IN THE

UNITED STATES COURT OF APPEALS

FOR THE FIRST CIRCUIT

LESTER GRINSPOON Petitioner, v. DRUG ENFORCEMENT ADMINISTRATION, Respondent.	)	No. 86-2007

Petition for Review of Order of
Drug Enforcement Administration

BRIEF FOR RESPONDENT

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Legislative History

Page

Regulations and Regulatory Notices and Orders

Other Authorities

Statement of Issues

I. Whether the Administrator Applied a Proper Standard in Determining Whether MDMA Has a "Currently Accepted Medical Use In Treatment in the United States" and an "Accepted Safety for Use. . . Under Medical Supervision."

II. Whether the Administrator Applied a Proper Standard and Fully Explained the Reasons for His Conclusion that MDMA Has a "High Potential for Abuse" and Whether There is Substantial Evidence to Support That Conclusion.

III. Whether the Administrator Improperly Failed to Consider the Impact on Research of Placing MDMA In Schedule I.

IV. Whether the Administrator Improperly Relied Upon, or Gave Undue Weight to, the "Evaluation and Recommendation" of the Department of Health and Human Services.

STATEMENT REGARDING ORAL ARGUMENT

Respondent believes that the facts and legal arguments surrounding this petition for review have been adequately presented in the brief and record and that oral arguments in this matter will not significantly aid this Court in reaching a decision regarding the merits of Petitioner's claims. (See Fed. R. App. P. 34(a); Local Rule 13(a)). As such, Respondent respectfully request that this Court decide Peitioner's petition for review based solely on the briefs submitted by the parties to this proceeding.

STATEMENT OF THE CASE

The Petition for Review of Final Order of Drug Enforcement Administration filed with this Court by Dr. Lester Grinspoon on January 12, 1987, challenges a Final Rule issued by the Administrator of the Drug Enforcement Administration (DEA), placing the substance 3,4 - methylenedioxymethamphetamine (MDMA) in Schedule I of the Controlled Substances Act. [1/] The Administrator based his action on the extensive administrative record developed in proceedings before an Administrative Law Judge (ALJ). In promulgating the Final Rule, the Administrator declined to adopt the recommendation of the ALJ that MDMA be placed in Schedule III of the Controlled Substances Act. Instead, he ordered that the substance be placed in Schedule I. His decision was based on findings that MDMA met all three of the statutory criteria for placement in Schedule I. Specifically, the Administrator found that (i) MDMA has a high potential for abuse, (ii) there is no accepted medical use for MDMA in

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1/ Section 301 of the Controlled Substances Act, 21 U.S.C. § 812, establishes five schedules of controlled substances. The schedules are subject to revision and the current schedules are published at 21 C.F.R. §§ 1308.11-1308.15 (1986). The five schedules form the basis of a scaled system of controls and penalties, with Schedule I substances being subject to the most severe controls and penalties and Schedule V substances being subject to the least severe controls and penalties. Substances may be placed in Schedule I based upon findings that they have (i) "a high potential for abuse," (ii) "no currently accepted medical use in treatment in the United States," and (iii) that they "lack accepted safety for use ... under medical supervision." 21 U.S.C. § 812(b)(1).

treatment in the United States; and (iii) MDMA lacks accepted safety for use under medical supervision. This Court's authority to review the Administrator's action exists under Section 507 of the Controlled Substances Act, 21 U.S.C. § 877.

Procedural History

On March 13, 1984, the Administrator submitted information relevant to the abuse potential and illicit trafficking of MDMA to the Assistant Secretary for Health of the Department of Health and Human Services (HHS). Briefly, this information established that MDMA (i) is an "analog" of the Schedule I controlled substance 3,4 - methylenedioxyamphetamine ("MDA"), (ii) produces stimulant and psychotomimetic effects in humans similar to those produced by MDA, (iii) has no legitimate use or manufacturer in the United States, (iv) has been clandestinely synthesized and encountered in illicit drug traffic, and (v) has been associated with medical emergencies reported on the Drug Abuse Warning Network. (J.A. 284-308). [2/] Pursuant to 21 U.S.C. § 811(b), the Administrator requested that HHS conduct a scientific and medical evaluation of the information relating to MDMA and make a recommendation concerning its proper scheduling. [3/]

2/ For purposes of this brief, "J.A." will designate the Joint Appendix followed by the relevant pages of that appendix.

3/ 21 U.S.C. § 811(b) provides, in pertinent part, that "[t]he Attorney General shall, before initiating [scheduling] proceedings ..., and after gathering the necessary data, request from the Secretary [of Health and Human Services] a scientific and medical evaluation, and his recommendations, as to whether such drug or other substance should be controlled or removed as a (Footnote Continued)

On June 6, 1984, the Administrator received a letter from the Assistant Secretary for Health stating that, after conducting a medical and scientific evaluation of the information concerning MDMA, HHS had concluded that MDMA has a high potential for abuse and presents a significant risk to the public health. The Assistant Secretary for Health recommended that MDMA be placed in Schedule I of the Controlled Substances Act. (J.A. 309-311). In making his findings and recommendations, the Assistant Secretary for Health considered each of the eight factors listed in 21 U.S.C. § 811(c), 4/ as he was required to do by 21 U.S.C. § 811(b). 5/

(Footnote Continued)
controlled substance .... 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 roles of the Attorney General and the Secretary of Health and Human Services under this statutory procedure have been delegated to the Administrator and the Assistant Secretary for Health of the Department of Health and Human Services, respectively.

4/ The eight factors which must be considered before a drug or other substance may be added to or removed from the schedules of controlled substances are: (i) the drug or other substance's actual or relative potential for abuse; (ii) scientific evidence concerning its pharmacological effect, if known; (iii) the state of current scientific knowledge regarding the drug or other substance, (iv) its history and current pattern of abuse, (v) the scope, duration, and significance of abuse, (vi) what, if any, risk there is to the public health, (vii) the drug or other substance's psychic or physiological dependence liability, and (viii) whether the substance is an immediate precursor of an already scheduled substance.

5/ 21 U.S.C. § 811(b) provides, in pertinent part, that "[i]n making [his] evaluation and recommendations, the Secretary shall consider the factors listed in paragraphs (2), (3), (6), (7), and (8) of subsection (c) [21 U.S.C. § 811(c)] ... and any scientific or medical considerations involved in paragraphs (1), (4), and (5) of such subsection."

On July 27, 1984, the Administrator issued a Notice of Proposed Rulemaking (49 Fed. Reg. 30210) in which he proposed, based on investigations by the DEA and on the scientific and medical evaluation and recommendation of the Assistant Secretary for Health, that MDMA be placed in Schedule I as a hallucinogenic controlled substance. In response to this Notice, DEA received sixteen comments and seven requests for a hearing. On November 13, 1984, the matter was referred to the 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.

The ALJ held five hearing sessions, during which he heard the testimony of 33 witnesses and received 95 exhibits into evidence. During the course of the hearing, the Administrator, in an independent action, placed MDMA in Schedule I pursuant to the temporary scheduling provisions of 21 U.S.C. § 811(h)(1), based on determinations that this action was necessary to avoid an imminent hazard to the public safety. See 50 Fed. Reg. 23118 (May 31, 1985). This Order became effective on July 1, 1985. 6/

On May 22, 1986, the ALJ issued his Opinion and Recommendations regarding the scheduling of MDMA. (J.A. 25-96). 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

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6/ Congress subsequently expressed its approval of the Administrator's action. See note 23, infra, and accompanying text.

criteria for placement of a drug or other substance in Schedule I.

The ALJ rejected a long-standing and consistent agency interpretation of the phrase "currently accepted medical use in treatment in the United States" as meaning that a drug or other substance has been evaluated as safe and effective for its proposed medical uses by the Food and Drug Administration ("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. He concluded, instead, that "accepted medical use" must be determined "by what is actually going on in the health care community." The ALJ then found that MDMA has an "accepted medical use in treatment in the United States" based on the testimony of 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 in what were, by their own admission, uncontrolled, non-research studies. Finally, with regard to the issue of abuse potential, the ALJ found the DEA had not met its burden in establishing that MDMA has a "high potential for abuse."

DEA filed exceptions to the Opinion and Recommendations of

the ALJ and, on July 24, 1986, the ALJ certified and transmitted the record to the Administrator for review and final action. On October 14, 1986, the Administrator promulgated the "Final Rule" that is the subject of this appeal. 7/ (J.A. 16-24). 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 as a hallucinogenic controlled substance. 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. Dr. Grinspoon, in his Petition for Review, now challenges those findings. As set forth below, those findings should be upheld because they (i) are based on permissible interpretations of the statutory language in which each of the criteria are phrased; (ii) are supported by substantial evidence; (iii) were made in accordance with the law and (iv) are not arbitrary or capricious.

Dr. Grinspoon also argues that the Administrator's action was arbitrary and capricious because the Administrator failed to give adequate weight to claims that medical research on MDMA would be foreclosed by placement of the substance in Schedule I and because the Administrator relied, in part, on recommendations from the Secretary of Health and Human Services which Dr.

7/ The "Final Rule" became effective on November 13, 1986.

Grinspoon claims were legally erroneous and procedurally improper. As set forth below, these arguments also lack merit.

ARGUMENT

I. THE ADMINISTRATOR APPLIED A PROPER STANDARD IN DETERMINING WHETHER MDMA HAS A "CURRENTLY ACCEPTED MEDICAL USE IN TREATMENT IN THE UNITED STATES" AND AN "ACCEPTED SAFETY FOR USE UNDER MEDICAL SUPERVISION"

The Administrator interpreted the statutory phrase "currently accepted medical use in treatment in the United States," as used in 21 U.S.C. § 812, to mean "that the Federal Food and Drug Administration has determined that [the] drug or other substance can be lawfully marketed in the United States." (J.A. 18, Finding 9). Thus, the Administrator adopted the long-standing interpretation of that phrase first formulated by the Food and Drug Administration ("FDA") in 1975 [8/] and most recently restated and explained in 1982 as follows:

> FDA interprets the term "accepted medical use" to mean lawfully marketed under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301, et seq.
>
> * * * *
>
> A drug may be marketed lawfully under the Federal Food, Drug, and Cosmetic Act after approval of a new drug application (NDA) for that drug. There are, theoretically, other ways in which a drug could be marketed legally. The drug could satisfy either the requirements for exemption from the

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8/ See Notice re: Scheduling of Marihuana, 40 Fed. Reg. 44164, 44165-67 (1975).

> definition of "new drug" in 21 U.S.C. 321(p) or the requirements for a "grandfather clause" from the new drug approval provision, see 21 U.S.C 321 (p)(1) and Pub. L. 87-781, sec. 107(c)(4).
>
> * * * *
>
> The mechanism set up by Congress for lawful marketing of a new drug requires submission of an NDA to FDA and FDA approval of that application before marketing. Before FDA can approve an NDA, however, the drug sponsor must submit data from an extensive battery of experimental testing on both animals and humans to establish the drug's safety and effectiveness for its proposed uses. In addition, the sponsor must submit data on manufacturing controls demonstrating that standards of identity, strength, quality, and purity will be met. Finally, the sponsor must submit labeling which adequately reflects the proper conditions for use. See 21 U.S.C. 355(d) and 21 C.F.R. 314.1. Only after FDA has evaluated this information can the agency make a decision on whether the NDA should be approved and the drug marketed.
>
> Thus, the lack of an approved NDA for a drug substance leads FDA to find that the substance lacks an "accepted medical use in treatment" for two reasons. First, if use of the drug is unlawful whenever interstate commerce is involved, medical use of the drug cannot be classified as accepted. Second, in the absence of the data necessary for approval of an NDA, the agency has no basis for concluding that medical use of the drug in treatment can be considered acceptable by medical standards.

Notice, Proposed Recommendations of FDA to DEA Regarding the Scheduling Status of Marihuana, 47 Fed. Reg. 28141, 28150-51 (1982) (emphasis supplied) (J.A. 314-326). As set forth below, Congress has expressed it approval of this interpretation several

times since 1984. [9/]

The Administrator interpreted the statutory phrase "accepted safety for use ... under medical supervision," as used in 21 U.S.C. § 812, as meaning "that [the] drug has been evaluated for safety by the [FDA] and approved for marketing in the United States." (J.A. 19, Finding 17). This interpretation, like the Administrator's interpretation of "accepted medical use," is consistent with the agency interpretation of that phrase first advanced by FDA in the marihuana re-scheduling proceedings in 1982 [10/] and subsequently approved by Congress.

Dr. Grinspoon now argues that these interpretations are legally erroneous. For the reasons set forth below, the Administrator's interpretations of these statutory phrases are proper and permissible and should be upheld as a matter of law.

Standard of Review: The most recent articulation by the Supreme Court of the approach to be taken and the standard to be applied when a court reviews an agency's construction of the statute it administers came in Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984). There the Court endorsed an approach employing two inquiries. Each of the two inquiries, as applied to the statutory criteria at issue in this case, is addressed below.

9/ See discussion, infra, at 19-22.

10/ See Notice, 47 Fed. Reg. at 28152.

Whether the Congressional Intent is Clear with Respect to the Meaning Statutory Provisions in Question: The first inquiry, under the approach endorsed by the Supreme Court, is 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 of 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.

Id. at 842-43 (emphasis supplied). The Court added in a footnote that "[i]f a court, employing traditional rules of statutory construction, ascertains that Congress had an intention on the precise question at issue, that intention is the law and must be given effect." Id. at 843 n. 9 (emphasis supplied).

Although Congress did not directly speak to the "question at issue" in this case -- the meaning of the phrases "currently accepted medical use in treatment in the United States" and "accepted safety for use ... under medical supervision" under 21 U.S.C. § 812(b) -- in enacting the Comprehensive Drug Abuse Act of 1970 ("the 1970 Act"), it has made its intentions clearly known. As set forth below, these intentions squarely support the Administrator's position.

(i) The Statutory Language: The only part of either statutory phrase that is specifically defined in the statute are the words "United States" as used in "accepted medical use in treatment in the United States." Section 102(28) of the

Controlled Substances Act, 21 U.S.C. § 802(28), [11/] provides that "[t]he term 'United States,' when used in a geographic sense, means all places ... subject to the jurisdiction of the United States" (emphasis supplied). As a matter of statutory construction, "[l]egislative declaration of the meaning that a term shall have ... is binding, so long as the prescribed meaning is not so discordant to common usage as to generate confusion." 2A Sutherland Statutory Construction § 47.07, at 133 (4th ed. 1984). It is clear, therefore, that the statutory criterion "accepted medical use in treatment in the United States" requires a determination of whether a drug or other substance has been accepted for use in treatment throughout the United States (i.e., in "all places" in the United States). It is highly improbable, to say the least, that a drug or other substance could ever be found to be accepted for medical use throughout the United States until it had been evaluated and found safe and effective by FDA, approved for marketing in interstate commerce under the FDCA, and therefore made generally and readily available to medical practitioners throughout the country.

The word "accepted" appears in both of the statutory phrases under discussion. It is not defined in either the statute or the legislative history of the 1970 Act. However, it is a common term and should be given its common meaning. See 2A Sutherland

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11/ Until the Anti-Drug Abuse Act of 1986 (Public Law No. 99-570) became effective on October 27, 1986, this definition was codified at 21 U.S.C. § 802(27).

Statutory Construction § 47.28, at 223 (4th ed. 1984) ("when common terms are used [in a statute] they should be given their common meaning"). The dictionary definition of the term "accepted," when used as an adjective, is as follows:

> accepted -- generally approved; widely used or found: generally agreed upon: unchallenged, conventional.

Webster's Third New International Dictionary, at 11 (1976). 12/ Thus, the statutory phrase "accepted medical use in treatment in the United States" clearly contemplates an administrative determination as to whether the drug or other substance has been "generally approved" for use in treatment throughout the United States (i.e., in "all places" in the United States) and the phrase "accepted safety for use ... under medical supervision" contemplates a determination as to whether the safety of the drug or other substance for use under medical supervision has been "generally approved" or "generally agreed upon." Again, it is highly improbable that the medical use and safety of a drug or other substance could ever be found to be "generally approved" or "generally agreed upon" until after it had been evaluated by FDA, found to be safe and effective for use, and therefore approved by FDA for marketing in interstate commerce.

The Administrator's position also is consistent with the

12/ See Maybury v. Secretary of Health and Human Services, 740 F.2d 100, 103 (1st Cir. 1984) (employing dictionary to determine meaning of statutory term).

interpretation given the term "accepted medical use in treatment in the United States," as used in the Uniform Controlled Substances Act. 13/ The Uniform Controlled Substances Act, like its federal counterpart, creates five schedules of controlled substances. Unif. Controlled Substances Act §§ 203-212, 9 U.L.A. 221-235 (1979). The scheduling criteria for placement of a drug in Schedule I of the Uniform Act are identical to those under 21 U.S.C. § 812(b), except that the word "currently" does not appear before the term "accepted medical use in treatment in the United States" in the Uniform Act. See, id. § 203(2), 9 U.L.A. at 221. The Commissioners' Notes to the section setting forth the Schedule I criteria under the Uniform Act explain that:

> 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. [Emphasis added]

Commissioners' Note, Unif. Controlled Substances Act § 203, 9

13/ The Uniform Controlled Substances Act was approved by the National Conference of Commissioners on Uniform State Laws for adoption by the states in 1970, the same year that the federal Controlled Substances Act was enacted. The Commissioners, in their general comments concerning the Act, stated that it had been modeled on the new federal statute 9 U.L.A. 187, 188 (1979). The Uniform Controlled Substance Act has since been adopted by 48 states, the District of Columbia, Guam, and the Virgin Islands. 9 U.L.A. Supp. 123-24 (1986).

U.L.A. at 221. Thus, the National Conference of Commissioners on Uniform State Laws, like the Administrator in the administrative proceeding below, equates the term "accepted medical use in treatment in the United States" with FDA approval of a drug or other substance for marketing in the United States.

The Commissioner's interpretation of the term "accepted medical use in the United States" -- which has been approved by the vast majority of states which have adopted the Uniform Act [14] -- is entitled to "special consideration" in construing the identical term as used in the Federal Controlled Substances Act. [15]

14/ Mr. David Joranson, of the Controlled Substances Board of the State of Wisconsin, testified in the administrative proceeding below that he sent a questionnaire to the scheduling authorities of the various states asking each of them, inter alia, if "the meaning of 'accepted medical use in treatment in the U.S.' under your law is consistent with the interpretation of the National Conference of Commissioners on Uniform State Laws [quoted in text, supra] ...." Mr. Joranson stated that 43 states responded to this questionnaire, 39 of whom (90%) answered this particular question affirmatively, only one of whom answered negatively, and the rest of whom did not answer the question. (Joranson, amended direct, pp. 3,4,5).

15/ See, e.g., 2A Sutherland Statutory Construction § 52.03, at 541 (4th ed. 1981): Cf. Director, Office of Workers' Compensation Programs v. Boughman, 545 F.2d 210, 213 (D.C. Cir. 1976) (construing Longshoremen's and Harbor Workers' Compensation Act, "by reference to numerous state statutes closely similar to [the federal Act]"); Kane v. McDaniel, 407 F. Supp. 1239, 1243 (W.D. Ky. 1975) (looking to legislative history of federal Controlled Substances Act in construing state drug statute because "it appears that substantial portions of the [state] statute were copied from the federal statute").

To summarize, the statutory language of the two scheduling criteria under discussion clearly indicates that whether a drug or substance has an "accepted medical use in treatment in the United States" must be determined on a nationwide basis and that both "accepted medical use in treatment" and "accepted safety for use . . . under medical supervision" are to be determined by what has been "generally approved" or "generally agreed to." The interpretation given to those criteria by the FDA and the Administrator in the administrative proceeding below are entirely consistent with the statutory language because the medical use and safety of a drug or other substance cannot be said to be "generally approved" or "generally agreed to" throughout the nation until the drug or other substance has been evaluated by FDA, found to be safe and effective for medical use, approved for marketing in interstate commerce under the FDCA, and thus made generally and readily available to medical practitioners nationwide. 16/

16/ Dr. Grinspoon refers to the fact that Congress made express reference to the FDCA in several subsections of the Act but not in the scheduling criteria under 21 U.S.C. § 812(b). (Pet. Brief at 13-14). He apparently would have this Court apply the maxim of statutory construction inclusio unius est exclusio alterius (express mention means implied exclusion) to infer from this silence that Congress intended to prohibit use of the FDCA as a standard in interpreting the scheduling criteria. However, that maxim "is a guide to construction and not a positive command ...." and "[w]hether the specification of one matter means the exclusion of another is a matter of legislative intent ...." Massachusetts Trustees of Eastern Gas and Fuel Associates v. U.S., 312 F.2d 214, 220 (1st Cir. 1963), aff'd 377 U.S. 235 (1964). Accord Campbell v. Wells Fargo Bank, N.A., 781 F.2d 440, 442 (5th Cir.) cert. denied, 106 S. Ct. 2279 (1986) (maxim "is

(Footnote Continued)

(ii) The Legislative History: The legislative history of the Comprehensive Drug Abuse Prevention and Enforcement Act of 1970 ("the 1970 Act") also supports the Administrator's interpretation of the statutory criteria.

The committee reports relating to the 1970 Act (reprinted in 1970 U.S. Code Cong. & Ad. News at 4566-660) do not define the statutory phrases "accepted medical use in treatment in the United States" and "accepted safety for use ... under medical supervision." They do, however, provide a clear indication of how and by whom determinations of whether a drug or other substance is safe and effective are to be made. The committee report of the House Interstate and Foreign Commerce Committee on the bill which was ultimately enacted as the 1970 Act discussed

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(Footnote Continued)
only an aid to statutory construction, not a rule of law. The controlling consideration is legislative intent, and the maxim can be overcome by a strong indication of contrary congressional intent"); Illinois Dep't of Public Aid v. Schweiker, 707 F.2d 273, 277 (7th Cir. 1983) ("[n]ot every silence is pregnant; [the maxim] is therefore an uncertain guide to interpreting statutes").

It is clear from the previous discussion that Congress intended the Administrator to adopt a standard by which it could be determined whether a drug or other substance had been ~~generally accepted~~ for medical use throughout the nation and generally approved as safe for such use. Congress did not specify the standard to be applied in making these determinations and there is no indication that it intended to exclude the "new drug" approval process under the FDCA as providing a workable standard. Indeed, as discussed in the next section of this brief, Congress specifically stated in the legislative history of the Act that the safety and efficacy of all narcotic and dangerous drugs were to be determined under the FDCA and has since approved the Administrator's interpretation several times in the post-enactment legislative history of the Act. The maxim clearly should not apply in light of this legislative history.

the effect the bill would have in implementing the twenty-five recommendations made in 1963 by the President's Advisory Commission on Narcotic and Drug Abuse (also known as "the Prettyman Commission") with respect to reforms of the nation's regulatory and law enforcement approach to the problem of drug abuse. See H.R. Rep. No 1444, 91st Cong., 2d Sess. (1970), reprinted in 1970 U.S. Code Cong. & Ad. News 4566, 4581-87 (1970). One of the recommendations of the Prettyman Commission had been that:

> a unit be established within the department of Health, Education, and Welfare [now Health and Human Services] to determine the safety and efficacy of and to regulate all narcotic and dangerous drugs .... This unit would also regulate the legitimate importation, exportation, manufacture, sale and other transfer of narcotic and dangerous drugs.

Id. at 4584. In discussing how this recommendation would be implemented under the 1970 Act and related governmental reorganization plans, the House Committee Report stated:

> Under Reorganization Plan No. 1 of 1968 [reprinted in 1968 U.S. Code Cong. & Ad. News, 4734-35 (1968)] 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 the Department of [Health and Human Services].

Id. at 4584. Thus, 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) [17] be determined by the Department of Health and Human Services under the Federal Food, Drug, and Cosmetic Act.

Further evidence that Congress intended the statutory phrase "accepted medical use in treatment in the United States" to mean that the drug or other substance may be lawfully marketed under the FDCA may be found in the congressional hearings on whether to place the drug alphacetylmethadol in Schedule I of the original Act. One witness expressed concern over the proposed placement of this drug in Schedule I, urging that it might be potentially useful in treating narcotic addicts. [18] In response, the Bureau of Narcotics and Dangerous Drugs submitted a "Justification for Placement of Alphacetylmethadol in Schedule I of the Controlled Dangerous Drug Act, S. 3246" in which it stated:

> Further, since the current use of alphacetylmethadol is limited to research, it has no currently accepted medical use -- that is, no IND [Investigational New Drug Application]

17/ The term "efficacy" as used in the above-quoted passage is synonymous with the term "effectiveness." See Webster's Third New International Dictionary 725 (1976) (defining "efficacy" as meaning "effectiveness"). When the FDA approves a New Drug Application under the Federal Food, Drug, and Cosmetic Act, it determines that the drug or other substance is both safe and effective for its proposed medical uses and thus may be legally marketed in interstate commerce. See 21 U.S.C. § 355(d). Such approval thereby establishes that the drug or other substance is acceptable for medical use throughout the United States and that it is safe for such use.

18/ See Drug Abuse Control Amendments -- 1970: Hearings on H.R. 11701 and H.R. 13743 Before the Subcommittee of Public Health and Welfare of the House Committee on Interstate and Foreign Commerce, 91st Cong, 2d Sess. at 313 (1970) (statement of Dr. Jonathan O. Cole).

> or NDA [New Drug Application] has been issued for it by the Food and Drug Administration

Id. at 715 (statement of John E. Ingersoll, Director, Bureau of Narcotics and Dangerous Drugs). Congress included alphacetylmethadol in Schedule I of the Controlled Substances Act as originally enacted. See 21 U.S.C. § 812, Schedule I(a)(3).

Since 1970, Congress has repeatedly approved the Administrator's construction of the statutory phrases "accepted medical use in treatment in the United States," and "accepted safety for use ... under medical supervision" as meaning that the drug or other substance has been approved for marketing by the FDA. In 1984, Congress enacted Public Law 98-329, 98 Stat. 280, which placed the substance methaqualone in Schedule I of the Controlled Substances Act. By that time, DEA and FDA had reiterated their interpretation of the phrase "accepted medical use in treatment in the United States" -- as meaning that the drug or other substance have been approved for marketing under the FDCA -- several times in a number of administrative actions dating back to 1975. 19/ In the only Committee Report concerning the Act to re-schedule methaqualone, Congress recognized and endorsed this long-standing and consistent administrative

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19/ See, e.g., Proposed Recommendation to the DEA Regarding the Scheduling Status of Marihuana and Its Components and Notice of a Public Hearing, 47 Fed. Reg. 28141, 28150 (1982) (J.A. 314-326); Notice, Proposed Recommendation to the DEA Regarding the Scheduling Status of Tetrahydrocannabinol, 47 Fed. Reg. 10080, 10084 (1982); Notice re: Marihuana Scheduling, 40 Fed. Reg. 44164, 44165 (1975).

interpretation when it declared:

> 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. [Citing the three scheduling criteria for Schedule I].

H.R. Rep. No. 534, 98th Cong., 2d Sess., 4 (1984), reprinted in 1984 U.S. Code Cong. & Ad. News 540, 543 (1984) (emphasis supplied). Thus, Congress recognized that FDA approval establishes that a drug or other substance has a "currently accepted medical use in treatment in the United States," and, therefore, that such a drug cannot be placed in Schedule I absent congressional action.

Congress again indicated its approval of the Administrator's interpretation of the statutory criteria when it enacted the Comprehensive Crime Control Act of 1984 [Pub. L. No. 98-473, 98 Stat. 1837 (1984)] which, inter alia, substantially amended various parts of the 1970 Act. Part of the Act -- designated the "Dangerous Drug Diversion Act of 1984 -- added new subsection "(h)" to 21 U.S.C. § 811, authorizing the Attorney General to temporarily place an unscheduled substance in Schedule I -- but only in Schedule I -- if he finds such action is necessary to avoid imminent hazard to the public safety. This provision extends to all unscheduled substances for which "no exemption or approval is in effect for the substance under section 355 of [the

FDCA]." 21 U.S.C. § 811(h)(1) (emphasis supplied). [20] The exclusion of substances approved by the FDA from temporary placement in Schedule I is consistent with the view that such approval establishes that the substances have an "accepted medical use in treatment in the United States" and "accepted safety for use ... under medical supervision" and therefore cannot properly be placed in Schedule I.

Another telling indication that Congress approves and accepts the Administrator's interpretation came with the very recent enactment of the Anti-Drug Abuse Act of 1986 (Pub. L. No. 99-570). [21] Subtitle E of Title I of that Act -- designated the "Controlled Substances Analogue Act of 1986" -- generally provides that "analogues" [22] of Schedule I and II controlled substances are subject to the same controls and penalties applicable to Schedule I substances. Congress expressly exempted from coverage under the Act those "analogues" for which "there is an approved new drug application." Pub. L. No. 99-570 § 1203 (codified as 21 U.S.C. § 802(32)(B)(ii)). The exemption of such analogues from Schedule I controls and penalties is consistent

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20/ Section 355 of the FDCA, 21 U.S.C. § 355, is the provision under which the FDA approves "new drugs" pursuant to New Drug Applications.

21/ The Anti-Drug Abuse Act of 1986 is reprinted in full in "Pamphlet 10A" of the 1986 U.S. Code Cong. & Ad. News (Dec. 1986).

22/ An "analogue" is defined in the Act as a chemical that is substantially similar to a Schedule I or II substance in chemical structure or pharmocological effect, See Pub. L. No. 99-570 § 1203.

with the Administrator's view that approval of a new drug application establishes that such analogues have an "accepted medical use in the United States" and "accepted safety for [such] use ... under medical supervision" and, therefore, should not properly be subject to the controls and penalties applicable to Schedule I substances. 23/

All of the foregoing legislative history -- in which Congress has repeatedly and consistently adopted and expressed its agreement with the Administrator's position -- is entitled to

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23/ As mentioned earlier (supra, at 4), the Administrator, on May 31, 1985, invoked his authority under 21 U.S.C. § 811(h) to place MDMA temporarily in Schedule I based on a finding that it presented an imminent hazard to the public health. In the legislative history of what became the "Controlled Substances Analogue Act of 1986," Congress recognized that MDMA is a dangerous analogue of the Schedule I controlled substance MDA and expressed its approval of the Administrator's action:

> The 98th Congress extended to DEA the power to control ... new substances on an emergency basis. DEA has used this authority five times to control 13 new dangerous drugs, including ... MDMA an analogue of MDA (a Schedule I substance). In the Committee's view, generally this authority has been used very effectively to address much of the designer drug problem.

H.R. Rep. No. 848, Part I, 99th Cong., 2d Sess. at 4-5 (1984) (emphasis supplied) (reproduced as Addendum A to this brief). This committee report concerned a predecessor bill of what became the Controlled Substances Analogue Act of 1986. The bill was substantially identical to the final Act and the committee report is listed as part of the legislative history of the Anti-Drug Abuse Act of 1986. See "Pamphlet 10C", 1986 U.S. Code Cong. & Ad. News at 5393 (Dec. 1986).

very substantial weight by this Court. The Supreme Court has held that "[w]hen a Congress that re-enacts a statute voices its approval of an administrative or other interpretation thereof, Congress is treated as having adopted that interpretation, and this Court is bound thereby". United States v. Board of Commissioners of Sheffield, Alabama, 435 U.S. 110, 134 (1978) (emphasis supplied). The same rule applies where, as here, Congress makes a minor addition to a statute and, in doing so, implicitly recognizes and approves a prior administrative interpretation of the statute. See Fletcher v. Warden, United States Penitentiary, Leavensworth, Kansas, 641 F.2d 850, 854 n. 5 (10th Cir.), cert. denied, sub nom. Johnson v. Smith, 453 U.S. 912 (1981). 24/

Against this weighty legislative history in support of the Administrator's position, Dr. Grinspoon offers only a few oral statements made by two witnesses during question-and-answer sessions before the congressional committee considering the bill which ultimately became the 1970 Act. (Petitioner's Brief at 14-15). These statements are entitled to little or no weight as indicia of congressional intent regarding the meaning of the two statutory criteria under discussion for the following reasons. First, the Supreme Court has held that "statements ... made to

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24/ Accord Hogan v. Heckler, 769 F.2d 886, 901-02 (1st Cir. 1986), cert. denied, 106 S. Ct. 3301 (1986) (upholding administrative regulations where, inter alia, "Congress not only acquiesced in the Secretary's construction of the Act, but expressly approved of her regulations").

committees of Congress ... are without weight in the interpretation of a statute." McCaughn v. Hershey Chocolate Co., 283 U.S. 488, 493-94 (1931). 25/ Second, one of the two witnesses quoted by Dr. Grinspoon -- Mr. John Ingersoll, then Director of the Bureau of Narcotics and Dangerous Drugs -- later submitted a written statement to the committee on behalf of his agency in which he made a statement which directly supports the Administrator's position. 26/ Third, there is no indication in the committee reports or post-enactment legislative history of the 1970 Act to suggest that Congress adopted or otherwise agreed

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25/ Accord Sierra Club v. Clark, 755 F.2d 608, 617 (8th Cir. 1985) (such statements are not to be accorded "undue weight"); Conference of State Bank Commissioners v. Conover, 715 F.2d 604, 614 (D.C. Cir. 1983), cert. denied, 466 U.S. 927 (1984); Autasia Intermodal Lines, Ltd. v. Federal Maritime Commission, 580 F.2d 642, 645 (D.C. Cir. 1978).

26/ The statement was made in the agency's written "Justification" for its recommendation that the substance alphacetylmethadol be placed in Schedule I. Mr. Ingersoll stated that the substance must be placed in Schedule I because, inter alia, "it has no currently accepted medical use -- that is no IND [Investigative New Drug Application] or NDA [New Drug Application] has been issued for it by the [FDA]." See discussion, supra at 18-19. The substance was listed in Schedule I when the Controlled Substance Act was passed by Congress. See 21 U.S.C. § 812, Schedule I(a)(3).

Respondent submits that, to the extent statements by individual witnesses are entitled to any weight at all as indicia of congressional intent, this written statement, made on behalf of the agency charged with enforcement of the statute after opportunity for deliberation, is entitled to considerably more weight than oral statements by individuals during question-and-answer sessions before congressional committees, particularly where, as here, Congress implicitly accepted the agency's written statement when it placed alphacetylmethadol in Schedule I without requiring the agency to poll the medical community on whether it has an "accepted medical use."

with the views as expressed in the witness statements quoted by Dr. Grinspoon. Indeed, as set forth above, all indications are that Congress clearly has accepted and approved the interpretations advanced by the Administrator.

(iii) Conclusion: Contrary to the arguments advanced by Dr. Grinspoon, the Administrator's interpretations of the statutory criteria under discussion are neither contrary to, nor inconsistent with, the statutory language or the Act's legislative history. Indeed, the Congressional intent concerning the meaning of the statutory criteria in question and the propriety of the Administrator's interpretation of those criteria is clear and there should be no need to address the second inquiry under the Chevron U.S.A. approach. Nonetheless, the following discussion makes clear that the Administrator's interpretation is proper under that inquiry.

Whether the Administrator's Interpretations are Based on Permissible Construction of the Statutory Criteria: The second inquiry under the Chevron U.S.A. approach was stated as follows:

> 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.

467 U.S. at 843. (emphasis supplied).

In addressing this inquiry, a reviewing court should be

cognizant of the fact that "[t]he power of an administrative agency to administer a congressionally created ... program necessarily requires the formulation of policy and the making of rules to fill any gap left, implicitly or explicitly, by Congress." Morton v. Ruiz, 415 U.S. 199, 231 (1974) (quoted with approval in Chevron U.S.A., 467 U.S. at 843). Indeed, the weight to be given an administrative construction varies depending on whether the delegation of interpretative authority is express or implied:

> If Congress has explicitly left a gap for the agency to fill, there is an express delegation of 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 as case, a court may not substitute its own construction for a reasonable interpretation made by the administrator of an agency.

467 U.S. at 843-44. In either situation, however, the reviewing court "need not conclude that the agency construction was the only one it permissibly could have adopted to uphold the construction, or even the reading the court would have reached if the question initially had arisen in a judicial proceeding." Id. at 843 n. 11 (emphasis supplied). Rather, it need only determine whether the construction was "reasonable" or permissible. See, e.g. Federal Election Commission v. Democratic Senatorial Campaign Committee, 454 U.S. 27, 39 (1981) ("the task for the [reviewing court] [is] not to interpret the statute as it

[thinks] best but rather the narrower inquiry into whether the [agency's] construction [is] 'sufficiently reasonable' to be accepted by [the] court").

The Administrator submits that Congress has expressly delegated to the Attorney General (and, through him, the Administrator) the authority to determine the meaning of the statutory criteria under discussion. 27/ Given this express delegation of interpretative authority, the Administrator's interpretations should be entitled to "controlling weight" because they are not "arbitrary, capricious, nor manifestly contrary to the statute." Chevron U.S.A., 467 U.S. at 844. Even if this Court were to find that the delegation of interpretative authority is implicit instead of explicit, however, the interpretations should be upheld as "reasonable."

As discussed previously, the Administrator's position is consistent with the statutory language and legislative history of the 1970 Act. Indeed, it has been recognized and approved by Congress several times since 1984. This approval by Congress, as well as the other authorities cited in the preceding section, establish that the Administrator's interpretations are reasonable and constitute permissible constructions of the statute.

In arguing that the Administrator's construction should not

27/ Section 201(a) of the 1970 Act, 21 U.S.C. § 811(a), expressly provides that the Attorney General is to make the findings prescribed under Section 302(b) of the Act, 21 U.S.C § 812(b), for placement of a drug or other substance on one of the five schedules.

be upheld, Dr. Grinspoon heavily relies on case law and administrative declarations to the effect that the FDA does not regulate the practice of medicine as between doctor and patient. (Pet. Brief at 17-20). But this reliance is entirely misplaced. The authorities cited by Dr. Grinspoon concern use of drugs previously approved for marketing by the FDA for a use not yet approved by the FDA (i.e., the use of a drug for a purpose not listed in the approved labeling or package insert for the drug). Such "approved" drugs already have some "accepted medical use in treatment in the United States" and have been established as safe for administration to humans under the conditions considered by FDA.

The authorities cited by Dr. Grinspoon simply hold that doctors who administer such drugs to humans for uses not considered, and therefore approved, by the FDA do not thereby violate the Federal Food, Drug, and Cosmetic Act, although they remain subject to state medical malpractice and products liability law for any adverse consequences resulting from such unapproved use. 28/ Those authorities do not negate the proposition that the prior FDA approval of a drug for a medical use establishes the "acceptance" of the drug as safe and effective for use "in the United States." They merely indicate that FDA cannot regulate a physician's use of an approved drug for uses not specified in the labeling of that drug. In short,

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28/ See, e.g., Proposed Rule (21 C.F.R. Part 312), 48 Fed. Reg. 26720, 26733 (June 1983).

the authorities relied on by Dr. Grinspoon simply are not relevant to the legal issues in this case, particularly since MDMA has not been approved by FDA for any use whatsoever.

Dr. Grinspoon also claims that the United States Court of Appeals for the District of Columbia "rejected" the Administrator's interpretation of the phrase "accepted medical use in treatment in the United States" in its decision in National Organization for the Reform of Marijuana Laws (NORML) v. Drug Enforcement Agency, 559 F.2d 735 (D.C. Cir. 1977). (Pet. Brief 15-16). This claim completely mischaracterizes what the court did in that case. The court simply questioned a conclusory statement made in a letter from the Assistant Secretary of Health to the Administrator stating that "[t]here is no accepted medical use of marihuana in the United States [because] [t]here is no approved New Drug Application for [marihuana]." The letter did not elaborate on the agency's reasons for equating the lack of an approved New Drug Application for marihuana under the FDCA with a finding that the drug has no "accepted medical use in treatment in the United States". The court simply stated that "[t]he interrelationship between the two Acts [the 1970 Act and the FDCA] is far from clear" and questioned whether Congress intended that FDA approval of a Schedule I drug must always precede the filing of a petition with DEA to remove the drug from Schedule I. It remanded the case for further proceedings consistent with its opinion. Id. at 750 n. 65. On remand, the Commissioner of the FDA published a Notice in the Federal Register, in which he noted this part of the court's opinion and fully explained the

reasoning behind the administrative interpretation. 47 Fed. Reg. 28141, 28150-51 (1982). (J.A. 314-326). 29/ Congress has subsequently expressed its agreement of the Administrator's interpretation. (See discussion, supra at 19-22).

Dr. Grinspoon also argues that use of the FDCA as the standard for establishing whether drugs have "an accepted medical use in treatment in the United States" is inappropriate because the FDCA regulates only the shipment of drugs in interstate commerce and does not reach the strictly intrastate manufacture and use of drugs not approved under the FDCA. (Pet. Brief at 20). But approval of a drug under the FDCA establishes its safety and effectiveness for the medical uses considered by the FDA and makes the drug available throughout the nation through shipment in interstate commerce. Such approval, therefore, provides a far more reliable indication that a drug has "an accepted medical use in treatment in the United States" (i.e., throughout the nation) than Dr. Grinspoon's proposal that MDMA be found to have "an accepted medical use in the United States" and

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29/ The Commissioner indicated that approval of an NDA for a Schedule I drug under the FDCA need not always precede a petition for re-scheduling the drug under the CSA so long as the petitioner submits sufficient data in support of its petition to allow DEA and FDA to conclude that the substance would qualify for NDA approval: "[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 the substances for NDA approval, confirms the finding that these substances do not meet this criterion ["accepted medical use in treatment in the United States"]. 47 Fed. Reg. at 28151.

State of Calif.

"accepted safety for use" based on the testimony of a few physicians. 30/

Finally, Dr. Grinspoon argues that use of approval under the FDCA to establish "accepted medical use" and "accepted safety for use" is inappropriate because so-called "orphan drugs" and drugs subject to "treatment INDs" may be lawfully administered to humans notwithstanding the fact that such drugs have not been approved for marketing pursuant to a New Drug Application. (Pet. Brief 20-21). It is difficult to discern the relevancy of this argument. MDMA is not an "orphan drug" and there is no "treatment IND" for MDMA. 31/ Rather, it is a "new drug" under

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30/ Dr. Grinspoon's argument is also inconsistent with the following congressional "finding and declaration" set forth in Section 101 of the Act:

> Controlled substances manufactured and distributed intrastate cannot be differentiated from controlled substances manufactured and distributed interstate. Thus, it is not feasible to distinguish in terms of controls between controlled substances manufactured and distributed interstate and controlled substances manufactured and distributed intrastate.

21 U.S.C. § 801(5). Thus, use of approval under the FDCA, which regulates interstate commerce, as the standard for determining whether a drug has an "accepted medical use in treatment in the United States" and "accepted safety for use ... under medical supervision" is not inappropriate although the controls promulgated using this standard will also reach drugs manufactured and distributed on a strictly intrastate basis.

31/ It should be noted that "orphan drugs" and drugs having "treatment INDs" do not have an "accepted medical use ... in the United States" because they have not been approved for general

(Footnote Continued)

By your def. - but not by ordinary usage

the FDCA for which there is no approved a New Drug Application. Thus, it has not been found safe and effective for medical use by the FDA, it has not been approved for marketing in interstate commerce, and it cannot be said to have an "accepted medical use in treatment in the United States" or an "accepted safety for use ... under medical supervision."

The inescapable conclusion, therefore, is that the Administrator's interpretations of the statutory criteria "accepted medical use in treatment in the United States" and "accepted safety for use ... under medical supervision" as meaning that the FDA has approved it for marketing in interstate commerce are entitled to deference by this Court. They are consistent with the statutory language and legislative history of the Act and have been subsequently approved by Congress in amending the Act. Since the interpretations are reasonable and permissible they should be accepted by this Court. See Chevron U.S.A., 467 U.S. at 844.

II. THE ADMINISTRATOR PROPERLY DETERMINED THAT MDMA HAS A "HIGH POTENTIAL FOR ABUSE

(A) The Administrator Applied a Proper Standard and Fully Explained the Reasons For His Decision: Dr. Grinspoon argues (i) that the Administrator failed to articulate any legal standards

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(Footnote Continued)
shipment in interstate commerce. Such drugs are permitted to be shipped in interstate commerce for limited use as designated in the drug's protocol on file with FDA. Since use of such drugs on humans is highly restricted, and is essentially for research purposes, these drugs do not have a "currently accepted medical use in treatment in the United States."

for assessing whether a substance has a "high potential for abuse," (ii) failed to apply any standard whatsoever in making this determination with respect to MDMA, and (iii) failed to provide a reasoned explanation for concluding that the evidence cited in support of his "Final Rule" justified a finding that MDMA has a "high potential for abuse." As set forth below, these arguments lack merit. Indeed, the Administrator, in making his determination that MDMA has an "high potential for abuse" applied the standards expressly approved by Congress in the legislative history of the Act and fully explained his reasons for concluding that MDMA met those standards.

The House Committee Report on the bill which ultimately became the 1970 Act set forth in considerable detail several alternative standards which may be applied in determining whether a drug or other substance has a "potential for abuse":

> (1) ...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
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> (2) ...significant diversion of the drug or drugs from ... legitimate drug channels; or
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> (3) Individuals are taking the drug...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 of

> such drugs, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advise, or that it has a substantial capability of creating hazards to the health of the user or the safety of the community.

H. Rep. No. 1444, 98th Cong. 2nd Sess. (1970), reprinted in 1970 U.S. Code Cong. & Ad. News 4566, 4601 (1970) (emphasis supplied). As indicated by use of the disjunctive connector "or", Congress believed that any one of these standards could be used to establish that a drug or other substance has a potential for abuse. The Administrator articulated findings based on the evidence which established that MDMA not only has a "potential for abuse," but also that it has a "high potential for abuse," under the third and fourth standards cited above.

The Administrator made twenty specific findings (Nos. 70-90) (J.A. 21-22, Findings 70-90) based on evidence that individuals were taking MDMA on their own initiative, rather than on the basis of medical advice, with alarming frequency. The findings included the following: (i) between the emergency placement of MDMA in Schedule I on July 1, 1985 and the closing of the administrative record on November 1, 1985 -- a period of only four months -- DEA laboratories received 14 exhibits of MDMA for Texas alone which contained over 35,000 dosage units of the substance (Finding No. 71); (ii) DEA had encountered five clandestine laboratories producing, or capable of producing, MDMA in kilogram (100,000 dosage unit) quantities (Finding No. 78); and (iii) Dr. Siegel, a witness in the administrative proceeding, had testified that "non-medical street use" of MDMA in the United

States had escalated from an estimated 10,000 doses distributed in all of 1976 to 30,000 doses per month (360,000 annually) in 1985 (Finding No. 83). 32/ Certainly, such findings support the Administrator's conclusion that MDMA has a "high potential for abuse."

More importantly, the Administrator made no less than 47 findings (J.A. 19-21, Findings 19-16) concerning evidence of the close structural and pharmacological similarity between MDMA and substances known to have a "high potential for abuse" and therefore placed in Schedules I and II. 33/ For example, the Administrator noted that the chemical structure of MDMA is substantially similar to those of amphetamine, methamphetamine, and 3,4-methylenedioxyamphetamine ("MDA") all of which are in Schedules I or II based, in part, upon their "high potential for abuse." He also cited animal studies, human behavioral studies, and a survey of MDMA users by Dr. Siegel which suggest that MDMA is related in its effects to the Schedule I or II substances MDA, LSD, cocaine, and mescaline. These findings alone would have been sufficient for the Administrator to conclude that MDMA has a

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32/ Indeed, the Administrator noted that Dr. Grinspoon himself had reported that MDMA was being taken by a growing number of people, particularly students and young professionals, in a casual and recreational manner. (J.A. 22, Finding 87).

33/ In the legislative history of the Controlled Substances Analogue Act of 1986, Congress reaffirmed the paramount importance of the structural and pharmacological similarity between an "analogue" and a Schedule I or II substance in determining whether the "analogue" should be subject to Schedule I controls and penalties. See H.R. Rep. No. 848, 99th Cong., 2d Sess. at 6 (1986) (reproduced as Addendum A to this brief).

"high potential for abuse" since they satisfy the fourth alternative standard set out in the legislative history on "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 [new] drug will have the same potentiality for abuse as such drugs." But the Administrator did not stop there. He also noted in his "Discussion" of the evidence that (i) the United Nations Commission on Narcotic Drugs had placed MDMA in Schedule I of the Convention on Psychotropic Substances and (ii) that MDMA had been placed in Schedule H of the Canadian Food and Drug Act along with MDA and LSD. (J.A. 23).

Dr. Grinspoon, in arguing that the Administrator applied no legal standard whatsoever in finding that MDMA has a "high potential for abuse," wholly ignores the four alternative standards previously discussed and points instead to a single passage in the legislative history of the 1970 Act on the meaning of the word "substantial," which he fails to quote in its entirety. ((Pet. Brief 25-26). The passage from the House Committee Report (which, in turn, was quoting from a committee report on the Drug Abuse Control Amendments of 1965) reads in its entirety:

> [T]he term "substantial" means more than a mere scintilla of isolated abuse, but less than a preponderance. Therefore, documentation that, say, several hundred thousand dosage units of a drug have been diverted would be 'substantial' evidence of abuse despite the fact that tens of millions of dosage units of that drug are legitimately used in the same time period.

H. Rep. No. 1444, reprinted in 1970 U.S. Code Cong. & Ad. News at

4602 (emphasis supplied). It is clear that Congress was merely giving an example of the level of proof -- an example which applies only to the second of the four alternative standards ("significant diversion of the drug or drugs from legitimate drug channels") and which is simply irrelevant as regards the scheduling of MDMA which does not exist in "legitimate drug channels" and therefore cannot be diverted. There is more than a preponderance of evidence to support the Administrator's conclusion that MDMA has a "high potential for abuse" under the third and fourth of the four alternative standards articulated by Congress.

Dr. Grinspoon also complains that the Administrator did not address or make specific findings with respect to the eight factors listed under Section 201(c) of the Controlled Substances Act, 21 U.S.C. § 811(c), in determining MDMA's potential for abuse. (Pet. Brief 23-24). But the House Committee Report on the 1970 Act clearly states that the eight factors "do not require specific findings to be made with respect to control under ... [the] schedules." 1970 U.S. Code Cong. & Ad. News at 4603. Rather, the factors need only "be considered in making the special findings required under Section 202(b) [21 U.S.C. § 812(b)] for control under such schedules." Id. A fair reading of the Administrator's Final Rule makes clear that he gave thorough consideration to the three factors directly relevant to determining "potential for abuse": (1) the "actual or relative potential for abuse; (4) the "history and current pattern of abuse"; and (5) the "scope, duration, and significance of abuse."

Thus, Dr. Grinspoon's complaint in this regard is without merit.

Dr. Grinspoon also points to the fact that amphetamine and methamphetamine -- drugs to which MDMA is closely related -- were originally placed in Schedule III of the Controlled Substances Act when it was enacted in 1970. (Pet. Brief 26-29). Drugs in Schedule III have less than the "high potential for abuse" required for placement of a drug in Schedules I and II. (See 21 U.S.C. § 812(b)(3)(A)). But Congress placed liquid methamphetamine -- to which MDMA is also structurally and pharmacologically related -- in Schedule II. (See 21 U.S.C. § 812, Schedule II(c)). Moreover, the Conference Committee Report on the 1970 Act plainly states that the floor managers of the bill understood that the Attorney General would initiate administrative proceedings to re-schedule some amphetamine-based substances from Schedule III to Schedule II soon after the bill's enactment. 34/ In fact, amphetamine and methamphetamine were re-scheduled to Schedule II effective July 7, 1971 based, in part, on their "high potential for abuse." 35/

Finally, Dr. Grinspoon argues, based on a statements made by an Administration witness in hearings before the House Committee considering the 1970 drug legislation, that the "relative potential abuse" of a substance may only be determined on the basis of actual abuse. (Pet. Brief at 30-32). But Dr.

34/ See Conf. Rep. No. 1603, 98th Cong., 2nd Sess. (1970), reprinted in 1970 U.S. Code Cong. & Ad. News 4657, 4659 (1970).

35/ 36 Fed. Reg. 12734 (July 7, 1971).

Grinspoon's reliance on these statements is misplaced. As earlier mentioned, statements by witnesses at congressional hearings are entitled to little or no weight as indicia of congressional intent on an issue. 36/ This is particularly true where, as here, the House Committee Report on the bill expressly states that "[w]ith respect to the question of the extent to which actual, as distinguished from potential, abuse [is] required to be established, ... 'the [Administrator] should not be required to wait until ... substantial problems have already arisen before designating a drug as subject to controls'." 37/ The Administrator in his Final Rule determined the "relative abuse" of MDMA by comparing it to the abuse potentials of drugs to which it is structurally and pharmacologically similar. This determination of "relative abuse" is consistent with one of the four alternative standards set forth in the legislative history of the 1970 Act and reaffirmed by Congress in 1986. 38/ The Administrator also considered evidence of "actual abuse" including, inter alia, testimony that there were approximately 360,000 "street distributions" of MDMA in 1985.

Thus, the Administrator applied the proper legal standards in determining that MDMA has a "high potential for abuse" and

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36/ See note 25, supra, and accompanying text.

37/ H. Rep. No. 1444, reprinted in 1970 U.S. Code Cong. & Ad. News at 4602 (quoting H.R. Rep. No. 130, 89th Cong., 1st Sess. at 7 (1965)).

38/ See note 33, supra.

fully explained his reasons for reaching that conclusion.

(B) The Administrator's Decision is Supported by "Substantial Evidence": Dr. Grinspoon argues that the Administrator's action was arbitrary, capricious and not in accordance with the law because there was "no evidence" in the record to support the Administrator's conclusion that MDMA has a high potential for abuse. (Pet. Brief at 1). As indicated in the preceding section of this brief, the Administrator cited to voluminous evidence and applied the proper legal standard in determining this issue. For the reasons set forth below, the Administrator's action is supported by "substantial evidence" and is neither arbitrary nor capricious nor contrary to the law.

The Supreme Court has stated the "substantial evidence standard as follows:

> [W]e have defined substantial evidence as "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." Universal Camera Corp. v. NLRB, 340 U.S. 474, 477 (1951). The reviewing court must take into account contradictory evidence in the record, id., at 487-488, but "the possibility of drawing two inconsistent conclusions from the evidence does not prevent an administrative agency's findings from being supported by substantial evidence," Consolo v.FMC, 383 U.S. 607, 620 (1966).

American Textile Manufacturers Institute, Inc. v. Donovan, 452 U.S. 490, 522-23 (1981). Thus, "[e]ven if reasonable minds could also go the other way, [this Court] must uphold the [agency] if its ultimate finding is supported by substantial evidence in the record as a whole." National Labor Relations Board v. J.K.

Electronics, Inc., 592 F.2d 5, 7 (1st Cir. 1979). [39]

Relevant aspects of the evidentiary findings supporting the Administrator's conclusions were recited in the previous section of this brief and will not be repeated here. Moreover, all of the findings in support of the Final Rule are part of the record on this appeal. Clearly there is substantial evidence in the record such that a reasonable mind might accept as supporting the conclusion that MDMA has a "high potential for abuse."

Dr. Grinspoon, in his brief, musters what record evidence he can to support his argument that MDMA does not have a "high potential for abuse. Much of his argument is to the effect that the Administrator chose to credit more recent evidence of high MDMA abuse [40] instead of pre-1985 evidence showing lesser levels of abuse. The law is clear, however, that, while a reviewing court "must take into account whatever in the record detracts

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39/ Where, as here, the Administrator expressly noted his disagreement with the recommendations of the ALJ, independently considered the record, and set forth the reasons for his disagreement, his determination must stand if supported by substantial evidence. See Normile v. McFague, 685 F.2d 9, 12 (1st Cir. 1982) (citing cases). Accord Reckitt & Colman, Ltd. v. Administrator, DEA 788 F.2d 22, 26 (D.C. Cir. 1986) ["The [DEA Administrator] and not the ALJ is the ultimate factfinder. While it is true that reviewing courts must take the ALJ's findings into account, the significance to be ascribed to them depends largely on the importance of credibility in the particular case. The dispute in this case centered not on the occurrence or nonoccurrence of historical facts, or other issues for which demeanor evidence would be highly probative, but rather on matters of scientific judgment and expertise. . . .On such matters, the Administrator remains free to disagree" (citations and quotations omitted)).

40/ See discussion, supra at 34-35.

from [the] weight" of the evidence supporting the Administrator's position, it may not "displace the [agency's] choice between two fairly conflicting views." Universal Camera Corp. v. National Labor Relations Board, 340 U.S. 474, 488 (1951). 41/

Dr. Grinspoon next complains of the Administrator's reliance on evidence concerning (i) the chemical structural similarity between MDMA and other Schedule I and II drugs; (ii) the similar pharmacological effects of MDMA and other drugs; 42/ (iii) animal drug discrimination studies; (iv) animal self-administration studies; and (v) recent studies of the neurotoxic effects of MDMA and related drugs on rats. Dr. Grinspoon would prefer that this Court give controlling weight to the evidence cited by him in his brief. But, again, the law is clear 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." United Steelworkers of America v. Marshall, 647 F.2d 1189, 1263 (D.C. Cir. 1980), cert. denied,

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41/ This is true even where a court might "justifiably had made a different choice had the matter been before it de novo." Id.

42/ As discussed in the preceding portion of this brief, consideration of structural and pharmacological similarities between MDMA and drugs in Schedules I and II is directly consistent with one of the four alternative standards articulated in the legislative history of the 1970 Act for determining "potential for abuse." Moreover, Congress recently affirmed the importance of such evidence when it passed the "Controlled Substances Analogue Act of 1986." See note 33, supra.

453 U.S. 913 (1981) (quoted with approval in Asarco, Inc. v. OSHA, 746 F.2d 483, 490 (9th Cir. 1984). 43/

Essentially, Dr. Grinspoon is asking this Court to credit evidence and witnesses favorable to his position on this issue rather than the evidence and witnesses given greater credence by the Administrator. But this Court's role "is not to reweigh the evidence de novo to determine how [it] would have resolved the matter." Thompson Medical Co, 791 F.2d at 196 (citations omitted). Its task "is only to determine if the [Administrator's] findings are supported by substantial evidence on the record as a whole." Id.

The findings set forth in the Administrator's Final Rule, particularly those concerning the more recent actual abuse of MDMA and the structural and pharmacological similarities between MDMA and other Schedule I and II drugs, are clearly sufficient to be accepted by a reasonable mind as supporting the conclusion that MDMA has a "high potential for abuse" and therefore constitute "substantial evidence" in support the Administrator's conclusion on this issue.

Furthermore, the Administrator's determination that MDMA has a high potential for abuse" was not arbitrary, capricious, or contrary to the law. The Administrator (i) examined the relevant

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43/ See also Thompson Medical Co., Inc. v. Federal Trade Commission, 791 F.2d 189, 196 (D.C. Cir. 1986) ("We deplore Thompson's attempt to retry this matter before us. Appellate courts have neither the expertise or the resources to evaluate complex scientific claims").

data and articulated a satisfactory explanation for his action including a rational connection between the facts found and the choice made; and (ii) based his decision on this issue on a consideration of the relevant factors set out in the statute and legislative history. Thus, his decision should be upheld. See Motor Vehicle Manufacturer's Association v. State Farm Mutual Automobile Insurance Co., 463 U.S. 29, 42-43 (1983).

III. THE ADMINISTRATOR DID NOT IMPROPERLY FAIL TO CONSIDER THE IMPACT ON RESEARCH OF PLACING MDMA IN SCHEDULE I.

Dr. Grinspoon argues that the Administrator, in his Final Rule, made no reference to evidence showing that the placement of MDMA in Schedule I would strongly discourage medical research on that drug. This assertion is simply wrong.

The Administrator, in the "Discussion" section of the Final Rule, stated that he "read with interest the comments from various parties concerning what effect placement of MDMA into Schedule I would have on legitimate research into the substance." (J.A. 23). He then went on for four paragraphs analyzing the effect of placement in Schedule I, as opposed to other Schedules, would have on research on MDMA. He concluded by stating that "[a] review of the above regulations demonstrates that those who wish to conduct research with MDMA have available avenues by which to pursue such research" (J.A. 23).

What is most remarkable about this passage, which Dr. Grinspoon insists does not exist, is that the Administrator was under no legal requirement to even consider the effect, if any, that placement of a drug in Schedule I would have on research.

There is simply nothing in the statutory language, the legislative history, or the implementing regulations making this topic a "relevant factor" for consideration in determining on what schedule, if any, a drug should be placed.

IV. THE ADMINISTRATOR DID NOT IMPROPERLY RELY UPON, OR GIVE UNDUE WEIGHT TO, THE "EVALUATION AND RECOMMENDATION" OF THE DEPARTMENT OF HHS

As noted above, the Administrator submitted information concerning MDMA to the Assistant Secretary for Health of the Department of Health and Human Services ("HHS") on March 13, 1984 and requested that HHS evaluate the information and make a recommendation regarding the proper scheduling of MDMA. This was done pursuant to 21 U.S.C. § 811(b). On June 6, 1984, the Assistant Secretary submitted his agency's "evaluation and recommendation" to the Administrator. HHS recommended that MDMA be placed in Schedule I. The singular effect of the "recommendation and evaluation" was to trigger the administrative proceedings in which Dr. Grinspoon and other parties were given full opportunity to submit evidence and make legal arguments. The Administrator, in his "Final Rule," made passing reference to the HHS evaluation and recommendation in two of his 92 findings of fact in support of his conclusion that MDMA should be placed in Schedule I. He never stated that he was bound by the "evaluation and recommendation" and there is no indication that he accorded any greater weight to the "evaluation and recommendation" than to any other item of evidence or testimony cited in the findings of fact.

Dr. Grinspoon now argues that the Administrator improperly relied upon the HHS "evaluation and recommendation" because that evaluation is legally defective on several grounds. As shown below, all of those grounds are without merit. 44/

44/ Dr. Grinspoon first argues that the HHS "evaluation and recommendation" is legally defective because the Administrator applied an improper legal standard in determining whether MDMA has a "currently accepted medical use in treatment in the United States." This argument is addressed in parts "I" and "II" of this brief and that discussion will not be repeated here.

Dr. Grinspoon next argues that the HHS "evaluation and recommendation" was legally defective, arbitrary, and capricious for failure to consider all "relevant factors," viz for failure to consult medical organizations or to consider data other than that submitted by the Administrator on MDMA's alleged "accepted medical use" and "safety" for such use. However, the "relevant factors" for HHS's "evaluation and recommendation" are the eight factors set out under 21 U.S.C. § 811(c), which HHS is required to consider as a matter of law under 21 U.S.C. § 211(b). The record makes it abundantly clear that HHS considered each of the eight factors. (J.A. 309-311). In doing so, it was under no legal requirement to consult with medical organizations or to consider data other than those submitted by the Administrator. See 21 U.S.C. § 811(b). Thus, HHS properly considered all "relevant factors" and its "evaluation and recommendation" is not legally defective or arbitrary and capricious. See, e.g., Bowman Transportation, Inc. v. Arkansas-Best Freight System, Inc., 419 U.S. 281, 285 (1974).

Dr. Grinspoon next contends that the HHS "evaluation and recommendation" is legally defective because the Assistant Secretary reached a conclusion different from that of the Commissioner of Food and Drugs without giving a reasonable explanation for doing so. This argument apparently refers to the fact that the Commissioner used the term "significant potential for abuse" instead of "high potential for abuse" in describing the abuse potential of MDMA. But the Commissioner (as well as all other participants in the HHS review) ultimately concluded that MDMA should be placed in Schedule I. (J.A. 281, 282, 309). Thus, he must have concluded that MDMA has a "high potential for abuse" notwithstanding his use of the word "significant." Because the Administrator reached the same ultimate conclusion as the Commissioner there was no difference of opinion and, therefore, no need to provide any reasoned explanation.

But even assuming arguendo that the "evaluation and recommendation" were in any respect legally defective and therefore incompetent as an item of evidence, there is still more than substantial evidence in the other 90 findings of fact to support the Administrator's conclusion. Thus, the Administrator's reliance on the HHS "evaluation and recommendation" would constitute harmless error. See, e.g., Carstens v. Nuclear Regulatory Commission, 742 F.2d 1546, 1558 (D.C. Cir. 1984), cert. denied, 105 S. Ct. 2675 (1985) (admission of incompetent evidence was harmless error where agency's findings supported by other "substantial evidence"); Braniff Airways, Inc. v. Civil Aeronautics Board, 379 F.2d 453, 456 (D.C. Cir. 1967) ("court will not reject an agency finding that is supported by substantial evidence merely because the agency also incidentally mentions incompetent...material").

Dr. Grinspoon also complains of two alleged procedural irregularities in the HHS review process: (i) the failure of the HHS staff to transmit a memorandum from the National Institute on Drug Abuse ("NIDA") -- in which NIDA stated that "direct evidence that MDMA has any abuse potential in animals is not substantiated, based on the evidence DEA provided" -- to the Assistant Secretary; and (ii) the alleged failure of HHS to follow "internal agency procedures" by failing to convene and consult its Drug Abuse Advisory Committee on the MDMA issue. Dr. Grinspoon bears the burden of demonstrating material prejudice

resulting from these alleged procedural irregularities. 45/

Dr. Grinspoon cannot carry this burden in this case for several reasons. First, as regards the NIDA memorandum, the ultimate conclusion reached by NIDA was that MDMA should be placed in Schedule I. This was the same conclusion ultimately reached by the Assistant Secretary. Thus, there was no prejudice to Dr. Grinspoon because of the failure to transmit that memorandum to the Assistant Secretary. Second, with respect to the failure to consult the Advisory Committee, there is no formalized internal procedural regulation requiring the Secretary to consult the Committee. Finally and most importantly, as regards both alleged irregularities, the singular effect of the HHS "evaluation and recommendation" was to cause the Administration to initiate the administrative proceedings at which Dr. Grinspoon and other interested parties were given full opportunity to introduce and make use of record evidence (including the NIDA memorandum) and to make legal arguments. It is difficult, therefore, to discern any prejudice to Dr. Grinspoon resulting from the HHS "evaluation and recommendation. See County of Del Norte v. United States, 732 F.2d 1462, 1467 (9th Cir. 1984), cert. denied, 469 U.S. 1189 (1985)

45/ See, e.g., Carstens v. NRC, 742 F.2d at 1558; Connor v. U.S. Civil Service Commission, 721 F.2d 1054, 1056 (6th Cir. 1983); Dodson v. National Transportation Safety Board, 644 F.2d 647, 652 (7th Cir. 1981); NLRB v. Lee Office Equipment, 572 F.2d 704, 708 (9th Cir. 1978).

("insubstantial errors in an administrative proceeding that prejudice no one do not require that administrative proceedings be set aside"); Dodson, 644 F.2d at 652 ("an agency action will not be upset in the event of a harmless procedural error. . . . especially . . . where the error was harmless because there was no resulting prejudice, or where the failure to follow the procedural rule inflicts no significant injury upon the party entitled to the rule's observance") (citations omitted)).

Finally, Dr. Grinspoon argues that the HHS "evaluation and recommendation" was not binding on the Administrator in promulgating the Final Rule. The Administrator, however, never stated that it was binding. In fact, he made only passing reference to it in just two of the 92 findings of fact cited in support of the Final Rule and there is no indication that the Administrator assigned greater weight to the HHS "evaluation and recommendation" then to any other piece of record evidence cited.

Thus, the Administrator's reliance on the HHS "evaluation and recommendation" was not improper or, if it was, any resulting error was harmless.

CONCLUSION

For all of the foregoing reasons, Dr. Grinspoon's petition should be denied and the Administrator's Final Rule placing MDMA in Schedule I of the Controlled Substances Act should be affirmed.

Respectfully submitted,

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ADDENDUM A

99TH CONGRESS
2d Session
HOUSE OF REPRESENTATIVES
REPT. 99-848
Part 1

DESIGNER DRUG ENFORCEMENT ACT OF 1986

SEPTEMBER 19, 1986.—Ordered to be printed

Mr. HUGHES, from the Committee on the Judiciary, submitted the following

REPORT

[To accompany H.R. 5246 which on July 24, 1986, was referred jointly to the Committee on the Judiciary and the Committee on Energy and Commerce]

[Including cost estimate of the Congressional Budget Office]

The Committee on the Judiciary, to whom was referred the bill (H.R. 5246) to amend the Controlled Substances Act to prohibit certain conduct with respect to controlled substance analogs, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Designer Drug Enforcement Act of 1986".

SEC. 2. INCLUSION OF DESIGNER DRUGS IN CONTROLLED SUBSTANCES ACT.

(a) DEFINITION.—Section 102 of the Controlled Substances Act (21 U.S.C. 802) is amended by adding at the end thereof the following:

"(31)(A) Except as provided in subparagraph (B), the term 'controlled substance analogue' means a substance—

"(i) the chemical structure of which is substantially similar to the chemical structure of a controlled substance in schedule I or II; and

"(ii)(I) which has a stimulant, depressant, or hallucinogenic effect on the central nervous system; or

"(II) with respect to a particular person, which such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance.

"(B) Such term does not include—

"(i) a controlled substance;

"(ii) any substance for which there is an approved new drug application;

"(iii) with respect to a particular person any substance, if an exemption is in effect for investigational use, for that person, under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) to the extent conduct with respect to such substance is pursuant to such exemption; or

"(iv) any substance to the extent not intended for human consumption before such an exemption takes effect with respect to that substance.".

(b) TREATMENT OF CONTROLLED SUBSTANCE ANALOGUES.—Part B of the Controlled Substances Act is amended by adding at the end the following new section:

TREATMENT OF CONTROLLED SUBSTANCE ANALOGUES

"SEC. 203. A controlled substance analogue shall, to the extent intended for human consumption, be treated, for the purposes of the Controlled Substances Act and the Controlled Substances Import and Export Act as a controlled substance in schedule I.".

(c) CLERICAL AMENDMENT.—The table of contents of the Comprehensive Drug Abuse Prevention and Control Act of 1970 is amended by inserting after the item relating to section 202 the following new item:

"Sec. 203. Treatment of controlled substance analogues.".

PURPOSE OF THE LEGISLATION

This bill will enable the Drug Enforcement Administration to investigate and prosecute clandestine chemists who develop subtle chemical variations of controlled substances (called analogues or "designer drugs") for illicit distribution and abuse.

SUMMARY OF THE LEGISLATION

The legislation is designed both to enable swift investigation and prosecution of illicit drug designers and to fully protect the interests of legitimate scientific investigation into the properties of drugs that may have important therapeutic potential.

The legislation is structured to make available all of the criminal and regulatory systems of control of the Controlled Substances Act and the Controlled Substances Import and Export Act. For criminal enforcement, under current law, those include up to a 15 year prison sentence (up to 30 years for a second offense), doubled penalties for selling to persons under age 21 or in or near schools, doubled penalties for repeat offenders, up to life imprisonment for those operating continuing criminal enterprises, authority to wiretap, and forfeiture of the violators' profits.[1]

The term "controlled substance analogue" is defined to conform as closely as possible to the policy of the Controlled Substances Act by requiring a chemical relationship to a substance which is controlled (i.e. a chemical structure substantially similar to that of any controlled substance) and either the existence of some stimulant, depressant or hallucinogenic effect on the central nervous system, or a representation or intent that the substance have a stimulant, depressant or hallucinogenic effect substantially similar to, or greater than, such effect of any controlled substance.

BACKGROUND

In 1983 the Administration's request to undertake "emergency scheduling" of substances which effect the central nervous when they are found to have created "an imminent danger to the public safety" was included in the Comprehensive Crime Control Act of

[1] On August 13, 1986, the Committee on the Judiciary ordered reported the bill H.R. 5394, the Narcotics Penalties and Enforcement Act of 1986 which will provide special mandatory penalties for manufacturers and traffickers in controlled substance analogues.

1983, submitted to the Congress by President Reagan on March 15, 1983 (House Document 98–32 and H.R. 2151).

On January 31, 1984, Representatives William J. Hughes and Harold S. Sawyer introduced that proposal, among other proposed amendments as H.R. 4698 (Congressional Record, January 31, 1984, page E 219).

On February 22, 1984 the Subcommittee on Crime began its investigation into the new chemical substances, "controlled substance analogues," that soon thereafter became popularly known as "designer drugs." At that time the Administration requested the authority to undertake "emergency scheduling" of substances which effect the central nervous when they are found to have created "an imminent danger to the public safety" such as "China white", a synthetic heroin, actually a fentanyl analog that had not yet been controlled.[2] The reason for the proposal was the DEA belief that the lag between the suggestion by the Attorney General (the Drug Enforcement Administration) that a substance ought to be controlled or rescheduled [3] and the required findings by the Secretary of Health and Human Services (the Food and Drug Administration) that a particular drug ought to be controlled or rescheduled [4] was too long. In the case of certain analogs of PCP it took 15 months for the substances to be scheduled. Under the "emergency scheduling" authority, DEA believed that the scheduling could be accomplished in 10 or 12 months less time.[5]

The Subcommittee on Crime marked up and reported H.R. 4698 on April 26, 1984 as a clean bill, H.R. 5656. On May 23, 1984 the Committee on the Judiciary ordered H.R. 5656 reported to the full House (H. Rept. 98–835, Part I). Section 3 of the bill created the procedure for scheduling substances on an expedited and temporary basis, to apply to "designer drugs" such as fentanyl analogues, MPPP and MPTP and PCP analogues.[6] This provision was enacted as section 508 of the Dangerous Drug Diversion Control Act (chapter V, part B of the Comprehensive Crime Control Act of 1984, P.L. 98–473, October 12, 1984).

Subcommittee Hearing

On May 1, 1986 the Subcommittee on Crime held a hearing on legislation relating to the problem of designer drugs. Testimony was taken from Representative Charles B. Rangel, 16th Congressional District of New York; Senator Lawton Chiles, Florida; Rich-

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[2] Testimony of Gene Haislip, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, before the Subcommittee on Crime of the House Committee on the Judiciary at hearings on H.R. 4698, Diversion of Prescription Drugs to Illegal Channels and the Dangerous Drug Diversion Control Act, February 22, 1984, Serial No. 139, 98th Cong. 2d sess. p. 148; and letter of April 2, 1984 from Chairman William J. Hughes to Gene Haislip and reply by Administrator Francis M. Mullen, Jr. on April 23, 1984 at pp. 156–7. See also "The War on Drugs Is Over. The Government Has Lost." by Jack Shafer, INQUIRY, February 1984, reprinted in the Hearings on H.R. 4698 at pp. 460–466.

[3] Under section 201(a) of the Controlled Substances Act (21 U.S.C. 811(a)).

[4] Under section 201(b) of the Controlled Substances Act (21 U.S.C. 811(b)).

[5] See letter of April 23, 1984 and attachments to Chairman William J. Hughes from DEA Administrator Francis M. Mullen, Jr. in Hearings before the Subcommittee on Crime of the House Committee on the Judiciary on H.R. 4698, Diversion of Prescription Drugs to Illegal Channels and the Dangerous Drug Diversion Control Act, February 22, 1984, Serial No. 139, 98th Cong. 2d sess. at pp. 157–9.

[6] House Report 98–835, Part I, at pp. 9–13.

ard Hawks, Ph.D., Chief, Research Technology Branch, Division of Preclinical Research, National Institute on Drug Abuse, Public Health Service, U.S. Department of Health and Human Services, accompanied by Vernon Houk, M.D., Director, Center for Environmental Health, Centers for Disease Control, U.S. Department of Health and Human Services; and Edward C. Tocus, Ph.D., Director, Drug Abuse Staff within the Center for Drugs and Biologics, Food and Drug Administration, U.S. Department of Health and Human Services; James N. Hall, Director, UpFront Drug Information Center, Miami, Florida; Robert T. Angarola, Esquire, Hyman, Phelps and McNamara, Washington, D.C.; Lester Grinspoon, M.D., Associate Professor of Psychiatry, Harvard Medical School, Cambridge, Massachusetts; Everett Ellinwood, M.D., Professor of Psychiatry and Pharmacology, Duke University Medical Center, on behalf of the American Psychiatric Association. The statement of Stephen S. Trott, Assistant Attorney General, Criminal Division, U.S. Department of Justice was received for the record.

Need for the Legislation

Designer drugs such as the fentanyl analogues have resulted in over one hundred drug overdoses because in some cases they are as much as 3000 times more potent than heroin. One designer drug (MPPP, an analogue of meperidine (Demerol)) has been marketed with processing impurities (MPTP) that has caused almost total paralysis in dozens of young people because MPTP is believed to cause parkinsonism. At least another 400 persons have been idenfified as being at serious risk of developing parkinsonism due to their exposure to the impurities associated with this designer drug.[7]

Each controlled substance has been precisely defined and has been demonstrated through scientific tests as having a potential for abuse, meaning that it has a stimulant, depressant or hallucinogenic effect on the central nervous system, which is the basis for the strict control of such substances (section 201(f) of the Controlled Substances Act (21 U.S.C. 811(f)).

Makers of "designer drugs" chemically alter a controlled substance by making slight alterations but maintaining the basic chemical structure of the drug in order to produce a new, uncontrolled chemical which produces an effect on the central nervous system like that of a controlled substance.

These new substances are not controlled and therefore their manufacture and distribution currently do not violate the Controlled Substances Act. The 98th Congress extended to DEA the power to control such new substances on an emergency basis. DEA has used the authority five times to control 13 new dangerous drugs, including 10 fentanyl analogues; MDMA, an analogue of MDA (a schedule I substance); and MPPP and PEPAP (analgues of meperidine). In the Committee's view, generally this authority has

[7] Testimony of Lawton Chiles, U.S. Senator from Florida at Hearings before the Subcommittee on Crime of the House Committee on the Judiciary on H.R. 2014, H.R. 2977, H.R. 3936, H.R. 5231, H.R. 5246, and S. 1437, Legislation relating to the Problem of Designer Drugs, May 1, 1986, 99th Cong. 2d sess.; and Hearing before the Senate Committee on the Budget, July 18, 1985, 99th Cong., 2d sess. S. Hrg. 99-124 chaired by Senator Chiles.

been used very effectively to address much of the designer drug problem.

However, DEA in the course of its investigations has found a very small number of illicit chemists have been very carefully developing new drugs to stay ahead of DEA's scheduling actions. As a consequence, even with the emergency scheduling authority, the public remains at risk, and dangerous chemists are able to escape prosecution due to the following factors. First, there is an enormous number of drugs which can yet be developed. Second, there is an unavoidable delay in discovering that such drugs are being distributed. Third, there is the unavoidable obstacle of establishing that these drugs are being abused and pose an imminent threat to the public health. Finally, there is the elapse of time needed to undertake and complete action to control the drugs. The only way to effectively protect the public is to investigate and prosecute these chemists for their new discoveries prior to formal control of the drugs.

On April 4, 1985, Representative Charles Rangel, Chairman of the House Select Committee on Narcotics Abuse and Control (joined by Mr. Gilman, the ranking minority member of the select committee), introduced H.R. 2014 to require the National Drug Enforcement Policy Board to provide a comprehensive assessment of the designer drug problem and to report to Congress.

On July 11, 1985, Representative Dan Lungren (joined by Mr. Fish, Mr. McCollum and Mr. Gekas, members of the Committee) introduced H.R. 2977 to create certain crimes with respect to designer drugs.

On December 12, 1985, Representative Larry Smith (joined by Mr. Fascell and Mr. Hyde) introduced H.R. 3936, the Drug Enforcement Amendments of 1985, which included provisions addressing designer drugs.

In December 1985, the Drug Enforcement Administration, Office of Diversion Control issued a report on controlled substance analogs. On March 5, 1986, the National Drug Enforcement Policy Board transmitted to the Congress its report on controlled substance analogs.

Committee Action

On July 24, 1986, Representative William J. Hughes introduced H.R. 5231, the Designer Drug Enforcement Act of 1986.

On July 24, 1986, the Subcommittee on Crime, a quorum being present, marked up H.R. 5231 and ordered it reported as a clean bill, H.R. 5246. On July 29, 1986, the Committee on the Judiciary, a quorum being present, marked up H.R. 5246 and ordered it favorably reported to the full House as a single amendment in the nature of a substitute.

Section-by-Section Analysis

Section 1 is the short title.

Section 2 provides for the inclusion of designer drugs ("controlled substance analogues") in the Controlled Substances Act.

(a) Definition:

The term "controlled substance analogue" means a substance—
(i) the chemical structure of which is substantially similar *to the chemical structure* of a controlled substance in schedule I or II; and
(ii) (I) which was a stimulant, depressant, or hallucinogenic effect on the central nervous system; or
(II) with respect to a particular person, which such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system caused by a controlled substance.

EXPLANATION

The first branch of this definition, (i), focuses on the chemical structure of the substance. The effects of a drug are generally a function of its chemical structure. Broad classes of related drugs will have substantially similar structures with subtle but important differences caused by relatively minor modification of the basic structure. Consequently, both legitimate and illegitimate chemists focus their research in the development of new psychoactive drugs on making subtle modifications of existing controlled substances.

The first branch of the definition is critically important because it serves to link the unknown drugs which are being controlled by this law to the drugs already controlled by the Controlled Substances Act. The Committee, by a voice vote, rejected an amendment to add an alternative definition of controlled substance analogue that did not include either a requirement of a chemical structure substantially similar to the chemical structure of a controlled substance in schedule I or II or an effect of the central nervous system (second branch of the definition) if the substance had been "specifically designed" to produce an effect "substantially similar" to that of a controlled substance in schedule I or II.

The second branch of the definition, (ii), is in the alternative. As a general rule, to justify the strict controls of this act, a "designer drug" ought to have not only a chemical structure like other controlled drugs but some relationship to the stimulant, depressant or hallucinogenic effect upon the central nervous system which is the justification for controlling drugs in the first place. However in the case in which there is no effect upon the central nervous system, then at least it must be shown that some person (namely, the defendant) intended or represented the substance to have an effect on the central nervous system that is substantially similar to or greater than the effect of a controlled substance.

The American Chemical Society, which strongly supported the legislation, urged that both chemical structure and central nervous system effect be required in the definition of controlled substance analogue in order to protect legitimate research.[8]

[8] See letter of May 1, 1986 to Rep. William J. Hughes from George C. Pimentel, President, American Chemical Society, page 3; and letter of July 23, 1986 to Eric E. Sterling, Assistant Counsel, Subcommittee on Crime from Anna Fotias, Manager, Department of Governmental Relations and Science Policy, American Chemical Society reprinted in Hearings before the Sub-

Continued

Coffee, for example, has a stimulant effect on the central nervous system, but it is not chemically substantially similar to a controlled substance. To punish someone under the Controlled Substances Act who makes or distributes a new substance that has a chemical structure similar to a controlled substance, there ought to be evidence either of some effect on the central nervous system (such as that of caffeine), or that the person has made a representation or has evidenced an intent that the drug mimic the effect of a controlled substance. If the person were to merely say this substance is as powerful as a cup of coffee, and no stimulant or other central nervous system effect is found, then no harm has been committed that ought to involve the Controlled Substances Act.

A pre-introduction discussion draft of H.R. 5231, circulated to Drug Enforcement Administration and the industry for comment, had proposed that the effect test in the second branch of the definition require that the analogue's effect be "substantially similar" to the effect of a controlled substance. The Drug Enforcement Administration had expressed concern that the conjunctive requirement of chemical structure and a "substantially similar" central nervous system effect might be difficult to prove. Before H.R. 5321 was introduced, Mr. Hughes modified the effect requirement in the bill so that the evidence of central nervous system effect is minimal compared to the research burden that Drug Enforcement Administration has to sustain in order to bring a drug under control.[9] Indeed, as defined in the bill, a person could be convicted of felony offenses regarding a particular controlled substance analogue which as a substance could not be scheduled under the Controlled Substances Act. This could result if the analogue's effects did not meet the requirements for scheduling under section 201(c) of the Controlled Substances Act (21 U.S.C. 811(c)), for example, the analogue could lack a potential for abuse or a psychic or physiological dependence liability.

Representative Lungren offered an amendment, adopted by the Committee by a voice vote, to add an alternative representation or intent that the analogue have an effect greater than a controlled substance. A trafficker in controlled substance analogues should not escape sanction because he represents the drug he is selling as, "The greatest high in the world, greater than anything known to DEA."

(B) Exceptions to the definition

One major concerns of the Committee in the development of this legislation was to guarantee that it did not interfere in legitimate pharmaceutical or medical research in any way.

In order to protect the many types of important scientific research involved in developing drugs to relieve pain or to aid in psychiatry and the treatment of emotional disorders, four exceptions to the definition of a controlled substance analogue have been provided by the Committee.

The term "controlled substance analogue" does not include:

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committee on Crime of the House Committee on the Judiciary on Legislation relating to the Problem of Designer Drugs, May 1, 1986, 99th Cong. 2d sess.

[9] Controlled Substances Act, section 201(a), (b) and (c): (21 U.S.C. 811(a), (b) and (c)).

(i) A controlled substance. If a substance has been scheduled as a controlled substance, then it cannot and should not be treated legally as a controlled substance analogue, even if its history of abuse was before it was controlled.

(ii) Any substance for which there is an approved new drug application. These are drugs which have been found by the Food and Drug Administration to be safe and effective and have been approved for marketing in interstate commerce. Such drugs, if they have a stimulant, depressant or hallucinogenic effect upon the central nervous system are brought to the attention of the Attorney General at the time the new drug application is submitted (section 201(f) of the Controlled Substances Act (21 U.S.C. 811(f)) and, if warranted, scheduled according the regular scheduling procedure of section 201(a) of the Controlled Substances Act (21 U.S.C. 811(a)).

(iii) With respect to a particular person, any substance for which an exemption from the Food and Drug Administration has been granted to permit "investigational use" of the drug by that person, to the extent conduct with respect to the substance is pursuant to the exemption. (Such exemptions under the Federal Food, Drug and Cosmetic Act are called "INDs".)

FDA allows drug manufacturers to carry out clinical research on human beings in the process of developing new drugs by allowing distribution of the drug in interstate commerce. These exemptions are specific as to substance and manufacturer. This exception is drafted to permit prosecution of a person who "diverts" the drug analogue from distribution for the purpose of research to illicit channels for the purpose of drug abuse.

(iv) Any substance to the extent not intended for human consumption before an exemption (that is, an IND) takes effect with respect to that substance. This provision is included in recognition of the fact that drug researchers compound new drugs with an intent that ultimately they will be developed to be sold for human consumption in the course of medical treatment. This provision has been included to assure that, in a temporal sense, to the extent the substance is not intended to be used or distributed for human consumption before the time that an exemption is issued, the substance will not be treated as a controlled substance analog. Similarly, these compounds as manufactured and distributed for research that does not involve human consumption are not considered controlled substance analogs unless they are diverted for human consumption.

(b) Treatment of controlled substance analogues

A new section 203 is added to the Controlled Substances Act to provide that a controlled substance analogue, to the extent it is intended for human consumption, is to be treated as a controlled substance in schedule I.

Substances in schedule I do not have any currently recognized medical use in treatment in the United States, but nonetheless, are often used in research—either in the area of drug abuse or, as in the case of marihuana, research in the treatment of the nausea related to cancer chemotherapy or in the treatment of glaucoma.

Section 303(f) of the Controlled Substances Act (21 U.S.C. 823(f)) authorizes researchers whose research involves human consump-

tion of schedule I substances to obtain specific registrations for research from DEA upon approval of their research protocols. Those scientific investigators (who are "practitioners" as defined in section 102(21) of the Controlled substances Act (21 U.S.C. 802(21) and are thus eligible for registration under section 303(f) (21 U.S.C. 823(f)) whose research is not undertaken pursuant to an IND or an NDA will be able to undertake research on controlled substance analogues upon obtaining specific registrations for research from the Drug Enforcement Administration upon approval of their research protocols by the Food and Drug Administration and the Drug Enforcement Administration.

It is the Committee's explicit intent that this Act not interfere in any way in legitimate pharmaceutical or medical research or treatment. The Committee debated an amendment offered by Mr. Morrison of Connecticut that would have created an additional exception to the definition of controlled substance analogue with respect to a practitioner who was registered with the Drug Enforcement Administration to conduct research using controlled substances, to the extent permitted under the Federal Food, Drug and Cosmetic Act, only amounts of analogues used in that practitioner's research. The concern was expressed that clinical research involving substances that might be treated as controlled substance analogues is permissible under the Federal Food, Drug and Cosmetic Act outside the exemption for interstate distribution of investigational new drugs. The amendment was withdrawn by unanimous consent to permit examination of the application of the Federal Food, Drug and Cosmetic Act so that the amendment could be perfected and offered on the floor in order to protect such research, if a further exception were found to be necessary.

COMMITTEE APPROVAL

On July 29, 1986, the Committee on the Judiciary, a quorum being present, marked up H.R. 5246 and ordered it favorably reported to the full House as a single amendment in the nature of a substitute by a voice vote.

OVERSIGHT FINDINGS

The Committee makes no oversight findings with respect to this legislation other than those included in the text of this report.

In regard to clause 2(l)(3)(D) of rule XI of the Rules of the House of Representatives, no oversight findings have been submitted to the Committee by the Committee on Government Operations.

NEW BUDGET AUTHORITY

In regard to clause 2(l)(3)(B) of rule XI of the Rules of the House of Representatives, H.R. 5246 creates no new budget authority or increased tax expenditures for the Federal Government.

INFLATIONARY IMPACT STATEMENT

Pursuant to clause 2(l)(4) of rule XI of the Rules of the House of Representatives, the Committee finds that the bill will have no

foreseeable inflationary impact on prices or costs in the operation of the national economy.

Federal Advisory Committee Act of 1972

The Committee finds that this legislation does not create any new advisory committees within the meaning of the Federal Advisory Committee Act of 1972.

Cost Estimate

In regard to clause 7 of rule XIII of the Rules of the House of Representatives, the Committee agrees with the cost estimate of the Congressional Budget Office.

Statement of the Congressional Budget Office

Pursuant to clause 2(l)(3)(C) of rule XI of the Rules of the House of Representatives, and section 403 of the Congressional Budget Act of 1974, the following is the cost estimate of H.R. 5246.

U.S. Congress,
Congressional Budget Office,
Washington, DC, August 11, 1986.

Hon. Peter W. Rodino, Jr.,
Chairman, Committee on the Judiciary,
Rayburn House Office Building, Washington, DC.

Dear Mr. Chairman: The Congressional Budget Office has reviewed H.R. 5246, the Designer Drug Enforcement Act of 1986, as ordered reported by the House Committee on the Judiciary, July 29, 1986. We estimate that no significant cost to the federal government and no cost to state or local governments would result from enactment of this bill.

H.R. 5246 would make "controlled substance analogs" subject to the Controlled Substances Act. This would enable the Drug Enforcement Administration to prosecute chemists who develop subtle chemical variations of controlled substances (called "designer drugs").

This bill would aid prosecution in cases brought by the Drug Enforcement Administration involving controlled substance analogs. It would not significantly change investigative efforts or costs as these drugs are currently investigated and tested. It would make possible prosecution and conviction in some cases where it is currently not possible.

If you wish further details on this estimate, we will be pleased to provide them.

With best wishes,
Sincerely

Rudolph G. Penner, *Director.*

Changes in Existing Law Made by the Bill, As Reported

In compliance with clause 3 of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omit-

ted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

CONTROLLED SUBSTANCES ACT

TABLE OF CONTENTS

* * * * * * *

TITLE II—CONTROL AND ENFORCEMENT

PART A—SHORT TITLE; FINDINGS AND DECLARATION; DEFINITIONS

DEFINITIONS

SEC. 102. As used in this title:
(1) * * *

* * * * * * *

(31)(A) Except as provided in subparagraph (B), the term "controlled substance analogues" means a substance—

(i) the chemical structure of which is substantially similar to the chemical structure of a controlled substance in schedule I or II; and

(ii)(I) which has a stimulant, depressant, or hallucinogenic effect on the central nervous system; or

(II) with respect to a particular person, which such person represents or intends to have a * * *

* * * * * * *

the central nervous system substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance.

(B) Such term does not include—

(i) a controlled substance;

(ii) any substance for which there is an approved new drug application;

(iii) with respect to a particular person any substance, if an exemption is in effect for investigational use, for that person, under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) to the extent conduct with respect to such substance is pursuant to such exemption; or

(iv) any substance to the extent not intended for human consumption before such an exemption takes effect with respect to that substance.

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PART B—AUTHORITY TO CONTROL; STANDARDS AND SCHEDULES

AUTHORITY AND CRITERIA FOR CLASSIFICATION OF SUBSTANCES

SEC. 201. (a) * * *

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TREATMENT OF CONTROLLED SUBSTANCE ANALOGUES

SEC. 203. A controlled substance analogue shall, to the extent intended for human consumption, be treated, for the purposes of the Controlled Substances Act and the Controlled Substances Import and Export Act as a controlled substance in schedule I.

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CERTIFICATE OF SERVICE

I hereby certify that on the 10th day of February 1987, I served the "Brief of Respondent" to which this certificate is attached by depositing two (2) copies thereof in the United States Mail addressed to:

Richard Cotton, Esq.
600 New Hampshire Ave., N.W.
Suite 600
Washington, D.C. 20037

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