NLWJC- Kagan

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Rohypnol [2]

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF NATIONAL DRUG CONTROL POLICY
Washington, D.C. 20503

January 23, 1996

MEMORANDUM TO ELENA KAGAN
DENNIS BURKE

FROM: EDWARD H. JURITH EHJ

RE: ROHYPNOL

I have further reviewed the law and legislative history surrounding 21 USC 811(h)(1) and the specific argument that the disjunctive nature of the statute would permit the Attorney General to place flunitrazepam (rohypnol) in Schedule 1 on an emergency basis. I ask that you consider the following case law and interpretations in deciding whether we can recommend using the emergency authority in this instance.

First, a plain reading of the statute yields the conclusion that the AG could not temporarily schedule a substance if it was already in Schedules II-V or if it was subject to an IND or NDA under section 355 granted by FDA. Moreover the statute in issue talks in terms of the "scheduling" of a drug. What is being proposed is a "rescheduling" of an previously scheduled drug. Using 811 in this manner would do disruption to the entire CSA scheduling scheme.

Second, can the AG temporarily place a drug in schedule I if it is not subject to a pending IND or NDA, even though it is listed in schedule IV? If that is correct, the converse would also be true -- the AG could place an FDA approved drug in schedule 1 if it is not already scheduled. I believe case law. logic, and the legislative history of the statute argue against this conclusion.

In Grinspoon v. DEA, 828 F.2d 881 (1st Cir, 1987), the court in reviewing the provisions of the emergency scheduling authority noted:

> "This provision allows the Attorney General to place certain substances into schedule I on a temporary basis without regard to the regular scheduling criteria and procedures if such emergency scheduling is 'necessary to avoid an imminent hazard to public safety.' 21 USC 811(h)(1). This amendment to the CSA, however, expressly states that the Attorney

> General's authority to schedule substances in this expedited manner does not apply where an "exemption or approval is in effect for the substances under section 355 of this title", i.e., where the FDA has permitted the substances to be marketed in interstate commerce."

Substances listed in schedules II-V in Section 812 all share the criteria of having a currently accepted medical use in treatment. Grinspoon specifically rejected the notion that a substance must have FDA approval or exemption to have a currently accepted medical use. Thereafter, DEA adopted a five criteria test which would allow it to conclude a medically useful drug not marketed in the United States has a "currently accepted medical use" under the Controlled Substances Act. The test is as follows; the drug's chemistry must be known and reproducible; there must be adequate safety studies, there must be adequate and well controlled studies proving efficacy, acceptance by qualified experts is required, and the scientific evidence must be widely available.

This five criteria test is set forth at 57 Fed. Reg, 10499-10508, March 26, 1992. In this notice DEA, specifically reference the fact that when the Controlled Substances Act was enacted, drugs with medical uses but without approved NDA's, were placed by Congress in Schedules II, III, IV and V. Citing Grinspoon, the notice states that "NDA approval is not the only method by which drugs can achieve Federal recognition as having medical uses" (at page 10504).

Thus, under Grinspoon, if a substance is listed in schedule II - V under section 812 (regardless of whether it has an exemption or approval under section 355) it has an accepted medical use, or if a substance is subject to an approval or exemption under section 355, the AG may not list the substance in schedule I on an emergency basis.

Legislative History

Addressing concerns of medical treatment House Report 98-835 states:

> The Subcommittee believed that these concerns raised significant questions about the impact an emergency scheduling authority would have on the manufacture and distribution of drugs that are currently used in medical treatment. In examining the particular substance for which the scheduling action was most necessary, the Subcommittee concluded that limiting the authority only to substances that have no currently accepted medical use in treatment addressed both the legitimate

> concerns of those in the health care industry and the principal danger to the public health.

The stated congressional intent was to limit the effect of 811(h) to substances that have no currently accepted medical use in treatment.

In essence, being listed in schedules II-V, indicates that a substance has an accepted medical use, as do drugs having an FDA approval or exemption under section 355. Congress did not intend that medically useful drugs be subject to emergency scheduling in schedule I -- which the CSA reserves for substances that have no currently accepted medical uses.

Practical Application

Moreover, the practical use of the emergency authority has been limited to drugs which fall outside the current schedules or lack NDA or IND status under section 355. As the attached list illustrates, it has been directed at fentanyl and other "designer drug" analogs which have a high potential for abuse.. This is not the case with medications that have been approved for medical use and otherwise scheduled.

Conclusion

Based on the above analysis, I do not believe we can utilize the emergency scheduling authority to "reschedule" rohypnol in Schedule I

I suggest we explore the following alternatives:

1. Formal rescheduling of rohypnol to schedule II or III. This will ensure tighter controls over the drug from an administrative point of view.

2. Propose legislation that enhances Federal penalties for use of a controlled substance in connection with a sexual assault.

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determine whether drug
constitutes "new drug"
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710 F.2d 1375.

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Inc., D.N.D.1992, 803

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ing held to determine whether the Food and Drug Administration acted rationally in requiring that preparations of vitamins A and D in excess of specified dosages be restricted to prescription sale and be labeled accordingly, for cross-examination by those opposing the actions taken by the Food and Drug Administration. National Nutritional Foods Ass'n v. Mathews, D.C.N.Y.1976, 418 F.Supp. 394.

§ 355. New drugs

(a) Necessity of effective approval of application

No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug.

(b) Filing application; contents

(1) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a) of this section. Such person shall submit to the Secretary as a part of the application (A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (B) a full list of the articles used as components of such drug; (C) a full statement of the composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (E) such samples of such drug and of the articles used as components thereof as the Secretary may require; and (F) specimens of the labeling proposed to be used for such drug. The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If an application is filed under this subsection for a drug and a patent which claims such drug or a method of using such drug is issued after the filing date but before approval of the application, the applicant shall amend the application to include the information required by the preceding sentence. Upon approval of the application, the Secretary shall publish information submitted under the two preceding sentences.

(2) An application submitted under paragraph (1) for a drug for which the investigations described in clause (A) of such paragraph and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted shall also include—

(A) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the drug for which such investigations were conducted or which claims a use for such drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under paragraph (1) or subsection (c) of this section—

(i) that such patent information has not been filed,

(ii) that such patent has expired,

(iii) of the date on which such patent will expire, or

(iv) that such patent is invalid or will not be infringed by the manufacture use, or sale of the new drug for which the application is submitted; and

(B) if with respect to the drug for which investigations described in paragraph (1)(A) were conducted information was filed under paragraph (1) or subsection (c) of this section for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

(3)(A) An applicant who makes a certification described in paragraph (2)(A)(iv) shall include in the application a statement that the applicant will give the notice required by subparagraph (B) to—

(i) each owner of the patent which is the subject of the certification or the representative of such owner designated to receive such notice, and

(ii) the holder of the approved application under subsection (b) of this section for the drug which is claimed by the patent or a use of which is claimed by the patent or the representative of such holder designated to receive such notice.

(B) The notice referred to in subparagraph (A) shall state that an application has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification. Such notice shall include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed.

(C) If an application is amended to include a certification described in paragraph (2)(A)(iv), the notice required by subparagraph (B) shall be given when the amended application is submitted.

(c) Period for approval of application; period for, notice, and expedition of hearing; period for issuance of order

(1) Within one hundred and eighty days after the filing of an application under subsection (b) of this section, or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either—

(A) Approve the application if he then finds that none of the grounds for denying approval specified in subsection (d) of this section applies, or

(B) Give the applicant notice of an opportunity for a hearing before the Secretary under subsection (d) of this section on the question whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(2) If the patent information described in subsection (b) of this section could not be filed with the submission of an application under subsection (b) of this section because the application was filed before the patent information was required under subsection (b) of this section or a patent was issued after the application was approved under such subsection, the holder of an approved application shall file with the Secretary the patent number and the expiration date of any patent which claims the drug for which the application was submitted or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If the holder of an approved application could not file patent information under subsection (b) of this section because it was not required at the time the application was approved, the holder shall file such information under this subsection not later than thirty days after September 24, 1984, and if the holder of an approved application could not file patent information under subsection (b) of this section because no patent had been issued when an application was filed or approved, the holder shall file such information under this subsection not later than thirty days after the date the patent involved is issued. Upon the submission of patent information under this subsection, the Secretary shall publish it.

(3) The approval of an application filed under subsection (b) of this section which contains a certification required by paragraph (2) of such subsection shall be made effective on the last applicable date determined under the following:

(A) If the applicant only made a certification described in clause (i) or (ii) of subsection (b)(2)(A) of this section or in both such clauses, the approval may be made effective immediately.

(B) If the applicant made a certification described in clause (iii) of subsection (b)(2)(A) of this section, the approval may be made effective on the date certified under clause (iii).

(C) If the applicant made a certification described in clause (iv) of subsection (b)(2)(A) of this section, the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (3)(B) is received. If such an action is brought before the expiration of such days, the approval may be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (3)(B) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

(i) if before the expiration of such period the cour is invalid or not infringed, the approval may be mac the court decision,

(ii) if before the expiration of such period the cour has been infringed, the approval may be made effe court orders under section 271(e)(4)(A) of Title 35, c

(iii) if before the expiration of such period the c injunction prohibiting the applicant from engaging in ture or sale of the drug until the court decides the is infringement and if the court decides that such infringed, the approval shall be made effective or decision.

In such an action, each of the parties shall reasonably co action. Until the expiration of forty-five days from the d paragraph (3)(B) is received, no action may be brought u 28 for a declaratory judgment with respect to the pat under such section 2201 shall be brought in the judicial di has its principal place of business or a regular and esta

(D)(i) If an application (other than an abbreviated new ted under subsection (b) of this section for a drug, no a any ester or salt of the active ingredient) of which has be application under subsection (b) of this section, was ap beginning January 1, 1982, and ending on September 24 not make the approval of another application for a drug fo described in clause (A) of subsection (b)(1) of this sectio applicant for approval of the application were not conduct and for which the applicant has not obtained a right of r person by or for whom the investigations were condu expiration of ten years from the date of the approval of approved under subsection (b) of this section.

(ii) If an application submitted under subsection (b) of active ingredient (including any ester or salt of the active been approved in any other application under subsecti approved after September 24, 1984, no application whic which the subsection (b) application was submitted and fo described in clause (A) of subsection (b)(1) of this sectio applicant for approval of the application were not conduct and for which the applicant has not obtained a right of r person by or for whom the investigations were conducte subsection (b) of this section before the expiration of five approval of the application under subsection (b) of this se application may be submitted under subsection (b) of this tion of four years from the date of the approval of the sub contains a certification of patent invalidity or noninfringe (iv) of subsection (b)(2)(A) of this section. The approval o be made effective in accordance with this paragraph exc patent infringement is commenced during the one-year pe months after the date of the approval of the subsection (month period referred to in subparagraph (C) shall be ex time (if any) which is required for seven and one-half ye the date of approval of the subsection (b) application.

(iii) If an application submitted under subsection (b) which includes an active ingredient (including any est ingredient) that has been approved in another applicatio tion (b) of this section, is approved after September 24, 19 contains reports of new clinical investigations (other th essential to the approval of the application and conduc applicant, the Secretary may not make the approval of under subsection (b) of this section for the conditions of ap approved subsection (b) application effective before the from the date of the approval of the application under sub if the investigations described in clause (A) of subsection relied upon by the applicant for approval of the applicatio

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of this section on the question whether such application is
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shorter or longer period as the court may order because
failed to reasonably cooperate in expediting the action.

(i) if before the expiration of such period the court decides that such patent is invalid or not infringed, the approval may be made effective on the date of the court decision,

(ii) if before the expiration of such period the court decides that such patent has been infringed, the approval may be made effective on such date as the court orders under section 271(e)(4)(A) of Title 35, or

(iii) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of such court decision.

In such an action, each of the parties shall reasonably cooperate in expediting the action. Until the expiration of forty-five days from the date the notice made under paragraph (3)(B) is received, no action may be brought under section 2201 of Title 28 for a declaratory judgment with respect to the patent. Any action brought under such section 2201 shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(D)(i) If an application (other than an abbreviated new drug application) submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of another application for a drug for which the investigations described in clause (A) of subsection (b)(1) of this section and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted effective before the expiration of ten years from the date of the approval of the application previously approved under subsection (b) of this section.

(ii) If an application submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, is approved after September 24, 1984, no application which refers to the drug for which the subsection (b) application was submitted and for which the investigations described in clause (A) of subsection (b)(1) of this section and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted may be submitted under subsection (b) of this section before the expiration of five years from the date of the approval of the application under subsection (b) of this section, except that such an application may be submitted under subsection (b) of this section after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in clause (iv) of subsection (b)(2)(A) of this section. The approval of such an application shall be made effective in accordance with this paragraph except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (C) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

(iii) If an application submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b) of this section, is approved after September 24, 1984, and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under subsection (b) of this section for the conditions of approval of such drug in the approved subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) of this section if the investigations described in clause (A) of subsection (b)(1) of this section and relied upon by the applicant for approval of the application were not conducted by

or for the applicant and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

(iv) If a supplement to an application approved under subsection (b) of this section is approved after September 24, 1984, and the supplement contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under subsection (b) of this section for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b) of this section if the investigations described in clause (A) of subsection (b)(1) of this section and relied upon by the applicant for approval of the application were not conducted by or for the applicant and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

(v) If an application (or supplement to an application) submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection and for which the investigations described in clause (A) of subsection (b)(1) of this section and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted and which refers to the drug for which the subsection (b) application was submitted effective before the expiration of two years from September 24, 1984.

(d) Grounds for refusing application; approval of application; "substantial evidence" defined

If the Secretary finds, after due notice to the applicant in accordance with subsection (c) of this section and giving him an opportunity for a hearing, in accordance with said subsection, that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b) of this section, do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions; or (5) evaluated on the basis of the information submitted to him as part of the application and any other information before him with respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or (6) the application failed to contain the patent information prescribed by subsection (b) of this section; or (7) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that clauses (1) through (6) do not apply, he shall issue an order approving the application. As used in this subsection and subsection (e) of this section, the term "substantial evidence" means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.

(e) Withdrawal of approval; grounds; immediate suspension upon finding imminent hazard to public health

The Secretary shall, after due notice and opportunity for hearing to the applicant, withdraw approval of an application with respect to any drug under this section if the Secretary finds (1) that clinical or other experience, tests, or other scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the

application was approved; (2) that new eviden such application or not available to the Se approved, or tests by new methods, or tes applicable when such application was approv available to the Secretary when the applicatio not shown to be safe for use under the condi application was approved; or (3) on the basis o to such drug, evaluated together with the evide was approved, that there is a lack of substan effect it purports or is represented to have recommended, or suggested in the labeling prescribed by subsection (c) of this section w receipt of written notice from the Secretary s tion; or (5) that the at the application contains *Provided*, That if the Secretary (or in his abse that there is an imminent hazard to the public such application immediately, and give the a afford the applicant the opportunity for an exp the authority conferred by this proviso to sus not be delegated. The Secretary may also, aft to the applicant, withdraw the approval of an a or (j) of this section with respect to any drug u that the applicant has failed to establish a sys has repeatedly or deliberately failed to main reports, in accordance with a regulation or ord to comply with the notice requirements of secti has refused to permit access to, or copying or v paragraph (2) of such subsection; or (2) that on evaluated together with the evidence before hin methods used in, or the facilities and controls u packing of such drug are inadequate to assu quality, and purity and were not made adequate written notice from the Secretary specifying the basis of new information before him, evaluated when the application was approved, the labeling of all material facts, is false or misleading in an a reasonable time after receipt of written no matter complained of. Any order under this which it is based.

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(j) Abbreviated new drug applications

(1) Any person may file with the Secreta approval of a new drug.

(2)(A) An abbreviated application for a new

(i) information to show that the conditio suggested in the labeling proposed for the n for a drug listed under paragraph (6) (herein "listed drug");

(ii)(I) if the listed drug referred to in cl information to show that the active ingredier the listed drug;

(II) if the listed drug referred to in ingredient, information to show that the acti same as those of the listed drug, or

(III) if the listed drug referred to in ingredient and if one of the active ingredien application is filed pursuant to the approval (C), information to show that the other acti same as the active ingredients of the liste different active ingredient is an active ingred does not meet the requirements of sectio

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pproval of application; "substantial evidence" defined

tice to the applicant in accordance with subsection
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(b) of this section; or (7) based on a fair evaluation
false or misleading in any particular; he shall issue
plication. If, after such notice and opportunity for
auses (1) through (6) do not apply, he shall issue an
s used in this subsection and subsection (e) of this
ıce" means evidence consisting of adequate and well-
linical investigations, by experts qualified by scienti-
uate the effectiveness of the drug involved, on the
sponsibly be concluded by such experts that the drug
is represented to have under the conditions of use
ested in the labeling or proposed labeling thereof.

immediate suspension upon finding imminent hazard to

notice and opportunity for hearing to the applicant,
n with respect to any drug under this section if the
other experience, tests, or other scientific data show
nder the conditions of use upon the basis of which the

application was approved; (2) that new evidence of clinical experience, not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved; or (3) on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof; or (4) the patent information prescribed by subsection (c) of this section was not filed within thirty days after the receipt of written notice from the Secretary specifying the failure to file such information; or (5) that the at the application contains any untrue statement of a material fact: *Provided*, That if the Secretary (or in his absence the officer acting as Secretary) finds that there is an imminent hazard to the public health, he may suspend the approval of such application immediately, and give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited hearing under this subsection; but the authority conferred by this proviso to suspend the approval of an application shall not be delegated. The Secretary may also, after due notice and opportunity for hearing to the applicant, withdraw the approval of an application submitted under subsection (b) or (j) of this section with respect to any drug under this section if the Secretary finds (1) that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports, in accordance with a regulation or order under subsection (k) of this section or to comply with the notice requirements of section 360(k)(2) of this title, or the applicant has refused to permit access to, or copying or verification of, such records as required by paragraph (2) of such subsection; or (2) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to assure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of; or (3) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the labeling of such drug, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of. Any order under this subsection shall state the findings upon which it is based.

[See main volume for text of (f) to (i)]

(j) Abbreviated new drug applications

(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

(2)(A) An abbreviated application for a new drug shall contain—

(i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (6) (hereinafter in this subsection referred to as a "listed drug");

(ii)(I) if the listed drug referred to in clause (i) has only one active ingredient, information to show that the active ingredient of the new drug is the same as that of the listed drug;

(II) if the listed drug referred to in clause (i) has more than one active ingredient, information to show that the active ingredients of the new drug are the same as those of the listed drug, or

(III) if the listed drug referred to in clause (i) has more than one active ingredient and if one of the active ingredients of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the other active ingredients of the new drug are the same as the active ingredients of the listed drug, information to show that the different active ingredient is an active ingredient of a listed drug or of a drug which does not meet the requirements of section 321(p) of this title, and such other

information respecting the different active ingredient with respect to which the petition was filed as the Secretary may require;

(iii) information to show that the route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug referred to in clause (i) or, if the route of administration, the dosage form, or the strength of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), such information respecting the route of administration, dosage form, or strength with respect to which the petition was filed as the Secretary may require;

(iv) information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in clause (i);

(v) information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers;

(vi) the items specified in clauses (B) through (F) of subsection (b)(1) of this section;

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c) of this section—

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) of this section for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii).

(B)(i) An applicant who makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give the notice required by clause (ii) to—

(I) each owner of the patent which is the subject of the certification or the representative of such owner designated to receive such notice, and

(II) the holder of the approved application under subsection (b) of this section for the drug which is claimed by the patent or a use of which is claimed by the patent or the representative of such holder designated to receive such notice.

(ii) The notice referred to in clause (i) shall state that an application, which contains data from bioavailability or bioequivalence studies, has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of such drug before the expiration of the patent referred to in the certification. Such notice shall include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed.

(iii) If an application is amended to include a certification described in subparagraph (A)(vii)(IV), the notice required by clause (ii) shall be given when the amended application is submitted.

(C) If a person wants to submit an abbreviated application for a new drug which has a different active ingredient or whose route of administration, dosage form, or strength differ from that of a listed drug, such person shall submit a petition to the Secretary

seeking permission to file such an application. ' prove a petition submitted under this subparagra petition is submitted. The Secretary shall appro finds—

(i) that investigations must be conducted t the drug or of any of its active ingredients, t form, or strength which differ from the liste

(ii) that any drug with a different activ evaluated for approval as safe and effective o: to be submitted in an abbreviated applicatio

(3) Subject to paragraph (4), the Secretary sh unless the Secretary finds—

(A) the methods used in, or the facilities a processing, and packing of the drug are in identity, strength, quality, and purity;

(B) information submitted with the applica the proposed conditions of use have been pr referred to in the application;

(C)(i) if the listed drug has only one act with the application is insufficient to show th. that of the listed drug;

(ii) if the listed drug has more than one ac with the application is insufficient to show th as the active ingredients of the listed drug,

(iii) if the listed drug has more than one is for a drug which has an active ingrec information submitted with the application is

(I) that the other active ingredients ar the listed drug, or

(II) that the different active ingredie drug or a drug which does not meet the title,

or no petition to file an application for t was approved under paragraph (2)(C);

(D)(i) if the application is for a drug whose or strength of the drug is the same as the ro strength of the listed drug referred to in the the application is insufficient to show that the or strength is the same as that of the listed

(ii) if the application is for a drug whose ro strength of the drug is different from that application, no petition to file an application f administration, dosage form, or strength w

(E) if the application was filed pursuant paragraph (2)(C), the application did not cor Secretary respecting the active ingredient, ro strength which is not the same;

(F) information submitted in the applicatio is bioequivalent to the listed drug referred to was filed pursuant to a petition approved submitted in the application is insufficient to new drug are of the same pharmacological or drug referred to in paragraph (2)(A)(i) and t have the same therapeutic effect as the liste for a condition of use referred to in such par

(G) information submitted in the applica labeling proposed for the drug is the same a drug referred to in the application except fo ences approved under a petition filed under and the listed drug are produced or dist

:rent active ingredient with respect to which the
:ry may require;

the route of administration, the dosage form, and
: the same as those of the listed drug referred to in
inistration, the dosage form, or the strength of the
application is filed pursuant to the approval of a
.ph (C), such information respecting the route of
strength with respect to which the petition was filed

the new drug is bioequivalent to the listed drug
t that if the application is filed pursuant to the
:r subparagraph (C), information to show that the
ug are of the same pharmacological or therapeutic
referred to in clause (i) and the new drug can be
peutic effect as the listed drug when administered
e referred to in clause (i);

.he labeling proposed for the new drug is the same
:e listed drug referred to in clause (i) except for
ifferences approved under a petition filed under
ie new drug and the listed drug are produced or
:turers;

uses (B) through (F) of subsection (b)(1) of this

pinion of the applicant and to the best of his
patent which claims the listed drug referred to in
e for such listed drug for which the applicant is
section and for which information is required to be
of this section—

.mation has not been filed,

expired,

h such patent will expire, or

invalid or will not be infringed by the manufacture,
rug for which the application is submitted; and

sted drug referred to in clause (i) information was
) of this section for a method of use patent which
ch the applicant is seeking approval under this
: method of use patent does not claim such a use.

: an abbreviated application contain information in
(i) through (viii).

certification described in subparagraph (A)(vii)(IV)
statement that the applicant will give the notice

t which is the subject of the certification or the
:signated to receive such notice, and

d application under subsection (b) of this section for
e patent or a use of which is claimed by the patent
older designated to receive such notice.

se (i) shall state that an application, which contains
ivalence studies, has been submitted under this
to which the certification is made to obtain approval
:ture, use, or sale of such drug before the expiration
ertification. Such notice shall include a detailed
sis of the applicant's opinion that the patent is not

to include a certification described in subparagraph
y clause (ii) shall be given when the amended

.n abbreviated application for a new drug which has
se route of administration, dosage form, or strength
ich person shall submit a petition to the Secretary

seeking permission to file such an application. The Secretary shall approve or disapprove a petition submitted under this subparagraph within ninety days of the date the petition is submitted. The Secretary shall approve such a petition unless the Secretary finds—

(i) that investigations must be conducted to show the safety and effectiveness of the drug or of any of its active ingredients, the route of administration, the dosage form, or strength which differ from the listed drug; or

(ii) that any drug with a different active ingredient may not be adequately evaluated for approval as safe and effective on the basis of the information required to be submitted in an abbreviated application.

(3) Subject to paragraph (4), the Secretary shall approve an application for a drug unless the Secretary finds—

(A) the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity;

(B) information submitted with the application is insufficient to show that each of the proposed conditions of use have been previously approved for the listed drug referred to in the application;

(C)(i) if the listed drug has only one active ingredient, information submitted with the application is insufficient to show that the active ingredient is the same as that of the listed drug;

(ii) if the listed drug has more than one active ingredient, information submitted with the application is insufficient to show that the active ingredients are the same as the active ingredients of the listed drug, or

(iii) if the listed drug has more than one active ingredient and if the application is for a drug which has an active ingredient different from the listed drug, information submitted with the application is insufficient to show—

(I) that the other active ingredients are the same as the active ingredients of the listed drug, or

(II) that the different active ingredient is an active ingredient of a listed drug or a drug which does not meet the requirements of section 321(p) of this title,

or no petition to file an application for the drug with the different ingredient was approved under paragraph (2)(C);

(D)(i) if the application is for a drug whose route of administration, dosage form, or strength of the drug is the same as the route of administration, dosage form, or strength of the listed drug referred to in the application, information submitted in the application is insufficient to show that the route of administration, dosage form, or strength is the same as that of the listed drug, or

(ii) if the application is for a drug whose route of administration, dosage form, or strength of the drug is different from that of the listed drug referred to in the application, no petition to file an application for the drug with the different route of administration, dosage form, or strength was approved under paragraph (2)(C);

(E) if the application was filed pursuant to the approval of a petition under paragraph (2)(C), the application did not contain the information required by the Secretary respecting the active ingredient, route of administration, dosage form, or strength which is not the same;

(F) information submitted in the application is insufficient to show that the drug is bioequivalent to the listed drug referred to in the application or, if the application was filed pursuant to a petition approved under paragraph (2)(C), information submitted in the application is insufficient to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in paragraph (2)(A)(i) and that the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in such paragraph;

(G) information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug referred to in the application except for changes required because of differences approved under a petition filed under paragraph (2)(C) or because the drug and the listed drug are produced or distributed by different manufacturers;

(H) information submitted in the application or any other information available to the Secretary shows that (i) the inactive ingredients of the drug are unsafe for use under the conditions prescribed, recommended, or suggested in the labeling proposed for the drug, or (ii) the composition of the drug is unsafe under such conditions because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included;

(I) the approval under subsection (c) of this section of the listed drug referred to in the application under this subsection has been withdrawn or suspended for grounds described in the first sentence of subsection (e) of this section, the Secretary has published a notice of opportunity for hearing to withdraw approval of the listed drug under subsection (c) of this section for grounds described in the first sentence of subsection (e) of this section, the approval under this subsection of the listed drug referred to in the application under this subsection has been withdrawn or suspended under paragraph (5), or the Secretary has determined that the listed drug has been withdrawn from sale for safety or effectiveness reasons;

(J) the application does not meet any other requirement of paragraph (2)(A); or

(K) the application contains an untrue statement of material fact.

(4)(A) Within one hundred and eighty days of the initial receipt of an application under paragraph (2) or within such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall approve or disapprove the application.

(B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined under the following:

(i) If the applicant only made a certification described in subclause (I) or (II) of paragraph (2)(A)(vii) or in both such subclauses, the approval may be made effective immediately.

(ii) If the applicant made a certification described in subclause (III) of paragraph (2)(A)(vii), the approval may be made effective on the date certified under subclause (III).

(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

(I) if before the expiration of such period the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of the court decision,

(II) if before the expiration of such period the court decides that such patent has been infringed, the approval shall be made effective on such date as the court orders under section 271(e)(4)(A) of Title 35 or

(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of such court decision.

In such an action, each of the parties shall reasonably cooperate in expediting the action. Until the expiration of forty-five days from the date the notice made under paragraph (2)(B)(i) is received, no action may be brought under section 2201 of Title 28 for a declaratory judgment with respect to the patent. Any action brought under section 2201 shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(iv) If the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application has been submitted under this subsection continuing such a certification, the application shall be made effective not earlier than one hundred and eighty days after—

(I) the date the Secretary receiv previous application of the first com previous application, or

(II) the date of a decision of a c holding the patent which is the subje infringed,

whichever is earlier.

(C) If the Secretary decides to disapprove a applicant notice of an opportunity for a hearin whether such application is approvable. If the for hearing by written request within thirty c commence not more than ninety days after the Secretary and the applicant otherwise agree conducted on an expedited basis and the Secre ninety days after the date fixed by the Secre

(D)(i) If an application (other than an abb under subsection (b) of this section for a drug. or salt of the active ingredient) of which has under subsection (b) of this section, was appr 1, 1982, and ending on September 24, 1984, the an application submitted under this subsectio subsection (b) application was submitted effect the date of the approval of the applicatio

(ii) If an application submitted under subs active ingredient (including any ester or salt o approved in any other application under subse September 24, 1984, no application may be sub to the drug for which the subsection (b) applic. of five years from the date of the approval of t section, except that such an application may be expiration of four years from the date of the a it contains a certification of patent invalidity o (IV) of paragraph (2)(A)(vii). The approval effective in accordance with subparagraph (infringement is commenced during the one-y after the date of the approval of the subsectio referred to in subparagraph (B)(iii) shall be e which is required for seven and one-half years of the subsection (b) application.

(iii) If an application submitted under subse includes an active ingredient (including any e has been approved in another application appr is approved after September 24, 1984, and if clinical investigations (other than bioavailabilit application and conducted or sponsored by th the approval of an application submitted unc approval of such drug in the subsection (b) ap three years from the date of the approval of t section for such drug.

(iv) If a supplement to an application appro approved after September 24, 1984, and the su investigations (other than bioavailability stu supplement and conducted or sponsored by th Secretary may not make the approval of an ap for a change approved in the supplement effe from the date of the approval of the supplem

(v) If an application (or supplement to an a of this section for a drug, which includes an act of the active ingredient) that has been approve (b) of this section, was approved during the ending on September 24, 1984, the Secreta

ed in the application or any other information available to
i) the inactive ingredients of the drug are unsafe for use
ribed, recommended, or suggested in the labeling pro-
ii) the composition of the drug is unsafe under such
type or quantity of inactive ingredients included or the
ive ingredients are included;

ubsection (c) of this section of the listed drug referred to
this subsection has been withdrawn or suspended for
first sentence of subsection (e) of this section, the
notice of opportunity for hearing to withdraw approval of
ction (c) of this section for grounds described in the first
of this section, the approval under this subsection of the
he application under this subsection has been withdrawn
raph (5), or the Secretary has determined that the listed
from sale for safety or effectiveness reasons;

not meet any other requirement of paragraph (2)(A); or

ains an untrue statement of material fact.

and eighty days of the initial receipt of an application
such additional period as may be agreed upon by the
e Secretary shall approve or disapprove the application.

lication submitted under paragraph (2) shall be made
date determined under the following:

made a certification described in subclause (I) or (II) of
both such subclauses, the approval may be made effective

e a certification described in subclause (III) of paragraph
y be made effective on the date certified under subclause

ade a certification described in subclause (IV) of para-
val shall be made effective immediately unless an action
nt of a patent which is the subject of the certification
orty-five days from the date the notice provided under
ved. If such an action is brought before the expiration of
all be made effective upon the expiration of the thirty-
n the date of the receipt of the notice provided under
shorter or longer period as the court may order because
failed to reasonably cooperate in expediting the action.

piration of such period the court decides that such patent
ged, the approval shall be made effective on the date of

piration of such period the court decides that such patent
e approval shall be made effective on such date as the
ction 271(e)(4)(A) of Title 35 or

expiration of such period the court grants a preliminary
the applicant from engaging in the commercial manufac-
g until the court decides the issues of patent validity and
the court decides that such patent is invalid or not
al shall be made effective on the date of such court

h of the parties shall reasonably cooperate in expediting
expiration of forty-five days from the date the notice
h (2)(B)(i) is received, no action may be brought under
28 for a declaratory judgment with respect to the patent.
nder section 2201 shall be brought in the judicial district
has its principal place of business or a regular and
usiness.

contains a certification described in subclause (IV) of
is for a drug for which a previous application has been
ection continuing such a certification, the application shall
lier than one hundred and eighty days after—

(I) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or

(II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed,

whichever is earlier.

(C) If the Secretary decides to disapprove an application, the Secretary shall give the applicant notice of an opportunity for a hearing before the Secretary on the question of whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(D)(i) If an application (other than an abbreviated new drug application) submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of ten years from the date of the approval of the application under subsection (b) of this section.

(ii) If an application submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, is approved after September 24, 1984, no application may be submitted under this subsection which refers to the drug for which the subsection (b) application was submitted before the expiration of five years from the date of the approval of the application under subsection (b) of this section, except that such an application may be submitted under this subsection after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in subclause (IV) of paragraph (2)(A)(vii). The approval of such an application shall be made effective in accordance with subparagraph (B) except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (B)(iii) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

(iii) If an application submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b) of this section, is approved after September 24, 1984, and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under this subsection for the conditions of approval of such drug in the subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) of this section for such drug.

(iv) If a supplement to an application approved under subsection (b) of this section is approved after September 24, 1984, and the supplement contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under this subsection for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b) of this section.

(v) If an application (or supplement to an application) submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an

application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted or which refers to a change approved in a supplement to the subsection (b) application effective before the expiration of two years from September 24, 1984.

(5) If a drug approved under this subsection refers in its approved application to a drug the approval of which was withdrawn or suspended for grounds described in the first sentence of subsection (e) of this section or was withdrawn or suspended under this paragraph or which, as determined by the Secretary, has been withdrawn from sale for safety or effectiveness reasons, the approval of the drug under this subsection shall be withdrawn or suspended—

(A) for the same period as the withdrawal or suspension under subsection (e) of this section or this paragraph, or

(B) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

(6)(A)(i) Within sixty days of September 24, 1984, the Secretary shall publish and make available to the public—

(I) a list in alphabetical order of the official and proprietary name of each drug which has been approved for safety and effectiveness under subsection (c) of this section before September 24, 1984;

(II) the date of approval if the drug is approved after 1981 and the number of the application which was approved; and

(III) whether in vitro or in vivo bioequivalence studies, or both such studies, are required for applications filed under this subsection which will refer to the drug published.

(ii) Every thirty days after the publication of the first list under clause (i) the Secretary shall revise the list to include each drug which has been approved for safety and effectiveness under subsection (c) of this section or approved under this subsection during the thirty-day period.

(iii) When patent information submitted under subsection (b) or (c) of this section respecting a drug included on the list is to be published by the Secretary, the Secretary shall, in revisions made under clause (ii), include such information for such drug.

(B) A drug approved for safety and effectiveness under subsection (c) of this section or approved under this subsection shall, for purposes of this subsection, be considered to have been published under subparagraph (A) on the date of its approval or September 24, 1984, whichever is later.

(C) If the approval of a drug was withdrawn or suspended for grounds described in the first sentence of subsection (e) of this section or was withdrawn or suspended under paragraph (5) or if the Secretary determines that a drug has been withdrawn from sale for safety or effectiveness reasons, it may not be published in the list under subparagraph (A) or, if the withdrawal or suspension occurred after its publication in such list, it shall be immediately removed from such list—

(i) for the same period as the withdrawal or suspension under subsection (e) of this section or paragraph (5), or

(ii) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

A notice of the removal shall be published in the Federal Register.

(7) For purposes of this subsection:

(A) The term "bioavailability" means the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action.

(B) A drug shall be considered to be bioequivalent to a listed drug if—

(i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses; or

(ii) the extent of absorpt
difference from the extent of
at the same molar dose of the
tal conditions in either a sing
the listed drug in the rate of a
its proposed labeling, is not e
concentrations on chronic use
drug.

(8) The Secretary shall, with res
subsection, maintain a record of—

(A) the name of the applicant,

(B) the name of the drug cove

(C) the name of each person
application was assigned and the

(D) the name of each person
application was assigned and the

The information the Secretary is requir
to an application submitted under this
after the approval of such application.

(k) Records and reports; required infor

(1) In the case of any drug for
subsection (b) or (j) of this section is i
such records, and make such report
experience and other data or inform
applicant with respect to such drug, a
order with respect to such applicatio
records and reports are necessary in
facilitate a determination, whether the
of this section. Regulations and o
subsection (i) of this section shall ha
medical profession and the interests o
deems it to be appropriate, for the ex
such regulations or orders are applica
obtained by the Secretary.

(2) Every person required under th
charge or custody thereof, shall, upon
the Secretary, permit such officer or e
and copy and verify such records.

(l) Public disclosure of safety and effect

Safety and effectiveness data and
application under subsection (b) of thi
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(1) if no work is being or will

(2) if the Secretary has determ
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(3) if approval of the applicatio
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(4) if the Secretary has dete

(5) upon the effective date of t
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›section which refers to the drug for which the
itted or which refers to a change approved in a
.ication effective before the expiration of two years

subsection refers in its approved application to a
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pproval of the drug under this subsection shall be

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ı withdrawn from sale, for the period of withdrawal
d ending on the date the Secretary determines that
for safety or effectiveness reasons.

ptember 24, 1984, the Secretary shall publish and

: of the official and proprietary name of each drug
.fety and effectiveness under subsection (c) of this
84;

: drug is approved after 1981 and the number of the
; and

·vo bioequivalence studies, or both such studies, are
ınder this subsection which will refer to the drug

publication of the first list under clause (i) the
lude each drug which has been approved for safety
c) of this section or approved under this subsection

.bmitted under subsection (b) or (c) of this section
:t is to be published by the Secretary, the Secretary
ıuse (ii), include such information for such drug.

.nd effectiveness under subsection (c) of this section
ıall, for purposes of this subsection, be considered to
graph (A) on the date of its approval or September

s withdrawn or suspended for grounds described in
f this section or was withdrawn or suspended under
:termines that a drug has been withdrawn from sale
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ıspension occurred after its publication in such list, it
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en withdrawn from sale, for the period of withdrawal
·od ending on the date the Secretary determines that
ıt for safety or effectiveness reasons.

ıblished in the Federal Register.

:ion:

ty" means the rate and extent to which the active
:dient is absorbed from a drug and becomes available

ered to be bioequivalent to a listed drug if—

: of absorption of the drug do not show a significant
and extent of absorption of the listed drug when
ıe molar dose of the therapeutic ingredient under
ditions in either a single dose or multiple doses; or

(ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.

(8) The Secretary shall, with respect to each application submitted under this subsection, maintain a record of—

(A) the name of the applicant,

(B) the name of the drug covered by the application,

(C) the name of each person to whom the review of the chemistry of the application was assigned and the date of such assignment, and

(D) the name of each person to whom the bioequivalence review for such application was assigned and the date of such assignment.

The information the Secretary is required to maintain under this paragraph with respect to an application submitted under this subsection shall be made available to the public after the approval of such application.

(k) Records and reports; required information; regulations and orders; access to records

(1) In the case of any drug for which an approval of an application filed under subsection (b) or (j) of this section is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to clinical experience and other data or information, received or otherwise obtained by such applicant with respect to such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) of this section. Regulations and orders issued under this subsection and under subsection (i) of this section shall have due regard for the professional ethics of the medical profession and the interests of patients and shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulations or orders are applicable, of similar information received or otherwise obtained by the Secretary.

(2) Every person required under this section to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

(l) Public disclosure of safety and effectiveness data

Safety and effectiveness data and information which has been submitted in an application under subsection (b) of this section for a drug and which has not previously been disclosed to the public shall be made available to the public, upon request, unless extraordinary circumstances are shown—

(1) if no work is being or will be undertaken to have the application approved,

(2) if the Secretary has determined that the application is not approvable and all legal appeals have been exhausted,

(3) if approval of the application under subsection (c) of this section is withdrawn and all legal appeals have been exhausted,

(4) if the Secretary has determined that such drug is not a new drug, or

(5) upon the effective date of the approval of the first application under subsection (j) of this section which refers to such drug or upon the date upon which the approval of an application under subsection (j) of this section which refers to such drug could be made effective if such an application had been submitted.

(m) "Patent" defined

For purposes of this section, the term "patent" means a patent issued by the Patent and Trademark Office of the Department of Commerce.

(As amended Aug. 16, 1972, Pub.L. 92-387, § 4(d), 86 Stat. 562; Sept. 24, 1984, Pub.L. 98-417, Title I, §§ 101, 102(a)-(b)(5), 103, 104, 98 Stat. 1585, 1592, 1593, 1597; May 13, 1992, Pub.L. 102-282, § 5, 106 Stat. 161; Aug. 13, 1993, Pub.L. 103-80, § 3(n), 107 Stat. 777.)

HISTORICAL AND STATUTORY NOTES

1993 Amendments

Subsec. (j)(6)(A)(ii). Pub.L. 103-80, § 3(n)(1)(A), corrected a typographical error in the original by substituting "Secretary" for "Secretry".

Subsec. (j)(6)(A)(iii). Pub.L. 103-80, § 3(n)(1)(B), inserted a comma after "published by the Secretary".

Subsec. (k)(1). Pub.L. 103-80, § 3(n)(2), struck out ": Provided, however, That regulations" and inserted in lieu thereof a period and "Regulations".

1992 Amendments

Subsec. (j)(8). Pub.L. 102-282, § 5, added par. (8).

1984 Amendment

Subsec. (a). Pub.L. 98-417, § 102(b)(1), added "or (j)" following "pursuant to subsection (b)".

Subsec. (b)(1). Pub.L. 98-417, § 103(a), designated the existing provisions of subsec. (b) as par. (1) thereof and redesignated existing cls. (1) through (6) of par. (1) as so redesignated as cls. (A) through (F) thereof, respectively.

Pub.L. 98-417, § 102(a)(1), added requirement that the applicant file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug, that the applicant amend the application to include such information if an application is filed under this subsection for a drug and a patent which claims such drug or a method of using such drug is issued after the filing date but before approval of the application, and that, upon approval of the application, the Secretary publish the information submitted.

Subsec. (b)(2), (3). Pub.L. 98-417, § 103(a), added pars. (2) and (3).

Subsec. (c)(1). Pub.L. 98-417, § 102(a)(2), designated the existing provisions of subsec. (c) as par. (1) thereof and in par. (1) as so designated redesignated former pars. (1) and (2) as subpars. (A) and (B), respectively.

Pub.L. 98-417, § 102(b)(2), substituted "subsection (b) of this section" for "this subsection".

Subsec. (c)(2). Pub.L. 98-417, § 102(a)(2), added par. (2).

Subsec. (c)(3). Pub.L. 98-417, § 103(b), added par. (3).

Subsec. (d)(6). Pub.L. 98-417, § 102(a)(3)(A), added cl. (6) relating to the failure of the application to contain the patent information prescribed by subsec. (b) of this section. Former cl. (6) was redesignated (7).

Subsec. (d)(7). Pub.L. 98-417, § 102(a)(3)(A), redesignated former cl. (6) as (7).

Subsec. (e). Pub.L. 98-417, § 102(a)(3)(B), added, in the first sentence covering the grounds for withdrawal of approval by the Secretary, a new cl. (4) relating to the failure to file the patent information prescribed by subsec. (c) of this section within 30 days after the receipt of written notice from the Secretary specifying the failure to file such information, and redesignated the former cl. (4) as (5).

Pub.L. 98-417, § 102(b)(3), inserted, in the provisions of the second sentence preceding cl. (1) of the enumeration of clauses covering the grounds for withdrawal of approval by the Secretary, the phrase "submitted under subsection (b) or (j) of this section" after "withdraw the approval of an application".

Pub.L. 98-417, § 102(b)(4), substituted, in cl. (1) of the second sentence covering the grounds for withdrawal of approval by the Secretary, the phrase "under subsection (k) of this section or to comply with the notice requirements of section 360(k)(2) of this title" for "under subsection (j) of this section or to comply with the notice requirements of section 360(j)(2) of this title".

Subsec. (j). Pub.L. 98-417, § 101, added subsec. (j). Former subsec. (j) was redesignated (k).

Subsec. (k). Pub.L. 98-417, § 101, redesignated former subsec. (j) as (k).

Subsec. (k)(1). Pub.L. 98-417, § 102(b)(5), substituted "under subsection (b) or (j) of this section" for "pursuant to this section".

Subsecs. (*l*), (m). Pub.L. 98-417, § 104, added subsecs. (*l*) and (m).

1972 Amendment

Subsec. (e). Pub.L. 92-387 inserted "or to comply with the notice requirements of section 360(j)(2)" in clause (1) of the second sentence relating to the maintenance of records.

Change of Name

The Department of Health, Education, and Welfare was redesignated the Department of Health and Human Services, and the Secretary of Health, Education, and Welfare or any other official of the Department of Health, Education and Welfare was redesignated the Secretary or official, as appropriate, of Health and Human Services, with any reference to the Department of Health, Education, and Welfare, the Secretary of Health, Education, and Welfare, or any official of the Department of Health, Education, and Welfare, in any law, rule, regulation, certificate, directive, instruction, or other official paper in force on the effective date of Pub.L. 96-88, as prescribed by section 601 of Pub.L.

96-88, Title VI, Oct. 17, 1979, 93 Stat. 696 out as a note under section 3401 of Title Education, deemed to refer and apply to Department of Health and Human Service the Secretary of Health and Human Serv respectively, except to the extent such refere is to a function or office transferred to Secretary of Education or the Departmen Education under Pub.L. 96-88, Title III, §§ to 307, Oct. 17 1979, 93 Stat. 677 to 681. section 3441 to 3447 and 3508 of Title 20.

Effective Date of 1984 Amendment

Section 105 of Pub.L. 98-417 provided t

"(a) The Secretary of Health and Hu Services shall promulgate, in accordance the notice and comment requirements of sec 553 of title 5, United States Code [section 55 Title 5, Government Organization and Emp ees], such regulations as may be necessary the administration of section 505 of the Fed Food, Drug, and Cosmetic Act [this section amended by sections 101, 102, and 103 of Act [enacting subsec. (j) of this section amending subsecs. (a) to (e) and (k)(1) of section and section 360cc(a) and (b) of this ti within one year of the date of enactment of Act [Sept. 24, 1984].

"(b) During the period beginning sixty after the date of the enactment of this Act [S 24, 1984], and ending on the date regulat promulgated under subsection (a) take ef abbreviated new drug applications may be mitted in accordance with the provisions of tion 314.2 of title 21 of the Code of Fed Regulations and shall be considered as suit for any drug which has been approved for sa and effectiveness under section 505(c) of Federal Food, Drug, and Cosmetic Act [sub (c) of this section] before the date of the en

CROSS

Patents, extension of patent term, see sec 156 of Title 35, Patents.

FEDERAL PRA

Review of administrative decisions in court appeals, see Wright, Miller, Cooper & Gr man: Jurisdiction § 3941.

WEST'S FEDER

Application for use of new drug, see § 3

CODE OF FE

Formal evidentiary public hearing, see CFR 12.1 et seq.

New animal drugs, see 21 CFR 510.3.

LAW REVIE

A survey of law regarding the liability manufacturers and sellers of drug products medical devices. Bryan J. Maedgen and She Lynn McCall, 18 St. Mary's L.J. 395 (19

Brother can you spare a drug: Should experimental drug distribution standards modified in response to the needs of pers with Aids? 19 Hofstra L.Rev. 191 (1990).

tions for potentially harmful drug without authorization by prescribing physician was immaterial since consistency in verdicts is not necessary. Dugan Drug Stores, Inc. v. U. S., C.A.Tex.1964, 326 F. 2d 835.

§ 354. Repealed. Pub.L. 86–618, Title I, § 103(a) (2), July 12, 1960, 74 Stat. 398

Historical Note

Section, Act June 25, 1938, c. 675, § 504, 52 Stat. 1052, required the Secretary to promulgate regulations for the listing of coal-tar colors for drugs and is covered by section 376 of this title.

Effective Date of Repeal. Repeal of section effective, subject to the provisions of section 203 of Pub.L. 86–618, on July 12, 1960, see section 202 of Pub.L. 86–618, set out as a note under section 376 of this title.

§ 355. New drugs—Necessity of effective approval of application

(a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) of this section is effective with respect to such drug.

Filing application; contents

(b) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a) of this section. Such person shall submit to the Secretary as a part of the application (1) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (2) a full list of the articles used as components of such drug; (3) a full statement of the composition of such drug; (4) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (5) such samples of such drug and of the articles used as components thereof as the Secretary may require; and (6) specimens of the labeling proposed to be used for such drug.

Period for approval of application; period for, notice, and expedition of hearing; period for issuance of order

(c) Within one hundred and eighty days after the filing of an application under this subsection, or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either—

(1) approve the application if he then finds that none of the grounds for denying approval specified in subsection (d) of this section applies, or

(2) give the applicant notice of an opportunity for a hearing before the Secretary under subsection (d) of this section on the question whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

Grounds for refusing application; approval of application; "substantial evidence" defined

(d) If the Secretary finds, after due notice to the applicant in accordance with subsection (c) of this section and giving him an opportunity for a hearing, in accordance with said subsection, that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b) of this section, do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions; or (5) evaluated on the basis of the information submitted to him as part of the application and any other information before him with respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or (6) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that clauses (1) through (6) do not apply, he shall issue an order approving the application. As used in this subsection and subsection (e) of this section, the term "substantial evidence" means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the

effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.

Withdrawal of approval; grounds; immediate suspension upon finding imminent hazard to public health

(e) The Secretary shall, after due notice and opportunity for hearing to the applicant, withdraw approval of an application with respect to any drug under this section if the Secretary finds (1) that clinical or other experience, tests, or other scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved; (2) that new evidence of clinical experience, not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved; or (3) on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof; or (4) that the application contains any untrue statement of a material fact: *Provided*, That if the Secretary (or in his absence the officer acting as Secretary) finds that there is an imminent hazard to the public health, he may suspend the approval of such application immediately, and give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited hearing under this subsection; but the authority conferred by this proviso to suspend the approval of an application shall not be delegated. The Secretary may also, after due notice and opportunity for hearing to the applicant, withdraw the approval of an application with respect to any drug under this section if the Secretary finds (1) that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports, in accordance with a regulation or order under subsection (j) of this section, or the applicant has refused to permit access to, or copying or verification of, such records as required by paragraph (2) of such subsection; or (2) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to assure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable

time after receipt of written notice from the Secretary specifying the matter complained of; or (3) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the labeling of such drug, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of. Any order under this subsection shall state the findings upon which it is based.

Revocation of order refusing, withdrawing or suspending approval of application

(f) Whenever the Secretary finds that the facts so require, he shall revoke any previous order under subsection (d) or (e) of this section refusing, withdrawing, or suspending approval of an application and shall approve such application or reinstate such approval, as may be appropriate.

Service of orders

(g) Orders of the Secretary issued under this section shall be served (1) in person by any officer or employee of the Department designated by the Secretary or (2) by mailing the order by registered mail or by certified mail addressed to the applicant or respondent at his last-known address in the records of the Secretary.

Appeal from order

(h) An appeal may be taken by the applicant from an order of the Secretary refusing or withdrawing approval of an application under this section. Such appeal shall be taken by filing in the United States court of appeals for the circuit wherein such applicant resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a written petition praying that the order of the Secretary be set aside. A copy of such petition shall be forthwith transmitted by the clerk of the court to the Secretary, or any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court the record upon which the order complained of was entered, as provided in section 2112 of Title 28. Upon the filing of such petition such court shall have exclusive jurisdiction to affirm or set aside such order, except that until the filing of the record the Secretary may modify or set aside his order. No objection to the order of the Secretary shall be considered by the court unless such objection shall have been urged before the Secretary or unless there were reasonable grounds for failure so to do. The finding of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive. If any person shall apply to the court for leave to

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Exemptions of drugs for research; discretionary and mandatory conditions; direct reports to Secretary

(i) The Secretary shall promulgate regulations for exempting from the operation of the foregoing subsections of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs. Such regulations may, within the discretion of the Secretary, among other conditions relating to the protection of the public health, provide for conditioning such exemption upon—

(1) the submission to the Secretary, before any clinical testing of a new drug is undertaken, of reports, by the manufacturer or the sponsor of the investigation of such drug, of preclinical tests (including tests on animals) of such drug adequate to justify the proposed clinical testing;

(2) the manufacturer or the sponsor of the investigation of a new drug proposed to be distributed to investigators for clinical testing obtaining a signed agreement from each of such investigators that patients to whom the drug is administered will be under his personal supervision, or under the supervision of investigators responsible to him, and that he will not supply such drug to any other investigator, or to clinics, for administration to human beings; and

(3) the establishment and maintenance of such records, and the making of such reports to the Secretary, by the manufacturer or the sponsor of the investigation of such drug, of data (including but not limited to analytical reports by investigators) obtained as the result of such investigational use of such drug, as the Secre-

tary finds will enable him to evaluate the safety and effectiveness of such drug in the event of the filing of an application pursuant to subsection (b) of this section.

Such regulations shall provide that such exemption shall be conditioned upon the manufacturer, or the sponsor of the investigation, requiring that experts using such drugs for investigational purposes certify to such manufacturer or sponsor that they will inform any human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and will obtain the consent of such human beings or their representatives, except where they deem it not feasible or, in their professional judgment, contrary to the best interests of such human beings. Nothing in this subsection shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs.

Records and reports; required information; regulations and orders; access to records

(j) (1) In the case of any drug for which an approval of an application filed pursuant to this section is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to clinical experience and other data or information, received or otherwise obtained by such applicant with respect to such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) of this section: *Provided, however,* That regulations and orders issued under this subsection and under subsection (i) of this section shall have due regard for the professional ethics of the medical profession and the interests of patients and shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulations or orders are applicable, of similar information received or otherwise obtained by the Secretary.

(2) Every person required under this section to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

June 25, 1938, c. 675, § 505, 52 Stat. 1052; 1940 Reorg.Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2422, 54 Stat. 1237; June 25, 1948, c. 646, § 32(b), 62 Stat. 991; May 24, 1949, c. 139, § 127, 63 Stat. 107; 1953 Reorg.Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat.

631; June 11,
1962, Pub.L. 87
(2), 76 Stat. 78

1962 Amendment.
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ı and the interests of patients
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ersons to whom such regula-
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s section to maintain records,
hereof, shall, upon request of
e Secretary, permit such offi-
o have access to and copy and

2; 1940 Reorg.Plan No. IV, §
Stat. 1237; June 25, 1948, c.
19, c. 139, § 127, 63 Stat. 107;
1, 1953, 18 F.R. 2053, 67 Stat.

631; June 11, 1960, Pub.L. 86-507, § 1(18), 74 Stat. 201; Oct. 10, 1962, Pub.L. 87-781, Title I, §§ 102(b)-(d), 103(a), (b), 104(a)-(d)(2), 76 Stat. 781-783, 784, 785.

Historical Note

1962 Amendment. Subsec. (a). Pub.L. 87-781, § 104(a), inserted "an approval of" preceding "an application."

Subsec. (b). Pub.L. 87-781, § 102(b), inserted "and whether such drug is effective in use" following "is safe for use."

Subsec. (c). Pub.L. 87-781, § 104(b), substituted provisions requiring the Secretary, within 180 days after filing an application, or such additional period as the Secretary and the applicant agree upon, to either approve the application, if meeting the requirements of subsec. (d) of this section, or give notice of opportunity for hearing on question of whether such application is approvable, and providing that if applicant requests hearing in writing within 30 days, the hearing shall begin within 90 days after expiration of said 30 days, unless the Secretary and applicant agree otherwise, that such hearing shall be expedited, and that the Secretary's order shall be issued within 90 days after date for filing final briefs, for provisions which had an application become effective on the sixtieth day after filing thereof unless prior thereto the Secretary postponed the date by written notice to such time, but not more than 180 days after filing, as the Secretary deemed necessary to study and investigate the application.

Subsec. (d). Pub.L. 87-781, § 102(c), inserted references to subsec. (e), added cls. (5) and (6), provided that if after notice and opportunity for hearing, the Secretary finds that cls. (1)-(6) do not apply, he shall approve the application, and defined "substantial evidence" as used in this subsection and subsec. (e) of this section.

Subsec. (e). Pub.L. 87-781, § 102(d) amended subsection generally, and among other changes, directed the Secretary to withdraw approval of an application if by tests, other scientific data or experience, or new evidence of clinical experience not contained in the application or available at the time of its approval, the drug is shown to be unsafe, or on the basis of new information, there is shown a lack of substantial evidence that the drug has the effect it is represented to have, and provided that if the Secretary, or acting Secretary, finds there is an imminent hazard to public health, he may suspend approval immediately, notify the applicant, and give him opportunity for an expedited hearing, that the Secretary may withdraw approval if the applicant fails to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain records and make reports, or has refused access to, or copying or verification of such records, or if the Secretary finds on new evidence that the methods, facilities and controls in the manufacturing, processing, and packing are inadequate to assure and preserve the drugs' identity, strength, quality and purity, and were not made adequate within a reasonable time after receipt of written notice thereof, or finds on new evidence, that the labeling is false or misleading and was not corrected within a reasonable time after receipt of written notice thereof.

Subsec. (f). Pub.L. 87-781, § 104(c), substituted provisions requiring the Secretary to revoke any previous order under subsecs. (d) or (e) of this section refusing, withdrawing, or suspending approval of an application and to approve such application or reinstate such approval, for provisions which required him to revoke an order refusing effectiveness to an application.

Subsec. (h). Pub.L. 87-781, § 104(d)(1), (2), inserted "as provided in section 2112 of Title 28", and "except that until the filing of the record the Secretary may modify or set aside his order", substituted "or withdrawing approval of an application under this section" for "to permit the application to become effective, or suspending the effectiveness of the application", "United States court of appeals for the circuit" for "district court of the United States within any district", "Court of Appeals for the District of Columbia Circuit" for "District Court for the District of Columbia", "transmitted by the clerk of the court to" for "served upon", and "by the Supreme Court of the United States upon

take its meaning from the statute that is being amended—ERISA. And ERISA, for whatever reason, defines the word "employer" only for subchapter I.[1] Defining its meaning for subchapter III is up to the courts. *Cf. Robinson v. C.I.R.*, 805 F.2d 38, 40 (1st Cir.1986).[2]

[3] This conclusion brings us back to what the Trustee is really asking us to do: to define the word "employer" to include controlling shareholders and officers. We decline, for the following reasons.

First, as mentioned before, the principle of limited liability for corporate debts is longstanding enough and important enough to be considered a background norm, against which Congress may act of course, but which is controlling in the absence of such action. *See Connors v. P & M Coal Co.*, 801 F.2d at 1376. In deciding whether Congress has acted to expand liability "federal courts will look closely at the purpose of the federal statute to determine whether the statute places importance on the corporate form...." *Town of Brookline v. Gorsuch*, 667 F.2d 215, 221 (1st Cir.1981) (citations omitted). The MPPAA does not on its face indicate any intention to treat corporate debts for withdrawal liability different from any other corporate debts. The way that one could have expected Congress to make such an intention felt was through a definition of the word "employer." Yet Congress did not define the word in the MPPAA. Nor did Congress provide an applicable definition in ERISA.

Furthermore, the purposes of the MPPAA, as described in the legislative history of that act, would not be served by an extension of personal liability for corporate withdrawal payments. The Act represents a balance between efforts to protect existing pension plan beneficiaries through a short term strategy of imposing burdens on current employer contributors and through a long term strategy of encouraging new employers to contribute to multi-employer pension funds. *See* H.R. No. 96-869, 96th Cong., 2d Sess., *reprinted in* 1980 U.S.Code Cong. & Admin.News at 2918, 2919-20, 2935. Imposing personal liability for withdrawal payments would hurt that long term strategy by discouraging controlling individuals from directing their corporations to participate in multi-employer pension funds.

Withdrawal liability under the MPPAA is quite different than payroll taxes under the Social Security Act and minimum wage payments under the Fair Labor Standards Act, two corporate debts for which controlling shareholders and officers can be held liable. *See Donovan v. Agnew*, 712 F.2d at 1511; *United States v. McMullen*, 516 F.2d 917, 920 (7th Cir.1975) (26 U.S.C. § 7512 imposes liability for payroll taxes on person with control over corporations affairs). Payroll taxes and minimum wage payments are liabilities which a corporation can choose to pay or not pay. A decision to forgo paying payroll taxes or wages is a conscious decision to prefer some creditors over the government or the corporation's employees. Corporations do not have the same control over withdrawal liability payments, especially in the context in which shareholder and officer liability is most likely to be relevant: bankruptcy. Withdrawal liability is not assessed until an employer "withdraws" from the pension plan, by ceasing to do business for instance. If the liabilities of the employer corporation exceed its assets, which is the likely condition when a pension fund seeks to recover against officers or shareholders personally, the corporation will enter into bankruptcy proceedings, thereby losing control over which creditors receive payments.

Given the control corporations have over payroll taxes and wages, personal liability for those debts should rarely have actually assessed. The *threat* of personal liability should be enough to induce the individuals who control corporations to prefer the IRS and employee creditors over other creditors in times of financial difficulty. If not, the individuals controlling the corporation accept a known risk. Personal liability for withdrawal payments, on the other hand, cannot be similarly avoided. This personal liability may well force corporations to more extreme efforts to avoid bankruptcy, but any benefit is likely to be marginal, since controlling shareholders can be expected to attempt to avoid bankruptcy generally, in the hope of obtaining some return on their investment. Rather than a rarely exercised threat that induces a desired behavior, personal liability for withdrawal payments would be a routine accompaniment to corporate bankruptcy proceedings. This personal liability would discourage controlling shareholders and officers from directing their corporations to contribute to multi-employer pension plans, thereby making it less likely that their employees will receive pension benefits. In the long run, personal liability would hurt even those employees who are already beneficiaries of multi-employer pension plans, because the vitality of those plans depends on new employers contributing to them. *See* House Report, 1980 U.S.Code Cong. & Admin. News at 2919-20, 2935.

The decision of the district court is *affirmed.*

1. In *Nachman Corp. v. Pension Benefit Guar. Corp.*, 446 U.S. 359, 370 n. 14, 100 S.Ct. 1723, 1731 n. 14, 64 L.Ed.2d 354 (1980), the Supreme Court noted that Congress made some Title I (subchapter I in the Code) definitions applicable to Title IV (part of subchapter III in the Code), *see, e.g.*, 29 U.S.C. § 1321(a)(1). "This specific incorporation suggests that Title I definitions do not apply elsewhere in the Act of their own force...." *Id.*

2. We do not reach the question whether the subchapter I definition includes controlling officers or shareholders, a question which has occasioned considerable litigation, and difference of opinion. *Compare, e.g., Solomon v. Klein*, 770 F.2d 352, 354 (3d Cir.1985) (controlling shareholder and officer not an "employer") *with, e.g., Mass. State Carpenters Pension Fund v. Atlantic Diving Co., Inc.*, 635 F.Supp. 9, 13-14 (D.Mass. 1984) (controlling shareholder or officer may be "employer"). We reserve this question for a case in which it makes a difference in the outcome.

Lester GRINSPOON, M.D., Petitioner,

v.

DRUG ENFORCEMENT ADMINISTRATION, Respondent.

No. 86-2007.

United States Court of Appeals, First Circuit.

Heard March 3, 1987.

Decided Sept. 18, 1987.

Administrative Drug Enforcement Administration issued final rule placing 3, 4-methylenedioxymethamphetamine into Schedule I of Controlled Substances Act. Researcher on therapeutic use of substance petitioned for review. The Court of Appeals, Coffin, Circuit Judge, held that: (1) absence of FDA interstate marketing approval was not conclusive evidence that substance had no currently accepted medical use or lacked accepted safety for use under medical supervision; (2) there was sufficient evidence to support finding that substance had high potential for abuse; and (3) administrator was not required to consider evidence that placement of substance into Schedule I would strongly discourage medical research on substance.

Rule vacated and remanded.

1. Drugs and Narcotics ⚷46

Absence of interstate marketing approval of substance by Federal Drug Administration is not conclusive evidence that substance has no currently accepted medical use and lacks accepted safety for use under medical supervision for purposes of determining whether substance should be placed in Schedule I under Controlled Substances Act. Comprehensive Drug Abuse Prevention and Control Act of 1970, § 202(b)(1), as amended, 21 U.S.C.A. § 812(b)(1).

2. Drugs and Narcotics ⚷46

Finding that 3, 4-methylenedioxymethamphetamine had "high" potential for

abuse was not arbitrary and capricious, where administrator of Drug Enforcement Administration considered close structural and pharmacological similarity between substance and other substances which had already been found to have high potential for abuse and placed in Schedule I, as well as studies which suggested that substance was related in its effect to Schedule I and II substances. Comprehensive Drug Abuse Prevention and Control Act of 1970, § 202(b)(1), as amended, 21 U.S.C.A. § 812(b)(1).

3. Drugs and Narcotics ⇐46

Alleged failure of administrator of Drug Enforcement Administration to consider impact of determination to place substance on Schedule I upon legitimate scientific research was not improper. Comprehensive Drug Abuse Prevention and Control Act of 1970, § 202(b)(1), as amended, 21 U.S.C.A. § 812(b)(1).

4. Administrative Law and Procedure ⇐764

Drugs and Narcotics ⇐46

Department of Health and Human Services' adoption of analysis already performed by Drug Enforcement Administration that substance should have been classified in Schedule I without consulting any organization medical professionals or its own panel of experts was harmless error, and did not require rescheduling of substance, where there was substantial evidence to support classification. Comprehensive Drug Abuse Prevention and Control Act of 1970, § 201(b, c), as amended, 21 U.S.C.A. § 811(b, c).

Richard Cotton, Washington, D.C., for petitioner.

Harry S. Harbin, Washington, D.C., with whom William F. Weld, Asst. Atty. Gen., Criminal Div., Boston, Mass., Charles S. Sapho, Chief, Narcotic and Dangerous Drug Section, Dennis F. Hoffman, Chief Counsel, Drug Enforcement Admin., Stephen E. Stone, Associate Chief Counsel, Drug Enforcement Admin., Washington, D.C., and Charlotte A. Johnson, were on brief, for respondent.

Before COFFIN and TORRUELLA, Circuit Judges, and PETTINE,* Senior District Judge.

COFFIN, Circuit Judge.

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

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

21 U.S.C. § 812(b)(1).

Dr. Lester Grinspoon, a psychiatrist and faculty member of the Harvard Medical School, petitions this court to review the final rule. Dr. Grinspoon seeks to conduct research on the therapeutic use of MDMA and believes that the imposition of Schedule I controls will effectively foreclose such research. He cites four reasons for vacating the Administrator's scheduling determination. The first reason advanced is that the Administrator applied the wrong legal standards for "currently accepted medical use in treatment in the United States" and

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

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

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

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

I. *Administrative History.*

In January of 1984, the DEA prepared a document entitled "Schedule I Control Recommendation Under the CSA for 3,4-Methylenedioxymethamphetamine (MDMA)." The control recommendation, which was based upon information compiled from various DEA data sources and scientific and medical literature, considered all three Schedule I criteria listed in section 812(b)(1) and concluded that (1) MDMA has a high potential for abuse; (2) MDMA has no known legitimate medical use for treatment in the United States; and (3) there is a lack of accepted safety for the use of MDMA under medical supervision. Based upon these findings, the DEA recommended that MDMA be placed into Schedule I of the CSA.

In March of 1984, pursuant to the procedures set out in the CSA, 28 U.S.C. 811(b),[2] the Administrator submitted the DEA's control recommendation to the Assistant Secretary for Health of the Department of Health and Human Services ("HHS") for scientific and medical evaluation and for an HHS recommendation as to whether MDMA should be controlled. The HHS evaluation was conducted by Dr. Charles Tocus, Chief of the Drug Abuse Staff of the Food and Drug Administration ("FDA"). Dr. Tocus stated in his affidavit that he searched the FDA files and found no reference to MDMA. Based upon this absence of information in the FDA files and a review of the information contained in the DEA control recommendation carried out by Dr. Tocus, HHS responded by making minor (typographical) corrections in the DEA's eight-factor analysis[3] and concurring in the recommendation that MDMA be placed into Schedule I.

Upon receiving the HHS evaluation and recommendation, the Administrator issued a Notice of Proposed Rulemaking with regard to placing MDMA into Schedule I of the CSA. 49 Fed.Reg. 30,210 (1984). Later, following the receipt of several com-

2. 21 U.S.C. § 811(b) provides that

> The Attorney General shall, before initiating proceedings under subsection (a) of this section to control a drug or other substance ..., and after gathering the necessary data, request from the Secretary a scientific and medical evaluation, and his recommendations, as to whether such drug or other substance should be so controlled.

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

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

21 U.S.C. § 811(c).

ments and requests for a hearing, the Administrator referred the matter to an Administrative Law Judge ("ALJ") with instructions to "conduct a hearing for the purpose of receiving factual evidence and expert opinion regarding the proposed scheduling of MDMA." 51 Fed.Reg. 36,552 (1986). During the course of the hearing, the ALJ heard 33 witnesses and received 95 exhibits into evidence.[4] On May 22, 1986, the ALJ issued a comprehensive opinion finding that MDMA fit none of the three criteria prerequisite to placement in Schedule I. Relying on the hearing testimony of experts in the health care community, the ALJ concluded that MDMA had an accepted medical use for treatment in the United States, 21 U.S.C. § 812(b)(1)(B), and an accepted safety for use under medical supervision, 21 U.S.C. § 812(b)(1)(C). The ALJ also found that the record did not establish that MDMA had a "high" potential for abuse. 21 U.S.C. § 812(b)(1)(A). The ALJ therefore recommended that MDMA be placed into Schedule III of the CSA.

The Administrator, however, declined to accept the reasoning and scheduling recommendation of the ALJ. In his October 13, 1986, decision, the Administrator held that the phrases "currently accepted medical use in treatment in the United States" and "accepted safety for use ... under medical supervision" as used in the CSA, 21 U.S.C. § 812(b)(1), both mean that the FDA has evaluated the substance for safety and approved it for interstate marketing in the United States pursuant to the Federal Food, Drug, and Cosmetic Act of 1938 ("FDCA"), 21 U.S.C. § 355. From these premises, the Administrator reasoned that because the FDA has not approved a new drug application ("NDA") or investigational new drug application ("IND") authorizing interstate marketing of MDMA under the FDCA, MDMA cannot be lawfully marketed and has neither a currently accepted medical use in treatment in the United States nor an accepted safety for use under medical supervision. Finally, the Administrator found that the DEA had sustained its burden of proving that MDMA has a high potential for abuse. The Administrator's final rule, effective November 13, 1986, placed MDMA into Schedule I. Dr. Grinspoon appeals from this final rule under the CSA, 21 U.S.C. § 877.

II. *Accepted Medical Use And Safety Under The CSA.*

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

A. *Standard of Review.*

The Administrator argues correctly that we must review his interpretation of the CSA in light of the guidelines set forth by the Supreme Court in *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984). In *Chevron* the Court explained that a reviewing court must employ a two-step analysis that focuses initially on the intentions of Congress:

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

Id. at 842–43, 104 S.Ct. at 2781 (emphasis supplied). In the absence of congressional intent, however, the court must proceed to a second inquiry:

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

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

Id. at 843, 104 S.Ct. at 2781–82 (footnote omitted; emphasis supplied).

It is undisputed that Congress has not directly spoken to the question at issue here, namely, the proper means of interpreting the second and third criteria of section 812(b)(1). The absence of express intent, however, does not compel us to proceed to the deferential second step of the *Chevron* scheme. As the Supreme Court indicated in a footnote to its *Chevron* opinion, "[i]f a court, employing traditional tools of statutory construction, ascertains that Congress had an intention on the precise question at issue, that intention is law and must be given effect." *Id.* at 843 n. 9, 104 S.Ct. at 2781 n. 9. Recently the Supreme Court has reaffirmed this proposition, holding in *INS v. Cardoza-Fonseca*, — U.S. —, 107 S.Ct. 1207, 94 L.Ed.2d 434 (1987), that a court faced with a "pure question of statutory interpretation" should rely upon traditional methods of statutory construction in an attempt to determine the intent of Congress. *Id.* 107 S.Ct. at 1221; *International Union, UAW v. Brook*, 816 F.2d 761, 764–65 (D.C.Cir. 1987) (applying "traditional tools" of statutory construction to invalidate agency's interpretation of statutory language as conflicting with intent of Congress).

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

B. *Statutory Language and Structure.*

The Administrator begins by arguing that the language of the CSA itself is evidence of congressional intent favoring his construction of the statute. His argument is based on the definitions of terms chosen by Congress in drafting the relevant provisions of the CSA. He first cites the definition of the term "United States" as used in "accepted medical use in treatment in the United States." 21 U.S.C. § 812(b)(1)(B). This term is the only portion of the Schedule I criteria that Congress has expressly defined in the CSA, providing that "[t]he term 'United States,' when used in a geographic sense, means *all places* ... subject

5. Contrary to the assertions of the Administrator, this is not a situation in which Congress has expressly vested the Administrator with authority to define general statutory criteria by issuing regulations. Were this such a case, such regulations would be controlling unless they were "arbitrary, capricious, or manifestly contrary to the statute." *Chevron*, 467 U.S. at 843–44, 104 S.Ct. at 2782. Here, the CSA expressly delegates to the Attorney General only the authority to make "the *findings* prescribed by subsection (b) of section 812 of this title for the schedule in which [a] drug is to be placed." 21 U.S.C. § 811(a)(1)(B) (emphasis supplied). This explicit delegation of authority to *apply* prescribed statutory criteria is not equivalent to an explicit delegation of authority to *define* those criteria.

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

to the jurisdiction of the United States." 21 U.S.C. § 802(28) (emphasis supplied). Coupling this statutory definition of "United States" with the dictionary definition of "accepted"—which means "generally approved" or "generally agreed upon"—the Administrator argues that the phrase "*accepted* medical use in treatment in the *United States*," 21 U.S.C. § 812(b)(1)(B), must contemplate an administrative determination that the substance has been "generally approved" for use in treatment in "all places" subject to United States jurisdiction. In other words, FDA interstate marketing approval is necessary to satisfy this criterion because, otherwise, the substance could not be deemed to be "generally approved" *everywhere* in the United States.[7]

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

Nor does the dictionary definition of "accepted" offered by the Administrator convince us that Congress intended FDA approval to be the equivalent of the second and third Schedule I criteria. Use of the term "accepted" in sections 812(b)(1)(B) and 812(b)(1)(C) may indicate that Congress intended the medical use or safety of the substance to be "generally agreed upon," but this alone does not inform us as to *who* must generally be in agreement. The Administrator reads "accepted" to mean that *the FDA* must have approved the drug for interstate marketing. Dr. Grinspoon, on the other hand, prefers to interpret "accepted" as meaning that the *medical community* generally agrees that the drug in question has a medical use and can be used safely under medical supervision. Our conclusion is that the term "accepted" does not cure the statute's ambiguity. We are simply unable to extrapolate from the drafters' choice of the word "accepted" and thereby ascertain a general congressional intention favoring the interpretation advanced by the Administrator.

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

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

8. The Commissioners' Notes provide:

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

9 U.L.A. at 221.

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

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

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

Another possible reason for failure to obtain FDA new drug approval is that the manufacture, distribution, and use of a substance might not involve interstate marketing.[10] Unlike the CSA scheduling restrictions, the FDCA interstate marketing provisions do not apply to drugs manufactured and marketed wholly intrastate. *Compare* 21 U.S.C. § 801(5) *with* 21 U.S.C. § 321(b), 331, 355(a). Thus, it is possible that a substance may have both an accepted medical use and safety for use under medical supervision, even though no one has deemed it necessary to seek approval for interstate marketing. Indeed, as Dr. Grinspoon argues, there is no economic or other incentive to seek interstate marketing approval for a drug like MDMA because it cannot be patented and exploited commercially. The prospect of commercial development, of course, is irrelevant to one

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

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

who, like Grinspoon, seeks only to do research.

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

C. *Legislative History.*

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

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

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

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

D. *Subsequent Legislation.*

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

First, in 1984, Congress amended the CSA to include an "emergency scheduling" provision. *See* 21 U.S.C. § 811(h). This provision allows the Attorney General to place certain substances into Schedule I on a temporary basis without regard to the regular scheduling criteria and procedures if such emergency scheduling is "necessary to avoid an imminent hazard to the public safety." 21 U.S.C. § 811(h)(1). This amendment to the CSA, however, expressly states that the Attorney General's authority to schedule substances in this expedited manner does not apply where an "exemption or approval is in effect for the substance under section 355 of this title," [11] *i.e.*, where the FDA has permitted the substance to be marketed in interstate commerce. *Id.* The fact that Congress expressly authorized the Attorney General to use expedited procedures and rely upon the absence of FDA interstate marketing approval, rather than the usual Schedule I criteria, only in temporary emergency situations suggests to us that these shorthand methods are not appropriate in routine (i.e., nonemergency) situations such as the one before us in the instant case. We do not interpret the explicit reference to FDA approval in the "emergency scheduling" provision to mean, as the Administrator would have us believe, that Congress sought to permit blind reliance on FDA standards as a legitimate shortcut in the general run of cases.

Second, Congress amended the CSA again in 1986 when it enacted the Controlled Substance Analogue Enforcement Act, Pub.L. No. 99–570, §§ 1201–04, 100 Stat. 3207 (codified at 21 U.S.C. §§ 802(32)(A), 813). This amendment defines a "controlled substance analogue" as a substance having a chemical structure and effect on the central nervous system substantially similar to that of a Schedule I or II controlled drug. 21 U.S.C. § 802(32)(A). It provides that analogues of Schedule I and II controlled substances shall, to the extent intended for human consumption, be subject to the same controls and penalties as the controlled substances themselves. 21 U.S.C. § 813. As the Administrator points out, the provision expressly excludes from its definition of "controlled substance analogue," and hence from the scope of the amendment's substantive controls pending final scheduling, any substance for which there is an approved new drug application or an exemption for investigational use under section 355 of the FDCA. 21 U.S.C. § 802(32)(B)(ii), (iii). Again, however, we are unpersuaded by the Administrator's argument that explicit permission to rely on FDA standards in the case of analogues evidences congressional approval of his use of this shorthand method in *all* scheduling determinations. We believe instead that the authorization to impose Schedule I controls based on the lack of FDA approval, rather than satisfaction of the scheduling

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

criteria set out in section 812(b)(1), in the unique situation of analogues intended for human consumption constitutes a special, and justifiable, exception to the general procedure mandated by section 812(b)(1). We believe, however, that in other cases involving nonanalogues, or analogues intended for uses other than human consumption, absolute reliance on the absence of FDA approval would be inappropriate and, indeed, contrary to the intent of Congress in enacting the CSA.

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

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

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

E. *Need For A Meaningful Hearing.*

We believe there is yet one additional policy reason, no doubt related to some of the other factors already discussed, for rejecting the construction of the CSA advanced by the Administrator as contrary to congressional intent. Under the statutory scheme set up by Congress, the Attorney General may not schedule a substance under the CSA without first obtaining the recommendation of the FDA, through its parent agency, HHS, 21 U.S.C. § 811(b), and providing an "opportunity for a hearing pursuant to the rulemaking procedures prescribed by [the Administrative Procedure Act]." 21 U.S.C. § 811(a). It is plain, therefore, that while Congress intended the recommendation of HHS to have significant weight in the decisionmaking process, it also intended that there be an opportunity for a meaningful hearing *after* receipt of the HHS report. It would surely be anomalous if the FDA's recommendation, based solely on the absence of approval for interstate marketing, sufficed to determine the ultimate conclusion prior to the hearing.

If we were to accept the Administrator's construction of section 812(b)(1) in this case, the opportunity for a meaningful hearing would be lost, and satisfaction of the "accepted medical use" and "accepted safety" criteria would turn solely on the existence of FDA approval for interstate marketing. A hearing on issues of the sort required by the statute—Does the substance have an accepted medical use in treatment in the United States? Is the substance safe for use under medical supervision?—would be reduced to an empty formality and, for participants like Dr. Grinspoon, would amount to an exercise in futility. We hesitate to interpret the CSA in a manner that would cause its important provision requiring a administrative hearing to be meaningless as to two of the

three requirements for scheduling a substance in Schedule I. We believe instead that, for the hearing opportunity to be a significant one on these issues, the agency must remain flexible enough to weigh and consider claims raised at the administrative hearing to the effect that a substance has an accepted use and is accepted as safe even though it is not approved for distribution in interstate commerce.

The importance of a meaningful hearing prior to scheduling can best be appreciated when one considers those situations for which Congress has permitted the Administrator to regulate substances in the absence of a hearing. Neither the emergency scheduling provision, 21 U.S.C. § 811(h), nor the provision for treatment of controlled substance analogues, 21 U.S.C. § 813, requires the Administrator to hold a hearing prior to taking regulatory action. Congress crafted both of these sections to serve as stop-gap measures to be employed pending a final scheduling determination by the DEA, following a full evidentiary hearing, for the substance in question. Significantly, it is only in these provisions for *temporary* controls pending final scheduling that Congress has emphasized the absence of FDA interstate marketing approval, 21 U.S.C. § 811(h)(1) (emergency scheduling provision); 21 U.S.C. § 802(32)(B)(ii), (iii) (controlled substance analogue act). In the case of emergency scheduling, it appears that Congress has already done the balancing and determined that the risk of ongoing abuse amounting to an "imminent hazard to the public safety" justifies temporary scheduling without a hearing in the absence of FDA approval. Likewise in the latter case, Congress has responded to the need for expedited investigation and prosecution of "clandestine chemists who develop subtle chemical variations of controlled substances (called analogues or 'designer drugs') for illicit distribution and use," H.R.Rep. No. 848, 99th Cong., 2d Sess., pt. 1, 2 (1986), and permitted Schedule I controls to take effect without first requiring a hearing so long as FDA approval is lacking. Thus, in both "emergency" situations for which Congress has seen fit to place particular weight on the absence of FDA interstate marketing approval, it has also determined that a hearing procedure is unwarranted. Clearly, this is not the case in the general administrative scheduling proceedings and the hearing requirement should be given full effect rather than being shortcircuited by blind reliance on the absence of FDA approval.

F. *Conclusion.*

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

Petitioner Grinspoon has offered his own theory concerning the type of inquiry the Administrator must make under the statute. He urges us to adopt a standard for the second and third criteria that is based upon the opinion of members of the medical community. He contends that Congress drafted the CSA with this type of standard in mind. To support this contention, Grinspoon cites the testimony of two representatives of the Bureau of Narcotics and Dangerous Drugs ("BNDD"), DEA's predecessor agency, during legislative consideration of Pub.L. No. 91-513, the Comprehensive Drug Abuse Prevention and Control Act of 1970. Michael R. Sonnenreich, Deputy Chief Counsel of the BNDD, testified that drugs in Schedule I would "have no medical use as determined by the medical community," and that "the medical community" would decide "whether or not the drug has [a] medical use...." Hearings on Drug Abuse Control Amendments Before

the Subcomm. on Public Health and Welfare of the House Comm. on Interstate and Foreign Commerce, 91st Cong., 2d Sess. 696, 718 (1970) ("House Hearings"). Likewise, John Ingersoll, Director of the BNDD, testified that substances placed in Schedule I would be those drugs that "the medical profession has already determined to have no legitimate medical use in the United States." House Hearings at 678.

While we acknowledge that the statements by the BNDD witnesses before the House Subcommittee tend to support Dr. Grinspoon's position, we do not believe they are entitled to much weight as indicia of congressional intent in fashioning the "accepted medical use" and "accepted safety for use ... under medical supervision" criteria. *See McCaughn v. Hershey Chocolate Co.*, 283 U.S. 488, 493-94, 51 S.Ct. 510, 512, 75 L.Ed. 1183 (1931) ("statements ... made to committees of Congress ... are without weight in the interpretation of a statute"). This is especially true where, as here, there is no indication whatsoever in either the legislative history or the history of any subsequent amendments that Congress concurred with the views expressed by the witnesses. In short, we do not find Grinspoon's evidence to be persuasive on the issue of affirmative congressional intent to have certain members of the medical community determine whether a substance has an "accepted medical use in treatment in the United States" or "accepted safety for use ... under medical supervision.".

The nature of our review further constrains us from requiring the Administrator to adopt Dr. Grinspoon's proposed construction of section 812(b)(1). Although we find that the Administrator's present interpretation of the second and third Schedule I criteria contravenes congressional intent, we are unable to ascertain with any certainty what Congress intended to be the proper interpretation of subsections (B) and (C). In other words, while we are satisfied that Congress intended to preclude reliance on the absence of FDA approval in assessing whether a substance has an "accepted medical use" and "accepted safety for use ... under medical supervision," we have found nothing to indicate how Congress affirmatively intended these two ambiguous statutory phrases to be construed and applied. It appears to us that Congress has implicitly delegated to the Administrator the authority to interpret these portions of the CSA, and we must therefore refrain from imposing our own statutory interpretation upon the agency. *Chevron*, 467 U.S. at 843, 104 S.Ct. at 2781. Hence, to avoid unduly infringing upon the Administrator's legitimate discretion to develop a legally acceptable standard—i.e., one that does not conflict with the intentions of Congress, and makes sense in light of the statutory language, the legislative history, and the purposes of the entire legislative scheme—we remand the rule to the Administrator for reconsideration and for further proceedings not inconsistent with this opinion.

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

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

A. *"High" Potential For Abuse.*

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

1. *Legal Standard.*

The CSA provides no definition of the phrase "high potential for abuse," but both parties agree that the legislative history of the statute provides guidance in this regard. Specifically, the report of the House Committee on Interstate and Foreign Commerce accompanying the bill that eventually became the CSA sets forth four alternative legal standards for determining when a substance possesses a "potential for abuse." Borrowing from regulations promulgated under the FDCA, the House Committee Report provides that the Administrator may determine a substance has potential for abuse if:

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

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

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

[2] While we acknowledge that the Administrator's final rule is silent with respect to the legal standard required for a finding of "high" potential for abuse, we do not find the Administrator's action to be arbitrary and capricious. The fourth standard contained in the segment of the Committee Report quoted above makes it quite clear that the Administrator can permissibly reach a conclusion regarding a substance's level of potential for abuse by comparing the substance to drugs already scheduled under the CSA. Here the Administrator has done just that, offering several findings concerning the evidence of close structural and pharmacological similarity between MDMA and other substances, such as MDA,[12] which already

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

have been found to have a high potential for abuse and have been placed in Schedule I or II. 51 Fed.Reg. 36,555–57 (1986). The Administrator also cited animal studies, human behavioral studies, and a survey of MDMA users which suggest that MDMA is related in its effects to Schedule I and II substances such as LSD, cocaine, mescaline, and MDA.[13] We believe this approach to ascertaining MDMA's potential for abuse is entirely consistent with the statutory scheme developed by Congress and therefore hold that the Administrator's method is not arbitrary and capricious.[14] The question remains, of course, whether the evidence collected by the Administrator is sufficient to justify his conclusion that MDMA has a high potential for abuse. Since Dr. Grinspoon has also challenged this aspect of the scheduling determination as arbitrary and capricious, we turn next to a discussion of this issue.

2. *Substantial Evidence.*

In reviewing the Administrator's conclusion regarding MDMA's potential for abuse, we must determine whether it is based on "substantial evidence," a term the Supreme Court has defined as " 'such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.' " *American Textile Manufacturers Institute, Inc. v. Donovan*, 452 U.S. 490, 522–23, 101 S.Ct. 2478, 2497, 69 L.Ed.2d 185 (1981) (quoting *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 477, 71 S.Ct. 456, 459, 95 L.Ed. 456 (1951)). The Court has further explained this lenient standard of review, stating that " 'the possibility of drawing two inconsistent conclusions from the evidence does not prevent an administrative agency's findings from being supported by substantial evidence.' " *Id.* (quoting *Consolo v. Federal Maritime Commission*, 383 U.S. 607, 620, 86 S.Ct. 1018, 1026, 16 L.Ed.2d 131 (1966)). In other words, "[e]ven if reasonable minds could also go the other way, we must uphold the [agency] if its ultimate finding is supported by substantial evidence in the record as a whole." *NLRB v. J.K. Electronics, Inc.*, 592 F.2d 5, 7 (1st Cir.1979).

The question before us, therefore, is whether there is substantial evidence in the administrative record to support the Administrator's determination that MDMA is "so related in [its] action to a drug or drugs already listed as having a [high] potential for abuse" that it is likely MDMA "will have the same potentiality for abuse as such drugs." House Committee Report, *supra*, at 4601. In support of his conclusion, the Administrator made 46 numbered findings related to MDMA's similarity to other drugs with a high potential for abuse. These findings were based on scientific evidence concerning the chemical structural similarity between MDMA and other Schedule I and II drugs; the similar pharmacological effects of MDMA and these other drugs; animal drug discrimination studies; animal self-administration studies; and recent studies of the neurotoxic effects of MDMA and related drugs on rats. Based on this evidence, the Administrator found, among other things, that (1) MDMA is the N-methyl analogue of MDA and retains the psychomimetic properties of MDA; (2) MDMA produces pharmacological effects in common with both central nervous system ("CNS") stimulants like amphetamine and hallucinogens like MDA in animals; (3) MDMA and MDA produce the same spectrum of pharmacological effects in mice, dogs, and monkeys when observed during toxicity studies; (4) MDMA, like MDA, amphetamine, and methamphetamine, produces neurotoxic effects when administered to animals; (5) MDMA and MDA may both produce the same neurotoxic effects to serotonergic nerves in humans; (6) in drug discrimination tests, rats trained to recognize amphetamine also recognized MDA and MDMA, and rats trained to recognize MDA also recognized MDMA; (7) based on recent tests involving human subjects, MDMA can be described as maintaining the same potency as MDA, but exhibiting subtle differences in the qualitative nature of the intoxication.

Dr. Grinspoon, in an item-by-item analysis contained in the proposed findings of fact and conclusions of law he submitted to the DEA, calls into question many of the Administrator's findings concerning MDMA's similarity to other drugs with a high potential for abuse. For instance, Grinspoon agrees that MDMA is a member of a family of psychoactive drugs, but disputes the validity of the inference drawn from the similarity by the Administrator. According to Grinspoon, "chemical similarity is not necessarily a good guide to the actual effects of a compound in the human body." Petitioner's Brief at 37. Grinspoon notes that of the 28 known phenethylamines, 17 were not scheduled under the CSA as late as December 1983. Even a subsequent review of these 17 substances by the World Health Organization's Expert Committee on Drug Dependence resulted in a recommendation that only nine of the substances be scheduled by member nations. Eight were thought harmless enough to remain unscheduled.[15] Also, referring to the Administrator's finding that MDMA, like MDA and amphetamine, is a central nervous system stimulant, Grinspoon asserts that this evidence of pharmacological similarity proves nothing. Several other substances also fit this description, including caffeine and six of the eight phenethylamines that are neither currently controlled nor recommended for control by WHO. Based on this, Grinspoon concludes that the mere fact that a substance is a CNS stimulant does not necessarily imply that it has a high potential for abuse.

In addition, Dr. Grinspoon (1) attacks the Administrator's other findings concerning MDMA's LD-50 rating[16] as being irrele-

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

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

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

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

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

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

vant to the "potential for abuse" inquiry; (2) discounts the importance of findings that MDMA is neurotoxic when administered to rats; (3) questions the relevancy of the findings related to animal drug discrimination studies; and (4) asserts that the Administrator has incorrectly interpreted the results of two animal self-administration studies. We have reviewed Dr. Grinspoon's item-by-item analysis closely, but find no basis sufficient to overturn the Administrator's decision. Grinspoon's reinterpretation of the scientific evidence before the agency surely demonstrates that the available evidence does not inexorably lead to a conclusion that MDMA is similar to drugs possessing a high potential for abuse. But, faced with such uncertainty, we must defer to the conclusion reached by the Administrator, even if we may have favored Dr. Grinspoon's approach had we studied the evidence in a *de novo* fashion. In reaching this conclusion, we follow the well-established maxim that "[w]here the agency presents scientifically respectable evidence which the petitioner can continually dispute with rival, and we will assume, equally respectable evidence, the court must not second-guess the particular way the agency chooses to weigh the conflicting evidence or resolve the dispute." *Asarco, Inc. v. OSHA*, 746 F.2d 483, 490 (9th Cir.1984) (quoting *United Steelworkers of America v. Marshall*, 647 F.2d 1189, 1263 (D.C.Cir.1980), *cert. denied*, 453 U.S. 913, 101 S.Ct. 3148, 69 L.Ed.2d 997 (1981)). We find this maxim to have particular force in a case such as this because, as one court has explained, "[a]ppellate courts have neither the expertise nor the resources to evaluate complex scientific claims." *Thompson Medical Co. v. FTC*, 791 F.2d 189, 196 (D.C.Cir.1986), *cert. denied*, — U.S. —, 107 S.Ct. 1289, 94 L.Ed.2d 146 (1987).

B. *Impact Of Scheduling On Research.*

Dr. Grinspoon also takes issue with the Administrator's alleged failure to consider evidence tending to show that placement of MDMA in Schedule I would strongly discourage medical research on the drug. Grinspoon contends that failure to consider the impact of a scheduling decision on legitimate research amounts to arbitrary and capricious action on the part of the Administrator because he did not weigh all relevant factors in making his decision. *Motor Vehicle Manufacturers Association v. State Farm Mutual Insurance Co.*, 463 U.S. 29, 42–43, 103 S.Ct. 2856, 2866, 77 L.Ed.2d 443 (1983). To buttress his contention, Grinspoon recites a litany of legal, administrative, and practical obstacles that hinder researchers seeking to conduct experiments with Schedule I drugs. These obstacles include mandatory FDA approval of research involving Schedule I substances, 21 C.F.R. § 1301.42(a)–(c); mandatory special registration with the DEA, 21 C.F.R. §§ 1301.33, 1301.42; mandatory reporting and security procedures beyond those required for drugs placed in Schedules II through V; unavoidable bureaucratic delays; and other adverse impacts due to the grave concern caused by a substance's placement in Schedule I, such as difficulty in obtaining volunteers for clinical studies and, for academic researchers, difficulty in securing approval from institutional review boards.

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

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

C. *Reliance Upon HHS Evaluation And Recommendation.*

Dr. Grinspoon's final dissatisfaction with the final rule is the Administrator's alleged reliance on the conclusions recommended by HHS on the criteria enumerated in section 812(b)(1). Grinspoon argues that the determination by the Secretary of HHS was arbitrary and capricious and not in accordance with law, and that all relevant scientific and medical evidence was not before the Secretary at the time of the determination. The record, in fact, reveals that HHS performed in a less than admirable fashion in making its recommendation to the Administrator. The record indicates that HHS failed to look beyond its own files upon receiving the Administrator's section 811(b) request for a scientific and medical evaluation; neglected to consult any organization of medical professionals or even the FDA's own panel of experts, the Drug Abuse Advisory Committee; and simply rubber-stamped the Administrator's conclusion by adopting the section 811(c) eight-factor analysis already performed by the DEA. There is also evidence that FDA analysts failed to forward a letter received from the National Institute of Drug Abuse, which stated that the evidence cited by the DEA did not support the existence of abuse potential in animals, to either the FDA Commissioner or the Assistant Secretary of HHS prior to the issuance of the HHS recommendation to the Administrator.[17]

[4] Despite these alleged procedural shortcomings, we fail to see how the procedure followed by HHS tainted the Administrator's determination. The CSA does not specify the steps to be taken by HHS; it simply requires the Administrator to request from the Secretary of HHS a scientific and medical evaluation. 21 U.S.C. § 811(b). Moreover, the HHS recommendation to schedule a substance is not binding[18] and, indeed, serves to trigger an administrative hearing at which interested persons may introduce evidence to rebut the Secretary's scheduling recommendation. Ultimately, of course, responsibility rests with the Administrator, not HHS, to ensure that the final rule rests on permissible legal standards and substantial evidence. It is true that the Administrator twice mentioned the HHS recommendation in his final rule, once in relation to the "accepted medical use" criterion and once in relation to the "high potential for abuse" criterion. With regard to the first mention, however, we have already determined that this aspect of the case must be remanded and reconsidered because the Administra-

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

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

tor interpreted the statutory language in a manner that is contrary to the intent of Congress. Because, on remand, the Administrator will not be able to rely on lack of FDA approval to demonstrate the absence of an accepted medical use, we need not discuss any possible reliance on the HHS recommendation regarding the absence of an accepted medical use. With regard to the second mention, we believe that the Administrator's conclusion that MDMA has a high potential for abuse is amply supported by a substantial amount of independent evidence. Because we believe that the Administrator's finding with regard to MDMA's potential for abuse is justified even in the absence of the HHS recommendation to place MDMA in Schedule I, we hold that any reliance on the HHS evaluation by the Administrator constitutes, at most, harmless error.

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

Aaron J. FURMAN, Martin J. Joel, Jr., Alvin Katz, Francis P. Maglio, Harvey Sheld, Everard M.C. Stamm and Robert C. Stamm, Plaintiffs,

Martin J. Joel, Jr., Harvey Sheld, Everard M.C. Stamm and Robert C. Stamm, Plaintiffs-Appellants,

v.

John CIRRITO, Harold S. Coleman, John A. Miller, Francis G. Rea, Peter M. Toczek and A.J. Yorke, Defendants-Appellees.

No. 18, Docket 86-7283.

United States Court of Appeals, Second Circuit.

Argued Oct. 20, 1986.

Decided Sept. 1, 1987.

Minority general partners of partnership brought civil claim against majority owners of partnership pursuant to RICO statute. The United States District Court for the Southern District of New York, Irving Ben Cooper, J., 578 F.Supp. 1535, dismissed action for failure to state claim, and appeal was taken. The Court of Appeals, 741 F.2d 524, affirmed. On petition for writ of certiorari, the United States Supreme Court, 105 S.Ct. 3550, vacated. Following vacation, 779 F.2d 36, and on remand, the district court concluded that complaint failed to allege any continuity of activity and dismissed RICO cause of action, and appeal was again taken. The Court of Appeals, Van Graafeiland, Circuit Judge, held that: (1) sale of partnership assets did not constitute wrongdoing to support RICO action; (2) majority partners were not guilty of any criminal conduct based on alleged failure to promptly inform minority partners that they would be required to sign written contract with purchasing partnership; and (3) even if minority partners spelled out some form of criminal fraud on part of majority partners, they failed to allege pattern of racketeering activity conducted in affairs of "enterprise."

Affirmed.

George C. Pratt, Circuit Judge, filed dissenting opinion.

1. Partnership ⇐70, 97

Rights and obligations of partners, as between themselves, are fixed by terms of partnership agreement; even terms which permit self-dealing by partner will be enforced.

2. Commerce ⇐82.72

Allegations by minority shareholders of partnership to effect that majority members committed mail fraud in selling assets of partnership was frivolous, and thus could not support action brought pursuant to RICO statute; partnership agreement gave absolute and sole discretion to majority members to sell partnership assets, and further, allegation that principal of another brokerage firm was "prepared to negotiate" purchase of partnership at higher price was inadequate to establish that other firm made offer to purchase. 18 U.S.C.A. §§ 1961–1968.

3. Commerce ⇐82.72

Allegations by minority partners that their signatures on written contract for sale of partnership assets were coerced by criminal conduct on part of majority partners and that minority partners were "forced to accept employment" on unfavorable terms was too conclusory to support charge of criminal wrongdoing in order to maintain action under RICO statute; each partner had right to negotiate on his or her behalf whether, and on what terms, he or she was willing to become associated with purchasing partnership, and even if minority partners lacked sufficient sophistication to know that they could not be bonded over to purchasing partnership without their consent, they made no allegation of anything that prevented them from refusing to sign contract unless they received more favorable treatment. 18 U.S.C.A. §§ 1961–1968.

4. Commerce ⇐82.72

Assuming that minority general partners' complaint spelled out some form of criminal fraud on part of majority partners in selling partnership assets, complaint failed to allege pattern of racketeering activity conducted in affairs of "enterprise" to enable minority partners to maintain RICO action; at time allegedly wrongful acts occurred, majority partners were not functioning as continuing unit in ongoing organization, as they were acting solely on their own to prevent alleged enterprise from being ongoing, continuing unit through sale of partnership. 18 U.S.C.A. §§ 1961–1968.

Seymour Shainswit, New York City (Cooper Cohen Singer Ecker & Shainswit and Steven E. Levitsky, New York City, of counsel), for plaintiffs-appellants.

Max Gitter, New York City (Paul, Weiss, Rifkind, Wharton & Garrison and Dorothy E. Roberts, New York City, of counsel), for defendants-appellees.

Before VAN GRAAFEILAND, NEWMAN and PRATT, Circuit Judges.

VAN GRAAFEILAND, Circuit Judge:

This is an appeal from an order of the United States District Court for the Southern District of New York (Cooper, J.) granting appellees' motion under Fed.R. Civ.P. 12(b)(1) and (6) to dismiss appellants' complaint, and from the judgment entered pursuant thereto. For the reasons that follow, we affirm.

Appellants' complaint states three causes of action, two that are state law claims of partnership fraud and breach of fiduciary duty and a third grounded on the Racketeer Influenced and Corrupt Organizations Act (RICO), 18 U.S.C. §§ 1961–68. It twice has been dismissed by the district court. The first dismissal was based on appellants' failure to allege a separate, distinct racketeering enterprise injury. 578 F.Supp. 1535 (S.D.N.Y.1984). This Court's affirmance of that decision, 741 F.2d 524, was vacated by the Supreme Court, 473 U.S. 922, 105 S.Ct. 3550, 87 L.Ed.2d 672 (1985), on the basis of its holdings in *Sedima, S.P.R.L. v. Imrex Co.*, 473 U.S. 479, 105 S.Ct. 3275, 87 L.Ed.2d 346 (1985), and *American Nat'l Bank & Trust Co. v. Haroco, Inc.*, 473 U.S. 606, 105 S.Ct. 3291, 87 L.Ed.2d 437 (1985) (per curiam). Following remand to the district court, appellees moved to dismiss for failure to allege a "pattern of racketeering activity", 18 U.S.C. § 1962(c), or, in the alternative, to compel arbitration pursuant to the Federal Arbitration Act, 9 U.S.C. §§ 1–14. Relying on *Sedima, supra*, 473 U.S. at 496 n. 14, 105 S.Ct. at 3285 n. 14; *id.* at 527–28, 105 S.Ct. at 3289–90 (Powell, J., dissenting), and cases that followed, the district court held that racketeering activity must be continuous and related in order to constitute a pattern and must be ongoing or occur in more than one criminal episode. Although the district court felt that appellees' alleged acts were related, it concluded that the complaint failed to allege any continuity of activity, and dismissed the RICO cause of action. The district court held

Tariff Act of 1930. On February 4, 1992, the Commission scheduled a public hearing in connection therewith for March 26, 1992. On March 17, 1992, the Commission received notice of withdrawal from the only scheduled witness for the hearing scheduled for March 26, 1992. Therefore, the public hearing in connection with this investigation (scheduled to be held beginning at 9:30 a.m. on March 26, 1992, at the U.S. International Trade Commission Building, 500 E Street, SW., Washington DC), is cancelled.

EFFECTIVE DATE: March 20, 1992.

FOR FURTHER INFORMATION CONTACT: Edward Carroll (202-205-1819), Office of Public Affairs, U.S. International Trade Commission. Hearing impaired persons can obtain information on this study by contacting the Commission's TDD terminal on (202-205-1810).

By order of the Commission.

Dated: March 24, 1992.

Kenneth R. Mason,

Secretary.

[FR Doc. 92-7160 Filed 3-25-92; 8:45 am]

BILLING CODE 7020-02-M

INTERSTATE COMMERCE COMMISSION

[Finance Docket No. 32016]

Sioux & Western Railroad Co.—Construction Exemption—Charles County, Mo; Notice

AGENCY: Interstate Commerce Commission.

ACTION: Notice of exemption.

SUMMARY: Pursuant to 49 U.S.C. 10505, the Interstate Commerce Commission conditionally exempts from the prior approval requirements of 49 U.S.C. 10901 the construction by the Sioux & Western Railroad Company of approximately 2 miles of rail line between the Sioux Plant and a Union Pacific Railroad Company line in Charles County, MO.

DATES: The exemption will not become effective until the environmental process is completed. At that time, the Commission will issue a further decision addressing the environmental matters and establishing an effective date for the exemption, if appropriate. Petitions to reopen must be filed by April 15, 1992.

ADDRESSES: Send pleadings referring to Finance Docket No. 32016 to:

(1) Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423.

(2) Petitioner's representative: John R. Molm, Esquire, Troutman, Sanders, Lockerman and Ashmore, 1400 Candler Building, 127 Peachtree Street, NE., Atlanta, GA 30303.

FOR FURTHER INFORMATION CONTACT: Joseph H. Dettmar, (202) 927-5660. (TDD for hearing impaired: (202) 927-5712.

SUPPLEMENTARY INFORMATION: Additional information is contained in the Commission's decision. To purchase a copy of the full decision, write to, call, or pick up in person from: Dynamic Concepts, Inc., room 2229, Interstate Commerce Commission Building, Washington, DC 20423. Telephone: (202) 289-4357/4359. (Assistance for the hearing impaired is available through TDD services (202) 927-5721.)

Decided: March 11, 1992.

By the Commission, Chairman Philbin, Vice Chairman McDonald, Commissioners Simmons, Phillips, and Emmett.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 92-7017 Filed 3-25-92; 8:45 am]

BILLING CODE 7035-01-M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 86-22]

Marijuana Scheduling Petition; Denial of Petition; Remand

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Final order.

SUMMARY: This is a final order of the Administrator of the Drug Enforcement Administration (DEA) concluding the plant material marijuana has no currently accepted medical use and denying the petition of the National Organization for Reform of Marijuana Laws (NORML) to reschedule marijuana from Schedule I to Schedule II of the Controlled Substances Act.

EFFECTIVE DATE: March 26, 1992.

FOR FURTHER INFORMATION CONTACT: Office of Congressional and Public Affairs, 202-307-7363.

SUPPLEMENTARY INFORMATION:

Background

On December 21, 1989, the former Administrator of DEA, following rulemaking on the record, which included a hearing before an administrative law judge, issued a final order concluding the plant material marijuana has no currently accepted medical use, and denying the petition of NORML to reschedule marijuana from Schedule I to Schedule II of the Controlled Substances Act. 54 FR 63767. On April 26, 1991, the United States Court of Appeals for the District of Columbia Circuit remanded the matter to the Administrator for clarification of DEA's interpretation of the term "currently accepted medical use in treatment in the United States." *Alliance for Cannabis Therapeutics* v. *DEA*, 930 F.2d 936.

Following a review of the entire record in this matter, and a comprehensive re-examination of the relevant statutory standard, I conclud that marijuana has no currently accepted medical use and must remai in Schedule I. Further hearings are unnecessary since the record is extraordinarily complete, all parties h ample opportunity and wide latitude t present evidence and to brief all relevant issues, and the narrow quest on remand centers exclusively on this Agency's legal interpretation of a statutorily-created standard.

Summary of the Decision

Does the marijuana plant have any currently accepted medical use in treatment in the United States, withir the meaning of the Federal Controlle Substances Act, 21 U.S.C. 801, *et seq.* Put simply, is marijuana good medici for illnesses we all fear, such as mult sclerosis (MS), glaucoma and cancer?

The answer might seem obvious based simply on common sense. Smoking causes lung cancer and othe deadly diseases. Americans take the medicines in pills, solutions, sprays, shots, drops, creams and sometimes suppositories, but never by smoking. medicine prescribed for us today is smoked.

With a little homework, one can le that marijuana has been rejected as medicine by the American Medical Association, the National Multiple Sclerosis Society, the American Glaucoma Society, the American Academy of Ophthalmology the American Cancer Society. Not one American health association accept marijuana as medicine.

For the last half century, drug evaluation experts at the United Sta Food and Drug Administration (FDA have been responsible for protecting Americans from unsafe and ineffect new medicines. Relying on the same scientific standards used to judge al other drugs, FDA experts repeatedly have rejected marijuana for medical

Yet claims persist that marijuana medical value. Are these claims tru What are the facts?

Between 1987 and 1988, DEA and NORML, under the guidance of an administrative law judge, collected relevant information on this subject Stacked together it stands nearly fi feet high. Is there reliable scientific evidence that marijuana is medicall

effective. If it has medical value, do its benefits outweight its risks? What do America's top medical and scientific experts say? Would they prescribe it for their patients, their families, their friends?

As the current Administrator of Drug Enforcement, and as a former United States District Judge, I have made a detailed review of the evidence in this record to find the answers.

There are significant short-term side effects and long-term risks linked to smoking marijuana. Marijuana is likely to be more cancer-causing than tobacco; damages brain cells; causes lung problems, such as bronchitis and emphysema; may weaken the body's antibacterial defenses in the lungs; lowers overall blood pressure, which could adversely affect the supply of blood to the head; causes sudden drops in blood pressure (orthostatic hypotension), rapid heart beat (tachycardia), and heart palpitations; suppresses luteinizing hormone secretion in women, which affects the production of progesterone, an important female hormone; causes anxiety and panic in some users because of its mind-altering effects; produces dizziness, trouble with thinking, trougle with concentrating, fatigue, and sleepiness; and impairs motor skills.

As a plant, marijuana can contain bacteria capable of causing serious infections in humans, such as salmonella enteritidis, Klebsiella pneumoniae, group D Streptoccoccus and pathogenic aspergillus.

Several of these risk stand out. The immune systems of cancer patients are weakened by radiation and chemotherapy, leaving them susceptible to infection. If they experiment with marijuana to control nausea, they risk weakening their immune systems further and exposing themselves to the infection-causing bacteria in the plant. It is estimated, for example, that at Memorial Sloan-Kettering Cancer Center 60 patients die each year from pathogenic aspergillus infections.

Glaucoma patients face possible blindness caused by very high fluid pressures within their eyes. If they experiment with marijuana to lower their eye fluid pressure, it can cause dramatic drops in their blood pressure and reduce the blood supply to their heads. Glaucoma experts testified this reduced the blood supply to the optic nerves and could speed up, rather than slow down, their loss of eyesight.

MS, glaucoma and cancer patients who have undiagnosed heart problems risk heart palpitations, very rapid heart beats and sudden dramatic drops in blood pressure if they experiment with marijuana. For MS and glaucoma patients who must take medications for the rest of their lives, experimenting with marijuana poses the additional risks of lung cancer, emphysema, bladder cancer and leukemia.

Many risks remain unknown. Marijuana contains over 400 separately identified chemicals. No one knows all the effects of burning these chemicals together and inhaling the burnt mix. Are these risks outweighed by medical benefits?

There are scientific studies showing pure THC (Delta-9-Tetrahydrocannabinol), one of the many chemicals found in marijuana, has some effect in controlling nausea and vomiting. Pure THC is pharmaceutically made in a clean capsule form, called Marinol, and is available for use by the medical community. More information on Marinol can be found in the "Physicians' Desk Reference," available in most libraries.

Since marijuana contains THC, you might think marijuana also would be effective. However, the effect of taking a drug in combination with other chemicals is seldom the same as taking just the pure drug. As already noted, marijuana contains over 400 other chemicals, not just THC. There are no reliable scientific studies that show marijuana to be significantly effective in controlling nausea and vomiting. People refer to the Sallan study as proving marijuana's effectiveness. They are mistaken. The Sallan study involved pure THC, not marijuana. People refer to the Chang study to support marijuana's effectiveness. They also are mistaken. Doctor Chang tested the combination of pure THC and marijuana to treat nausea and vomiting. The preliminary results he got were probably due to the THC, not the marijuana. Because he tested the combination, we cannot tell just what effects can be attributed to marijuana alone. People cite a third study, done by Doctor Levitt, as proof marijuana is effective. They are mistaken. Doctor Levitt compared marijuana to THC in controlling nausea and vomiting, and he concluded that THC was the more effective drug.

A librarian can help locate copies of thes studies should you want to see them for yourself. Sallan, et al., "Antiemetic Effect of Delta-9-Tetrahydrocannibinol in Patients Receiving Cancer Chemotherapy," 293 New England Journal of Medicine 795–797 (1975); Chang, et al., "Delta-9-Tetrahydrocannabinol as an Antiemetic in Cancer Patients Receiving High-Dose Methotrexate," 91 Annals of Internal Medicine 819–824 (1979); Levitt, et al., "Randomized Double Blind Comparis of Delta-9-Tetrahydrocannabinol (TH and Marijuana As Chemotherapy Antiemetics," (Meeting Abstract) 3 Proceedings of the Annual Meeting of the American Society of Clinical Oncology 91 (1984).

During the 1970's and 1980's, a num of states set up research programs to give marijuana to cancer and glaucom patients, on the chance it might help. Some people point to these programs proof of marijuana's usefulness. Unfortunately, all research is not necessarily good scientific research. These state programs failed to follow responsible scientific methods. Patien took marijuana together with their regular medicines, so it is impossible say whether marijuana helped them. Observations or results were not scientifically measured. Procedures were so poor that much critical resea data were lost or never recorded. Although these programs were well-intentioned, they are not scientific pr of anything.

Some people refer to a study by Doctor Thomas Ungerleider as proof marijuana reduced nausea in bone marrow transplant patients. Unfortunately, Doctor Ungerleider neglected to follow responsible scientific methods in his study. Like state programs, it proves nothing. Do Ungerleider chose not to publish his study evidently because of its serious weaknesses. He admitted as much w questioned under oath.

Those who say there are reliable scientific studies showing marijuana an effective drug for teating nausea vomiting are wrong. No such studies exist.

Our nation's top cancer experts re marijuana for medical use. Doctor D S. Ettinger, a professor of oncology a the Johns Hopkins University Schoo Medicine, an author of over 100 scholarly articles on cancer treatme and a nationally respected cancer expert, testified:

> There is no indication that marijuana effective in treating nausea and vomiting resulting from radiation treatment or oth causes. No legitimate studies have been conducted which make such conclusions

Doctor Richard J. Gralla, a profes of medicine at Cornell University Medical College, an associate atten physician at the Memorial Sloan-Kettering Cancer Center, and an ex in cancer research, testified:

> Most experts would say, and our stud support, that the cannabinoids in genera not very effective against the major caus nausea and vomiting.

Doctor Gralla added:

I have found that because of the negative side effects and problems associated with marijuana * * *, most medical oncologists and researchers have little interest in marijuana for the treatment of nausea and vomiting in their patients.

Doctor John Laszlo, Vice President of Research for the American Cancer Society, an expert who has spent 37 years researching cancer treatments, and who has written a leading textbook on the subject, "Antiemetics and Cancer Chemotherapy," testified there is not enough scientific evidence to justify using marijuana to treat nausea and vomiting. Not one nationally-recognized cancer expert could be found to testify on marijuana's behalf.

To be an effective treatment for glaucoma, a drug must: (i) Lower the pressure within the eye (intraocular pressure), (ii) for prolonged periods of time, and (iii) actually preserve sight (visual fields). Five scientific studies are cited as evidence marijuana is an effective glaucoma treatment. Those who cite these studies are mistaken. These studies tested pure THC, not marijuana. W.D. Purnell and J.M. Gregg, "Delta-9-Tetrahydorcannabinol, Euphoria and Intraocular Pressure in Man," 7 Annals of Ophthalmology 921–923 (1975); M. Perez-Reyes, D. Wagner, M.E. Wall, and K.H. Davis, "Intravenous Administration of Cannabinoids on Intraocular Pressure," The Pharmacology of Marijuana 829–832 (M.C. Braude and S. Szara eds. 1976); J.C. Merritt, S.M. McKinnon, J.R. Armstrong, G. Hatem, and L.A. Reid, "Oral Delta-9-Tetrahydrocannabinol in Hyperogeneous Glaucomas," 12 Annals of Ophthalmology 947 (1980); K. Green and M. Roth, "Ocular Effects of Topical Administration of Delta-9-Tetrahydrocannabinol in Man," 100 Archives of Ophthalmology 265–267 (1982); and W.M. Jay and K. Green, "Multiple-Drop Study of Topically Applied 1% Delta-9-Tetrahydrocannabinol in Human Eyes," 101 Archives of Ophthalmology 591–593 (1983).

Threee studies show very heavy doses of marijuana, taken for short periods of time, can reduce eye pressure. R.S. Hepler, I.M. Frank, and T.J. Ungerleider, "Pupillary Constriction After Marijuana Smoking," 74 American Journal of Ophthalmology 1185–1190 (1972); R.S. Hepler, I.M. Frank, and R. Petrus, "Ocular Effects of Marijuana Smoking," The Pharmacology of Marijuana 815–824 (1976); and J.C. Merritt, W.J. Crawford, P.C. Alexander, A.L. Anduze and S.S. Gelbart, "Effect of Marijuana on Intraocular and Blood Pressure in Glaucoma," 87 Ophthalmology 222–228 (1980).

Unusally large doses or marijuana were needed in these three studies to achieve the desired effect. Heavy marijuana use produces dizziness, trouble with thinking, impaired motor skills, fatigue and sleepiness. The 1976 study by Doctors Hepler, Frank and Petrus emphasized "Our subjects were sometimes too sleepy to permit measurement of intraocular pressures * * * 3 hours after intoxication." If a glaucoma patient were to smoke marijuana 8 to 10 times every day for the rest of his life, would he be alert and energetic enough to live a relatively normal life? Would he develop other diseases? No scientific studies exist to answer these questions. Robert Randall claims to have saved his sight by smoking 8 to 10 marijuana cigarettes every day. Under oath he admits he stays at home most days, follows no daily schedule or routine, and has not held a regular job in over 15 years. He also has avoided having a comprehensive medical examination since 1975.

No scientific studies have shown marijuana can reduce eye pressure over long periods of time.

No scientific studies have shown marijuana can save eyesight.

America's top glaucoma experts reject marijuana as medicine. Doctor Keith Green is a professor of Ophthalmology who serves, or has served, on the editorial boards of eight prestigious eye journals (Ophthalmic Research, Oftalmo Abstracto, Current Eye Research, Experimental Eye Research, Investigative Opthalmology, American Journal of Ophthalmology, Archives of Ophthalmology, and Survey of Ophthalmology). Doctor Green has conducted extensive basic and clinical research using marijuana and THC to treat glaucoma patients. He has authored over 200 books or research articles in ophthalmology and is a highly respected expert on this subject. Doctor Green testified:

There is no scientific evidence * * * that indicates that marijuana is effective in regulating the progression of symptoms associated with glaucoma. * * * It is clear that there is no evidence that marijuana use prevents the progression of visual loss in glaucoma. * * * The quantities of the drug required to reduce intraocular pressure in glaucoma sufferers are large, and would require the inhalation of at least six marijuana cigarettes each day. * * * Smoking is not a desirable form of treatment for many reasons * * * [M]arijuana . . . has little potential future as a glaucoma medication.

Doctor George Spaeth is the Direc of the Glaucoma Service at Wills Ey Hospital in Philadelphia, the largest service in the United States devoted researching and treating glaucoma a to teaching other doctors about this disease. Doctor Spaeth is President the American Glaucoma Society. He professor of ophthalmology, the edit a scholarly eye journal (Ophthalmic Surgery), and the author of over 200 research articles on glaucoma. He testified:

I have not found any documentary evidence which indicates that a single p has had his or her natural history of the disease altered by smoking marijuana.

Amputees and victims of MS can suffer from extreme muscle spasms. claimed marijuana is useful in treat spasticity. Three unusually small, inconclusive studies have tried usin pure THC, not marijuana, to treat spasticity. D.J. Petro and C. Ellenbe "Treatment of Human Spasticity w Delta-9-Tetrahydro-cannabinol," 21 Journal of Clinical Pharmacology 41 416S (1981) (included only nine patients). Two of the studies are m abstracts, or short digests, without detail. Hanigan, Destee & Troung A B45, Clin. Pharmacol. Ther. 198 (198 (included only five patients), and Sandyk, Cannoe, Stern and Snider Abstr. PP 331, 36 Neurology 342 (19 (included only three patients).

No scientific studies exist which marijuana to relieve spasticity.

National experts on MS reject marijuana as medicine. Doctor Ken P. Johnson is Chariman of the Department of Neurology at the University of Maryland School of Medicine. He manages that Maryla Center for MS, one of the most acti MS research and treatment centers the United States. He sits on the editorial boards of noted medical journals related to MS (Neurology Journal of Neuroimmunology). He i author of over 100 scientific and m articles on MS. Doctor Johnson has spent most of his long career researching MS and has diagnosed treated more than 6,000 patients w MS. Doctor Johnson testified:

At this time, I am not aware of * * * legitimate medical research in which marijuana was used to treat the sympt multiple sclerosis. * * * To conclude t marijuana is therapeutically effective conducting rigorous testing would be professionally irresponsible.

Doctor Stephen Reingold is Assi Vice President of Research for the National Multiple Sclerosis Societ which spends over $7 million each

on MS research. Only the Federal Government spends more. Doctor Reingold testified:

> I could find no actual published research which has used marijuana * * * In the existing research using THC, the results were inconclusive * * * In the absence of any well-designed, well-controlled research * * *, the National Multiple Sclerosis Society * * * does not endorse or advocate its use * * *.

Doctor Donald H. Silberberg is Chairman of the Department of Neurology at the University of Pennsylvania School of Medicine and Chief of the Neurology Service at the Hospital of Pennsylvania. Doctor Silberberg is on the editorial board of Annals of Neurology and is President of the National Medical Advisory Board for the National Multiple Sclerosis Society. He has been actively researching and treating MS for most of his career, has written over 130 medical articles on MS and is Co-Director of a large MS research center at the University of Pennsylvania. Doctor Silberberg testified:

> I have not found any legitimate medical or scientific works which show that marijuana * * * is medically effective in treating multiple sclerosis or spasticity. * * * The long-term treatment of the symptoms of multiple sclerosis through the use of marijuana could be devastating. * * * [T]he use of [marijuana], especially for long-term treatment * * * would be worse than the original disease itself.

The only favorable evidence that could be found by NORML and DEA consists of stories by marijuana users who claim to have been helped by the drug. Scientists call these stories anecdotes. They do not accept them as reliable proofs. The FDA's regulations, for example, provide that in deciding whether a new drug is a safe and effective medicine, "isolated case reports * * * will not be considered." 21 CFR 314.126(e). Why do scientists consider stories from patients and their doctors to be unreliable?

First, sick people are not objective scientific observers, especially when it comes to their own health. We all have heard of the placebo effect. Patients have a tendency to respond to drugs as they believe is expected of them. Imagine how magnified this placebo effect can be when a suffering person experiments on himself, praying for some relief. Many stories no doubt are due to the placebo effect, not to any real medical effects of marijuana.

Second, most of the stories come from people who took marijuana at the same time they took prescription drugs for their symptoms. For example, Robert Randall claims marijuana has saved his sight, yet he has taken standard glaucoma drugs continuously since 1972. There is no objective way to tell from these stories whether it is marijuana that is helpful, or the proven, traditional medicines. Even these users can never know for sure.

Third, any mind-altering drug that produces euphoria can make a sick person think he feels better. Stories from patients who claim marijuana helps them may be the result of the mind-altering effects of the drug, not the results of improvements in their conditions.

Fourth, long-time abusers of marijuana are not immune to illness. Many eventually get cancer, glaucoma, MS and other diseases. People who become dependent on mind-altering drugs tend to rationalize their behavior. They invent excuses, which they can come to believe, to justify their drug dependence. Stories of marijuana's benefits from sick people with a prior history of marijuana abuse may be based on rationalizations caused by drug dependence, not on any medical benefits caused by the drug. Robert Randall, for example, admits under oath to becoming a regular user in 1968, four years before he showed the first signs of, and was diagnosed as having, glaucoma. Since then he has smoked marijuana 8 to 10 times every day.

A century ago many Americans relied on stories to pick their medicines, especially from snake oil salesmen. Thanks to scientific advances and to the passage of the Federal Food, Drug and Cosmetic Act (FDCA) in 1906, 21 U.S.C. 301 *et seq.*, we now rely on rigorous scientific proof to assure the safety and effectiveness of new drugs. Mere stories are not considered an acceptable way to judge whether dangerous drugs should be used as medicines.

There are doctors willing to testify that marijuana has medical uses. NORML found over a dozen to testify in this case. We have a natural tendency to believe doctors. We assume their opinions are entitled to respect. But what if a doctor is giving an opinion beyond his professional competence? Evaluating the safety and effectiveness of drugs is a specialized area. Does the doctor have this specialized expertise? Is he familiar with all the published scientific studies? Or is he improperly basing his opinion on mere stories or anecdotal evidence? Does he really know what he is talking about? Does he have a personal motive to exaggerate or lie? Questions like these led the United States Supreme Court, in 1973, to warn about the opinions of doctors concerning the value of drugs as medicine, when not supported by rigorous scientific testing. *Weinberger* v. *Hynson, Etc.*, U.S. 609, 639:

> [I]mpressions or beliefs of physicians, matter how fervently held, are treacherc

Nearly half the doctors who testif for NORML are psychiatrists. They not specialize in treating or researcl cancer, glaucoma or MS. One is a general practitioner who works as a wellness counselor at a health spa. Under oath he admits to using every illegal, mind-altering drug he has ev studied, and he prides himself on recommending drugs that would ne be recommended by medical schoo reputable physicians. Another is a general practitioner who quit practi in 1974. He admits he has not kept u new medical and scientific informa about marijuana for 18 years.

Only one of the doctors called by NORML is a nationally-recognized expert. Doctor John C. Merritt is a board-certified ophthalmologist an researcher who has authored artic the use of marijuana and cannabin to reduce eye pressure. He is in pr practice and sees mostly children w suffer from glaucoma. Doctor Merr testified, "[M]arijuana is a highly effective IOP-lowering drug which be of critical value to some glaucor patients who, without marijuana, w progressively go blind." The last scientific study using marijuana in glaucoma patients, published by D Merritt in 1979, concluded:

> It is because of the frequency and se with which the untoward events occur that marijuana inhalation is not an idea therapeutic modality for glaucoma pati

One year later, in 1980, Doctor M gave the following testimony, unde oath, before the United States Con House Select Committee on Narcot Abuse and Control:

> For me to sit here and say that the lo pressure effects occurred repeatedly, d and day out, I have no data, and neithe anyone else, and that is the real crux o matter. When we are talking about tree disease like glaucoma, which is a chron disease, the real issue is, does the mari repeatedly lower the intraocular pressu have shown you no * * * studies, and knowledge there is no data to that effe

Doctor Merritt was unable to ex under oath, the contradictory posit he has taken on this subject.

Each of NORML's doctors testifi opinion is based on the published scientific studies. With one except none of them could identify under the scientific studies they swore th relied on. Only one had enough knowledge to discuss the scientific technicalities involved. Eventually

one admitted he was basing his opinion on anecdotal evidence, on stories he heard from patients, and on his impressions about the drug.

Sadly, Doctor Ivan Silverberg, an oncologist from San Francisco, exaggerated while on the witness stand. At first he swore "there is voluminous medical research which shows marijuana is effective in easing nausea and vomiting." Pushed on cross-examination to identify this voluminous research, Doctor Silverberg replied, "Well * * *, I'm going to have to back off a little bit from that." How far would Doctor Silverberg back off? Was he aware, at least, of the approximate number of scientific studies that have been done using marijuana to treat nausea? Under oath, he replied, "I would doubt very few. But, no, I'm not."

Beyond doubt, the claims that marijuana is medicine are false, dangerous and cruel.

Sick men, women and children can be fooled by these claims and experiment with the drug. Instead of being helped, they risk serious side effects. If they neglect their regular medicines while trying marijuana, the damage could be irreversible. It is a cruel hoax to offer false hope to desperately ill people.

Those who insist marijuana has medical uses would serve society better by promoting or sponsoring more legitimate scientific research, rather than throwing their time, money and rhetoric into lobbying, public relations campaigns and perennial litigation.

Clarification of Currently Accepted Medical Use

The Controlled Substances Act of 1970 divides the universe of all durgs of abuse into five sets or schedules. Drugs in Schedule I are subject to the most severe controls, because they have a high potential for abuse and no currently accepted medical use in treatment in the United States. 21 U.S.C. 812 (b)(1). Drugs of abuse which have currently accepted medical use in treatment in the United States are placed in Schedules II, III, IV and V. Regrettably, the Controlled Substances Act does not speak directly to what is meant by "currently accepted medical use."

A century before the Controlled Substances Act was enacted, the determination of what drugs to accept as medicine was totally democratic and totally standardless. Each patient and each physician was free to decide for himself, often based on no more than anecdotal evidence. This state of affairs became unsatisfactory to a majority of the American people. In 1906, Congress intervened with the passage of the Food, Drug and Cosmetic Act (FDCA). A shift began away from anecdotal evidence to objectively conducted scientific research, away from uninformed opinions of lay persons and local doctors to expert opinions of specialists trained to evaluate the safety and effectiveness of drugs, and away from totally democratic decision-making to oversight by the Federal Government.

By 1969, Congress had developed detailed Federal statutory criteria under the FDCA to determine whether drugs are acceptable for medical use. Those deemed acceptable can be marketed nationally. Those deemed unacceptable are subject to Federal seizure if marketed interstate. The FDCA is a very complex regulatory scheme not easily summarized. However, it is fair to say that drugs falling into one of four FDCA categories were accepted by Congress for medical use.

First, Congress accepted new drugs which have been approved by FDA's experts as safe and effective for use in treatment, based on substantial scientific evidence. 21 U.S.C. 321(p) and 355 (so-called "NDA-approved drugs").

Second, Congress accepted those drugs "generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective," based on substantial scientific evidence. 21 U.S.C. 321(p) and 355; *Weinberger* v. *Bentex Pharmaceuticals, Inc.*, 412 U.S. 645 (1973). An acronym for this category is "human GRASE drugs" (Generally Recognized As Safe and Effective). These drugs achieve acceptance through rigorous scientific proof, through a past history of widespread use in treatment in the United States, and through recognition by a consensus of drug experts outside the FDA.

Third, Congress accepted for use in veterinary medicine those drugs "generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective," based on substantial scientific evidence. 21 U.S.C. 321(w) and 355. An acronym for these is "animal GRASE drugs." They achieve acceptance through rigorous scientific evidence and through recognition by a consensus of drug experts outside the FDA. Unlike human GRASE drugs, animal GRASE drugs need not have a past history of widespread use.

Finally, Congress accepted those drugs marketed prior to 1938 which had been subject to the 1906 provisions of the FDCA, provided these very old drugs retain their exact formulations and are never promoted for new uses. 21 U.S.C. 321(p) and (w). These are politically "grandfathered" drugs. They need not meet modern standards for safety and effectiveness.

A fifth group of drugs was accepted for research use only, not for use in treatment of patients. 21 U.S.C. 355(i) (so-called "IND or approved investigational new drugs").

Drugs intended for medical use and shipped interstate are subject to Fede seizure under the FDCA if they do not within one of the above accepted sets groupings. It seems fair to say that seizable drugs were rejected by Congress for medical uses.

In enacting the Controlled Substanc Act in 1970, could Congress have intended to create a totally new Fede standard for determining whether dru have accepted medical uses? Or did Congress intend to rely on standards had developed over the prior 64 year under the FDCA? There is nothing in Controlled Substances Act, its legislative history, or its purposes tha would indicate Congress intended to depart radically from existing Federa law.

Indeed, it seems likely that the cor standards developed under the FDC represent a long-term consensus of expert medical and scientific opinion concerning when a drug should be accepted by anyone as safe and effective for medical use.

Fortunately, there is a way to corroborate what Congress intended Congress did more than just announc criteria for scheduling drugs of abuse under the Controlled Substances Act Congress applied those criteria to an initial listing of drugs that it placed i the original five schedules of the Act

NDA-approved drugs were placed Congress into Schedules II, III, IV an of the Act. For example, pethidine (a known as meperidine) received New Drug Application (NDA) approval in 1942. Congress put it into Schedule II(b)(14). Methamphetamine had an approved NDA. Congress put it into Schedule III(a)(3). I am not aware of drug with an approved NDA that Congress originally put into Schedul

Drugs with medical uses, but with approved NDA's also were placed b Congress into Schedules II, III, IV ar For example, cocaine was put into Schedule II(a)(4). Codeine combinat were put into Schedules III(d)(1) an Morphine combinations were put in Schedule III(d)(8). Phenobarbital we put into Schedule IV(11). Barbiturat were put into Schedule III(b)(1). Amphetamines were put into Sched III(a)(1).

The Court of Appeals for the First Circuit was correct when it decided

Grinspoon v. *DEA*, 828 F.2d 881 (1987) that NDA approval is not the only method by which drugs can achieve Federal recognition as having medical uses. Congress put both GRASE drugs and pre-1938-grandfathered drugs into Schedules II, III, IV and V of the CSA.

Drugs recognized under the FDCA for research use only, not for use in treatment, such as alphacetylmethadol and marijuana, were placed by Congress into Schedule I.

Unfortunately, Federal records are not complete enough to do a comprehensive mathematical mapping, tracing every drug in the initial Controlled Substances Act schedules back to its legal status under the FDCA. Nevertheless, determining legislative intent does not require mathematical certainty. Probability based on circumstantial evidence, on samplings, and on inductive reasoning can suffice, especially when there is nowhere else to turn.

The pattern of initial scheduling of drugs in the Controlled Substance Act, viewed in light of the prior legal status of these drugs under the FDCA, convinces me that Congress equated the term "currently accepted medical use in treatment in the United States" as used in the Controlled Substances Act with the core FDCA standards for acceptance of drugs for medical use.

This is not to say that every FDCA requirement for GRASE status, or for NDA approval, is pertinent to scheduling determinations under the Controlled Substances Act. There are differences. But the core FDCA criteria appear to have guided the Congress in the decisions it made concerning the initial scheduling of drugs in the Act.

These same core FDCA criteria served as the basis for an eight-point test used by my predecessor as Administrator to describe drugs with currently accepted medical uses. 54 FR 53783 (December 29, 1989):

1. Scientifically determined and accepted knowledge of its chemistry;
2. The toxicology and pharmacology of the substance in animals;
3. Establishment of its effectiveness in humans through scientifically designed clinical trials;
4. General availability of the substance and information regarding the substance and its use;
5. Recognition of its clinical use in generally accepted pharmacopeia, medical references, jounals or textbooks;
6. Specific indications for the treatment of recognized disorders;
7. Recognition of the use of the substance by organizations or associations of physicians; and
8. Recognition and use of the substance by a substantial segment of the medical practitioners in the United States.

Some uncertainty remains over the precise meaning and application of parts of this test. Therefore, the Court of Appeals for the District of Columbia Circuit remanded these proceedings for a further explanation. In addition to addressing those parts of the test that concerned the Court of Appeals, it would be useful to clarify the entire test, pinpoint its origins, and identify which elements are both necessary and sufficient to establish a prima facie case of currently accepted medical use. This is not an effort to change the substantive law. The statutory meaning of currently accepted medical use remains the same as enacted by Congress in 1970. My purpose simply is to clarify this Agency's understanding of the law.

A. The Drug's Chemistry Must Be Known and Reproducible

The ability to recreate a drug in standardized dosages is fundamental to testing that drug and to using it as a medicine. Knowing the composition, properties, methods of production, and methods of analysis of a drug is essential to reproducing it in standardized dosages. To be GRASE or to receive NDA approval, a drug's chemistry must be known and reproducible. See *e.g.*, 21 CFR 314.50(d)(1) and 314.126(b)(7)(d); *Dorovic* v. *Richardson*, 749 F.2d 242, 251 (7th Cir. 1973). The listing of a drug in a current edition of one of the official compendia normally satisfies this requirement. 21 U.S.C. 321(j); 21 CFR 314.50(d)(1).

The first element of our eight-point test, namely, "scientifically determined and acccepted knowledge of its chemistry," should be clarified to read:

The substance's chemistry must be scientifically established to permit it to be reproduced into dosages which can be standardized. The listing of the substance in a current edition of one of the official compendia, as defined by section 201(j) of the Food, Drug and Cosmetic Act, 21 U.S.C. 321(j), is sufficient generally to meet this requirement.

Acceptance of this knowledge will be discussed elsewhere.

B. There Must Be Adequate Safety Studies

No drug can be considered safe in the abstract. Safety has meaning only when judged against the intended use of the drug, its known effectiveness, its known and potential risks, the severity of the illness to be treated, and the availability of alternative therapies. *Hess & Clark Division of Rhodia, Inc.* v. *FDA*, 495 F.2d 975, 993 (D.C. Cir. 1974). To know the risks, there must be adequate stud all methods reasonably applicabl show the pharmacological and toxicological effects of the drug. 2 314.125(b)(2). This includes anima studies and clinical trials in large numbers of humans. 21 CFR 312.2 studies need not be well-controlle they must be adequate. *Edison Pharmaceuticals Co.* v. *FDA*, 600 F 831 (D.C. Cir. 1979). Short term (ac studies of a drug intended to treat term (chronic) illnesses, such as glaucoma or MS, are clearly inad *United States* v. Naremco, Inc., 55 1138, 1143 (8th Cir. 1977). The sec element of our eight-point test, na "the toxicology and pharmacolog substance in animals," should be clarified as follows:

There must be adequate pharmacol and toxicological studies, done by all methods reasonably applicable, on th of which it could fairly and responsib concluded, by experts qualified by sc training and experience to evaluate t and effectiveness of drugs, that the su is safe for treating a specific, recogni disorder.

It must be emphasized that wh existence of adequate safety test separate analytical question, the ultimate determination of whethe drug is safe for a specific use is n distinct issue. Safety and effectiv are inextricably linked in a risks-benefits calculation. A determina that a drug is ineffective is tantar to a determination that it is unsa *United States* v. *Rutherford*, 442 (1970).

The scheduling criteria of the Controlled Substances Act appe treat the lack of medical use and safety as separate consideration rulings of this Agency purported safety as a distinct factor. 53 FR (February 22, 1988). In retrospect inconsistent with scientific realit Safety cannot be treated as a sep analytical question.

C. There Must Be Adequate and Controlled Studies Proving Effic

Since 1962, Congress has prohi the FDA to approve an NDA unle applicant submits adequate, well contolled, well-designed, well-conducted, and well-documente studies, performed by qualified investigators, which prove the ef of a drug for its intended use. 21 355(d); 21 CFR 314.126. Similarly, cannot be considered GRASE un is supported by this same quanti quality of scienfitic proof. 21 CFR 314.200(e)(i); *Weinberger* v. *Hyn Etc.*, 412 U.S. 609, 629 (1973).

Studies involving related, but not identical, drugs are irrelevant. *United States* v. *Articles of Food & Drug*, 518 F.2d 743, 747 (5th Cir. 1975). Studies involving the same drug combined with other drugs are irrelevant. *United States* v. *Articles of Drug * * * Promise Toothpaste, 826 F.2d 564, 570 (7th Cir. 1987)*. *Incomplete studies are insufficient. United States* v. *Articles of Food & Drug, supra*. Uncontrolled studies are insufficient. 21 U.S.C. 355(d); *Cooper Labs* v. *FDA*, 501 F.2d 772, 778 (D.C. Cir. 1974). Statistically insignificant studies are insufficient. 21 CFR 312.21, 314.50(d)(6) and 314.126(b)(7). Poorly designed studies are insufficient. 21 CFR 314.126(b)(2). Poorly conducted studies are insufficient. 21 CFR part 58—Good Laboratory Practices. Poorly documented studies are insufficient. 21 CFR 312.58 and 314.200(e)(4). Studies by investigators who are not qualified, both to conduct and to evaluate them are insufficient. 21 U.S.C. 355(d). Moreover, since scientific reliability requires a double examination with similar results, one valid study is insufficient. There must be two or more valid studies which corroborate each other. See 1 J. O'Reilley "Food and Drug Administration" 13–55 n.12 (1985).

Lay testimonials, impressions of physicians, isolated case studies, random clinical experience, reports so lacking in details they cannot be scientifically evaluated, and all other forms of anecdotal proof are entirely irrelevant. 21 CFR 314.126(e); *Weingerger* v. *Hynson, Etc.*, 412 U.S. 609, 630 (1973).

Element three of our eight-point test, namely, "establishment of its effectiveness in humans through scientifically designed clinical trials," should be restated as:

> There must be adequate, well-controlled, well-designed, well-conducted and well-documented studies, including clinical investigations, by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, on the basis of which it could fairly and responsibly be concluded by such experts that the substance will have the intended effect in treating a specific, recognized disorder.

D. Acceptance by Qualified Experts Is Required

The opinions of lay persons are totally irrelevant to whether a drug is GRASE or meets NDA requirements. The observations and opinions of medical practioners who are not experts in evaluating drugs also are irrelevant to whether a drug is GRASE or meets NDA requirements. *Weinberger* v. *Hynson, Etc.*, 412 U.S. 609, 619 (1973). By explicit requirements in the FDCA since 1938, the only body of opinion that counts is that of experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs. 21 U.S.C. 321 (p) and (w).

From this, one would conclude that expert acceptance of a drug as safe and effective for its intended use is essential to a drug having a currently accepted medical use under the CSA. How widespread must this expert acceptance be?

To be GRASE, a drug must be "generally recognized" among experts as safe and effective for its intended use. The drug must be known or familiar to the national community of relevant experts. *United States* v. *Articles of Drug* * * *Furestrol Vaginal Suppositories*, 294 F. Supp. 1307, 1309 (N.D. Ga. 1968) *aff'd*, 415 F.2d 390 (5th Cir. 1969). To determine if a drug is known to the community of experts, courts have looked to whether there is widely available scientific literature about the drug, *Premo Pharmaceutical Laboratories, Inc.* v. *United States*, 629 F.2d 795, 803 (2d Cir. 1980), whether it is widely taught in medical schools, *Lemmon Pharmaceuticals Co.* v. *Richardson*, 319 F. Sup. 375, 378 (E.D. Pa. 1970), and whether it is widely discussed by experts. *United States* v. *Bentex Ulcerine*, 469 F. 2d 875, 880 (5th Cir. 1972).

The recognition of a drug as GRASE need not be universal. General recognition is sufficient. *United States* v. *41 Cartons* * * *Ferro-Lac*, 420 F.2d 1126, 1132 (5th Cir. 1970). The Supreme Court has interpreted this to mean a consensus of experts is familiar with and accepts a drug as safe and effective. *Weinberger* v. *Hynson, Etc.*, 412 U.S. 609, 629 (1973). However, if there is a serious dispute among the experts, a drug cannot be considered GRASE. *United States* v. *An Article of Food* * * *Coco Rico*, 752 F.2d 11, 15 (1st Cir. 1985); *Merrit Corp.* v. *Folsom*, 165 F. Supp. 418, 421 (D.D.C. 1958).

During the NDA process, the FDA may reach out to the expert community for its views. 21 CFR 314.103(c)(3). The FDA need not determine that a drug is generally known and accepted by the expert community. Nor must the FDA develop a consensus of opinion among outside experts. The FDA has both the experts and the statutory mandate to resolve conflicts over the safety and efficacy of new drugs. *Weinberger* v. *Bentex Pharmaceuticals, Inc.*, 412 U.S.C 638, 653 (1973).

In drafting the Controlled Substances Act, Congress appears to have accommodated, rather than chosen from these different FDCA standards. Clearly, the Controlled Substances Act does n authorize the Attorney General, nor b delegation the DEA Administrator, to make the ultimate medical and policy decision as to whether a drug should used as medicine. Instead, he is limite to determing whether others accept a drug for medical use. Any other construction would have the efect of reading the word "accepted" out of th statutory standard. Since Congress recognized NDA-approved drugs as having currently accepted medical us without any need for a national consensus of experts. FDA acceptanc of a drug through the NDA process would seem to satisfy the Controlled Substances Act. And, since Congress recognized GRASE drugs as having currently accepted medical uses, without the need for NDA approval, acceptance of a drug by a national consensus of experts also would seer satisfy the Act.

When a drug lacks NDA approval is not accepted by a consensus of experts outside FDA, it cannot be fou by the Attorney General or his deleg to have a currently accepted medical use. To do so would require the Attorney Genral to resolve complex scientific and medical disputes amon experts, to decide the ultimate medic policy question, rather than merely determine whether the drug is accep by others.

Because the recognition of a drug b non-experts is irrelevant to GRASE status, to NDA approval, and to currently accepted medical use unde the Controlled Substances Act, point seven and eight of our eight-point tes should be combined and restated as follows:

> The drug has a New Drug Application (NDA) approved by the Food and Drug Administration pursuant to the Food, Dru and Cosmetic Act, 21 U.S.C. 355. Or, a consensus of the national community of experts, qualified by scientific training ar experience to evaluate the safety and effectiveness of drugs, accepts the safety effectiveness of the substance for use in treating a specific, recognized disorder. A material conflict of opinion among exper precludes a finding of consensus.

This restatement also incorporates component of part one of our eight-p test concerning "accepted knowledg its chemistry."

E. The Scientific Evidence Must Be Widely Available

Nothing in the FDCA, nor in FDA regulations, requires that scientific evidence supporting an NDA be published. This stems from the fact a consensus of experts outside FDA

not required for NDA approval. In contrast, most courts have held that a drug cannot be considered GRASE unless the supporting scientific evidence appears in the published scientific and medical literature. Without published studies, it would be difficult for the community of experts outside FDA to develop an informed acceptance of a drug for medical use. *Cooper Labs Inc. v. FDA*, 501 F.2d 772, 786 (D.C. Cir. 1974).

Point four of the eight-point test focuses, in part, on the "general availability of information regarding the substance and its use." This should be clarified to read:

In the absence of NDA approval, information concerning the chemistry, pharmacology, toxicology and effectiveness of the substance must be reported, published, or otherwise widely available, in sufficient detail to permit experts, qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, to fairly and responsibly conclude the substance is safe and effective for use in treating a specific, recognized disorder.

F. General Availability of a Drug Is Irrelevant

The second component of point four of the eight—point test involves the "general availability of the substance" for use in treatment. The second component of point eight focuses on "use of the substance by a substantial segment of the medical practitioners in the United States." These elements justifiably concerned the Court of Appeals, leading to the remand in this case.

Under the FDCA, a human GRASE drug must have a material history of past use in treatment in the United States. 21 U.S.C. 321(p)(2) (which has ". . . otherwise than in such investigations, been used to a material extent or a material time); *Weinberger v. Hynson, Etc.*, 412 U.S. 609, 631 (1973). Rigorous scientific proofs and current unanimous acceptance by the medical and scientific community are not enough for a human drug to be GRASE. *Tri-Bio Labs, Inc. v. United States*, 836 F.2d 135, 142 n.8 (3d Cir. 1987). The general availability of a drug for use in treatment is a factor courts have considered to determine if a human drug is GRASE.

In contrast, a drug can achieve current acceptance for human medical use through the NDA process without a past history of use in treatment. Also, animal drugs can become accepted as GRASE without any past history of medical use. Given this conflict in FDCA standards, which did Congress choose when drafting the CSA?

As the Court of Appeals points out, requiring a material history of past use in treatment before recognizing a drug as having a currently accepted medical use, would permanently freeze all Schedule I drugs into Schedule I. 930 F.2d at 940. Clearly, Congress did not intend this result. Moreover, the use of the word "currently" before the term "accepted medical use" would indicate Congress rejected the human GRASE requirement of past material use in treatment. I conclude that the general availability of a drug is irrelevant to whether it has a currently accepted medical use in treatment within the meaning of the Controlled Substances Act.

G. Recognition in Generally Accepted Texts Is Irrelevant

Point five of the eight-point test deals with "recognition of its clinical use in generally accepted pharmacopeia, medical references, journals or textbooks." The listing of a drug in an official compendium is sufficient to show its chemistry is scientifically established. This appears in my clarification to point one. The requirement that information concerning the chemistry, pharmacology, toxicology and effectiveness of the substance be reported, published or otherwise widely available, is explained adequately in revised point four. To the extent the scheduling of a drug directly influences its recognition in publications, this element is subject to the same criticism identified by the Court of Appeals concerning point four. Therefore, this should not be treated as a distinct requirement.

H. Specific, Recognized Disorders Are the Referent

It is impossible to judge the safety and effectiveness of a drug except in relation to a specific intended use. A drug cannot obtain NDA approval or GRASE status except in relation to the treatment of a specific, recognized disorder. This is an essential aspect of whether a drug has currently accepted medical use. Rather than standing alone, this requirement will be more clearly understood by incorporating it into the other critical elements.

To summarize, the five necessary elements of a drug with currently accepted medical use in treatment in the United States are:

(i) The Drug's Chemistry Must Be Known and Reproducible

The substance's chemistry must be scientifically established to permit it to be reproduced into dosages which can be standardized. The listing of the substance in a current edition of one of the official compendia, as defined by section 201 Food, Drug and Cosmetic Act, 21 U.S 321(j), is sufficient generally to meet requirement.

(ii) There Must Be Adequate Safety S

There must be adequate pharmacc and toxicological studies done by all reasonably applicable on the basis o it could fairly and responsibly be cor by experts qualified by scientific trai experience to evaluate the safety an effectiveness of drugs, that the subst safe for treating a specific, recognize disorder.

(iii) There Must Be Adequate and W Controlled Studies Proving Efficacy

There must be adequate, well-cont well-designed, well-conducted and w documented studies, including clinic investigations, by experts qualified b scientific training and experience to the safety and effectiveness of drugs basis of which it could fairly and res be concluded by such experts, that t substance will have its intended effc treating a specific, recognized disorc

(iv) The Drug Must Be Accepted by Experts

The drug must have a New Drug Application (NDA) approved by the Drug Administration, pursuant to the Drug and Cosmetic Act, 21 U.S.C. 35 consensus of the national communit experts, qualified by scientific traini experience to evaluate the safety an effectiveness of drugs, must accept th and effectiveness of the substance o treating a specific, recognized disorc material conflict of opinion among e precludes a finding of consensus.

(v) The Scientific Evidence Must Be Available

In the absence of NDA approval, information concerning the chemistr pharmacology, toxicology and effect of the substance must be reported, p or otherwise widely available in sul detail to permit experts, qualified by scientific training and experience to the safety and effectiveness of drugs and responsibly conclude the substa safe and effective for use in treating specific, recognized disorder.

Together these five elements constitute prima facie evidence drug has currently accepted mec in treatment in the United States interest of total clarity, let me er those proofs that are irrelevant t determination of currently accep medical use, and that will not be considered by the Administrator

(i) Isolated case reports;

(ii) Clinical impressions of practit

(iii) Opinions of persons not quali scientific training and experience to the safety and effectiveness of the s at issue;

(iv) Studies or reports so lacking i as to preclude responsible scientific evaluation;

(v) Studies or reports involving drug substances other than the precise substance at issue:

(vi) Studies or reports involving the substance at issue combined with other drug substances:

(vii) Studies conducted by persons not qualified by scientific training and experience to evaluate the safety and effectivness of the substance at issue:

(viii) Opinions of experts based entirely on unrevealed or unspecified information:

(ix) Opinions of experts based entirely on theoretical evaluations of safety or effectiveness.

Bad Medicine By Any Standard

My predecessor as DEA Adminstrator developed and relied upon an eight-point test to determine whether marijuana has accepted medical uses. 54 FR 53783 (December 29, 1989):

1. Scientifically determined and accepted knowledge of its chemistry:

2. the toxicology and pharmacology of the substance in animals:

3. Establishment of its effectiveness in humans through scientifically designed clinical trials:

4. General availability of the substance and information regarding the substance and its use:

5. Recognition of its clincial use in generally accepted pharmacopeia, medical references, journals or textbooks:

6. Specific indications for the treatment of recognized disorders:

7. Recognition of the use of the substance by organizations or associations of physicians: and

8. Recognition and use of the substance by a substantial segment of the medical practitioners in the United States.

The Court of Appeals remanded the decision of my predecessor for clarification of what role factors (4), (5) and (8) of the initial eight-point test played in his reasoning. For ease of discussion, these factors can be divided as follows:

(4)(a) General availability of the substance * * *;

(4)(b) General availability of * * * information regarding the substance and its use:

(5) Recognition of its clinical use in generally accepted pharmacopeia, medical references, journals or textbooks:

(8)(a) Recognition * * * of the substance by a substantial segment of the medical practitioners in the United States: and

(8)(b) [U]use of the substance by a substantial segment of the medical practitioners in the United States.

I have found no evidence indicating initial factors (4)(a) or (8)(b) played any role in my predecessor's decision. In light of my understanding of the legal standard involved, these factors are irrelevant to whether marijuana has a currently accepted medical use.

My predecessor emphasized the lack of scientific evidence of marijuana's effectiveness, and the limited data available on its risks, as reflected in the published scientific studies. He also emphasized the importance of this data to the conclusions reached by experts concerning the drug. 54 FR 53783. I take this to mean that, under initial factor (4)(b), he believed the information available to experts is insufficient for them responsibly and fairly to conclude the marijuana is safe and effective for use as medicine.

Marijuana is not recognized as medicine in generally accepted pharmacopeia, medical references and textbooks, as noted by my predecessor. 54 FR 53784. I take this to mean, under initial factor (5), that he determined that marijuana's chemistry is neither known, nor reproducible, as evidenced by its absence from the official pharmacopeia. Finally, my predecessor concluded, under initial factor (8)(a), that the vast majority of physicians does not accept marijuana as having medical use. 54 FR 53784. Along the way, he found that highly respected oncologists and antiemetic researchers reject marijuana for use in controlling nausea and vomiting. 54 FR 53777, that experts experienced in researching glaucoma medications reject marijuana for use in treating glaucoma. 54 FR 53779, and that noted neurologists who specialize in treating and conducting research in spasticity reject marijuana for use by MS patients. 54 FR 53780. I take this to mean my predecessor found no national consensus of qualified experts accepts marijuana's value as medicine.

Certainly I cannot know my predecessor's unstated reasoning. However, I have reviewed the entire record *de novo*, and I am convinced that his application of the initial eight-point test to this record correctly resulted in the conclusion that marijuana has no currently accepted medical use in treatment in the United States. Therefore, I adopt in their entirety the findings of facts and conclusions of law reached by the former Administrator in his final order of December 21, 1989, 54 FR 53767.

Pursuant to the remand of the Court of Appeals, I have condensed and clarified the initial standard into a five-point test. My application of the refined, five-point test to this record is set out briefly below.

First, marijuana's chemistry is neither fully known, nor reproducible. Thus far, over 400 different chemicals have been identified in the plant. The proportions and concentrations differ from plant to plant, depending on growing conditions, age of the plant, harvesting and storage factors. THC levels can vary from less than 0.2% to over 10%. It is not known how smoking or burning the plant material affects the composition of these chemicals. It is not possible t reproduce the drug in dosages whic can be considered standardized by currently accepted scientific criteri Marijuana is not recognized in any current edition of the official compe 21 U.S.C. 321(j).

Second, adequate safety studies not been done. All reasonably applicable pharmacological and toxicological studies have not been carried out. Most of the chronic ani studies have been conducted with or intravenous THC, not with marij Pharmacological data on marijuana bioavailability, metabolic pathway pharmacokinetics in inadequate. St in humans are too small and too fe Sophisticated epidemiological stud marijuana use in large populations required, similar to those done for tobacco use. Far too many questio remain unknown for experts fairly responsibly to conclude marijuana safe for any use.

Third, there are no adequate, we controlled scientific studies provin marijuana is effective for anything

Fourth, marijuana is not accepte medical use in treatment by even a respectable minority, much less a consensus, of experts trained to eva drugs. The FDA's expert drug eval have rejected marijuana for medic. No NDA has been approved by FD marijuana. The testimony of natio recognized experts overwhelmingl rejects marijuana as medicine, compared to the scientifically emp testimony of the psychiatrists, a wellness counselor and general practitioners presented by NORM

Fifth, given my conclusions on p one, two and three, it follows that published scientific evidence is no adequate to permit experts to fairl responsibly conclude that marijua safe and effective for use in huma

A failure to meet just one of the points precludes a drug from havir currently accepted medical use. Marijuana fails all five points of th

NORML has argued, unsuccessf that the legal standard for current accepted medical use should be w a respectable minority of physicia accepts the drug. The key to this medical malpractice defense is th minority opinion must be recogniz respectable, as competent, by mer of the profession.

In the absence of reliable evide adequately establishing marijuana chemistry, pharmacology, toxicolo and effectiveness, no responsible physician could conclude that ma

is safe and effective for medical use. To quote Doctor Kenneth P. Johnson, Chairman of the Department of Neurology at the University of Maryland, and the author of over 100 scientific and medical articles on MS: "To conclude that marijuana is therapeutically effective without conducting rigorous testing would be professionally irresponsible."

By any modern scientific standard, marijuana is no medicine.

Under the authority vested in the Attorney General by section 201(a) of the Controlled Substances Act, 21 U.S.C. 811(a), and delegated to the Administrator of the Drug Enforcement Administration by regulations of the Department of Justice, 28 CFR 0.100(b), the Administrator hereby orders that marijuana remain in Schedule I as listed in 21 CFR 1308.11(d)(14).

Dated: March 18, 1992.

Robert C. Bonner,

Administrator.

[FR Doc. 92-6714 Filed 3-25-92; 8:45 am]

BILLING CODE 4410-09-M

NUCLEAR REGULATORY COMMISSION

ENVIRONMENTAL PROTECTION AGENCY

Proposed Guidance Document on the Testing of Mixed Radioactive and Hazardous Waste

AGENCIES: Nuclear Regulatory Commission, Environmental Protection Agency.

ACTION: Notice of availability and request for public comment.

SUMMARY: The Nuclear Regulatory Commission (NRC) and the Environmental Protection Agency (EPA) are jointly issuing a proposed guidance document on the testing of mixed radioactive and hazardous waste (mixed waste). This guidance document was developed to assist mixed waste generators in identifying and performing the testing required under the Federal regulations that implement the Resource Conservation and Recovery Act Subtitle C hazardous waste program and to ensure that employee radiation exposures are maintained As Low As Reasonably Achievable (ALARA). The agencies are soliciting comments from interested members of the regulated community, the States, and the public.

Interested individuals may provide the agencies with their comments on the proposed guidance document by forwarding their written comments to the NRC at the address listed in the "ADDRESSES" section. Interested parties may also participate in a public meeting being held to solicit oral comments on the proposed guidance document. Interested individuals will be given an opportunity to speak for fifteen minutes at this meeting. This time allowance may be extended, on request for good cause, if the schedule of speakers permits this extension.

DATES: The agencies will accept written comments until May 26, 1992. Individuals submitting comments after this date cannot be assured that the agencies will be able to afford their comments full consideration in any revisions that may be made to the proposed guidance document.

The public meeting to solicit oral comments on the proposed guidance document will be held on April 14, 1992, from 8:30 a.m. until 4:30 p.m. at the Mayflower/Stouffer Hotel, New York Room 1127 Connecticut Avenue NW., Washington, DC 20036, telephone (202) 347-3000.

ADDRESSES: Copies of the proposed guidance document may be obtained by contacting Dominick A. Orlando, NRC Mixed Waste Project Manager, Division of Low-Level Waste Management and Decommissioning, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 504-2566.

Written comments on the proposed guidance document should be directed to David L. Meyer, Chief, Regulatory Publications Branch, Division of Freedom of Information and Publications Service, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555 or hand delivered to the Commission's offices at 7920 Norfolk Avenue, Bethesda, MD between the hours of 7:45 a.m. and 4:14 p.m. on Federal workdays.

Requests to speak at the public meeting should be submitted, in writing, to EPA. The written request should be addressed to Reid Rosnick, Mixed Waste Coordinator, Permits and State Programs Branch, Office of Solid Waste (OS-342), U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460. Interested speakers should include in the written request a statement identifying the topics to be addressed in their presentations, the names and affiliations of the individual(s) that will speak, and the amount of time the speaker(s) will require. A transcript of the oral proceedings will be included in the record for this action.

FOR FURTHER INFORMATION CONTACT: Dominick A. Orlando, Mixed Waste Project Manager, Division of Low-Level Waste Management and Decommissioning, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (30 504-2566 or: Reid Rosnick, Mixed W Coordinator, Permits and State Programs Division, Office of Solid Waste, U.S. Environmental Protectio Agency, 401 M Street SW., Washingt DC 20460, telephone (202) 260-4755.

Dated at Rockville, MD this 19th day o March, 1992.

For the U.S. Nuclear Regulatory Commission.

Robert M. Bernero,

Director, Office of Nuclear Material Safe and Safeguards.

For the U.S. Environmental Protection Agency.

Sylvia K. Lowrance,

Director, Office of Solid Waste.

[FR Doc. 92-7031 Filed 3-25-92; 8:45 am]

BILLING CODE 7590-01-M

OFFICE OF MANAGEMENT AND BUDGET

Circular No. A-76: Performance of Commercial Activities; Amendmen

AGENCY: Office of Management and Budget.

ACTION: Issuance of Transmittal Memorandum No. 11, amending OM Circular No. A-76, "Performance of Commercial Activities."

SUMMARY: This notice contains Transmittal No. 11, dated February _____ 1992, to OMB Circular No. A "Performance of Commercial Activities."

This Transmittal Memorandum updates the Federal pay raise assumptions and inflation factors u for computing the Government's in-house personnel and non-pay cost increases for Fiscal Years 1992 thro 1997. The Federal pay raise assump and the non-pay category rates are contained in the President's Budget Fiscal Year 1993. The factors conta in OMB Circular No. A-76, Transm Memorandum No. 10, dated Februa 1991, are outdated.

The revision does not require an agency to (1) create or maintain a duplicate control/monitoring/repor system or (2) adopt any additional controls, not presently in complian with Federal Acquisition Regulatio (FAR).

FOR FURTHER INFORMATION CONTAC Mr. David Childs, Federal Services Branch, General Management Divi

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

Schedules of Controlled Substances; Temporary Placement of Bromazepam, Camazepam, Clobazam, Clotiazepam, Cloxazolam, Delorazepam, Estazolam, Ethyl Loflazepate, Fludiazepam, Flunitrazepam, Haloxazolam, Ketazolam, Loprazolam, Lormetazepam, Medazepam, Nimetazepam, Nitrazepam, Nordiazepam, Oxazolam, Pinazepam, and Tetrazepam into Schedule IV

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Finale rule.

SUMMARY: This final rule is issued by the Administrator of the Drug Enforcement Administration to temporarily place twenty-one (21) benzodiazepine substances into Schedule IV of the Controlled Substances Act (CSA) (21 U.S.A. 801 *et seq.*). The 21 benzodiazepine substances are bromazepam, camazepam, clobazam, clotiazepam, cloxazolam, delorazepam, estazolam, ethyl loflazepate, fludiazepam, flunitrazepam, haloxazolam, ketazolam, loprazolam, lormetazepam, medazepam, nimetazepam, nitrazepam, nordiazepam, oxazolam, pinazepam, and tetrazepam. This temporary scheduling action is required in order for the United States to discharge its obligations under the Convention on Psychotropic Substances, 1971. The effects of this rule will be to require that the manufacture, distribution, dispensing, security, registration, record keeping, reporting, inventory, exportation and importation of each of the 21 benzodiazepines are subject to controls for Schedule IV substances. The temporary scheduling order for each substance shall remain in effect until the process of permanent scheduling, pursuant to sections 201 (a) and (b) (21 U.S.C. 811 (a) and (b)) of the CSA, is completed.

EFFECTIVE DATE: November 5, 1984.

FOR FURTHER INFORMATION CONTACT: Howard McClain, Jr., Chief, Drug Control Section, Drug Enforcement Administration, Washington, DC 20537, Telephone: (202) 633-1368.

SUPPLEMENTARY INFORMATION:

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Narcotics, Prescription drugs.

By notice of March 29, 1984, the Secretary-General of the United Nations advised the Secretary of State of the United States that the Commission on Narcotic Drugs (CND) has decided that the above 21 benzodiazepine substances be added to Schedule IV of the Convention on Psychotropic Substances, 1971.

In a letter dated May 1, 1984, the Assistant Secretary for Health, on behalf of the Secretary of the Department of Health and Human Services (DHHS), advised the Administrator of the Drug Enforcement Administration that the 21 benzodiazepines be controlled in CSA Schedule IV, using authority provided by sections 201(d)(3)(B) and 201(d)(4)(A) and (C) of the CSA. This allows for the issuance of a temporary order controlling a substance in Schedule IV or V, depending upon whichever is most appropriate to carry out the minimum United States obligations, within the time period required by paragraph 7 of article 2 of the Convention, that is, within 180 days after the date of the CND communication. The findings pursuant to sections 201 (a), (b) and 202(b) which concern an assessment of the abuse potential for each of the 21 benzodiazepines are neither established nor required for this temporary scheduling order.

On Wednesday, August 1, 1984, a notice was published in the Federal Register (49 FR 30748-9) proposing to temporarily place the 21 benzodiazepines into Schedule IV of the CSA. By this action, the United States would be in compliance with the drug control treaty, the Convention on Psychotropic Substances, 1971. All interested persons were given until August 31, 1984 to submit any comments or objections regarding the proposal. No comments or objections were received in response to the proposal nor were there any requests for a hearing.

Therefore, under the authority vested in the Attorney General by section 201(d)(4) (A) and (C) of the CSA (21 U.S.C. 811(d)(4) (A) and (C)) and delegated to the Administrator of the Drug Enforcement Administration by regulations of the Department of Justice (28 CFR Part 0.100), the Administrator hereby orders that paragraph (c) of § 1308.14 be amended by revising the list of controlled substances to read as follows:

§ 1308.14 Schedule IV.

* * * * *

(c) * * *

(1) Alprazolam	2882
(2) Barbital	2145
(3) Bromazepam	2748
(4) Camazepam	2749
(5) Chloral betaine	2460
(6) Chloral hydrate	2465
(7) Chlordiazepoxide	2744
(8) Clobazam	2751
(9) Clonazepam	2737
(10) Clorazepate	2768
(11) Clotiazepam	2752
(12) Cloxazolam	2753
(13) Delorazepam	2754
(14) Diazepam	2765
(15) Estazolam	2756
(16) Ethchlorvynol	2540
(17) Ethinamate	2545
(18) Ethyl loflazepate	2758
(19) Fludiazepam	2759
(20) Flunitrazepam	2763

(21) Flurazepam 2767
(22) Halazepam 2762
(23) Haloxazolam 2771
(24) Ketazolam 2772
(25) Loprazolam 2773
(26) Lorazepam 2885
(27) Lormetazepam 2774
(28) Mebutamate 2800
(29) Medazepam 2836
(30) Meprobamate 2820
(31) Methohexital 2264
(32) Methylphenobarbital (mephobarbital) 2250
(33) Nimetazepam 2837
(34) Nitrazepam 2834
(35) Nordiazepam 2838
(36) Oxazepam 2835
(37) Oxazolam 2839
(38) Paraldehyde 2585
(39) Petrichloral 2591
(40) Phenobarbital 2285
(41) Pinazepam 2883
(42) Prazepam 2764
(43) Temazepam 2925
(44) Tetrazepam 2886
(45) Triazolam 2887

* * * * *

Effective Dates for applicable regulations:

All regulations applicable to each of the 21 benzodiazepines as temporarily controlled substances in Schedule IV of the CSA are effective on November 5, 1984, except as otherwise provided below:

1. *Registration.* Any person who manufactures, distributes, imports or exports any of the 21 benzodiazepines or who engages in research or conducts instructional activities, must apply for registration by November 5, 1984, to conduct such activities in accordance with Parts 1301 and 1311 of Title 21 of the Code of Federal Regulations.

2. *Security.* Each of the 21 benzodiazepines must be manufactured, distributed and stored in accordance with §§ 1301.71–1301.76 of Title 21 of the Code of Federal Regulations.

3. *Labeling and Packaging.* All labels and labeling for commercial containers of each of the 21 benzodiazepines must comply with the requirements of §§ 1302.03–1302.05 and 1302.08 of Title 21 of the Code of Federal Regulations by February 4, 1985.

4. *Inventory.* Every registrant required to keep records who possesses any quantity of any of the 21 benzodiazepines must take inventories pursuant to §§ 1304.11–1304.19 of Title 21 of the Code of Federal Regulations, of all stocks of these substances on hand.

5. *Records and Reports.* All registrants required to keep records and submit reports pursuant to Part 1304 of Title 21 of the Code of Federal Regulations shall do so regarding each of the 21 benzodiazepines.

6. *Prescriptions.* None of the 21 benzodiazepines can be prescribed since none have attained accepted medical use in treatment status in the United States, as would be indicated by approval of a new drug application by the Foods and Drug Administration.

7. *Importation and Exportations.* All importation and exportation of each of the 21 benzodiazepines shall be in compliance with Part 1312 of Title 21 of the Code of Federal Regulations.

8. *Criminal Liability.* The Administrator, Drug Enforcement Administration, hereby orders that any activity with respect to each of the 21 benzodiazepines not authorized by, or in violation of, the Controlled Substances Act or the Controlled Substances Import and Export Act, conducted after (November 5, 1984) shall be unlawful, except that any person who is not now registered to handles each benzodiazepine but who is entitled to registration under such Acts may continue to conduct normal business or professional practice with any of the 21 benzodiazepines between the date on which this rule is published and the date which the person obtains or is denied registration provided that the application for such registration is submitted on or before November 5, 1984.

Pursuant to 5 U.S.C. 605(b), the Administrator certifies that the placement of the 21 benzodiazepines into Schedule IV of the CSA will have no impact upon small businesses or other entities whose interests must be considered under the Regulatory Flexibility Act (Pub. L. 96–354). This action involves the initial control of substances with no legitimate medical use in the United States and must be carried out in order to fulfill United States international treaty obligations, in any event.

In accordance with the provisions of 21 U.S.C. 811(d), this scheduling action is a formal rulemaking that is required by United States obligations under international convention, that is, the Convention on Psychotropic Substances, 1971. Such formal proceedings are conducted pursuant to the provisions of 5 U.S.C. 556 and 557, and as such, have been exempted from the consultation requirements of Executive Order 12991 (46 FR 13193).

Dated: October 1, 1984.

Francis M. Mullen, Jr.,

Administrator, Drug Enforcement Administration.

[FR Doc. 84-26360 Filed 10-4-84; 8:45 am]

BILLING CODE 4410-09-M

98TH CONGRESS 2d Session | HOUSE OF REPRESENTATIVES | REPT. 98-835 Part 1

DANGEROUS DRUG DIVERSION CONTROL ACT OF 1984

JUNE 12, 1984.—Ordered to be printed

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

REPORT

[To accompany H.R. 5656 which on May 15, 1984, 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. 5656) to amend the Controlled Substances Act to strengthen the authority to prevent diversion of controlled substances, and for other purposes, 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 out all after the enacting clause and insert in lieu thereof the following:

That (a) this Act may be cited as the "Dangerous Drug Diversion Control Act of 1984".

(b) Whenever in sections 2 through 14 an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Controlled Substances Act, and whenever in sections 15 through 21 an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Controlled Substances Import and Export Act.

SEC. 2. (a) Section 102 (21 U.S.C. 802) is amended by redesignating paragraphs (14) through (29) as paragraphs (15) through (30), respectively, and by adding after paragraph (13) the following:

"(14) The term 'isomer' means the optical isomer, except as used in schedule I(c) and schedule II(a)(4). As used in schedule I(c), the term 'isomer' means the optical, positional, or geometric isomer. As used in schedule II(a)(4), the term 'isomer' means the optical or geometric isomer.".

(b) Paragraph (17) (as so redesignated) of section 102 is amended to read as follows:

"(17) The term 'narcotic drug' means any of the following whether produced directly or indirectly by extraction from substances of vegetable origin, or independ-

31-006 O

The Subcommittee felt that these concerns were meritorious and narrowed the scope fo the factor to apply to "such other conduct which may threaten the public health and safety." This change satisfactorily responds to those concerns.

Seizing drugs of an out-of-business registrant

The American Pharmaceutical Association and the American Veterinary Medical Association expressed concern that a minimum 90-day period before the Attorney General could destroy the controlled substances sealed or seized from an out-of-business registrant provided for in H.R. 4698 was too short. The Subcommittee took these meritorious concerns into consideration in revising section 8 by lengthening the period of time and adding certain protective procedures.

Emergency scheduling

The proposal for emergency scheduling was subject to extensive comment and concern by the American Medical Association, the American Pharmaceutical Association, the American Veterinary Medical Association and the Pharmaceutical Manufacturers Association. All of these concerns were based on a perception that drugs currently used in medical treatment might be subject to temporary control by the Attorney General who would take into consideration principally law enforcement issues. Consequently, several witnesses urged that the bill permit emergency scheduling only if there were affirmative concurrence of the Secretary of Health and Human Services. Indeed, it appeared that the Administration had this understanding of its proposal in view of the testimony of the Department of Health and Human Services.

The Subcommittee believed that these concerns raised significant questions about the impact an emergency scheduling authority would have on the manufacture and distribution of drugs that are currently used in medical treatment. In examining the particular substances for which the scheduling action was most necessary, the Subcommittee concluded that limiting the authority only to substances that have no currently accepted medical use in treatment addressed both the legitimate concerns of those in the health care industry and the principal danger to the public health.

Registration of importers and exporters

The original version to these amendments (H.R. 4698) included two sections (sections 19 and 21) that were designed to eliminate the cross-references from the Controlled Substances Import and Export Act (section 1008 (a) and (c)) (21 U.S.C. 958 (a) and (c)) to the Controlled Substances Act (section 303(a) and (d) (21 U.S.C. 823 (a) and (d)) with respect to the registration criteria for importers and exporters.

At full Committee markup of the Subcommittee's reported bill, those sections were deleted because by eliminating language that related to the manufacture of drugs, they created the appearance of a change in policy although no policy change was intended.

The current law is settled, and does not need to be revised to resolve any ambiguity. The Administration and the affected parties

urged that the current law be retained. The Committee agreed and struck out those two sections.

Hearing on application for registration to import Schedule I and II substances

The Administration had urged that section 1008(h) (21 U.S.C. 958(h)) be amended to eliminate a right for registered bulk manufacturers to intervene in the application of a party to become an importer of Schedule I or II substances. A recent proceeding under this section lasted for several years and involved a commitment of several thousand hours of DEA staff time. The Administration suggested that the hearing did not substantially contribute to the determination of the legal and factual issues involved.

The Committee believes that the opportunity for public hearings in these matters are important and should be retained. The questions of additional registration often involves economic questions concerning the adequacy of competitive conditions for which expert testimony can be valuable. Therefore, the Committee deleted that portion of section 22 of the Subcommittee's reported bill which would have eliminated the right to a public hearing. This action retains current law.

The Committee, however, wants to express its concern that these hearings not be permitted to be used for purposes of unreasonable delay in the consideration of meritorious applications for registration. The Committee urges that these matters be resolved expeditiously.

Section-by-Section Analysis

Section 1. Short Title: The Dangerous Drug Diversion Control Act of 1984.

Section 2. (a) The term "isomer" is defined to eliminate the potential ambiguity regarding different types of isomers used in the definitions of various controlled substances.

(b) The term "narcotic drug" is redefined for added clarity with respect to the derivatives of opium and opiates and the derivatives of coca leaves, including cocaine and ecgonine. Newly included in the term are "poppy straw", and "concentrate of poppy straw", major narcotic raw materials that are imported into the United States.

(c) Schedule II(A)(4) is amended to explicitly include as a derivative of coca leaves cocaine and ecgonine and their salts, isomers, derivatives and salts of isomers and derivatives. Coupled with the definition of the term "isomer", as used in this paragraph of Schedule II. defenses to prosecutions under the Act with respect to cocaine will be precluded from raising what has been called the "isomer defense."

Section 3. This section creates a new procedure for scheduling substances on an expedited and temporary basis which have no currently accepted medical use in treatment in the United States when they are found by the Attorney General to pose an imminent hazard to the public health.

This new procedure is intended by the Committee to apply to what has been called "designer drugs", new chemical analogs or

variations of existing controlled substances, or other new substances, which have a psychedelic, stimulant or depressant effect, and have a high potential for abuse.

Examples of such drugs include PCE and PHP which have been clandestinely developed and manufactured to imitate the effects of the controlled psychedelic drug, PCP. Other substances, fentanyl analogs, have been developed and marketed illicitly as "synthetic heroin". In other cases, substances which have been known to chemists for some time, are "discovered" by illicit drug researchers to have psychedelic effects. The substance, MPPP, is an example, which is similar to the schedule II drug, meperidine (Demerol). In 1982, illicitly manufactured MPPP was sold in California. It was contaminated in the course of its improper manufacture with a related toxic chemical, MPTP, which caused Parkinson's disease-like symptoms in the users. Over 140 cases of MPTP induced Parkinson's Disease symptoms have been confirmed. The MPPP/MPTP incident appears to have been single incident. However, the ability to establish controls on MPPP, if its production for drug abuse were to be encountered more often, would be important to protect the public health and to prosecute those who wantonly risk the public health.

Section 3 of the bill adds a new subsection (h) to the section relating to scheduling.

Paragraph (1) provides that the Attorney General by order may schedule a substance in Schedule I without regard to the requirement of 21 U.S.C 811(b) relating to the Secretary of Health and Human Services if the scheduling is necessary to avoid an imminent hazard to the public safety.

The order may only be issued after 30 days have elapsed from the date of publication of a notice of intention to issue such a order in the Federal Register along with the grounds upon which such an order is to be issued. The order may only be issued after 30 days have elapsed from the date the Attorney General transmits notice of the proposed order to the Secretary of Health and Human Services. The two 30-days periods may be concurrent.

Paragraph (2) provides that the scheduling shall expire at the end of 1 year from the issuance of the order. However, if a rulemaking proceeding to schedule the substance has been initiated pursuant to section 201(a)(1) (21 U.S.C. 811(a)(1)), the Attorney General may extend the temporary scheduling for up to 6 months.

Paragraph (3) provides that the Attorney General in finding that a substance poses an imminent hazard to the public safety shall consider three factors in paragraphs (4), (5) and (6) of section 201(c):

The substance's "history and current pattern of abuse"; "The scope, duration and significance of abuse"; "What, if any, risk there is to the public health"; and include in the consideration actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution.

Paragraph (4) provides that the Attorney General transmit to the Secretary of Health and Human Services notice of the order to schedule a substance that he proposes to issue. The Attorney General is directed to take into consideration any comments submitted by the Secretary in response to the transmitted notice. The Attorney General's authority to issue a temporary scheduling order is

List of Substances placed in "Temporary Scheduling to Avoid Imminent Hazards to Public Safety" Pursuant to 21 U.S.C. 811(h)

Methcathinone	Sch I
Aminorex	Sch I
Alpha-Ethyltryptamine	Sch I
4-bromo-2,5-dimethoxyphenethylamine	Sch I
Thenylfentanyl	Sch I
Benzylfentanyl	Sch I
N,N-Dimethylamphetamine	Sch I
4-Methylaminorex	Sch I
Beta-Hydroxy-3-methylfentanyl	Sch I
Acetyl-alpha-methylfentanyl	Sch I
Alpha-methylthiofentanyl	Sch I
Beta-hydroxyfentanyl	Sch I
3-methylthiofentanyl	Sch I
Thiofentanyl	Sch I
3,4-methylenedioxy-N-ethylamphetamine	Sch I
N-hydroxy-3,4-methylenedioxyampetamine	Sch I
Para-fluorofentanyl	Sch I
N-ethyl MDA	Sch I
N-hydroxy MDA	Sch I
3,4-methylenedioxymethamphetamine	Sch I
3-methylfentanyl	Sch I
1-methyl-4-phenyl-4-propionoxypiperidine (MPPP)	Sch I
1-(2-phenethyl)-4-phenyl-4-acetoxypiperidine (PEPAP)	Sch I

OFFICE OF NATIONAL DRUG CONTROL POLICY
EXECUTIVE OFFICE OF THE PRESIDENT
Washington, D.C. 20500

Elena Kagan
WH Counsel
125 OEOB

Ed Jurith - Pkg/memorandum
S6709

PHOTOCOPY
PRESERVATION

1) Direction?
2) If not, anything else?
- importation

as a result of a review under paragraph 8 of article 2 of the Convention of the scheduling decision with respect to which a notice of qualified acceptance was transmitted in accordance with clause (ii) or (iii) of paragraph (3)(C)—

(i) the decision is reversed, and

(ii) the drug or substance subject to such decision is not required to be controlled under schedule IV or V to carry out the minimum United States obligations under paragraph 7 of article 2 of the Convention,

the order issued under this subparagraph with respect to such drug or substance shall expire upon receipt by the United States of the review decision. If, as a result of action taken pursuant to action initiated under a request transmitted under clause (iv) of paragraph (3)(C), the drug or substance with respect to which such action was taken is not required to be controlled under schedule IV or V, the order issued under this paragraph with respect to such drug or substance shall expire upon receipt by the United States of a notice of the action taken with respect to such drug or substance under the Convention.

(C) An order issued under subparagraph (A) or (B) may be issued without regard to the findings required by subsection (a) of this section or by section 812(b) of this title and without regard to the procedures prescribed by subsection (a) or (b) of this section.

(5) Nothing in the amendments made by the Psychotropic Substances Act of 1978 or the regulations or orders promulgated thereunder shall be construed to preclude requests by the Secretary of Health and Human Services or the Attorney General through the Secretary of State, pursuant to article 2 or other applicable provisions of the Convention, for review of scheduling decisions under such Convention, based on new or additional information.

Immediate precursors

(e) The Attorney General may, without regard to the findings required by subsection (a) of this section or section 812(b) of this title and without regard to the procedures prescribed by subsections (a) and (b) of this section, place an immediate precursor in the same schedule in which the controlled substance of which it is an immediate precursor is placed or in any other schedule with a higher numerical designation. If the Attorney General designates a substance as an immediate precursor and places it in a schedule, other substances shall not be placed in a schedule solely because they are its precursors.

Abuse potential

(f) If, at the time a new-drug application is submitted to the Secretary for any drug having a stimulant, depressant, or hallucinogenic effect on the central nervous system, it appears that such drug has an abuse potential, such information shall be forwarded by the Secretary to the Attorney General.

Non-narcotic substances sold over the counter without prescription; dextromethorphan

(g)(1) The Attorney General shall by regulation exclude any non-narcotic substance from a schedule if such substance may, under the Federal Food, Drug, and Cosmetic Act, be lawfully sold over the counter without a prescription.

(2) Dextromethorphan shall not be deemed to be included in any schedule by reason of enactment of this subchapter unless controlled after October 27, 1970 pursuant to the foregoing provisions of this section.

(3) The Attorney General may, by regulation, exempt any compound, mixture, or preparation containing a controlled substance from the application of all or any part of this subchapter if he finds such compound, mixture, or preparation meets the requirements of one of the following categories:

(A) A mixture, or preparation containing a non-narcotic controlled substance, which mixture or preparation is approved for prescription use, and which contains one or more other active ingredients which are not listed in any schedule and which are included therein in such combinations, quantity, proportion, or concentration as to vitiate the potential for abuse.

(B) A compound, mixture, or preparation which contains any controlled substance, which is not for administration to a human being or animal, and which is packaged in such form or concentration, or with adulterants or denaturants, so that as packaged it does not present any significant potential for abuse.

Temporary scheduling to avoid imminent hazards to public safety

(h)(1) If the Attorney General finds that the scheduling of a substance in schedule I on a temporary basis is necessary to avoid an imminent hazard to the public safety, he may, by order and without regard to the requirements of subsection (b) of this section relating to the Secretary of Health and Human Services, schedule such substance in schedule I if the substance is not listed in any other schedule in section 812 of this title or if no exemption or approval is in effect for the substance under section 355 of this title. Such an order may not be issued before the expiration of thirty days from—

E X E C U T I V E O F F I C E O F T H E P R E S I D E N T

10-Jan-1996 02:58pm

TO: Robert Wasserman
TO: Edward H. Jurith

FROM: Dennis Burke
Domestic Policy Council

SUBJECT: Title 21 Section 811

Title 21 Section 811 (h)(1) gives the AG the authority to schedule a substance in schedule I on a temporary basis. What is preventing President from directing the AG to do this for Rohypnol?

E X E C U T I V E O F F I C E O F T H E P R E S I D E N T

11-Jan-1996 12:54pm

TO: Edward H. Jurith

FROM: Dennis Burke
Domestic Policy Council

CC: Robert Wasserman

SUBJECT: Attached is beginning of Draft Memo on Rohypnol

Here is the beginning of a draft memo for Panetta that outlines what kind of action the President can take on this drug.

This is on the fast track, so any help you can provide as soon as possible is greatly appreciated.

Needless to say, Biden would be included in anything we do on this if it is approved.

Please approach this from what we can do (if not as outlined, then how) as opposed to why we should not do it.

Thanks, Ed.

Presidential Memorandum on the drug, Rohypnol

Proposed Action

President signs a Memorandum to the Attorney General to schedule Rohypnol as a Schedule I substance (subjecting it to the strongest possible restrictions under the law) under the Drug Abuse and Prevention Control Act.

Purpose

This drug is widely used by adolescents, the one age segment in which drug use is increasing. Senator Biden has written a report and is proposing legislation to increase the restrictions on this drug. This Presidential Memorandum will show action and leadership -- that he is willing to address the growing youth drug use problem head-on, do all within his power to curb its use, and not wait for the legislative process to accomplish a goal that he can implement immediately.

Background

Rohypnol is a drug that has recently hit the youth scene and has quickly become popular. It was first documented in the U.S. in June 1993 by the National Institute on Drug Abuse. Its use incredibly pervasive in South Florida and its use by teenager has now been reported in 30 States.

Rohypnol is classified as a depressant, and as such, it can be fatal if combined with alcohol. Although it is marketed legally in many countries around the world, it has no legal use in the United States. Where Rohypnol is available legally, it is primarily used as sedative/hypnotic to treat insomnia and for some anastethetic procedures.

Rohypnol has been widely reported as used for date rape. In fact, in many areas and in a number of newspaper accounts, Rohypnol has been referred to as a "date rapte drug."

The most famous example of Rohypnol overdose made the news when Kurt Cobain, lead singer of the rock band Nirvana, attempted suicide with a near fatal mixture of champagne and Rohypnol (Cobain was more successful the next time when he used a shotgun).

Biden?

What does changing to Schedule I really mean?

Do we the authority to only do it temporarily?

E X E C U T I V E O F F I C E O F T H E P R E S I D E N T

11-Jan-1996 04:38pm

TO: Dennis Burke
TO: Dennis Burke

FROM: Edward H. Jurith
National Drug Control Policy

SUBJECT: Rohypnol

I have reviewed 21 USC 811(h) again. I question its applicability to what we want to accomplish. Under the section the AG can only use emergency scheduling if the substance is not listed in any other schedule under section 812 of this Title. It is my understanding that Rohypnol is currently listed in Schedule 4.

Also, Rohypnol is currently not prescribed in the United States. This apparently due to a marketing decision made by ROCHE when they first began to market benzodiazepines. They found that valium and some other benzos were successful in the US market.

E X E C U T I V E O F F I C E O F T H E P R E S I D E N T

11-Jan-1996 04:50pm

TO: Edward H. Jurith

FROM: Dennis Burke
Domestic Policy Council

SUBJECT: RE: Rohypnol

Thanks.

Let me know for a fact whether it is Schedule 4 or not. If it is -- what alternatives does the President have?

If it is not prescribed in the U.S., how is it showing up -- who is bringing it in, etc?

E X E C U T I V E O F F I C E O F T H E P R E S I D E N T

11-Jan-1996 10:39pm

TO: Edward H. Jurith

FROM: Dennis Burke
Domestic Policy Council

SUBJECT: 811 (h)(1)

When we spoke today, you said that your reading of this statute precluded the President from directing the Attorney General from scheduling Rohypnol as a Schedule I controlled substance because this drug is currently a Schedule IV drug and the statute only applies to drugs that are "not listed in any other schedule in section 812 of this title..."

However, the statute goes on to provide other exceptions -- "or if no exemption or approval is in effect for the substance under section 355 of this title."

1) Do you know what this phrase is referring to?

2) Do you know for a fact that an exemption or approval is in effect for Rohypnol thereby preventing a Temporary Scheduling from being ordered?

3) Did your earlier e-mail mean that Roche has FDA approval to market this drug in this country but they just don't exercise it?

4) You never answered my earlier question -- how are adolescents getting these drugs in this country if no one is manufacturing it here -- is it being shipped in?

Thanks.

E X E C U T I V E O F F I C E O F T H E P R E S I D E N T

12-Jan-1996 12:49pm

TO: Dennis Burke

FROM: Edward H. Jurith
National Drug Control Policy

SUBJECT: 811 (h)(1)

In response you your e-mail:

(1) "or if no exemption or approval is in effect for the substance under section 355 of this title" refers to "new drugs" under IND (Investigational New Drug) or NDA (New Drug Application) status. Thus, if a drug is in IND or NDA status, this section also does not apply.

(2) Rohypnol is already in schedule 4 and therefore not in IND or NDA status.

"exemp or approval" or something diff.

(3) Roche never applied to the FDA. It made a marketing decision that its existing benzodiazepines met its US markets needs.

(4) The drug is being smuggled in from Mexico and Colombia. Drug distributors and retailers in these countries are selling Rohypnol for illicit purposes. Because Texas and Florida are both on the piplines of drugs smuggled from Mexico and Colombia respectively, they have emerged as leading targets for this product. We may want to think about some strong diplomatic overture by the AG and Sec. State to these nations as part of our response to this problem.

E X E C U T I V E O F F I C E O F T H E P R E S I D E N T

12-Jan-1996 01:08pm

TO: Edward H. Jurith

FROM: Dennis Burke
Domestic Policy Council

SUBJECT: RE: 811 (h)(1)

true? / what does it mean?

So, if no exemption or approval is in effect, then the AG can temporarily schedule it. Right?

They have no FDA approval to make this drug in the U.S. so the AG can temporarily schedule this drug as Schedule I -- isn't that what this provision is intended to mean?

Great idea on the diplomatic overtures, too.

E X E C U T I V E O F F I C E O F T H E P R E S I D E N T

12-Jan-1996 01:42pm

TO: Dennis Burke

FROM: Edward H. Jurith
National Drug Control Policy

SUBJECT: Re: 811(h)(1)

I believe you are misreading either the statute or my e-mail.

I do not believe the AG can temporarily reschedule this drug.

The statute is disjunctive. The AG cannot reschedule if a drug is already scheduled (as is rohypnol), nor can the AG reschedule if the drug is subject to approval or exemption as a new drug. no!

The fact that the FDA has not approved this drug does not negate the fact that the drug has already been scheduled under Section 812.

he's reading the "OR" as "AND"

no ~~no~~ may reschedule if 1 or other is true

E X E C U T I V E O F F I C E O F T H E P R E S I D E N T

12-Jan-1996 02:13pm

TO: Edward H. Jurith

FROM: Dennis Burke
Domestic Policy Council

SUBJECT: Re: 811(h)(1)

Yes, maybe I am losing my legal mind -- the way I was reading this provision was:

If the AG finds ... he may...schedule such substance in schedule I if:

1) the substance is not listed in any other schedule ...

or

2) no exemption or approval is in effect for the substance....

I would have thought the intent of the drafters would be to give the AG this temporary power over non-approved drugs and not approved drugs. It would be the same theoretical (indeed practical) reason behind 1).

What's included 4?
How does a drug get
here if it's not approved?

E X E C U T I V E O F F I C E O F T H E P R E S I D E N T

19-Jan-1996 11:28am

TO: Elena Kagan

FROM: Dennis Burke
Domestic Policy Council

SUBJECT: RE: drugs

Yes, the event is done and it went well; Chris Cerf did an awesome job on this one.

Unfortunately, I have to do some background research for the State of the Union and Bruce Reed is about to fire me if I don't get it done immediately. I have to give a speech out of town and my flight leaves at 5:30 -- looks like I might be cancelling it.

Do you have anytime on Monday? This thing can't move until you have everything you need on it, anyways, so I am going to have to tell Rahm that we are backed up because of me.

I sent this info to Cathy Russell, too. She claims that some guy on the Deputy's staff says that Jurith is right but she was distracted and didn't remember much about her conversation w/ him.

E X E C U T I V E O F F I C E O F T H E P R E S I D E N T

18-Jan-1996 04:24pm

TO: Elena Kagan

FROM: Dennis Burke
Domestic Policy Council

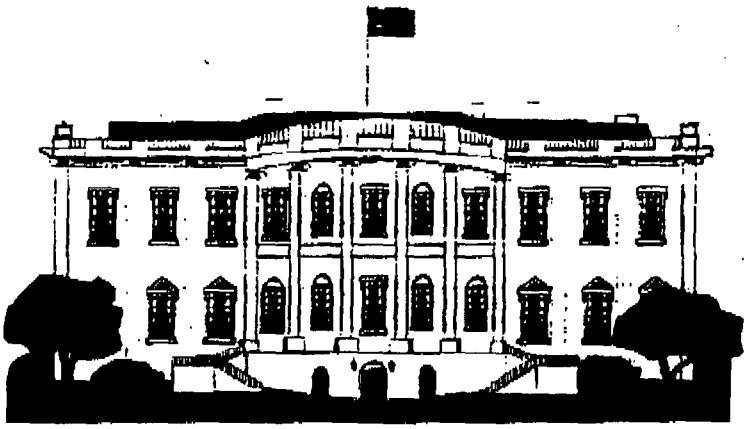
SUBJECT: Callback

Sorry, for asking you to help me and then disappearing. I am working on that Missing Children Memorandum for tomorrow and it has had a few major blow ups.

I will call you as soon as I can get out of the woods. Thanks.

This is an interesting place to work.

OFFICE OF NATIONAL DRUG CONTROL POLICY
EXECUTIVE OFFICE OF THE PRESIDENT
Washington, D.C. 20500



FACSIMILE TRANSMITTAL SHEET

Number of pages including cover: 2

Date: 3/1/96

To: Elena Kagan

Fax Number: 66677

Office Number: _____

Comments: _____

From: EDWARD H. JURITH
GENERAL COUNSEL

Fax Number: 395-6708

Office Number: 395-6709

U.S. CUSTOMS ROHYPNOL ACTION PLAN:

BACKGROUND: Rohypnol is a depressant drug that is manufactured outside of the United States and is not approved for use in the United States. Rohypnol has become a drug of abuse nationwide.

In the past, individuals have imported Rohypnol based on the Drug Enforcement Administration (DEA) regulation, 21 CFR 1311.27, which allows personal use quantities of prescription drugs. The U.S. Customs Service has recently conferred with both DEA and the Food and Drug Administration (FDA) to discuss ways to minimize the abuse of this substance.

Section 801 of the Federal Food, Drug, and Cosmetic Act (21 USC 355) prohibits the introduction into the U.S. of any new drug which is unapproved for use in the U.S. Rohypnol falls in the FDA new unapproved drug category and is thereby a prohibited importation under 21 USC 331(d).

The U.S. Customs Service has proposed the following enforcement effort, which will be coordinated with the DEA and FDA.

The following action plan will be initiated:

1. An electronic mail message will be distributed to all appropriate U.S. Customs personnel advising of Customs actions to be taken with respect to Rohypnol. All attempted importations of Rohypnol will be seized by Customs pursuant to 19 USC 1595a(c)(2)(A-B) for violation of 21 USC 331(d) and 355(a).

2. Flyers will be distributed at ports of entry nationwide which will state the U.S. Customs, FDA and DEA policy on the importation of Rohypnol.

3. Travellers declaring Rohypnol at ports of entry or at any U.S. Customs facility with or without a foreign prescription will be advised that the drug is prohibited, and the drug will be seized.

4. All undeclared quantities of Rohypnol will be treated as undeclared/smuggled goods under 19 USC 1497 and 18 USC 545.

331 & 355

① "is it interstate commerce?"

② mere fact that it doesn't have FDA approval ...

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