No. 86-2007

12/22/87

IN THE UNITED STATES COURT OF APPEALS

FOR THE FIRST CIRCUIT

LESTER GRINSPOON,

Petitioner

v.

DRUG ENFORCEMENT ADMINISTRATION,

Respondent

PETITION FOR REVIEW OF FINAL ORDER
OF DRUG ENFORCEMENT ADMINISTRATION

PETITION FOR HEARING WITH SUGGESTION
FOR REHEARING EN BANC

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CERTIFICATE REQUIRED BY LOCAL RULE 35

I express belief, based on a reasoned and studied professional judgment, that this appeal involves the following question of exceptional importance:

> Whether the Administrator of the Drug Enforcement Administration applied a proper and legally permissible standard in determining that MDMA has no "currently accepted medical use in treatment in the United States" and no "accepted safety for use . . . under medical supervision."

I also express belief, based upon reasoned and studied professional judgment, that the panel's decision in this case, a case of first impression, is inconsistent with the Supreme Court's decision in Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984).

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The Drug Enforcement Administration (DEA) petitions this Court, pursuant to Rules 25 and 40, Fed. R. App. P., for rehearing, and suggests rehearing en banc, of that part of its September 18, 1987 decision which held that the Administrator of the DEA applied an improper or impermissible legal standard in determining that the substance MDMA has "no currently accepted medical use in treatment in the United States" and "no accepted safety for use . . . under medical supervision." As shown below, the panel's decision is based upon a misconception concerning the standard applied by the Administrator and this misconception led to a result inconsistent with the guidelines for judicial review of such standards established by the Supreme Court in Chevron, U.S.A., Inc., v. Natural Resources Defense Council, Inc., 467

U.S. 837 (1984). Moreover, the panel's decision, if permitted to stand, will (i) invalidate a long-standing agency interpretation of the statute it administers under which at least 28 controlled substances have been placed in Schedule I; (ii) jeopardize all federal convictions in cases involving MDMA since November 13, 1986 (the effective date of the Administrator's order placing MDMA in Schedule I) and the many MDMA cases currently under indictment; and (iii) jeopardize numerous convictions and prosecutions in the many States which have adopted the Uniform Controlled Substances Act and, under that Act, have placed MDMA in Schedule I of their state statutes in reliance on the Administrator's order.

QUESTION PRESENTED

Whether the Administrator of the Drug Enforcement Administration applied a proper and legally permissible standard in determining that the substance MDMA has no "currently accepted medical use in treatment in the United States" and no "accepted safety for use . . . under medical supervision," as those terms are used in the scheduling criteria for Schedule I of the Controlled Substances Act, 21 U.S.C. § 812(b)(1).

STATEMENT

As summarized in the panel opinion, reported at 828 F.2d 881, the pertinent fact are as follows. In July 1984, the Administrator of the DEA, following a preliminary evaluation by DEA and the Food and Drug Administration (FDA), issued a Notice of Proposed Rulemaking (49 Fed. Reg. 30210) in which he proposed that the substance 3,4 - methylenedioxymethamphetamine (MDMA) be

placed in Schedule I of the Controlled Substances Act as a hallucinogenic controlled substance. DEA received several comments and requests for a hearing in response to this notice and, in November 1984, the matter was referred to an Administrative Law Judge (ALJ) who was directed to hold a hearing regarding the proposed scheduling of MDMA and to make findings and recommendations on the appropriate scheduling action to be taken with respect to MDMA.

Following that hearing, the ALJ issued his Opinion and Recommendations regarding the scheduling of MDMA. The ALJ recommended that MDMA be placed in Schedule III of the Controlled Substances Act. He found that MDMA did not meet any of the three criteria for placement of a substance in Schedule I. In doing so, the ALJ rejected a long-standing and consistent agency interpretation of the statutory phrases "currently accepted medical use in treatment in the United States" and "accepted safety for use . . . under medical supervision" as meaning in most cases that a substance has been evaluated as safe and effective for its proposed medical uses by the FDA and therefore approved for marketing throughout the United States under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 et seq. Instead, he concluded that "accepted medical use" must be determined "by what is actually going on in the health care community" and then found that MDMA has an "accepted medical use in treatment in the United States" based on the testimony of only four psychiatrists from New Mexico, California and Massachusetts who had either administered MDMA to humans or taken it

themselves, and the supporting testimony of seven witnesses who had never used MDMA in their respective practices. With regard to the issue of whether MDMA has an "accepted safety for use . . . under medical supervision", the ALJ found that MDMA does not lack accepted safety for use because the same small group of psychiatrists had either administered it to themselves or to willing human subjects without adverse consequences in what were, by their own admission, uncontrolled, non-research studies.

On October 14, 1986, the Administrator promulgated the "Final Rule" that is the subject of this appeal. Based on a careful and extensive review of the entire record, the Administrator declined to adopt the recommendation of the ALJ and found that there was substantial evidence in the record to support placement of MDMA in Schedule I. The Administrator separately addressed each of the three statutory criteria that must be satisfied before a drug or other substance may be placed in Schedule I and found that each of them had been met. The Administrator adhered to the long-standing agency interpretation of the phrases "currently accepted medical use in treatment in the United States" and "accepted safety for use . . . under medical supervision" in 21 U.S.C. § 812(b) as meaning in most cases that the drug has been evaluated by the FDA for safety and approved for interstate marketing in the United States pursuant to the FDCA. Because MDMA had not been evaluated as safe and effective by the FDA, no new drug application (NDA) or investigational new drug application (IND) had been approved for the substance and it could not be marketed in interstate commerce

and thereby made generally available for use by medical practitioners. Moreover, no satisfactory independent evidence had been introduced which would meet FDA standards of safety and efficacy or support a conclusion that MDMA had achieved a "currently accepted medical use in the United States" notwithstanding the absence of FDA approval. The Administrator also found that MDMA has a "high potential for abuse." He therefore ordered it placed in Schedule I.

Dr. Grinspoon thereupon petitioned this Court for review of the Administrator's order pursuant to 21 U.S.C. § 877. The reviewing panel (Judges Coffin, Torruella, and Pettine) held that the Administrator had properly found that MDMA has a "high potential for abuse" (828 F.2d at 892-98), a holding which is not challenged in this Petition for Rehearing. However, the panel rejected as contrary to congressional intent the long-standing agency interpretation of the statutory criteria "accepted medical use in treatment in the United States and "accepted safety for use under medical supervision," which the panel misread as requiring in all cases that the substance in question have been previously evaluated as safe and effective for medical use by the FDA and approved for interstate marketing under the FDCA. 828 F.2d at 884-92. As stated earlier, this misreading led to a result inconsistent with the deferential standards of judicial review established in Chevron U.S.A.

REASONS FOR GRANTING THE PETITION

1. Standard of Review: The panel correctly identified the standard for judicial review of an agency's interpretation of the

statute it administers as that enunciated by the Supreme Court in Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984). This two-part standard was stated by the Chevron U.S.A. Court as follows:

> When a court reviews an agency's construction of the statute which it administers, it is confronted with two questions. First, always, is the question whether Congress has 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
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> * * * *
>
> [I]f 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 842-43 (emphasis supplied; footnotes omitted). In answering the latter question, "[t]he reviewing court need not conclude that the agency construction was the only one it permissibly could have adopted to uphold the construction . . . ." Id. at 843 n.11 (emphasis supplied). Moreover,

> [i]f Congress has explicitly left a gap for the agency to fill, there is an express delegation or authority to the agency to elucidate a specific provision of the statute by regulation. Such legislative regulations are given controlling weight unless they are arbitrary, capricious, or manifestly contrary to the statute. Sometimes the legislative delegation to an agency on a particular question is implicit rather than explicit. In such a case, a court may not substitute its own construction of a statutory provision for a reasonable interpretation made by the administrator of an agency.

Id. at 843 (emphasis supplied; footnote omitted). In all cases, however, "considerable weight should be accorded to an [agency's] construction of a statutory scheme it is entrusted to administer." Id. at 844 (emphasis supplied).

The panel, in applying this standard, determined that "Congress neither expressed nor implied an affirmative intent regarding how the [two scheduling] criteria should be interpreted". 828 F.2d at 885 (emphasis supplied). It did find, however, that Congress intended "to preclude reliance on the absence of FDA approval" in determining whether those criteria are satisfied. Id. at 892. The panel then concluded that the Administrator's standard, which it read as requiring absolute reliance on the presence or absence of FDA approval in every case, was contrary to this intent. Id. This conclusion is improper for all of the following reasons.

2. The Administrator's Standard is Not Inflexible: The panel throughout its opinion assumes that the Administrator's standard requires absolute, singular reliance in every case on the mere presence or absence of FDA approval in determining a drug's safety and medical usefulness. This is simply untrue. 1/

1/ For example, the panel points out that a drug's safety and medical usefulness conceivably could be established by evidence of strictly intrastate production and use even without FDA approval. However, the Administrator's standard allows for this possibility and, in fact, the FDA expressly stated in the marijuana rescheduling proceedings that it has "considered whether there is any basis to conclude that [marijuana has] an 'accepted medical use' by virtue of totally intrastate production and use and has found no basis for such a conclusion." 47 Fed.
(Footnote Continued)

The Administrator's standard is flexible and allows for alternative means of establishing a drug's safety and medical usefulness even in the absence of FDA approval. Indeed, the Administrator considered such evidence in this case when he noted that a handful of practitioners in various states had used MDMA in the treatment of humans. (Joint Appendix ("J.A.") at 17). However, such alternative evidence must always be sufficient to meet FDA standards for safety and efficacy and to establish that the substance has a generally accepted medical use in the United States. Thus, the Administrator rejected the previously

(Footnote Continued)
Reg. 28141, 28150-51. As mentioned in DEA's brief (at 30 n.29), the FDA also found that "[t]he lack of data from any sources demonstrating that use of these substances is medically acceptable (i.e., that sufficient data exists to qualify for NDA approval, confirms the finding that these substances do not meet this criterion." Id. at 28151. This statement is clearly consistent with the Administrator's flexible standard which requires that any independent evidence be sufficient to meet FDA standards of safety and efficacy.

The panel also concludes that the Administrator's standard is unreasonable because FDA approval may be withheld on grounds other than a drug's lack of safety and efficacy in its proposed treatment (e.g. because the application does not contain necessary patent information or because the proposed labeling was false or misleading). Assuming, however, that in such a case the FDA would have before it satisfactory evidence of the drugs safety and efficacy for treatment, the FDA presumably would not recommend that the drug be placed in Schedule I and the Administrator would not order the drug to be so scheduled.

Finally, the panel insists that the Administrator's standard eliminates any possibility of a meaningful hearing with respect to the two statutory criteria. As set forth above, however, parties are given every opportunity to present evidence equivalent to that required for FDA approval and to establish that the drug has an "accepted medical use" by alternative means. Thus, the Administrator's flexible standard allows for a meaningful hearing regarding the two scheduling criteria and such a hearing was held in this case.

mentioned evidence because "[t]he fact that a handful of physicians are of the opinion that a substance may have therapeutic value is not an acceptable alternative to the thorough clinical and preclinical evaluation which precedes [FDA] approval." (J.A. at 22). The panel, by mischaracterizing the Administrator's standard as one of "blind reliance" on the presence or absence of FDA approval in all cases (828 F.2d at 829), erroneously predetermined the issue of whether the standard is contrary to congressional intent or "reasonable" and "permissible" under the Chevron U.S.A. guidelines.

3. Congressional Intent: As stated earlier, the panel found that Congress "intended to preclude reliance on the absence of FDA approval" in determining whether a substance is safe and acceptable for medical use and concluded that the Administrator's standard was contrary to this intent based on the mistaken notion that the standard requires singular and exclusive reliance on the presence or absence of FDA approval in all cases. The panel's misinterpretation of the Administrator's flexible standard is evident from such statements as "[w]e do not interpret the explicit reference to FDA approval in the 'emergency scheduling' provision to mean . . . that Congress sought to permit blind reliance on FDA standards as a legitimate shortcut in the general run of cases." (828 F.2d at 889; emphasis supplied); and "[w]e believe that . . . absolute reliance on the absence of FDA approval would be inappropriate and contrary to the intent of Congress" (828 F.2d at 894; emphasis supplied). It appears from these statements that what the panel apparently meant to say that

Congress intended to preclude absolute reliance on the absence of FDA approval in all cases as the sole means for determining that a drug is not safe and acceptable for medical use.

The Administrator's standard does not require such absolute reliance. It is premised on the notion that either FDA approval or independent evidence sufficient to meet FDA standards of safety and efficacy, provides a reasonable, prudent and highly reliable standard for determining that a drug is safe and acceptable for medical use. Under this standard, however, the absence of FDA approval does not conclusively negate the possibility that the drug is otherwise safe and effective for medical use. Such safety and medical acceptability may be established by independent evidence sufficient to meet FDA standards of safety and efficacy.

This standard is entirely consistent with the legislative intent behind the methaqualone legislation. As the panel noted, "the methaqualone legislation demonstrates Congress' belief that FDA approval is sufficient to establish the existence of an acceptable medical use, but not that the lack of FDA approval . . . necessarily negates the possibility that the substance in question has an accepted medical use and is safe for use under medical supervision." Id. at 890. The Administrator's standard is also consistent with -- or at least not contrary to -- the other expressions of legislative intent identified in DEA's brief and in the panel's opinion.

Thus, to the extent that the congressional intent on this issue is clear, the Administrator's construction is entirely

consistent with that intent and should be upheld under the first prong Chevron U.S.A. standard. To the extent that the legislative history is in any way ambiguous, the Administrator's construction is both "reasonable" and "permissible" and therefore proper under the second prong of the Chevron U.S.A. standard for the following reasons.

4. "Currently Accepted Medical Use in Treatment in the United States": The FDA approval process provides a reasonable and permissible means for determining whether a drug has an accepted medical use in treatment in the United States because, once FDA approves the drug, it may be lawfully marketed in interstate commerce and thereby made generally available for use by medical practitioners throughout the country. (See J.A. at 22). There are certainly other means by which a drug's "accepted medical use" may be established and the flexible standard adopted by the Administrator allows for such means. The Chevron U.S.A. Court expressly instructed that "[t]he reviewing court need not conclude that the agency construction was not the only one it permissibly could have adopted"; the construction need only be "reasonable" and "permissible" in order to be upheld. The flexible standard chosen by the Administrator clearly satisfies this mandate.

5. "Accepted Safety for Use Under Medical Supervision": The FDA will not approve a "new drug application" until it is persuaded by toxicity studies, carcinogenic studies, reproductive studies in animals, studies on side effects in humans, and other carefully controlled studies that the drug is safe and effective

for its proposed use in the treatment of humans (J.A. at 18). The Administrator's standard, which requires either FDA approval or evidence of safety sufficient to obtain such approval, is clearly a prudent, reasonable and permissible means of establishing a drug's safety for use under medical supervision. In this case, the Administrator found not only that MDMA lacked FDA approval, but also that ". . . a review of the scientific literature led an FDA official who evaluates the safety and efficacy of drugs to conclude that the literature does not support the safety of MDMA for use under medical supervision." (J.A. at 18-19, Finding 14). Again, this flexible standard provides both a "reasonable" and "permissible" means for establishing a drug's safety and should be upheld by this Court under the Chevron U.S.A. guidelines.

CONCLUSION

For all of the foregoing reasons, the petition for rehearing should be granted.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing Petition For Rehearing With Suggestion For Rehearing En Banc was served this 6th day of November, 1987, by mail, first-class postage prepaid, on:

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