drugs. These obstacles include mandatory FDA approval of research involving Schedule I substances, 21 C.F.R. § 1301.42(a)-(c); mandatory special registration with the DEA, 21 C.F.R. §§ 1301.33, 1301.42; mandatory reporting and security procedures beyond those required for drugs placed in Schedules II through V; unavoidable bureaucratic delays; and other adverse impacts due to the grave concern caused by a substance's placement in Schedule I, such as difficulty in obtaining volunteers for clinical studies and, for academic researchers, difficulty in securing approval from institutional review boards.

Again, we do not doubt that Dr. Grinspoon has correctly identified several ways in which the placement of MDMA in Schedule I will impede his research and the efforts of other researchers interested in exploring the possibility of clinical uses for MDMA. We must conclude, nevertheless, that the existence of such hurdles does not render the Administrator's scheduling decision arbitrary and capricious. First, it is simply untrue that the Administrator failed to consider the impact on medical research that would be caused by a decision to place MDMA in Schedule I. In the final rule, the Administrator states explicitly that he "read with interest the comments from various parties in the record concerning the effect placement of MDMA into Schedule I would have on legitimate research into the substance." 51 Fed. Reg. 36,559 (1986). After several paragraphs discussing the contours of the additional Schedule I

controls, the Administrator concludes that "those who wish to conduct research with MDMA have available avenues by which to pursue such research." Id.

Second, and more importantly, Dr. Grinspoon has identified nothing in the CSA, its legislative history, or its implementing regulations that can be read to require the Administrator to consider the impact of a scheduling determination upon legitimate scientific research. From our review of the CSA, we can only conclude that Congress has already weighed the costs and benefits of legitimate research on dangerous drugs and has determined, in a categorical manner, that if the three Schedule I criteria are satisfied, see 21 U.S.C. § 812(b)(1), then the substance should be subject to Schedule I controls even if this action will create administrative and other burdens for researchers. Here there is no dispute that the Administrator considered all of the section 812(b)(1) criteria in arriving at his final rule, so we are left with a situation in which there can be no complaint that the Administrator failed to consider any relevant factor.

C. Reliance Upon HHS Evaluation And Recommendation.

Dr. Grinspoon's final dissatisfaction with the final rule is the Administrator's alleged reliance on the conclusions recommended by HHS on the criteria enumerated in section 812(b)(1). Grinspoon argues that the determination by the Secretary of HHS was arbitrary and capricious and not in accordance with law, and that all relevant scientific and medical evidence was not before the Secretary at the time of the determination. The record, in fact, reveals that HHS

performed in a less than admirable fashion in making its recommendation to the Administrator. The record indicates that HHS failed to look beyond its own files upon receiving the Admistrator's section 811(b) request for a scientific and medical evaluation; neglected to consult any organization of medical professionals or even the FDA's own panel of experts, the Drug Abuse Advisory Committee; and simply rubber-stamped the Administrator's conclusion by adopting the section 811(c) eight-factor analysis already performed by the DEA. There is also evidence that FDA analysts failed to forward a letter received from the National Institute of Drug Abuse, which stated that the evidence cited by the DEA did not support the existence of abuse potential in animals, to either the FDA Commissioner or the Assistant Secretary of HHS prior to the issuance of the HHS recommendation to the Administrator.[17]

Despite these alleged procedural shortcomings, we fail to see how the procedure followed by HHS tainted the Administrator's determination. The CSA does not specify the steps to be taken by HHS; it simply requires the Administrator to request from the Secretary of HHS a scientific and medical evaluation. 21 U.S.C. § 811(b). Moreover, the HHS recommendation to schedule a substance

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17. Dr. Grinspoon also complains that the Acting Assistant Secretary of Health concluded erroneously that MDMA had a "high" potential for abuse because the recommendation of FDA's Deputy Commissioner described MDMA's potential for abuse as "significant," rather than "high." In light of the fact that the FDA Deputy Commissioner recommended placement of MDMA in Schedule I, we attribute no significance to this semantic argument.

is not binding[18] and, indeed, serves to trigger an administrative hearing at which interested persons may introduce evidence to rebut the Secretary's scheduling recommendation. Ultimately, of course, responsibility rests with the Administrator, not HHS, to ensure that the final rule rests on permissible legal standards and substantial evidence. It is true that the Administrator twice mentioned the HHS recommendation in his final rule, once in relation to the "accepted medical use" criterion and once in relation to the "high potential for abuse" criterion. With regard to the first mention, however, we have already determined that this aspect of the case must be remanded and reconsidered because the Administrator interpreted the statutory language in a manner that is contrary to the intent of Congress. Because, on remand, the Administrator will not be able to rely on lack of FDA approval to demonstrate the absence of an accepted medical use, we need not discuss any possible reliance on the HHS recommendation regarding the absence of an accepted medical use. With regard to the second mention, we believe that the Administrator's conclusion that MDMA has a high potential for abuse is amply supported by a substantial amount of independent evidence. Because we believe that the Administrator's finding with regard to MDMA's potential for abuse is justified even in the absence of the

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18. According to section 811(b), the HHS recommendation is binding as to "scientific and medical" matters, but not with respect to the appropriate schedule in which to place a particular substance. The exception to this rule is that, "if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance." 21 U.S.C. § 812(b) (emphasis supplied).

HHS recommendation to place MDMA in Schedule I, we hold that any reliance on the HHS evaluation by the Administrator constitutes, at most, harmless error.

For the foregoing reasons, the rule is vacated and remanded to the Administrator for further proceedings consistent with this opinion.

Adm. Office, U.S. Courts — Blanchard Press, Inc., Boston, Mass.

UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

No. 86-2007

LESTER GRINSPOON, M.D.,
Petitioner,

v.

DRUG ENFORCEMMENT ADMINISTRATION,
Respondent.

DECREE

Entered: September 18, 1987

This cause came on to be heard on petition for review of an order of the Drug Enforcement Administration, and was argued by counsel.

Upon consideration whereof, It is here ordered, adjudged, and decreed as follows: The petition for review is granted. The rule is vacated and the cause is remanded to the Administrator for further proceedings consistent with the opinion filed this day.

One half costs to petitioner.

By the Court:

Francis P. Scigliano

Clerk.

[cc: Messrs. Cotton and Harbin]

OFFICE OF THE CLERK
UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

FRANCIS P. SCIGLIANO
CLERK

1606 JOHN W. McCORMACK
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September 18, 1987

To Counsel:

Re: No. 86-2007. Lester Grinspoon, M.D. v. Drug Enforcement Administration.

Dear Sirs:

Enclosed to each of you is a printed copy of the opinion of the Court and typewritten copy of the Decree in this case.

Under paragraph (a) of F.R.A.P. Rule 39, one half costs are taxable in favor of the petitioner. Under paragraph (c) of this Rule, petitioner may recover the expense of reproducing his brief and appendix provided he files and itemized and verified bill of such costs, with proof of service, by October 2, 1987. The entry deposit of $65.00, if on was paid, should be included in the bill of costs.

Sincerely yours,

Francis P. Scigliano

Clerk.

FPS/pm

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