



U.S. Drug Enforcement Administration
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Controlled Substances Act

The Controlled Substances Act (CSA), Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, is the legal foundation of the government's fight against the abuse of drugs and other substances. This law is a consolidation of numerous laws regulating the manufacture and distribution of narcotics, stimulants, depressants, hallucinogens, anabolic steroids, and chemicals used in the illicit production of controlled substances.

The CSA places all substances that are regulated under existing federal law into one of five schedules. This placement is based upon the substance's medicinal value, harmfulness, and potential for abuse or addiction. Schedule I is reserved for the most dangerous drugs that have no recognized medical use, while Schedule V is the classification used for the least dangerous drugs. The act also provides a mechanism for substances to be controlled, added to a schedule, decontrolled, removed from control, rescheduled, or transferred from one schedule to another.

Proceedings to add, delete, or change the schedule of a drug or other substance may be initiated by the Drug Enforcement Administration (DEA), the Department of Health and Human Services (HHS), or by petition from any interested party, including the manufacturer of a drug, a medical society or association, a pharmacy association, a public interest group concerned with drug abuse, a state or local government agency, or an individual citizen. When a petition is received by the DEA, the agency begins its own investigation of the drug.

The DEA also may begin an investigation of a drug at any time based upon information received from law enforcement laboratories, state and local law enforcement and regulatory agencies, or other sources of information.

Once the DEA has collected the necessary data, the DEA Administrator, by authority of the Attorney General, requests from the HHS a scientific and medical evaluation and recommendation as to whether the drug or other substance should be controlled or removed from control. This request is sent to the Assistant Secretary of Health of the HHS. Then, the HHS solicits information from the Commissioner of the Food and Drug Administration and evaluations and recommendations from the National Institute on Drug Abuse, and on occasion, from the scientific and medical community at large. The Assistant Secretary, by authority of the Secretary, compiles the information and transmits back to the DEA a medical and scientific evaluation regarding the drug or other substance, a recommendation as to whether the drug should be controlled, and in what schedule it should be placed.

The medical and scientific evaluations are binding to the DEA with respect to scientific and medical matters. The recommendation on scheduling is binding only to the extent that if HHS recommends that the substance not be controlled, the DEA may not control the substance.

Once the DEA has received the scientific and medical evaluation from HHS, the Administrator will evaluate all available data and make a final decision whether to propose that a drug or other substance be controlled and into which schedule it should be placed.

The CSA also creates a closed system of distribution for those authorized to handle controlled substances. The cornerstone of this system is the registration of all those authorized by the DEA to handle controlled substances. All individuals and firms that are registered are required to maintain complete and accurate inventories and records of all transactions involving controlled substances, as well as security for the storage of controlled substances.

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*** CURRENT THROUGH 104-115, 3/12/96, EXCEPT FOR PLs-104, 106, 114 ***

TITLE 21. FOOD AND DRUGS

CHAPTER 13. DRUG ABUSE PREVENTION AND CONTROL

CONTROL AND ENFORCEMENT

INTRODUCTORY PROVISIONS

21 USCS Section 801 (1996)

Section 801. Findings and declarations

The Congress makes the following findings and declarations:

- (1) Many of the drugs included within this title have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people.
- (2) The illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people.
- (3) A major portion of the traffic in controlled substances flows through interstate and foreign commerce. Incidents of the traffic which are not an integral part of the interstate or foreign flow, such as manufacture, local distribution, and possession, nonetheless have a substantial and direct effect upon interstate commerce because--
 - (A) after manufacture, many controlled substances are transported in interstate commerce,
 - (B) controlled substances distributed locally usually have been transported in interstate commerce immediately before their distribution, and

(C) controlled substances possessed commonly flow through interstate commerce immediately prior to such possession.

(4) Local distribution and possession of controlled substances contribute to swelling the interstate traffic in such substances.

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

(6) Federal control of the intrastate incidents of the traffic in controlled substances is essential to the effective control of the interstate incidents of such traffic.

(7) The United States is a party to the Single Convention on Narcotic Drugs, 1961, and other international conventions designed to establish effective control over international and domestic traffic in controlled substances.

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TITLE 21. FOOD AND DRUGS

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21 USCS Section 801A (1996)

Section 801a. Congressional findings and declarations

The Congress makes the following findings and declarations:

(1) The Congress has long recognized the danger involved in the manufacture, distribution, and use of certain psychotropic substances for nonscientific and nonmedical purposes, and has provided strong and effective legislation to control illicit trafficking and to regulate legitimate uses of psychotropic substances in this country. Abuse of psychotropic substances has become a phenomenon common to many countries, however, and is not confined to national borders. It is, therefore, essential that the United States cooperate with other nations in establishing effective controls over international traffic in such substances.

(2) The United States has joined with other countries in executing an international treaty, entitled the

Convention on Psychotropic Substances and signed at Vienna, Austria, on February 21, 1971, which is designed to establish suitable controls over the manufacture, distribution, transfer, and use of certain psychotropic substances. The Convention is not self-executing, and the obligations of the United States thereunder may only be performed pursuant to appropriate legislation. It is the intent of the Congress that the amendments made by this Act, together with the existing law, will enable the United States to meet all of its obligations under the Convention and that no further legislation will be necessary for that purpose.

(3) In implementing the Convention on Psychotropic Substances, the Congress intends that, consistent with the obligations of the United States under the Convention, control of psychotropic substances in the United States should be accomplished within the framework of the procedures and criteria for classification of substances provided in the Comprehensive Drug Abuse Prevention and Control Act of 1970. This will insure that (A) the availability of psychotropic substances to manufacturers, distributors, dispensers, and researchers for useful and legitimate medical and scientific purposes will not be unduly restricted; (B) nothing in the Convention will interfere with bona fide research activities; and (C) nothing in the Convention will interfere with ethical medical practice in this country as determined by the Secretary of Health, Education, and Welfare [Secretary of Health and Human Services] on the basis of a consensus of the views of the American medical and scientific community.

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21 USCS Section 801A (1996)

HISTORY: (Nov. 10, 1978, P.L. 95-633, Title I, Section 101, 92 Stat. 3768)

HISTORY; ANCILLARY LAWS AND DIRECTIVES

REFERENCES IN TEXT:

"This Act", referred to in this section, is Act Nov. 10, 1978, P.L. 95-633, 92 Stat. 2768, which enacted this section, among other things. For full classification of such Act, consult USCS Tables volumes.

"The Comprehensive Drug Abuse Prevention and Control Act of 1970", referred to in this section, is Act Oct. 27, 1970, P. L. 91-513, 84 Stat. 1236, which appears generally as *21 USCS Sections 801 et seq.* For full classification of such Act, consult USCS Tables volumes.

EXPLANATORY NOTES:

The bracketed words "Secretary of Health and Human Services" are inserted on authority of Act Oct. 17, 1979, P. L. 96-88, Title V, Section 509, 93 Stat. 695, which appears as *20 USCS Section 3508*, and which redesignated the Secretary of Health, Education, and Welfare as the Secretary of Health and Human Services and provided that any reference to the Secretary of Health, Education, and Welfare, in any law in force on the effective date of such Act Oct. 17, 1979, shall be deemed to refer and apply to the Secretary of Health and Human Services, except to the extent such reference is to a function or office transferred to the Secretary of Education or the Department of Education under such Act Oct. 17, 1979.

This section was enacted as part of Act Nov. 10, 1978, P. L. 95-633, and not as part of Act Oct. 27, 1970, P. L. 91-513, which generally comprises this chapter.

EFFECTIVE DATE OF SECTION:

For the effective date of this section, see the other provisions note to this section.

OTHER PROVISIONS:

Effective date of Act Nov. 10, 1978. Act Nov. 10, 1978, P.L. 95-633, Title I, Section 112, 92 Stat. 3774, provided: "This title and the amendments made by this title [enacting this section, among other things; for full classification of such Title, consult USCS Tables volumes] shall take effect on the date the Convention on Psychotropic Substances, signed at Vienna, Austria on February 21, 1971, enters into force in respect to the United States on July 15, 1980.

NOTES:

RESEARCH GUIDE

AM JUR:

25 Am Jur 2d, Drugs and Controlled Substances Section 19.

FORMS:

15 Federal Procedural Forms L Ed, Statutes of Limitation, and Other Time Limits Section 61:32.

IMMIGRATION LAW SERVICE:

1 Immigration Law Service, Requirements Pertaining to All Applicants Section 4:74.

2 Immigration Law Service, Other Documents Section 32:42.

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21 USCS Section 802 (1996)

Section 802. Definitions

As used in this title:

(1) The term "addict" means any individual who habitually uses any narcotic drug so as to endanger the public morals, health, safety, or welfare, or who is so far addicted to the use of narcotic drugs as to have lost the power of self-control with reference to his addiction.

(2) The term "administer" refers to the direct application of a controlled substance to the body of a patient or research subject by--

(A) a practitioner (or, in his presence, by his authorized agent), or

(B) the patient or research subject at the direction and in the presence of the practitioner,

whether such application be by injection, inhalation, ingestion, or any other means.

(3) The term "agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser; except that such term does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman, when acting in the usual and lawful course of the carrier's or warehouseman's business.

(4) The term "Drug Enforcement Administration" means the Drug Enforcement Administration in the Department of Justice.

(5) The term "control" means to add a drug or other substance, or immediate precursor, to a schedule under part B of this title, whether by transfer from another schedule or otherwise.

(6) The term "controlled substance" means a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V of part B of this title [21 USCS Section 812]. The term does not include distilled spirits, wine, malt beverages, or tobacco, as those terms are defined or used in subtitle E of the Internal Revenue Code of 1954 [26 USCS Sections 5001 et seq.].

(7) The term "counterfeit substance" means a controlled substance which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, number, or device, or any likeness thereof, of a manufacturer, distributor, or dispenser other than the

person or persons who in fact manufactured, distributed, or dispensed such substance and which thereby falsely purports or is represented to be the product of, or to have been distributed by, such other manufacturer, distributor, or dispenser.

(8) The terms "deliver" or "delivery" mean the actual, constructive, or attempted transfer of a controlled substance or a listed chemical, whether or not there exists an agency relationship.

(9) The term "depressant or stimulant substance" means--

(A) a drug which contains any quantity of (i) barbituric acid or any of the salts of barbituric acid; or (ii) any derivative of barbituric acid which has been designated by the Secretary as habit forming under section 502(d) of the Federal Food, Drug, and Cosmetic Act (21 U. S. C. 352(d)) [21 USCS Section 352(d)]; or

(B) a drug which contains any quantity of (i) amphetamine or any of its optical isomers; (ii) any salt of amphetamine or any salt of an optical isomer of amphetamine; or (iii) any substance which the Attorney General, after investigation, has found to be, and by regulation designated as, habit forming because of its stimulant effect on the central nervous system; or

(C) lysergic acid diethylamide; or

(D) any drug which contains any quantity of a substance which the Attorney General, after investigation, has found to have, and by regulation designated as having, a potential for abuse because of its depressant or stimulant effect on the central nervous system or its hallucinogenic effect.

(10) The term "dispense" means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling, or compounding necessary to prepare the substance for such delivery. The term "dispenser" means a practitioner who so delivers a controlled substance to an ultimate user or research subject.

(11) The term "distribute" means to deliver (other than by administering or dispensing) a controlled substance or a listed chemical. The term "distributor" means a person who so delivers a controlled substance or a listed chemical.

(12) The term "drug" has the meaning given that term by section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act [21 USCS Section 321(g)(1)].

(13) The term "felony" means any Federal or State offense classified by applicable Federal or State law as a felony.

(14) The term "isomer" means the optical isomer, except as used in schedule I(c) and schedule II(a)(4) [21 USCS Section 812]. As used in schedule I(c) [21 USCS Section 812], the term "isomer" means any optical, positional, or geometric isomer. As used in schedule II(a)(4) [21 USCS Section 812], the term "isomer" means any optical or geometric isomer.

(15) The term "manufacture" means the production, preparation, propagation, compounding, or processing of a drug or other substance, either directly or indirectly or by extraction from substances of

natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of such substance or labeling or relabeling of its container; except that such term does not include the preparation, compounding, packaging, or labeling of a drug or other substance in conformity with applicable State or local law by a practitioner as an incident to his administration or dispensing of such drug or substance in the course of his professional practice. The term "manufacturer" means a person who manufactures a drug or other substance.

(16) The term "marihuana" means all parts of the plant *Cannabis sativa* L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. Such term does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.

(17) The term "narcotic drug" means any of the following whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(A) Opium, opiates, derivatives of opium and opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation. Such term does not include the isoquinoline alkaloids of opium.

(B) Poppy straw and concentrate of poppy straw.

(C) Coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed.

(D) Cocaine, its salts, optical and geometric isomers, and salts of isomers.

(E) Ecgonine, its derivatives, their salts, isomers, and salts of isomers.

(F) Any compound, mixture, or preparation which contains any quantity of any of the substances referred to in subparagraphs (A) through (E).

(18) The term "opiate" means any drug or other substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability.

(19) The term "opium poppy" means the plant of the species *Papaver somniferum* L., except the seed thereof.

(20) The term "poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.

(21) The term "practitioner" means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of

professional practice or research.

(22) The term "production" includes the manufacture, planting, cultivation, growing, or harvesting of a controlled substance.

(23) The term "immediate precursor" means a substance--

(A) which the Attorney General has found to be and by regulation designated as being the principal compound used, or produced primarily for use, in the manufacture of a controlled substance;

(B) which is an immediate chemical intermediary used or likely to be used in the manufacture of such controlled substance; and

(C) the control of which is necessary to prevent, curtail, or limit the manufacture of such controlled substance.

(24) The term "Secretary," unless the context otherwise indicates, means the Secretary of Health, Education, and Welfare [Secretary of Health and Human Services]

(25) The term "serious bodily injury" means bodily injury which involves--

(A) a substantial risk of death;

(B) protracted and obvious disfigurement; or

(C) protracted loss or impairment of the function of a bodily member, organ, or mental faculty.

(26) The term "State" means any state, territory, or possession of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Trust Territory of the Pacific Islands, and the Canal Zone.

(27) The term "ultimate user" means a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household.

(28) The term "United States", when used in a geographic sense, means all places and waters, continental or insular, subject to the jurisdiction of the United States.

(29) The term "maintenance treatment" means the dispensing, for a period in excess of twenty-one days, of a narcotic drug in the treatment of an individual for dependence upon heroin or other morphine-like drugs.

(30) The term "detoxification treatment" means the dispensing, for a period not in excess of one hundred and eighty days, of a narcotic drug in decreasing doses to an individual in order to alleviate adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state within such period.

(31) The term "Convention on Psychotropic Substances" means the Convention on Psychotropic

Substances signed at Vienna, Austria, on February 21, 1971; and the term "Single Convention on Narcotic Drugs" means the Single Convention on Narcotic Drugs signed at New York, New York, on March 30, 1961.

(32)

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

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

(ii) which has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II; or

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

(B) Such term does not include--

(i) a controlled substance;

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

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

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

(33) The term "listed chemical" means any list I chemical or any list II chemical.

(34) The term "list I chemical" means a chemical specified by regulation of the Attorney General as a chemical that is used in manufacturing a controlled substance in violation of this title and is important to the manufacture of the controlled substances, and such term includes (until otherwise specified by regulation of the Attorney General, as considered appropriate by the Attorney General or upon petition to the Attorney General by any person) the following:

(A) Anthranilic acid, its esters, and its salts.

(B) Benzyl cyanide.

(C) Ephedrine, its salts, optical isomers, and salts of optical isomers.

- (D) Ergonovine and its salts.
- (E) Ergotamine and its salts.
- (F) N-Acetylanthranilic acid, its esters, and its salts.
- (G) Norpseudoephedrine, its salts, optical isomers, and salts of optical isomers.
- (H) Phenylacetic acid, its esters, and its salts.
- (I) Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers.
- (J) Piperidine and its salts.
- (K) Pseudoephedrine, its salts, optical isomers, and salts of optical isomers.
- (L) 3,4-Methylenedioxyphenyl-2-propanone.
- (M) Methylamine.
- (N) Ethylamine.
- (O) Propionic anhydride.
- (P) Insosafrole.
- (Q) Safrole.
- (R) Piperonal.
- (S) N-Methylephedrine.
- (T) N-methylpseudoephedrine.
- (U) Hydriotic acid.
- (V) Benzaldehyde.
- (W) Nitroethane.
- (X) Any salt, optical isomer, or salt of an optical isomer of the chemicals listed in subparagraphs (M) through (U) of this paragraph.

(35) The term " list II chemical" means a chemical (other than a list I chemical) specified by regulation of the Attorney General as a chemical that is used in manufacturing a controlled substance in violation of this title, and such term includes (until otherwise specified by regulation of the Attorney General, as considered appropriate by the Attorney General or upon petition to the Attorney General by any person) the following chemicals:

- (A) Acetic anhydride.
- (B) Acetone.
- (C) Benzyl chloride.
- (D) Ethyl ether.
- (E) [Repealed]
- (F) Potassium permanganate.
- (G) 2-Butanone.
- (H) Toluene.

(36) The term "regular customer" means, with respect to a regulated person, a customer with whom the regulated person has an established business relationship that is reported to the Attorney General.

(37) The term "regular importer" means, with respect to a listed chemical, a person that has an established record as an importer of that listed chemical that is reported to the Attorney General.

(38) The term "regulated person" means a person who manufactures, distributes, imports, or exports a listed chemical, a tableting machine, or an encapsulating machine or who acts as a broker or trader for an international transaction involving a listed chemical, a tableting machine, or an encapsulating machine.

(39) The term "regulated transaction" means--

(A) a distribution, receipt, sale, importation, or exportation of, or an international transaction involving shipment of, a listed chemical, or if the Attorney General establishes a threshold amount for a specific listed chemical, a threshold amount, including a cumulative threshold amount for multiple transactions (as determined by the Attorney General, in consultation with the chemical industry and taking into consideration the quantities normally used for lawful purposes), of a listed chemical, except that such term does not include--

(i) a domestic lawful distribution in the usual course of business between agents or employees of a single regulated person;

(ii) a delivery of a listed chemical to or by a common or contract carrier for carriage in the lawful and usual course of the business of the common or contract carrier, or to or by a warehouseman for storage in the lawful and usual course of the business of the warehouseman, except that if the carriage or storage is in connection with the distribution, importation, or exportation of a listed chemical to a third person, this clause does not relieve a distributor, importer, or exporter from compliance with section 310 [21 USCS Section 830];

(iii) any category of transaction or any category of transaction for a specific listed chemical or chemicals specified by regulation of the Attorney General as excluded from this

definition as unnecessary for enforcement of this title or title III;

(iv) any transaction in a listed chemical that is contained in a drug that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) unless--

(I)

(aa) the drug contains ephedrine or its salts, optical isomers, or salts of optical isomers as the only active medicinal ingredient or contains ephedrine or its salts, optical isomers, or salts of optical isomers and therapeutically insignificant quantities of another active medicinal ingredient; or

(bb) the Attorney General has determined under section-204 [21 USCS Section 814] that the drug or group of drugs is being diverted to obtain the listed chemical for use in the illicit production of a controlled substance; and

(II) the quantity of ephedrine or other listed chemical contained in the drug included in the transaction or multiple transactions equals or exceeds the threshold established for that chemical by the Attorney General; or

(v) any transaction in a chemical mixture which the Attorney General has by regulation designated as exempt from the application of this title and title III based on a finding that the mixture is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance and that the listed chemical or chemicals contained in the mixture cannot be readily recovered; and

(B) a distribution, importation, or exportation of a tableting machine or encapsulating machine.

(40) The term "chemical mixture" means a combination of two or more chemical substances, at least one of which is not a list I chemical or a list II chemical, except that such term does not include any combination of a list I chemical or a list II chemical with another chemical that is present solely as an impurity.

(41)

(A) The term "anabolic steroid" means any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogens, progestins, and corticosteroids) that promotes muscle growth, and includes--

(i) boldenone,

(ii) chlorotestosterone,

(iii) clostebol,

(iv) dehydrochlormethyltestosterone,

(v) dihydrotestosterone,

- (vi) drostanolone,
- (vii) ethylestrenol,
- (viii) fluoxymesterone,
- (ix) formebulone,
- (x) mesterolone,
- (xi) methandienone,
- (xii) methandranone,
- (xiii) methandriol,
- (xiv) methandrostenolone,
- (xv) methenolone,
- (xvi) methyltestosterone,
- (xvii) mibolerone,
- (xviii) nandrolone,
- (xix) norethandrolone,
- (xx) oxandrolone,
- (xxi) oxymesterone,
- (xxii) oxymetholone,
- (xxiii) stanolone,
- (xxiv) stanozolol,
- (xxv) testolactone,
- (xxvi) testosterone,
- (xxvii) trenbolone, and
- (xxviii) any salt, ester, or isomer of a drug or substance described or listed in this paragraph, if that salt, ester, or isomer promotes muscle growth.

(B)

(i) Except as provided in clause (ii), such term does not include an anabolic steroid which is expressly intended for administration through implants to cattle or other nonhuman species and which has been approved by the Secretary of Health and Human Services for such administration.

(ii) If any person prescribes, dispenses, or distributes such steroid for human use, such person shall be considered to have prescribed, dispensed, or distributed an anabolic steroid within the meaning of subparagraph (A).

(42) The term "international transaction" means a transaction involving the shipment of a listed chemical across an international border (other than a United States border) in which a broker or trader located in the United States participates.

(43) The terms "broker" and "trader" mean a person that assists in arranging an international transaction in a listed chemical by--

(A) negotiating contracts;

(B) serving as an agent or intermediary; or

(C) bringing together a buyer and seller, a buyer and transporter, or a seller and transporter.

[(44)](43) The term "felony drug offense" means an offense that is punishable by imprisonment for more than one year under any law of the United States or of a State or foreign country that prohibits or restricts conduct relating to narcotic drugs, marihuana, or depressant or stimulant substances.

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TITLE 21. FOOD AND DRUGS

CHAPTER 13. DRUG ABUSE PREVENTION AND CONTROL

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INTRODUCTORY PROVISIONS

21 USCS Section 803 (1996)

Section 803. [Repealed]

HISTORY; ANCILLARY LAWS AND DIRECTIVES

This section (Act Oct. 27, 1970, P. L. 91-513, Title II, Part A, Section 103, 84 Stat. 1245) was repealed

by Act Oct. 18, 1977, P. L. 95-137, Section 1 (b), 91 Stat. 1169. This section authorized the Bureau of Narcotics and Dangerous Drugs to add 300 agents and necessary supporting personnel.

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TITLE 21. FOOD AND DRUGS

CHAPTER 13. DRUG ABUSE PREVENTION AND CONTROL

AUTHORITY TO CONTROL; STANDARDS AND SCHEDULES

21 USCS Section 811 (1996)

Section 811. Authority and criteria for classification of substances

(a) Rules and regulations of Attorney General; hearing. The Attorney General shall apply the provisions of this title to the controlled substances listed in the schedules established by section 202 of this title [21 *USCS Section 812*] and to any other drug or other substance added to such schedules under this title. Except as provided in subsections (d) and (e), the Attorney General may by rule--

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

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

(B) makes with respect to such drug or other substance the findings prescribed by subsection (b) of section 202 [21 *USCS Section 812*(b)] for the schedule in which such drug is to be placed; or

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

Rules of the Attorney General under this subsection shall be made on the record after opportunity for a hearing pursuant to the rulemaking procedures prescribed by subchapter II of chapter 5 of title 5 of the United States Code [5 *USCS 551* et seq.]. Proceedings for the issuance, amendment, or repeal of such rules may be initiated by the Attorney General (1) on his own motion, (2) at the request of the Secretary, or (3) on the petition of any interested party.

(b) Evaluation of drugs and other substances. The Attorney General shall, before initiating proceedings under subsection (a) to control a drug or other substance or to remove a drug or other substance entirely from the schedules, and after gathering the necessary data, request from the Secretary a scientific and medical evaluation, and his recommendations, as to whether such drug or other substance should be so controlled or removed as a controlled substance. In making such evaluation and recommendations, the

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

(c) Factors determinative of control or removal from schedules. In making any finding under subsection (a) of this section or under subsection (b) of section 202 [21 USCS Section 812(b)], the Attorney General shall consider the following factors with respect to each drug or other substance proposed to be controlled or removed from the schedules:

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

(d) International treaties, conventions, and protocols requiring control; procedures respecting changes in drug schedules of Convention on Psychotropic Substances.

(1) If control is required by United States obligations under international treaties, conventions, or protocols in effect on the effective date of this part, the Attorney General shall issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings required by subsection (a) of this section or section 202(b) [21 USCS Section 812(b)] and without regard to the procedures prescribed by subsections (a) and (b) of this section.

(2)

(A) Whenever the Secretary of State receives notification from the Secretary-General of the United Nations that information has been transmitted by or to the World Health Organization, pursuant to article 2 of the Convention on Psychotropic Substances, which

may justify adding a drug or other substance to one of the schedules of the Convention, transferring a drug or substance from one schedule to another, or deleting it from the schedules, the Secretary of State shall immediately transmit the notice to the Secretary of Health, Education, and Welfare [Secretary of Health and Human Services] who shall publish it in the Federal Register and provide opportunity to interested persons to submit to him comments respecting the scientific and medical evaluations which he is to prepare respecting such drug or substance. The Secretary of Health, Education, and Welfare [Secretary of Health and Human Services] shall prepare for transmission through the Secretary of State to the World Health Organization such medical and scientific evaluations as may be appropriate regarding the possible action that could be proposed by the World Health Organization respecting the drug or substance with respect to which a notice was transmitted under this subparagraph.

(B) Whenever the Secretary of State receives information that the Commission on Narcotic Drugs of the United Nations proposes to decide whether to add a drug or other substance to one of the schedules of the Convention, transfer a drug or substance from one schedule to another, or delete it from the schedules, the Secretary of State shall transmit timely notice to the Secretary of Health, Education, and Welfare [Secretary of Health and Human Services] of such information who shall publish a summary of such information in the Federal Register and provide opportunity to interested persons to submit to him comments respecting the recommendation which he is to furnish, pursuant to this subparagraph, respecting such proposal. The Secretary of Health, Education, and Welfare [Secretary of Health and Human Services] shall evaluate the proposal and furnish a recommendation to the Secretary of State which shall be binding on the representative of the United States in discussions and negotiations relating to the proposal.

(3) When the United States receives notification of a scheduling decision pursuant to article 2 of the Convention of Psychotropic Substances that a drug or other substance has been added or transferred to a schedule specified in the notification or receives notification (referred to in this subsection as a "schedule notice") that existing legal controls applicable under this title to a drug or substance and the controls required by the Federal Food, Drug, and Cosmetic Act [21 USCS Sections 301 et seq.] do not meet the requirements of the schedule of the Convention in which such drug or substance has been placed, the Secretary of Health, Education, and Welfare [Secretary of Health and Human Services], after consultation with the Attorney General, shall first determine whether existing legal controls under this title applicable to the drug or substance and the controls required by the Federal Food, Drug, and Cosmetic Act [21 USCS Sections 301 et seq.], meet the requirements of the schedule specified in the notification or schedule notice and shall take the following action:

(A) If such requirements are met by such existing controls but the Secretary of Health, Education, and Welfare [Secretary of Health and Human Services] nonetheless believes that more stringent controls should be applied to the drug or substance, the Secretary shall recommend to the Attorney General that he initiate proceedings for scheduling the drug or substance, pursuant to subsections (a) and (b) of this section, to apply to such controls.

(B) If such requirements are not met by such existing controls and the Secretary of Health, Education, and Welfare [Secretary of Health and Human Services] concurs in the scheduling decision or schedule notice transmitted by the notification, the Secretary shall recommend to the Attorney General that he initiate proceedings for scheduling the drug or substance under the appropriate schedule pursuant to subsections (a) and (b) of this section.

(C) If such requirements are not met by such existing controls and the Secretary of Health, Education, and Welfare [Secretary of Health and Human Services] does not concur in the scheduling decision or schedule notice transmitted by the notification, the Secretary shall--

(i) if he deems that additional controls are necessary to protect the public health and safety, recommend to the Attorney General that he initiate proceedings for scheduling the drug or substance pursuant to subsections (a) and (b) of this section, to apply such additional controls;

(ii) request the Secretary of State to transmit a notice of qualified acceptance, within the period specified in the Convention, pursuant to paragraph 7 of article 2 of the Convention, to the Secretary-General of the United Nations;

(iii) request the Secretary of State to transmit a notice of qualified acceptance as prescribed in clause (ii) and request the Secretary of State to ask for a review by the Economic and Social Council of the United Nations, in accordance with paragraph 8 of article 2 of the Convention, of the scheduling decision; or

(iv) in the case of a schedule notice, request the Secretary of State to take appropriate action under the Convention to initiate proceedings to remove the drug or substance from the schedules under the Convention or to transfer the drug or substance to a schedule under the Convention different from the one specified in the schedule notice.

(4)

(A) If the Attorney General determines, after consultation with the Secretary of Health, Education, and Welfare [Secretary of Health and Human Services], that proceedings initiated under recommendations made under paragraph [subparagraph] (B) or (C)(i) of paragraph (3) will not be completed within the time period required by paragraph 7 of article 2 of the Convention, the Attorney General, after consultation with the Secretary and after providing interested persons opportunity to submit comments respecting the requirements of the temporary order to be issued under this sentence, shall issue a temporary order controlling the drug or substance under schedule IV or V, whichever is most appropriate to carry out the minimum United States obligations under paragraph 7 of article 2 of the Convention. As a part of such order, the Attorney General shall, after consultation with the Secretary, except such drug or substance from the application of any provision of part C of this title [21 USCS 821 et seq.] which he finds is not required to carry out the United States obligations under paragraph 7 of article 2 of the Convention. In the case of proceedings initiated under subparagraph (B) of paragraph (3), the Attorney General, concurrently with the issuance of such order, shall request the Secretary of State to transmit a notice of qualified acceptance to the Secretary-General of the United Nations pursuant to paragraph 7 of article 2 of the Convention. A temporary order issued under this subparagraph controlling a drug or other substance subject to proceedings initiated under subsections (a) and (b) of this section shall expire upon the effective date of the application to the drug or substance of the controls resulting from such proceedings.

(B) After a notice of qualified acceptance of a scheduling decision with respect to a drug or other substance is transmitted to the Secretary-General of the United Nations in accordance with clause (ii) or (iii) of paragraph (3)(C) or after a request has been made under clause (iv) of such paragraph with respect to a drug or substance described in a schedule notice, the

Attorney General, after consultation with the Secretary of Health, Education, and Welfare [Secretary of Health and Human Services] and after providing interested persons opportunity to submit comments respecting the requirements of the order to be issued under this sentence, shall issue an order controlling the drug or substance under schedule IV or V, whichever is most appropriate to carry out the minimum United States obligations under paragraph 7 of article 2 of the Convention in the case of a drug or substance for which a notice of qualified acceptance was transmitted or whichever the Attorney General determines is appropriate in the case of a drug or substance described in a schedule notice. As a part of such order, the Attorney General shall, after consultation with the Secretary, except such drug or substance from the application of any provision of part C of this title [21 USCS 821 et seq.] which he finds is not required to carry out the United States obligations under paragraph 7 of article 2 of the Convention. If, 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 202(b) [21 USCS Section 812(b)] 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, Education, and Welfare [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.

(e) Immediate precursors. The Attorney General may, without regard to the findings required by subsection (a) of this section or section 202(b) [21 USCS Section 812(b)] 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.

(f) Abuse potential. 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.

(g) Non-narcotic substances sold over the counter without a prescription; dextromethorphan.

(1) The Attorney General shall by regulation exclude any nonnarcotic substance from a schedule if such substance may, under the Federal Food, Drug, and Cosmetic Act [21 *USCS Section 301 et seq.*], 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 title unless controlled after the date of such enactment [enacted Oct. 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 title if he finds such compound, mixture, or preparation meets the requirements of one of the following categories:

(A) A mixture, or preparation containing a nonnarcotic 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.

(h) Temporary scheduling of substance in schedule I to avoid imminent public safety hazard.

(1) If the Attorney General finds that the scheduling of a substance in schedule I [21 *USCS Section 812*] 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) relating to the Secretary of Health and Human Services, schedule such substance in schedule I [21 *USCS Section 812*] if the substance is not listed in any other schedule in section 202 [21 *USCS Section 812*] or if no exemption or approval is in effect for the substance under section 505 of the Federal Food, Drug, and Cosmetic Act [21 *USCS Section 355*]. Such an order may not be issued before the expiration of thirty days from--

(A) the date of the publication by the Attorney General of a notice in the Federal Register of the intention to issue such order and the grounds upon which such order is to be issued, and

(B) the date the Attorney General has transmitted the notice required by paragraph (4).

(2) The scheduling of a substance under this subsection shall expire at the end of one year from the date of the issuance of the order scheduling such substance, except that the Attorney General may, during the pendency of proceedings under subsection (a)(1) with respect to the substance, extend the temporary scheduling for up to six months.

(3) When issuing an order under paragraph (1), the Attorney General shall be required to consider, with respect to the finding of an imminent hazard to the public safety, only those factors set forth in paragraphs (4), (5), and (6) of subsection (c), including actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution.

(4) The Attorney General shall transmit notice of an order proposed to be issued under paragraph (1) to the Secretary of Health and Human Services. In issuing an order under paragraph (1), the Attorney General shall take into consideration any comments submitted by the Secretary in response to a notice transmitted pursuant to this paragraph.

(5) An order issued under paragraph (1) with respect to a substance shall be vacated upon the conclusion of a subsequent rulemaking proceeding initiated under subsection (a) with respect to such substance.

(6) An order issued under paragraph (1) is not subject to judicial review.

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*** CURRENT THROUGH 104-115, 3/12/96, EXCEPT FOR PLs 104, 106, 114 ***

TITLE 21. FOOD AND DRUGS

CHAPTER 13. DRUG ABUSE PREVENTION AND CONTROL

CONTROL AND ENFORCEMENT

INTRODUCTORY PROVISIONS

21 USCS Section 812 (1996).

Section 812. Schedules of controlled substances

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

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

(1) SCHEDULE I.

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has no currently accepted medical use in treatment in the United States.

(C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.

(2) SCHEDULE II.

(A) The drug or other substance has a high potential for abuse.

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

(C) Abuse of the drug or other substances may lead to severe psychological or physical dependence.

(3) SCHEDULE III.

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

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

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

(4) SCHEDULE IV.

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

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

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

(5) SCHEDULE V.

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

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

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

(c) Initial schedules of controlled substances. **** (Current Schedule, April 1, 1997) **** Schedules I, II, III, IV, and V shall, unless and until amended pursuant to section 201 [21 USCS Section 811], consist of the following drugs or other substances, by whatever official name, common or usual name, chemical name, or brand name designated:

SCHEDULE I

(a) Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

- (1) Acetylmethadol.
- (2) Allylprodine.
- (3) Alphacetylmethadol.
- (4) Alphameprodine.
- (5) Alphamethadol.
- (6) Benzethidine.
- (7) Betacetylmethadol.
- (8) Betameprodine.
- (9) Betamethadol.
- (10) Betaprodine.
- (11) Clonitazene.
- (12) Dextromoramide.
- (13) Dextrophan.
- (14) Diampromide.
- (15) Diethylthiambutene.
- (16) Dimenoxadol.
- (17) Dimepheptanol.

- (18) Dimethylthiambutene.
- (19) Dioxaphetyl butyrate.
- (20) Dipipanone.
- (21) Ethylmethylthiambutene.
- (22) Etonitazene.
- (23) Etoxeridine.
- (24) Furethidine.
- (25) Hydroxypethidine.
- (26) Ketobemidone.
- (27) Levomoramide.
- (28) Levophenacymorphan.
- (29) Morpheridine.
- (30) Noracymethadol.
- (31) Norlevorphanol.
- (32) Normethadone.
- (33) Norpipanone.
- (34) Phenadoxone.
- (35) Phenampromide.
- (36) Phenomorphan.
- (37) Phenoperidine.
- (38) Piritramide.
- (39) Proheptazine.
- (40) Properidine.
- (41) Racemoramide.
- (42) Trimeperidine.

(b) Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

- (1) Acetorphine.
- (2) Acetyldihydrocodeine.
- (3) Benzylmorphine.
- (4) Codeine methylbromide.
- (5) Codeine-N-Oxide.
- (6) Cyprenorphine.
- (7) Desomorphine.
- (8) Dihydromorphine.
- (9) Etorphine.
- (10) Heroin.
- (11) Hydromorphanol.
- (12) Methyldesorphine.
- (13) Methylhydromorphine.
- (14) Morphine methylbromide.
- (15) Morphine methylsulfonate.
- (16) Morphine-N-Oxide.
- (17) Myrophine.
- (18) Nicocodeine.
- (19) Nicomorphine.
- (20) Normorphine.
- (21) Pholcodine.
- (22) Thebacon.

(c) Unless specifically excepted or unless listed in another schedule, any material,

compound, mixture, or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

- (1) 3, 4-methylenedioxy amphetamine.
- (2) 5-methoxy-3, 4-methylenedioxy amphetamine
- (3) 3, 4, 5-trimethoxy amphetamine.
- (4) Bufotenine.
- (5) Diethyltryptamine.
- (6) Dimethyltryptamine.
- (7) 4-methyl-2, 5-dimethoxyamphetamine.
- (8) Ibogaine.
- (9) Lysergic acid diethylamide.
- (10) Marijuana.
- (11) Mescaline.
- (12) Peyote.
- (13) N-ethyl-3-piperidyl benzilate.
- (14) N-methyl-3-piperidyl benzilate.
- (15) Psilocybin.
- (16) Psilocyn.
- (17) Tetrahydrocannabinols.

SCHEDULE II.

(a) Unless specifically excepted or unless listed in another schedule, any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

- (1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate.

(2) Any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause (1), except that these substances shall not include the isoquinoline alkaloids of opium.

(3) Opium poppy and poppy straw.

(4) coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed; cocaine, its salts, optical and geometric isomers, and salts of isomers; ecgonine, its derivatives, their salts, isomers, and salts of isomers; or any compound, mixture, or preparation which contains any quantity of any of the substances referred to in this paragraph.

(b) Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

(1) Alphaprodine.

(2) Anileridine.

(3) Bezitramide.

(4) Dihydrocodeine.

(5) Diphenoxylate.

(6) Fentanyl.

(7) Isomethadone.

(8) Levomethorphan.

(9) Levorphanol.

(10) Metazocine.

(11) Methadone.

(12) Methadone-Intermediate, 4-cyano-2-dimethylamino-4, 4-diphenyl butane.

(13) Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropane-carboxylic acid.

(14) Pethidine.

(15) Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine.

(16) Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate.

(17) Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid.

(18) Phenazocine.

(19) Piminodine.

(20) Racemethorphan.

(21) Racemorphan.

(c) Unless specifically excepted or unless listed in another schedule, any injectable liquid which contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers.

SCHEDULE III.

(a) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:

(1) Amphetamine, its salts, optical isomers, and salts of its optical isomers.

(2) Phenmetrazine and its salts.

(3) Any substance (except an injectable liquid) which contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers.

(4) Methylphenidate.

(b) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system:

(1) Any substance which contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid.

(2) Chorexadol.

(3) Glutethimide.

(4) Lysergic acid.

(5) Lysergic acid amide.

(6) Methyprylon.

(7) Phencyclidine.

(8) Sulfondiethylmethane.

(9) Sulfonethylmethane.

(10) Sulfonmethane.

(c) Nalorphine.

(d) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, or any salts thereof:

(1) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium.

(2) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(3) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium.

(4) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(5) Not more than 1.8 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(6) Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(7) Not more than 500 milligrams of opium per 100 milliliters or per 100 grams, or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(8) Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(e) Anabolic steroids.

4 SCHEDULE IV.

(1) Barbital.

(2) Chloral betaine.

(3) Chloral hydrate.

- (4) Ethchlorvynol.
- (5) Ethinamate.
- (6) Methohexital.
- (7) Meprobamate.
- (8) Methylphenobarbital.
- (9) Paraldehyde.
- (10) Petrichloral.
- (11) Phenobarbital.
- (5) SCHEDULE V.

Any compound, mixture, or preparation containing any of the following limited quantities of narcotic drugs, which shall include one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone:

- (1) Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams.
- (2) Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams.
- (3) Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams.
- (4) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.
- (5) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams.

(d) [Repealed]

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TITLE 21. FOOD AND DRUGS

CHAPTER 13. DRUG ABUSE PREVENTION AND CONTROL

AUTHORITY TO CONTROL;
STANDARDS AND SCHEDULES

21 USCS Section 813 (1996)

Section 813. Treatment of controlled substance analogues

A controlled substance analogue shall, to the extent intended for human consumption, be treated, for the purposes of any Federal law as a controlled substance in schedule I.

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TITLE 21. FOOD AND DRUGS

CHAPTER 13. DRUG ABUSE PREVENTION AND CONTROL

AUTHORITY TO CONTROL;
STANDARDS AND SCHEDULES

21 USCS Section 814 (1996)

Section 814. Removal of exemption of certain drugs

(a) Removal of exemption. The Attorney General shall by regulation remove from exemption under section 102(39)(A)(iv) [21 USCS Section 802(39)(A)(iv)] a drug or group of drugs that the Attorney General finds is being diverted to obtain a listed chemical for use in the illicit production of a controlled substance.

(b) Factors to be considered. In removing a drug or group of drugs from exemption under subsection (a), the Attorney General shall consider, with respect to a drug or group of drugs that is proposed to be removed from exemption--

- (1) the scope, duration, and significance of the diversion;
- (2) whether the drug or group of drugs is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance; and
- (3) whether the listed chemical can be readily recovered from the drug or group of drugs.

(c) Specificity of designation . The Attorney General shall limit the designation of a drug or a group of drugs removed from exemption under subsection (a) to the most particularly identifiable type of drug or group of drugs for which evidence of diversion exists unless there is evidence, based on the pattern of diversion and other relevant factors, that the diversion will not be limited to that particular drug or group of drugs.

(d) Reinstatement of exemption with respect to particular drug products .

(1) Reinstatement. On application by a manufacturer of a particular drug product that has been removed from exemption under subsection (a), the Attorney General shall by regulation reinstate the exemption with respect to that particular drug product if the Attorney General determines that the particular drug product is manufactured and distributed in a manner that prevents diversion.

(2) Factors to be considered. In deciding whether to reinstate the exemption with respect to a particular drug product under paragraph (1), the Attorney General shall consider--

(A) the package sizes and manner of packaging of the drug product;

(B) the manner of distribution and advertising of the drug product;

(C) evidence of diversion of the drug product;

(D) any actions taken by the manufacturer to prevent diversion of the drug product; and

(E) such other factors as are relevant to and consistent with the public health and safety, including the factors described in subsection (b) as applied to the drug product.

(3) Status pending application for reinstatement. A transaction involving a particular drug product that is the subject of a bona fide pending application for reinstatement of exemption filed with the Attorney General not later than 60 days after a regulation removing the exemption is issued pursuant to subsection (a) shall not be considered to be a regulated transaction if the transaction occurs during the pendency of the application and, if the Attorney General denies the application, during the period of 60 days following the date on which the Attorney General denies the application, unless--

(A) the Attorney General has evidence that, applying the factors described in subsection (b) to the drug product, the drug product is being diverted; and

(B) the Attorney General so notifies the applicant.

(4) Amendment and modification. A regulation reinstating an exemption under paragraph (1) may be modified or revoked with respect to a particular drug product upon a finding that--

(A) applying the factors described in subsection (b) to the drug product, the drug product is being diverted; or

(B) there is a significant change in the data that led to the issuance of the regulation.

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REGISTRATION OF MANUFACTURES, DISTRIBUTORS , AND DISPENSERS OF
CONTROLLED

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21 USCS Section 821 (1996)

Section 821. Rules and regulations

The Attorney General is authorized to promulgate rules and regulations and to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances and to the registration and control of regulated persons and of regulated transactions.

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21 USCS Section 822 (1996)

Section 822. Persons required to register

(a) Annual registration.

(1) Every person who manufactures or distributes any controlled substance or list I chemical, or who proposes to engage in the manufacture or distribution of any controlled substance or list I chemical, shall obtain annually a registration issued by the Attorney General in accordance with the rules and regulations promulgated by him.

(2) Every person who dispenses, or who proposes to dispense, any controlled substance, shall obtain from the Attorney General a registration issued in accordance with the rules and regulations promulgated by him. The Attorney General shall, by regulation, determine the period of such registrations. In no event, however, shall such registrations be issued for less than one year nor for more than three years.

(b) Authorized activities. Persons registered by the Attorney General under this title to manufacture, distribute, or dispense controlled substances or list I chemicals are authorized to possess, manufacture, distribute, or dispense such substances or chemicals (including any such activity in the conduct of research) to the extent authorized by their registration and in conformity with the other provisions of this title.

(c) Exceptions. The following persons shall not be required to register and may lawfully possess any controlled substance or list I chemical under this title:

(1) An agent or employee of any registered manufacturer, distributor, or dispenser of any controlled substance or list I chemical if such agent or employee is acting in the usual course of his business or employment.

(2) A common or contract carrier or warehouseman, or an employee thereof, whose possession of the controlled substance or list I chemical is in the usual course of his business or employment.

(3) An ultimate user who possesses such substance for a purpose specified in section 102 (25) [21 USCS Section 802(25)].

(d) Waiver. The Attorney General may, by regulation, waive the requirement for registration of certain manufacturers, distributors, or dispensers if he finds it consistent with the public health and safety.

(e) Separate registration. A separate registration shall be required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances or list I chemicals.

(f) Inspection. The Attorney General is authorized to inspect the establishment of a registrant or applicant for registration in accordance with the rules and regulations promulgated by him.

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21 USCS Section 823 (1996)

Section 823. Registration requirements

(a) Manufacturers of controlled substances in schedule I or II. The Attorney General shall register an applicant to manufacture controlled substances in schedule I or II if he determines that such registration is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on the effective date of this part. In determining the public interest, the following factors shall be considered:

- (1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes;
- (2) compliance with applicable State and local law;
- (3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;
- (4) prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;
- (5) past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion; and
- (6) such other factors as may be relevant to and consistent with the public health and safety.

(b) Distributors of controlled substances in schedule I or II. The Attorney General shall register an applicant to distribute a controlled substance in schedule I or II unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

- (1) maintenance of effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;
- (2) compliance with applicable State and local law;
- (3) prior conviction record of applicant under Federal or State laws relating to the

manufacture, distribution, or dispensing of such substances;

(4) past experience in the distribution of controlled substances; and

(5) such other factors as may be relevant to and consistent with the public health and safety.

(c) Limits of authorized activities. Registration granted under subsections (a) and (b) of this section shall not entitle a registrant to (1) manufacture or distribute controlled substances in schedule I or II other than those specified in the registration, or (2) manufacture any quantity of those controlled substances in excess of the quota assigned pursuant to section 306 [21 USCS Section 826].

(d) Manufacturers of controlled substances in schedule III, IV, or V. The Attorney General shall register an applicant to manufacture controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule III, IV, or V compounded therefrom into other than legitimate medical, scientific, or industrial channels;

(2) compliance with applicable State and local law;

(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) past experience in the manufacture, distribution, and dispensing of controlled substances, and the existence in the establishment of effective controls against diversion; and

(6) such other factors as may be relevant to and consistent with the public health and safety.

(e) Distributors of controlled substances in schedule III, IV, or V. The Attorney General shall register an applicant to distribute controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

(2) compliance with applicable State and local law;

(3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(4) past experience in the distribution of controlled substances; and

(5) such other factors as may be relevant to and consistent with the public health and safety.

(f) Research; pharmacies; research applications; construction of Article 7 of the Convention on Psychotropic Substances. The Attorney General shall register practitioners (including pharmacies, as distinguished from pharmacists) to dispense, or conduct research with, controlled substances in schedule II, III, IV, or V, if the applicant is authorized to dispense, or conduct research with respect to, controlled substances under the laws of the State in which he practices. The Attorney General may deny an application for such registration if he determines that the issuance of such registration would be inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

- (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
- (2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.
- (3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
- (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
- (5) Such other conduct which may threaten the public health and safety.

Separate registration under this part [21 USCS Section 821 et seq.] for practitioners engaging in research with controlled substances in schedule II, III, IV, or V, who are already registered under this part [21 USCS Section 821 et seq.] in another capacity, shall not be required. Registration applications by practitioners wishing to conduct research with controlled substances in schedule I shall be referred to the Secretary, who shall determine the qualifications and competency of each practitioner requesting registration, as well as the merits of the research protocol. The Secretary, in determining the merits of each research protocol, shall consult with the Attorney General as to effective procedures to adequately safeguard against diversion of such controlled substances from legitimate medical or scientific use. Registration for the purpose of bona fide research with controlled substances in schedule I by a practitioner deemed qualified by the Secretary may be denied by the Attorney General only on a ground specified in section 304(a) [21 USCS Section 824(a)]. Article 7 of the Convention on Psychotropic Substances shall not be construed to prohibit, or impose additional restrictions upon, research involving drugs or other substances scheduled under the convention which is conducted in conformity with this subsection and other applicable provisions of this title.

(g) Practitioners dispensing narcotic drugs for narcotic treatment; annual registration; separate registration; qualifications. Practitioners who dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment shall obtain annually a separate registration for that purpose. The Attorney General shall register an applicant to dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment (or both)--

- (1) if the applicant is a practitioner who is determined by the Secretary to be qualified (under standards established by the Secretary) to engage in the treatment with respect to which registration is sought;
- (2) if the Attorney General determines that the applicant will comply with standards established by the Attorney General respecting (A) security of stocks of narcotic drugs for

such treatment, and (B) the maintenance of records (in accordance with section 307 [21 USCS Section 827]) on such drugs; and

(3) if the Secretary determines that the applicant will comply with standards established by the Secretary (after consultation with the Attorney General) respecting the quantities of narcotic drugs which may be provided for unsupervised use by individuals in such treatment.

(h) Registration requirements for list I chemical distribution; public interest determination. The Attorney General shall register an applicant to distribute a list I chemical unless the Attorney General determines that registration of the applicant is inconsistent with the public interest. Registration under this subsection shall not be required for the distribution of a drug product that is exempted under section 102 (39)(A)(iv) [21 USCS Section 802(39)(A)(iv)]. In determining the public interest for the purposes of this subsection, the Attorney General shall consider--

- (1) maintenance by the applicant of effective controls against diversion of listed chemicals into other than legitimate channels;
- (2) compliance by the applicant with applicable Federal, State, and local law;
- (3) any prior conviction record of the applicant under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law;
- (4) any past experience of the applicant in the manufacture and distribution of chemicals; and
- (5) such other factors as are relevant to and consistent with the public health and safety.

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21 USCS Section 824 (1996)

Section 824. Denial, revocation, or suspension of registration

(a) Grounds. A registration pursuant to section 303 [21 USCS Section 823] to manufacture, distribute, or dispense a controlled substance or a list I chemical may be suspended or revoked by the Attorney General upon a finding that the registrant--

(1) has materially falsified any application filed pursuant to or required by this title or title III;

(2) has been convicted of a felony under this title or title III or any other law of the United States, or of any State, relating to any substance defined in this title as a controlled substance or a list I chemical;

(3) has had his State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the manufacturing, distribution, or dispensing of controlled substances or list I chemicals or has had the suspension, revocation, or denial of his registration recommended by competent State authority;

(4) has committed such acts as would render his registration under section 303 [21 USCS Section 823] inconsistent with the public interest as determined under such section; or

(5) has been excluded (or directed to be excluded) from participation in a program pursuant to section 1128(a) of the Social Security Act [42 USCS Section 1320a-7(a)]

A registration pursuant to section 303(g) [21 USCS Section 823(g)] to dispense a narcotic drug for maintenance treatment or detoxification treatment may be suspended or revoked by the Attorney General upon a finding that the registrant has failed to comply with any standard referred to in section 303(g) [21 USCS Section 823(g)].

(b) Limits of revocation or suspension. The Attorney General may limit revocation or suspension of a registration to the particular controlled substance or list I chemical with respect to which grounds for revocation or suspension exist.

(c) Service of show cause order; proceedings. Before taking action pursuant to this section, or pursuant to a denial of registration under section 303 [21 USCS Section 823], the Attorney General shall serve upon the applicant or registrant an order to show cause why registration should not be denied, revoked, or suspended. The order to show cause shall contain a statement of the basis thereof and shall call upon the applicant or registrant to appear before the Attorney General at a time and place stated in the order, but in no event less than thirty days after the date of receipt of the order. Proceedings to deny, revoke, or suspend shall be conducted pursuant to this section in accordance with subchapter II of chapter 5 of title 5 of the United States Code [5 USCS Section 551 et seq.]. Such proceedings shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under this title or any other law of the United States.

(d) Suspension of registration in cases of imminent danger. The Attorney General may, in his discretion, suspend any registration simultaneously with the institution of proceedings under this section, in cases where he finds that there is an imminent danger to the public health or safety. A failure to comply with a standard referred to in section 303(g) [21 USCS Section 823(g)] may be treated under this subsection as grounds for immediate suspension of a registration granted under such section. A suspension under this subsection shall continue in effect until the conclusion of such proceedings, including judicial review thereof, unless sooner withdrawn by the Attorney General or dissolved by a court of competent

jurisdiction.

(e) Suspension and revocation of quotas. The suspension or revocation of a registration under this section shall operate to suspend or revoke any quota applicable under section 306 [21 USCS Section 826].

(f) Disposition of controlled substances or list I chemicals. In the event the Attorney General suspends or revokes a registration granted under section 303 [21 USCS Section 823], all controlled substances or list I chemicals owned or possessed by the registrant pursuant to such registration at the time of suspension or the effective date of the revocation order, as the case may be, may, in the discretion of the Attorney General, be placed under seal. No disposition may be made of any controlled substances or list I chemicals under seal until the time for taking an appeal has elapsed or until all appeals have been concluded except that a court, upon application therefor, may at any time order the sale of perishable controlled substances or list I chemicals. Any such order shall require the deposit of the proceeds of the sale with the court. Upon a revocation order becoming final, all such controlled substances or list I chemicals (or proceeds of sale deposited in court) shall be forfeited to the United States; and the Attorney General shall dispose of such controlled substances or list I chemicals in accordance with section 511(e) [21 USCS Section 881(e)]. All right, title, and interest in such controlled substances or list I chemicals shall vest in the United States upon a revocation order becoming final.

(g) Seizure or placing under seal of controlled substances or list I chemicals upon expiration of registration or cessation of practice or business. The Attorney General may, in his discretion, seize or place under seal any controlled substances or list I chemicals owned or possessed by a registrant whose registration has expired or who has ceased to practice or do business in the manner contemplated by his registration. Such controlled substances or list I chemicals shall be held for the benefit of the registrant, or his successor in interest. The Attorney General shall notify a registrant, or his successor in interest, who has any controlled substance or list I chemical seized or placed under seal of the procedures to be followed to secure the return of the controlled substance or list I chemical and the conditions under which it will be returned. The Attorney General may not dispose of any controlled substance or list I chemical seized or placed under seal under this subsection until the expiration of one hundred and eighty days from the date such substance or chemical was seized or placed under seal.

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21 USCS Section 825 (1996)

Section 825. Labeling and packaging

(a) Symbol. It shall be unlawful to distribute a controlled substance in a commercial container unless such container, when and as required by regulations of the Attorney General, bears a label (as defined in section 201(k) of the Federal Food, Drug, and Cosmetic Act [21 USCS Section 321(k)]) containing an identifying symbol for such substance in accordance with such regulations. A different symbol shall be required for each schedule of controlled substances.

(b) Unlawful distribution without identifying symbol. It shall be unlawful for the manufacturer of any controlled substance to distribute such substance unless the labeling (as defined in section 201(m) of the Federal Food, Drug, and Cosmetic Act [21 USCS Section 321(m)]) of such substance contains, when and as required by regulations of the Attorney General, the identifying symbol required under subsection (a).

(c) Warning on label. The Secretary shall prescribe regulations under section 503(b) of the Federal Food, Drug, and Cosmetic Act [21 USCS Section 353(b)] which shall provide that the label of a drug listed in schedule II, III, or IV shall, when dispensed to or for a patient, contain a clear, concise warning that it is a crime to transfer the drug to any person other than the patient.

(d) Containers to be securely sealed. It shall be unlawful to distribute controlled substances in schedule I or II, and narcotic drugs in schedule III or IV, unless the bottle or other container, stopper, covering, or wrapper thereof is securely sealed as required by regulations of the Attorney General.

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21 USCS Section 826 (1996)

Section 826. Production quotas for controlled substances

(a) Establishment of total annual needs. The Attorney General shall determine the total quantity and establish production quotas for each basic class of controlled substance in schedules I and II to be manufactured each calendar year to provide for the estimated medical, scientific, research, and industrial

needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks. Production quotas shall be established in terms of quantities of each basic class of controlled substance and not in terms of individual pharmaceutical dosage forms prepared from or containing such a controlled substance.

(b) Individual production quotas; revised quotas. The Attorney General shall limit or reduce individual production quotas to the extent necessary to prevent the aggregate of individual quotas from exceeding the amount determined necessary each year by the Attorney General under subsection (a). The quota of each registered manufacturer for each basic class of controlled substance in schedule I or II shall be revised in the same proportion as the limitation or reduction of the aggregate of the quotas. However, if any registrant, before the issuance of a limitation or reduction in quota, has manufactured in excess of his revised quota, the amount of the excess shall be subtracted from his quota for the following year.

(c) Manufacturing quotas for registered manufacturers. On or before October 1 of each year, upon application therefor by a registered manufacturer, the Attorney General shall fix a manufacturing quota for the basic classes of controlled substances in schedules I and II that the manufacturer seeks to produce. The quota shall be subject to the provisions of subsections (a) and (b) of this section. In fixing such quotas, the Attorney General shall determine the manufacturer's estimated disposal, inventory, and other requirements for the calendar year; and, in making his determination, the Attorney General shall consider the manufacturer's current rate of disposal, the trend of the national disposal rate during the preceding calendar year, the manufacturer's production cycle and inventory position, the economic availability of raw materials, yield and stability problems, emergencies such as strikes and fires, and other factors.

(d) Quotas for registrants who have not manufactured controlled substance during one or more preceding years. The Attorney General shall, upon application and subject to the provisions of subsections (a) and (b) of this section, fix a quota for a basic class of controlled substance in schedule I or II for any registrant who has not manufactured that basic class of controlled substance during one or more preceding calendar years. In fixing such quota, the Attorney General shall take into account the registrant's reasonably anticipated requirements for the current year; and, in making his determination of such requirements, he shall consider such factors specified in subsection (c) of this section as may be relevant.

(e) Quota increases. At any time during the year any registrant who has applied for or received a manufacturing quota for a basic class of controlled substance in schedule I or II may apply for an increase in that quota to meet his estimated disposal, inventory, and other requirements during the remainder of that year. In passing upon the application the Attorney General shall take into consideration any occurrences since the filing of the registrant's initial quota application that may require an increased manufacturing rate by the registrant during the balance of the year. In passing upon the application the Attorney General may also take into account the amount, if any, by which the determination of the Attorney General under subsection (a) of this section exceeds the aggregate of the quotas of all registrants under this section.

(f) Incidental production exception. Notwithstanding any other provisions of this title, no registration or quota may be required for the manufacture of such quantities of controlled substances in schedules I and II as incidentally and necessarily result from the manufacturing process used for the manufacture of a controlled substance with respect to which its manufacturer is duly registered under this title. The Attorney General may, by regulation, prescribe restrictions on the retention and disposal of such incidentally produced substances.

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21 USCS Section 827 (1996)

Section 827. Records and reports of registrants

(a) Inventory. Except as provided in subsection (c)--

(1) every registrant under this title shall, on the effective date of this section, or as soon thereafter as such registrant first engages in the manufacture, distribution, or dispensing of controlled substances; and every second year thereafter, make a complete and accurate record of all stocks thereof on hand, except that the regulations prescribed under this section shall permit each such biennial inventory (following the initial inventory required by this paragraph) to be prepared on such registrant's regular general physical inventory date (if any) which is nearest to and does not vary by more than six months from the biennial date that would otherwise apply;

(2) on the effective date of each regulation of the Attorney General controlling a substance that immediately prior to such date was not a controlled substance, each registrant under this title manufacturing, distributing, or dispensing such substance shall make a complete and accurate record of all stocks thereof on hand; and

(3) on and after the effective date of this section, every registrant under this title manufacturing, distributing, or dispensing a controlled substance or substances shall maintain, on a current basis, a complete and accurate record of each such substance manufactured, received, sold, delivered, or otherwise disposed of by him, except that this paragraph shall not require the maintenance of a perpetual inventory.

(b) Availability of records. Every inventory or other record required under this section (1) shall be in accordance with, and contain such relevant information as may be required by, regulations of the Attorney General, (2) shall (A) be maintained separately from all other records of the registrant, or (B) alternatively, in the case of nonnarcotic controlled substances, be in such form that information required by the Attorney General is readily retrievable from the ordinary business records of the registrant, and (3) shall be kept and be available, for at least two years, for inspection and copying by officers or employees of the United States authorized by the Attorney General.

(c) Nonapplicability. The foregoing provisions of this section shall not apply--

(1)

(A) to the prescribing of controlled substances in schedule II, III, IV, or V by practitioners acting in the lawful course of their professional practice unless such substance is prescribed in the course of maintenance or detoxification treatment of an individual; or

(B) to the administering of a controlled substance in schedule II, III, IV, or V unless the practitioner regularly engages in the dispensing or administering of controlled substances and charges his patients, either separately or together with charges for other professional services, for substances so dispensed or administered or unless such substance is administered in the course of maintenance treatment or detoxification treatment of an individual;

(2)

(A) to the use of controlled substances, at establishments registered under this title which keep records with respect to such substances, in research conducted in conformity with an exemption granted under section 505(i) or 512(j) of the Federal Food, Drug, and Cosmetic Act [21 USCS 355(i), 360b(j)];

(B) to the use of controlled substances, at establishments registered under this title which keep records with respect to such substances, in preclinical research or in teaching; or

(3) to the extent of any exemption granted to any person, with respect to all or part of such provisions, by the Attorney General by or pursuant to regulation on the basis of a finding that the application of such provisions (or part thereof) to such person is not necessary for carrying out the purposes of this title.

Nothing in the Convention on Psychotropic Substances shall be construed as superseding or otherwise affecting the provisions of paragraph (1)(B), (2), or (3) of this subsection.

(d) Periodic reports to Attorney General. Every manufacturer registered under section 303 [21 USCS Section 823] shall, at such time or times and in such form as the Attorney General may require, make periodic reports to the Attorney General of every sale, delivery, or other disposal by him of any controlled substance, and each distributor shall make such reports with respect to narcotic controlled substances, identifying by the registration number assigned under this title the person or establishment (unless exempt from registration under section 302(d) [21 USCS Section 822(d)]) to whom such sale, delivery, or other disposal was made.

(e) Reporting and recordkeeping requirements of drug conventions. In addition to the reporting and recordkeeping requirements under any other provision of this title, each manufacturer registered under section 303 [21 USCS Section 823] shall, with respect to narcotic and nonnarcotic controlled substances manufactured by it, make such reports to the Attorney General, and maintain such records, as the Attorney General may require to enable the United States to meet its obligations under articles 19 and 20 of the Single Convention on Narcotic Drugs and article 16 of the Convention on Psychotropic Substances. The Attorney General shall administer the requirements of this subsection in such a manner as to avoid the unnecessary imposition of duplicative requirements under this title on manufacturers

subject to the requirements of this subsection.

(f) Investigational uses of drugs; procedures. Regulations under sections 505(i) and 512(j) of the Federal Food, Drug, and Cosmetic Act [21 USCS 355(i), 360b(j)], relating to investigational use of drugs, shall include such procedures as the Secretary, after consultation with the Attorney General, determines are necessary to insure the security and accountability of controlled substances used in research to which such regulations apply.

(g) Change of address. Every registrant under this title shall be required to report any change of professional or business address in such manner as the Attorney General shall by regulation require.

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21 USCS Section 828 (1996)

Section 828. Order forms

(a) Unlawful distribution of controlled substances. It shall be unlawful for any person to distribute a controlled substance in schedule I or II to another except in pursuance of a written order of the person to whom such substance is distributed, made on a form to be issued by the Attorney General in blank in accordance with subsection (d) and regulations prescribed by him pursuant to this section.

(b) Nonapplicability of provisions. Nothing in subsection (a) shall apply to--

(1) the exportation of such substances from the United States in conformity with title III;

(2) the delivery of such a substance to or by a common or contract carrier for carriage in the lawful and usual course of its business, or to or by a warehouseman for storage in the lawful and usual course of its business; but where such carriage or storage is in connection with the distribution by the owner of the substance to a third person, this paragraph shall not relieve the distributor from compliance with subsection (a).

(c) Preservation and availability.

(1) Every person who in pursuance of an order required under subsection (a) distributes a controlled substance shall preserve such order for a period of two years, and shall make such order available for inspection and copying by officers and employees of the United States duly authorized for that purpose by the Attorney General, and by officers or employees of States or their political subdivisions who are charged with the enforcement of State or local laws regulating the production, or regulating the distribution or dispensing, of controlled substances and who are authorized under such laws to inspect such orders.

(2) Every person who gives an order required under subsection (a) shall, at or before the time of giving such order, make or cause to be made a duplicate thereof on a form to be issued by the Attorney General in blank in accordance with subsection (d) and regulations prescribed by him pursuant to this section, and shall, if such order is accepted, preserve such duplicate for a period of two years and make it available for inspection and copying by the officers and employees mentioned in paragraph (1) of this subsection.

(d) Issuance.

(1) The Attorney General shall issue forms pursuant to subsections (a) and (c)(2) only to persons validly registered under section 303 [21 USCS Section 823] (or exempted from registration under section 302(d) [21 USCS Section 822(d)]). Whenever any such form is issued to a person, the Attorney General shall, before delivery thereof, insert therein the name of such person, and it shall be unlawful for any other person (A) to use such form for the purpose of obtaining controlled substances or (B) to furnish such form to any person with intent thereby to procure the distribution of such substances.

(2) The Attorney General may charge reasonable fees for the issuance of such forms in such amounts as he may prescribe for the purpose of covering the cost to the United States of issuing such forms, and other necessary activities in connection therewith.

(e) Unlawful acts. It shall be unlawful for any person to obtain by means of order forms issued under this section controlled substances for any purpose other than their use, distribution, dispensing, or administration in the conduct of a lawful business in such substances or in the course of his professional practice or research.

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TITLE 21. FOOD AND DRUGS

CHAPTER 13. DRUG ABUSE PREVENTION AND CONTROL

REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF
CONTROLLED

SUBSTANCES; PIPERDINE REPORTING

21 USCS Section 829 (1996)Section 829. Prescriptions

(a) Schedule II substances. Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act [21 USCS 301 et seq.], may be dispensed without the written prescription of a practitioner, except that in emergency situations, as prescribed by the Secretary by regulation after consultation with the Attorney General, such drug may be dispensed upon oral prescription in accordance with section 503(b) of that Act [21 USCS Section 353(b)]. Prescriptions shall be retained in conformity with the requirements of section 307 of this title [21 USCS Section 827]. No prescription for a controlled substance in schedule II may be refilled.

(b) Schedule III and IV substances. Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule III or IV, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act [21 USCS Section 301 et seq.], may be dispensed without a written or oral prescription in conformity with section 503(b) of that Act [21 USCS Section 353(b)]. Such prescriptions may not be filled or refilled more than six months after the date thereof or be refilled more than five times after the date of the prescription unless renewed by the practitioner.

(c) Schedule V substances. No controlled substance in schedule V which is a drug may be distributed or dispensed other than for a medical purpose.

(d) Non-prescription drugs with abuse potential. Whenever it appears to the Attorney General that a drug not considered to be a prescription drug under the Federal Food, Drug, and Cosmetic Act [21 USCS Section 301 et seq.] should be so considered because of its abuse potential, he shall so advise the Secretary and furnish to him all available data relevant thereto.

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TITLE 21. FOOD AND DRUGS

CHAPTER 13. DRUG ABUSE PREVENTION AND CONTROL

REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF
CONTROLLED

SUBSTANCES; PIPERDINE REPORTING

21 USCS Section 830 (1996)

Section 830. Regulation of listed chemicals and certain machines

(a)

(1) Each regulated person who engages in a regulated transaction involving a listed chemical, a tableting machine, or an encapsulating machine shall keep a record of the transaction--

(A) for 4 years after the date of the transaction, if the listed chemical is a list I chemical or if the transaction involves a tableting machine or an encapsulating machine; and

(B) for 2 years after the date of the transaction, if the listed chemical is a list II chemical.

(2) A record under this subsection shall be retrievable and shall include the date of the regulated transaction, the identity of each party to the regulated transaction, a statement of the quantity and form of the listed chemical, a description of the tableting machine or encapsulating machine, and a description of the method of transfer. Such record shall be available for inspection and copying by the Attorney General.

(3) It is the duty of each regulated person who engages in a regulated transaction to identify each other party to the transaction. It is the duty of such other party to present proof of identity to the regulated person. The Attorney General shall specify by regulation the types of documents and other evidence that constitute proof of identity for purposes of this paragraph.

(b)

(1) Each regulated person shall report to the Attorney General, in such form and manner as the Attorney General shall prescribe by regulation--

(A) any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of this title;

(B) any proposed regulated transaction with a person whose description or other identifying characteristic the Attorney General furnishes in advance to the regulated person;

(C) any unusual or excessive loss or disappearance of a listed chemical under the control of the regulated person; and

(D) any regulated transaction in a tableting machine or an encapsulating machine.

Each report under subparagraph (A) shall be made at the earliest practicable opportunity after the regulated person becomes aware of the circumstance involved. A regulated person may not complete a transaction with a person whose description or identifying characteristic is furnished to the regulated person under subparagraph (B) unless the transaction is approved by the Attorney General. The Attorney General shall make available to regulated persons guidance documents describing transactions and circumstances for which reports are required under subparagraph (A) and subparagraph (C).

(2) A regulated person that manufactures a listed chemical shall report annually to the Attorney General, in such form and manner and containing such specific data as the

Attorney General shall prescribe by regulation, information concerning listed chemicals manufactured by the person. The requirement of the preceding sentence shall not apply to the manufacture of a drug product that is exempted under section 102(39)(A)(iv) [21 USCS Section 802(39)(A)(iv)].

(c)

(1) Except as provided in paragraph (2), any information obtained by the Attorney General under this section which is exempt from disclosure under section 552(a) of title 5, United States Code, by reason of section 552(b)(4) of such title, is confidential and may not be disclosed to any person.

(2) Information referred to in paragraph (1) may be disclosed only--

(A) to an officer or employee of the United States engaged in carrying out this title, title III, or the customs laws;

(B) when relevant in any investigation or proceeding for the enforcement of this title, title III, or the custom laws;

(C) when necessary to comply with an obligation of the United States under a treaty or other international agreement; or

(D) to a State or local official or employee in conjunction with the enforcement of controlled substances laws or chemical control laws.

(3) The Attorney General shall--

(A) take such action as may be necessary to prevent unauthorized disclosure of information by any person to whom such information is disclosed under paragraph (2); and

(B) issue guidelines that limit, to the maximum extent feasible, the disclosure of proprietary business information, including the names or identities of United States exporters of listed chemicals, to any person to whom such information is disclosed under paragraph (2).

(4) Any person who is aggrieved by a disclosure of information in violation of this section may bring a civil action against the violator for appropriate relief.

(5) Notwithstanding paragraph (4), a civil action may not be brought under such paragraph against investigative or law enforcement personnel of the Drug Enforcement Administration.

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TITLE 21. FOOD AND DRUGS

CHAPTER 13. DRUG ABUSE, PREVENTION AND CONTROL

OFFENSES AND PENALTIES

21 USCS Section 841 (1996)

Section 841. Prohibited acts A

(a) Unlawful acts. Except as authorized by this title, it shall be unlawful for any person knowingly or intentionally--

(1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance; or

(2) to create, distribute, or dispense, or possess with intent to distribute or dispense, a counterfeit substance.

(b) Penalties. Except as otherwise provided in section 409, 418, 419, or 420 [21 USCS Section 849, 859, 860, or 861], any person who violates subsection (a) of this section shall be sentenced as follows:

(1)

(A) In the case of a violation of subsection (a) of this section involving--

(i) 1 kilogram or more of a mixture or substance containing a detectable amount of heroin;

(ii) 5 kilograms or more of a mixture or substance containing a detectable amount of--

(I) coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed;

(II) cocaine, its salts, optical and geometric isomers, and salts of isomers;

(III) ecgonine, its derivatives, their salts, isomers, and salts of isomers; or

(IV) any compound, mixture, or preparation which contains any quantity of any of the substances referred to in subclauses (I) through (III);

(iii) 50 grams or more of a mixture or substance described in clause (ii) which contains cocaine base;

(iv) 100 grams or more of phencyclidine (PCP) or 1 kilogram or more of a mixture or substance containing a detectable amount of phencyclidine (PCP);

(v) 10 grams or more of a mixture or substance containing a detectable amount of lysergic acid diethylamide (LSD);

(vi) 400 grams or more of a mixture or substance containing a detectable amount of N-phenyl-N- [1-(2-phenylethyl)-4-piperidinyl] propanamide or 100 grams or more of a mixture or substance containing a detectable amount of any analogue of N-phenyl-N- [1-(2-phenylethyl)-4-piperidinyl] propanamide;

(vii) 1000 kilograms or more of a mixture or substance containing a detectable amount of marihuana, or 1,000 or more marihuana plants regardless of weight; or

(viii) 100 grams or more of methamphetamine, its salts, isomers, and salts of its isomers or 1 kilogram or more of a mixture or substance containing a detectable amount of methamphetamine, its salts, isomers, or salts of its isomers;

such person shall be sentenced to a term of imprisonment which may not be less than 10 years or more than life and if death or serious bodily injury results from the use of such substance shall be not less than 20 years or more than life, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18, United States Code, or \$ 4,000,000 if the defendant is an individual or \$ 10,000,000 if the defendant is other than an individual, or both. If any person commits such a violation after a prior conviction for a felony drug offense has become final, such person shall be sentenced to a term of imprisonment which may not be less than 20 years and not more than life imprisonment and if death or serious bodily injury results from the use of such substance shall be sentenced to life imprisonment, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18, United States Code, or \$ 8,000,000 if the defendant is an individual or \$ 20,000,000 if the defendant is other than an individual, or both. If any person commits a violation of this subparagraph or of section 409, 418, 419, or 420 [21 USCS Section 849, 859, 860, or 861] after two or more prior convictions for a felony drug offense have become final, such person shall be sentenced to a mandatory term of life imprisonment without release and fined in accordance with the preceding sentence. Any sentence under this subparagraph shall, in the absence of such a prior conviction, impose a term of supervised release of at least 5 years in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a term of supervised release of at least 10 years in addition to such term of imprisonment. Notwithstanding any other provision of law, the court shall not place on probation or suspend the sentence of any person sentenced under this subparagraph. No person sentenced under this subparagraph shall be eligible for parole during the term of imprisonment imposed therein.

(B) In the case of a violation of subsection (a) of this section involving--

(i) 100 grams or more of a mixture or substance containing a detectable amount of heroin;

(ii) 500 grams or more of a mixture or substance containing a detectable amount of--

(I) coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed;

(II) cocaine, its salts, optical and geometric isomers, and salts of isomers;

(III) ecgonine, its derivatives, their salts, isomers, and salts of isomers; or

(IV) any compound, mixture, or preparation which contains any quantity of any of the substances referred to in subclauses (I) through (III);

(iii) 5 grams or more of a mixture or substance described in clause (ii) which contains

cocaine base;

(iv) 10 grams or more of phencyclidine (PCP) or 100 grams or more of a mixture or substance containing a detectable amount of phencyclidine (PCP);

(v) 1 gram or more of a mixture or substance containing a detectable amount of lysergic acid diethylamide (LSD);

(vi) 40 grams or more of a mixture or substance containing a detectable amount of N-phenyl-N- [1-(2-phenylethyl)-4-piperidinyl] propanamide or 10 grams or more of a mixture or substance containing a detectable amount of any analogue of N-phenyl-N- [1-(2-phenylethyl)-4-piperidinyl] propanamide;

(vii) 100 kilograms or more of a mixture or substance containing a detectable amount of marihuana, or 100 or more marihuana plants regardless of weight; or

(viii) 10 grams or more of methamphetamine, its salts, isomers, and salts of its isomers or 100 grams or more of a mixture or substance containing a detectable amount of methamphetamine, its salts, isomers, or salts of its isomers;

such person shall be sentenced to a term of imprisonment which may not be less than 5 years and not more than 40 years and if death or serious bodily injury results from the use of such substance shall be not less than 20 years or more than life, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18, United States Code, or \$ 2,000,000 if the defendant is an individual or \$ 5,000,000 if the defendant is other than an individual, or both. If any person commits such a violation after a prior conviction for a felony drug offense has become final, such person shall be sentenced to a term of imprisonment which may not be less than 10 years and not more than life imprisonment and if death or serious bodily injury results from the use of such substance shall be sentenced to life imprisonment, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18, United States Code, or \$ 4,000,000 if the defendant is an individual or \$ 10,000,000 if the defendant is other than an individual, or both. Any sentence imposed under this subparagraph shall, in the absence of such a prior conviction, include a term of supervised release of at least 4 years in addition to such term of imprisonment and shall, if there was such a prior conviction, include a term of supervised release of at least 8 years in addition to such term of imprisonment. Notwithstanding any other provision of law, the court shall not place on probation or suspend the sentence of any person sentenced under this subparagraph. No person sentenced under this subparagraph shall be eligible for parole during the term of imprisonment imposed therein.

(C) In the case of a controlled substance in schedule I or II except as provided in subparagraphs (A), (B), and (D), such person shall be sentenced to a term of imprisonment of not more than 20 years and if death or serious bodily injury results from the use of such substance shall be sentenced to a term of imprisonment of not less than twenty years or more than life, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18, United States Code, or \$ 1,000,000 if the defendant is an individual or \$ 5,000,000 if the defendant is other than an individual, or both. If any person commits such a violation after a prior conviction for a felony drug offense has become final, such person shall be sentenced to a term of imprisonment of not more than 30 years and if death or serious bodily injury results from the use of such substance shall be sentenced to life imprisonment, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18, United States Code, or \$ 2,000,000 if the defendant is an

individual or \$ 10,000,000 if the defendant is other than an individual, or both. Any sentence imposing a term of imprisonment under this paragraph shall, in the absence of such a prior conviction, impose a term of supervised release of at least 3 years in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a term of supervised release of at least 6 years in addition to such term of imprisonment.

Notwithstanding any other provision of law, the court shall not place on probation or suspend the sentence of any person sentenced under the provisions of this subparagraph which provide for a mandatory term of imprisonment if death or serious bodily injury results, nor shall a person so sentenced be eligible for parole during the term of such a sentence.

(D) In the case of less than 50 kilograms of marihuana, except in the case of 50 or more marihuana plants regardless of weight, 10 kilograms of hashish, or one kilogram of hashish oil or in the case of any controlled substance in schedule III, such person shall, except as provided in paragraphs (4) and (5) of this subsection, be sentenced to a term of imprisonment of not more than 5 years, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18, United States Code, or \$ 250,000 if the defendant is an individual or \$ 1,000,000 if the defendant is other than an individual, or both. If any person commits such a violation after a prior conviction for a felony drug offense has become final, such person shall be sentenced to a term of imprisonment of not more than 10 years, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18, United States Code, or \$ 500,000 if the defendant is an individual or \$ 2,000,000 if the defendant is other than an individual, or both. Any sentence imposing a term of imprisonment under this paragraph shall, in the absence of such a prior conviction, impose a term of supervised release of at least 2 years in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a special parole term of at least 4 years in addition to such term of imprisonment.

(2) In the case of a controlled substance in schedule IV, such person shall be sentenced to a term of imprisonment of not more than 3 years, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18, United States Code, or \$ 250,000 if the defendant is an individual or \$ 1,000,000 if the defendant is other than an individual, or both. If any person commits such a violation after one or more prior convictions of him for an offense punishable under this paragraph, or for a felony under any other provision of this title, or title III or other law of a State, the United States, or a foreign country relating to narcotic drugs, marihuana, or depressant or stimulant substances, have become final, such person shall be sentenced to a term of imprisonment of not more than 6 years, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18, United States Code, or \$ 500,000 if the defendant is an individual or \$ 2,000,000 if the defendant is other than an individual, or both. Any sentence imposing a term of imprisonment under this paragraph shall, in the absence of such a prior conviction, impose a term of supervised release of at least one year in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a special parole term of at least 2 years in addition to such term of imprisonment.

(3) In the case of a controlled substance in schedule V, such person shall be sentenced to a term of imprisonment of not more than one year, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18, United States Code, or \$ 100,000 if the defendant is an individual or \$ 250,000 if the defendant is other than an individual, or both. If any person commits such a violation after one or more convictions of him for an offense punishable under this paragraph, or for a crime under any other provision of this

title or title III or other law of a State, the United States, or a foreign country relating to narcotic drugs, marihuana, or depressant or stimulant substances, have become final, such person shall be sentenced to a term of imprisonment of not more than 2 years, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18, United States Code, or \$ 200,000 if the defendant is an individual or \$ 500,000 if the defendant is other than an individual, or both.

(4) Notwithstanding paragraph (1)(D) of this subsection, any person who violates subsection (a) of this section by distributing a small amount of marihuana for no remuneration shall be treated as provided in section 404 [21 USCS Section 844] and section 3607 of title 18, United States Code.

(5) Any person who violates subsection (a) of this section by cultivating a controlled substance on Federal property shall be imprisoned as provided in this subsection and shall be fined any amount not to exceed--

(A) the amount authorized in accordance with this section;

(B) the amount authorized in accordance with the provisions of title 18, United States Code;

(C) \$ 500,000 if the defendant is an individual; or

(D) \$ 1,000,000 if the defendant is other than an individual; or both.

(6) Any person who violates subsection (a), or attempts to do so, and knowingly or intentionally uses a poison, chemical, or other hazardous substance on Federal land, and, by such use--

(A) creates a serious hazard to humans, wildlife, or domestic animals,

(B) degrades or harms the environment or natural resources, or

(C) pollutes an aquifer, spring, stream, river, or body of water, shall be fined in accordance with title 18, United States Code, or imprisoned not more than five years, or both.

(c) [Caution: for effective date and savings provisions, see Section 235 of Act Oct. 12, 1984, P.L. 98-473, which appears as 18 USCS Section 3551 note] A term of supervised release imposed under this section or section 418, 419, or 420 [21 USCS Section 859, 860, or 861] may be revoked if its terms and conditions are violated. In such circumstances the original term of imprisonment shall be increased by the period of the term of supervised release and the resulting new term of imprisonment shall not be diminished by the time which was spent on special parole. A person whose term of supervised release has been revoked may be required to serve all or part of the remainder of the new term of imprisonment. A term of supervised release provided for in this section or section 418, 419, or 420 [21 USCS Section 859, 860, or 861] shall be in addition to, and not in lieu of, any other parole provided for by law.

(d) Any person who knowingly or intentionally--

(1) possesses a listed chemical with intent to manufacture a controlled substance except as authorized by this title;

(2) possesses or distributes a listed chemical knowing, or having reasonable cause to believe, that the listed chemical will be used to manufacture a controlled substance except as authorized by this title; or

(3) with the intent of causing the evasion of the recordkeeping or reporting requirements of section 310 [21 USCS Section 830], or the regulations issued under that section, receives or distributes a reportable amount of any listed chemical in units small enough so that the making of records or filing of reports under that section is not required;

shall be fined in accordance with title 18, United States Code, or imprisoned not more than 10 years, or both.

(e) Penalty.

(1) Any person who assembles, maintains, places, or causes to be placed a boobytrap on Federal property where a controlled substance is being manufactured, distributed, or dispensed shall be sentenced to a term of imprisonment for not more than 10 years and shall be fined not more than \$ 10,000.

(2) If any person commits such a violation after 1 or more prior convictions for an offense punishable under this subsection, such person shall be sentenced to a term of imprisonment of not more than 20 years and shall be fined not more than \$ 20,000.

(3) For the purposes of this subsection, the term "boobytrap" means any concealed or camouflaged device designed to cause bodily injury when triggered by any action of any unsuspecting person making contact with the device. Such term includes guns, ammunition, or explosive devices attached to trip wires or other triggering mechanisms, sharpened stakes, and lines or wires with hooks attached.

(f) In addition to any other applicable penalty, any person convicted of a felony violation of this section relating to the receipt, distribution, or importation of a listed chemical may be enjoined from engaging in any regulated transaction involving a listed chemical for not more than ten years.

(g)

(1) Whoever knowingly distributes a listed chemical in violation of this title (other than in violation of a recordkeeping or reporting requirement of section 310 [21 USCS Section 830]) shall be fined under title 18, United States Code, or imprisoned not more than 5 years, or both.

(2) Whoever possesses any listed chemical, with knowledge that the recordkeeping or reporting requirements of section 310 [21 USCS Section 830] have not been adhered to, if, after such knowledge is acquired, such person does not take immediate steps to remedy the violation shall be fined under title 18, United States Code, or imprisoned not more than one year, or both.

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TITLE 21. FOOD AND DRUGS

CHAPTER 13. DRUG ABUSE PREVENTION AND CONTROL

OFFENSES AND PENALTIES

21 USCS Section 842 (1996)

Section 842. Prohibited acts B

(a) Unlawful acts. It shall be unlawful for any person--

- (1) who is subject to the requirements of part C [21 USCS 21 et seq.] to distribute or dispense a controlled substance in violation of section 309 [21 USCS Section 829];
- (2) who is a registrant to distribute or dispense a controlled substance not authorized by his registration to another registrant or other authorized person or to manufacture a controlled substance not authorized by his registration;
- (3) who is a registrant to distribute a controlled substance in violation of section 305 of this title [21 USCS Section 825];
- (4) to remove, alter, or obliterate a symbol or label required by section 305 of this title [21 USCS Section 825];
- (5) to refuse or fail to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required under this title or title III;
- (6) to refuse any entry into any premises or inspection authorized by this title or title III;
- (7) to remove, break, injure, or deface a seal placed upon controlled substances pursuant to section 304(f) or 511 [21 USCS 824(f), 881] or to remove or dispose of substances so placed under seal;
- (8) to use, to his own advantage, or to reveal, other than to duly authorized officers or employees of the United States, or to the courts when relevant in any judicial proceeding under this title or title III, any information acquired in the course of an inspection authorized by this title concerning any method or process which as a trade secret is entitled to protection, or to use to his own advantage or reveal (other than as authorized by section 310) any information that is confidential under such section;
- (9) who is a regulated person to engage in a regulated transaction without obtaining the identification required by 310(a)(3) [21 USCS Section 830(a)(3)]; or
- (10) to fail to keep a record or make a report under section 310 [21 USCS Section 830].

(b) Manufacture. It shall be unlawful for any person who is a registrant to manufacture a controlled substance in schedule I or II which is--

(1) not expressly authorized by his registration and by a quota assigned to him pursuant to section 306 [21 USCS Section 826]; or

(2) in excess of a quota assigned to him pursuant to section 306 [21 USCS Section 826].

(c) Penalties.

(1) Except as provided in paragraph (2), any person who violates this section shall, with respect to any such violation, be subject to a civil penalty of not more than \$ 25,000. The district courts of the United States (or, where there is no such court in the case of any territory or possession of the United States, then the court in such territory or possession having the jurisdiction of a district court of the United States in cases arising under the Constitution and laws of the United States) shall have jurisdiction in accordance with section 1355 of title 28 [28 USCS Section 1355] of the United States Code to enforce this paragraph.

(2)

(A) If a violation of this section is prosecuted by an information or indictment which alleges that the violation was committed knowingly and the trier of fact specifically finds that the violation was so committed, such person shall, except as otherwise provided in subparagraph (B) of this paragraph, be sentenced to imprisonment of not more than one year or a fine of not more than \$ 25,000, or both.

(B) If a violation referred to in subparagraph (A) was committed after one or more prior convictions of the offender for an offense punishable under this paragraph (2), or for a crime under any other provision of this title or title III or other law of the United States relating to narcotic drugs, marihuana, or depressant or stimulant substances, have become final, such person shall be sentenced to a term of imprisonment of not more than 2 years, a fine of \$ 50,000, or both.

(C) [Deleted]

(3) Except under the conditions specified in paragraph (2) of this subsection, a violation of this section does not constitute a crime, and a judgment for the United States and imposition of a civil penalty pursuant to paragraph (1) shall not give rise to any disability or legal disadvantage based on conviction for a criminal offense.

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TITLE 21. FOOD AND DRUGS

CHAPTER 13. DRUG ABUSE PREVENTION AND CONTROL

OFFENSES AND PENALTIES

21 USCS Section 843 (1996)

Section 843. Prohibited acts C

(a) Unlawful acts. It shall be unlawful for any person knowingly or intentionally--

(1) who is a registrant to distribute a controlled substance classified in schedule I or II, in the course of his legitimate business, except pursuant to an order or an order form as required by section 308 of this title [21 USCS Section 828];

(2) to use in the course of the manufacture, distribution, or dispensing of a controlled substance, or to use for the purpose of acquiring or obtaining a controlled substance, a registration number which is fictitious, revoked, suspended, expired, or issued to another person;

(3) to acquire or obtain possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge;

(4)

(A) to furnish false or fraudulent material information in, or omit any material information from, any application, report, record, or other document required to be made, kept, or filed under this title or title III, or (B) to present false or fraudulent identification where the person is receiving or purchasing or a listed chemical and the person is required to present identification under section 310(a) [21 USCS Section 830(a)];

(5) to make, distribute, or possess any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render such drug a counterfeit substance; or

(6) to possess any three-neck round-bottom flask, tableting machine, encapsulating machine, or gelatin capsule, or any equipment, chemical, product, or material which may be used to manufacture a controlled substance or listed chemical, knowing, intending, or having reasonable cause to believe, that it will be used to manufacture a controlled substance or listed chemical in violation of this title or title III;

(7) to manufacture, distribute, export, or import any three-neck round-bottom flask, tableting machine, encapsulating machine, or gelatin capsule, or any equipment, chemical, product, or material which may be used to manufacture a controlled substance or listed chemical, knowing, intending, or having reasonable cause to believe, that it will be used to manufacture a controlled substance or listed chemical in violation of this title or title III or, in the case of an exportation, in violation of this title or title III or of the laws of the country to which it is exported;

(8) to create a chemical mixture for the purpose of evading a requirement of section 310 [21 USCS Section 830] or to receive a chemical mixture created for that purpose; or

(9) to distribute, import, or export a list I chemical without the registration required by this title or title III.

(b) Communication facility. It shall be unlawful for any person knowingly or intentionally to use any communication facility in committing or in causing or facilitating the commission of any act or acts constituting a felony under any provision of this title or title III. Each separate use of a communication facility shall be a separate offense under this subsection. For purposes of this subsection, the term "communication facility" means any and all public and private instrumentalities used or useful in the transmission of writing, signs, signals, pictures, or sounds of all kinds and includes mail, telephone, wire, radio, and all other means of communication.

(c) Advertising. It shall be unlawful for any person to place in any newspaper, magazine, handbill, or other publications, any written advertisement knowing that it has the purpose of seeking or offering illegally to receive, buy, or distribute a Schedule I controlled substance. As used in this section the term "advertisement" includes, in addition to its ordinary meaning, such advertisements as those for a catalog of Schedule I controlled substances and any similar written advertisement that has the purpose of seeking or offering illegally to receive, buy, or distribute a Schedule I controlled substance. The term "advertisement" does not include material which merely advocates the use of a similar material, which advocates a position or practice, and does not attempt to propose or facilitate an actual transaction in a Schedule I controlled substance.

(d) Penalties. Any person who violates this section shall be sentenced to a term of imprisonment of not more than 4 years, a fine of not more than \$ 30,000, or both; except that if any person commits such a violation after one or more prior convictions of him for violation of this section, or for a felony under any other provision of this title or title III or other law of the United States relating to narcotic drugs, marihuana, or depressant or stimulant substances, have become final, such person shall be sentenced to a term of imprisonment of not more than 8 years, a fine of not more than \$ 60,000, or both.

(e) Additional penalties. In addition to any other applicable penalty, any person convicted of a felony violation of this section relating to the receipt, distribution, or importation of a listed chemical may be enjoined from engaging in any regulated transaction involving a listed chemical for not more than ten years.

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TITLE 21. FOOD AND DRUGS

CHAPTER 13. DRUG ABUSE PREVENTION AND CONTROL

OFFENSES AND PENALTIES

21 USCS Section 844 (1996)

Section 844. Penalty for simple possession

(a) It shall be unlawful for any person knowingly or intentionally to possess a controlled substance unless such substance was obtained directly, or pursuant to a valid prescription or order, from a practitioner, while acting in the course of his professional practice, or except as otherwise authorized by this title or title III. Any person who violates this subsection may be sentenced to a term of imprisonment of not more than 1 year, and shall be fined a minimum of \$ 1,000, or both, except that if he commits such offense after a prior conviction under this title or title III, or a prior conviction for any drug or narcotic offense chargeable under the law of any State, has become final, he shall be sentenced to a term of imprisonment for not less than 15 days but not more than 2 years, and shall be fined a minimum of \$ 2,500, except, further, that if he commits such offense after two or more prior convictions under this title or title III, or two or more prior convictions for any drug or narcotic offense chargeable under the law of any State, or a combination of two or more such offenses have become final, he shall be sentenced to a term of imprisonment for not less than 90 days but not more than 3 years, and shall be fined a minimum of \$ 5,000. Notwithstanding the preceding sentence, a person convicted under this subsection for the possession of a mixture or substance which contains cocaine base shall be imprisoned not less than 5 years and not more than 20 years, and fined a minimum of \$ 1,000, if the conviction is a first conviction under this subsection and the amount of the mixture or substance exceeds 5 grams, if the conviction is after a prior conviction for the possession of such a mixture or substance under this subsection becomes final and the amount of the mixture or substance exceeds 3 grams, or if the conviction is after 2 or more prior convictions for the possession of such a mixture or substance under this subsection become final and the amount of the mixture or substance exceeds 1 gram. The imposition or execution of a minimum sentence required to be imposed under this subsection shall not be suspended or deferred. Further, upon conviction, a person who violates this subsection shall be fined the reasonable costs of the investigation and prosecution of the offense, including the costs of prosecution of an offense as defined in sections 1918 and 1920 of title 28, United States Code, except that this sentence shall not apply and a fine under this section need not be imposed if the court determines under the provision of title 18 that the defendant lacks the ability to pay.

(b) [Repealed]

(c) As used in this section, the term "drug or narcotic offense" means any offense which proscribes the possession, distribution, manufacture, cultivation, sale, transfer, or the attempt or conspiracy to possess, distribute, manufacture, cultivate, sell or transfer any substance the possession of which is prohibited under this title.

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TITLE 21. FOOD AND DRUGS

CHAPTER 13. DRUG ABUSE PREVENTION AND CONTROL

OFFENSES AND PENALTIES

21 USCS Section 844a (1996)

Section 844a. Civil penalty for possession of small amounts of certain controlled substances

(a) In general. Any individual who knowingly possesses a controlled substance that is listed in section 401(b)(1)(A) [21 USCS Section 841(b)(1)(A)] in violation of section 404 [21 USCS Section 844(b)(1)(A)] in an amount that, as specified by regulation of the Attorney General, is a personal use amount shall be liable to the United States for a civil penalty in an amount not to exceed \$ 10,000 for each such violation.

(b) Income and net assets. The income and net assets of an individual shall not be relevant to the determination whether to assess a civil penalty under this section or to prosecute the individual criminally. However, in determining the amount of a penalty under this section, the income and net assets of an individual shall be considered.

(c) Prior conviction. A civil penalty may not be assessed under this section if the individual previously was convicted of a Federal or State offense relating to a controlled substance.

(d) Limitation on number of assessments. A civil penalty may not be assessed on an individual under this section on more than two separate occasions.

(e) Assessment. A civil penalty under this section may be assessed by the Attorney General only by an order made on the record after opportunity for a hearing in accordance with section 554 of title 5, United States Code. The Attorney General shall provide written notice to the individual who is the subject of the proposed order informing the individual of the opportunity to receive such a hearing with respect to the proposed order. The hearing may be held only if the individual makes a request for the hearing before the expiration of the 30-day period beginning on the date such notice is issued.

(f) Compromise. The Attorney General may compromise, modify, or remit, with or without conditions, any civil penalty imposed under this section.

(g) Judicial Review. If the Attorney General issues an order pursuant to subsection (e) after a hearing described in such subsection, the individual who is the subject of the order may, before the expiration of the 30-day period beginning on the date the order is issued, bring a civil action in the appropriate district court of the United States. In such action, the law and the facts of the violation and the assessment of the civil penalty shall be determined de novo, and shall include the right of a trial by jury, the right to counsel, and the right to confront witnesses. The facts of the violation shall be proved beyond a reasonable doubt.

(h) Civil action. If an individual does not request a hearing pursuant to subsection (e) and the Attorney General issues an order pursuant to such subsection, or if an individual does not under subsection (g) seek judicial review of such an order, the Attorney General may commence a civil action in any appropriate district court of the United States for the purpose of recovering the amount assessed and an amount representing interest at a rate computed in accordance with section 1961 of title 28, United States Code. Such interest shall accrue from the expiration of the 30-day period described in subsection (g). In such an action, the decision of the Attorney General to issue the order, and the amount of the

penalty assessed by the Attorney General, shall not be subject to review.

(i) Limitation. The Attorney General may not under this subsection [section] commence proceeding against an individual after the expiration of the 5-year period beginning on the date on which the individual allegedly violated subsection (a).

(j) Expungement procedures. The Attorney General shall dismiss the proceedings under this section against an individual upon application of such individual at any time after the expiration of 3 years if--

- (1) the individual has not previously been assessed a civil penalty under this section;
- (2) the individual has paid the assessment;
- (3) the individual has complied with any conditions imposed by the Attorney General;
- (4) the individual has not been convicted of a Federal or State offense relating to a controlled substance; and
- (5) the individual agrees to submit to a drug test, and such test shows the individual to be drug free.

A nonpublic record of a disposition under this subsection shall be retained by the Department of Justice solely for the purpose of determining in any subsequent proceeding whether the person qualified for a civil penalty or expungement under this section. If a record is expunged under this subsection, an individual concerning whom such an expungement has been made shall not be held thereafter under any provision of law to be guilty of perjury, false swearing, or making a false statement by reason of his failure to recite or acknowledge a proceeding under this section or the results thereof in response to an inquiry made of him for any purpose.

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TITLE 21. FOOD AND DRUGS

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21 USCS Section 845 (1996)

Section 845. [Transferred]

HISTORY; ANCILLARY LAWS AND DIRECTIVES

(Oct. 27, 1970, P. L. 91-513, Title II, Part D, Section 405, 84 Stat. 1265.)

EXPLANATORY NOTES:

This section was redesignated and appears as *21 USCS Section 859*.

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21 USCS Section 845a (1996)

Section 845a. [Transferred]

HISTORY; ANCILLARY LAWS AND DIRECTIVES

EXPLANATORY NOTES:

This section was redesignated and appears as *21 USCS Section 860*.

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21 USCS Section 845b (1996)

Section 845b. [Transferred]

HISTORY; ANCILLARY LAWS AND DIRECTIVES

EXPLANATORY NOTES:

This section was redesignated and appears as *21 USCS Section 861*.

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21 USCS Section 846 (1996)

Section 846. Attempt and conspiracy

Any person who attempts or conspires to commit any offense defined in this title shall be subject to the same penalties as those prescribed for the offense, the commission of which was the object of the attempt or conspiracy.

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21 USCS Section 847 (1996)

Section 847. Additional penalties

Any penalty imposed for violation of this title shall be in addition to, and not in lieu of, any civil or administrative penalty or sanction authorized by law.

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21 USCS Section 848 (1996)

Section 848. Continuing criminal enterprise

(a) Penalties; forfeitures. Any person who engages in a continuing criminal enterprise shall be sentenced to a term of imprisonment which may not be less than 20 years and which may be up to life imprisonment, to a fine not to exceed the greater of that authorized in accordance with the provisions of title 18, United States Code, or \$ 2,000,000 if the defendant is an individual or \$5,000,000 if the defendant is other than an individual, and to the forfeiture prescribed in section 413 of this title [21 USCS Section 853]; except that if any person engages in such activity after one or more prior convictions of him under this section have become final, he shall be sentenced to a term of imprisonment which may not be less than 30 years and which may be up to life imprisonment, to a fine not to exceed the greater of twice the amount authorized in accordance with the provisions of title 18, United States Code, or \$ 4,000,000 if the defendant is an individual or \$ 10,000,000 if the defendant is other than an individual, and to the forfeiture prescribed in section 413 of this title [21 USCS Section 853].

(b) Life imprisonment for principal administrator, organizer, or leader of enterprise; excessive quantity of substance or money received. Any person who engages in a continuing criminal enterprise shall be imprisoned for life and fined in accordance with subsection (a), if--

(1) such person is the principal administrator, organizer, or leader of the enterprise or is one of several such principal administrators, organizers, or leaders; and

(2)

(A) the violation referred to in subsection (c)(1) involved at least 300 times the quantity of a substance described in subsection 401(b)(1)(B) of this Act [21 USCS Section 841(b)(1)(B)], or

(B) the enterprise, or any other enterprise in which the defendant was the principal or one of several principal administrators, organizers, or leaders, received \$ 10 million dollars in

gross receipts during any twelve-month period of its existence for the manufacture, importation, or distribution of a substance described in section 401(b)(1)(B) of this Act [21 *USCS Section 841(b)(1)(B)*].

(c) "Continuing criminal enterprise" defined. For purposes of subsection (a), a person is engaged in a continuing criminal enterprise if--

(1) he violates any provision of this title or title III the punishment for which is a felony, and

(2) such violation is a part of a continuing series of violations of this title or title III--

(A) which are undertaken by such person in concert with five or more other persons with respect to whom such person occupies a position of organizer, a supervisory position, or any other position of management, and

(B) from which such person obtains substantial income or resources.

(d) Suspension of sentence and probation prohibited. In the case of any sentence imposed under this section, imposition or execution of such sentence shall not be suspended, probation shall not be granted, and the Act of July 15, 1932 (D. C. Code, secs. 24-203-24-207), shall not apply.

(e) Death Penalty.

(1) In addition to the other penalties set forth in this section--

(A) any person engaging in or working in furtherance of a continuing criminal enterprise, or any person engaging in an offense punishable under section 841(b)(1)(A) or section 960(b)(1) [21 *USCS Section 841(b)(1)(A)* or 960(b)(1)] who intentionally kills or counsels, commands, induces, procures, or causes the intentional killing of an individual and such killing results, shall be sentenced to any term of imprisonment, which shall not be less than 20 years, and which may be up to life imprisonment, or may be sentenced to death; and

(B) any person, during the commission of, in furtherance of, or while attempting to avoid apprehension, prosecution or service of a prison sentence for, a felony violation of this title or title III who intentionally kills or counsels, commands, induces, procures, or causes the intentional killing of any Federal, State, or local law enforcement officer engaged in, or on account of, the performance of such officer's official duties and such killing results, shall be sentenced to any term of imprisonment, which shall not be less than 20 years, and which may be up to life imprisonment, or may be sentenced to death.

(2) As used in paragraph (1)(b), the term "law enforcement officer" means a public servant authorized by law or by a Government agency or Congress to conduct or engage in the prevention, investigation, prosecution or adjudication of an offense, and includes those engaged in corrections, probation, or parole functions.

(f) [Not enacted]

(g) Hearing required with respect to the death penalty. A person shall be subjected to the penalty of death for any offense under this section only if a hearing is held in accordance with this section.

(h) Notice by the Government in death penalty cases.

(1) Whenever the Government intends to seek the death penalty for an offense under this section for which one of the sentences provided is death, the attorney for the Government, a reasonable time before trial or acceptance by the court of a plea of guilty, shall sign and file with the court, and serve upon the defendant, a notice--

(A) that the Government in the event of conviction will seek the sentence of death; and

(B) setting forth the aggravating factors enumerated in subsection (n) and any other aggravating factors which the Government will seek to prove as the basis for the death penalty.

(2) The court may permit the attorney for the Government to amend this notice for good cause shown.

(i) Hearing before court or jury.

(1) When the attorney for the Government has filed a notice as required under subsection (h) and the defendant is found guilty of or pleads guilty to an offense under subsection (e), the judge who presided at the trial or before whom the guilty plea was entered, or any other judge if the judge who presided at the trial or before whom the guilty plea was entered is unavailable, shall conduct a separate sentencing hearing to determine the punishment to be imposed. The hearing shall be conducted--

(A) before the jury which determined the defendant's guilt;

(B) before a jury impaneled for the purpose of the hearing if--

(i) the defendant was convicted upon a plea of guilty;

(ii) the defendant was convicted after a trial before the court sitting without a jury;

(iii) the jury which determined the defendant's guilt has been discharged for good cause; or

(iv) after initial imposition of a sentence under this section, redetermination of the sentence under this section is necessary; or

(C) before the court alone, upon the motion of the defendant and with the approval of the Government.

(2) A jury impaneled under paragraph (1)(B) shall consist of 12 members, unless, at any time before the conclusion of the hearing, the parties stipulate with the approval of the court that it shall consist of any number less than 12.

(j) Proof of aggravating and mitigating factors. Notwithstanding rule 32(c) of the Federal Rules of Criminal Procedure, when a defendant is found guilty of or pleads guilty to an offense under subsection (e), no presentence report shall be prepared. In the sentencing hearing, information may be presented as to matters relating to any of the aggravating or mitigating factors set forth in subsections (m) and (n), or

any other mitigating factor or any other aggravating factor for which notice has been provided under subsection (h)(1)(B). Where information is presented relating to any of the aggravating factors set forth in subsection (n), information may be presented relating to any other aggravating factor for which notice has been provided under subsection (h)(1)(B). Information presented may include the trial transcript and exhibits if the hearing is held before a jury or judge not present during the trial, or at the trial judge's discretion. Any other information relevant to such mitigating or aggravating factors may be presented by either the Government or the defendant, regardless of its admissibility under the rules governing admission of evidence at criminal trials, except that information may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury. The Government and the defendant shall be permitted to rebut any information received at the hearing and shall be given fair opportunity to present argument as to the adequacy of the information to establish the existence of any of the aggravating or mitigating factors and as to appropriateness in that case of imposing a sentence of death. The Government shall open the argument. The defendant shall be permitted to reply. The Government shall then be permitted to reply in rebuttal. The burden of establishing the existence of any aggravating factor is on the Government, and is not satisfied unless established beyond a reasonable doubt. The burden of establishing the existence of any mitigating factor is on the defendant, and is not satisfied unless established by a preponderance of the evidence.

(k) Return of findings. The jury, or if there is no jury, the court, shall consider all the information received during the hearing. It shall return special findings identifying any aggravating factors set forth in subsection (n), found to exist. If one of the aggravating factors set forth in subsection (n)(1) and another of the aggravating factors set forth in paragraphs (2) through (12) of subsection (n) is found to exist, a special finding identifying any other aggravating factor for which notice has been provided under subsection (h)(1)(B), may be returned. A finding with respect to a mitigating factor may be made by one or more of the members of the jury, and any member of the jury who finds the existence of a mitigating factor may consider such a factor established for purposes of this subsection, regardless of the number of jurors who concur that the factor has been established. A finding with respect to any aggravating factor must be unanimous. If an aggravating factor set forth in subsection (n)(1) is not found to exist or an aggravating factor set forth in subsection (n)(1) is found to exist but no other aggravating factor set forth in subsection (n) is found to exist, the court shall impose a sentence, other than death, authorized by law. If an aggravating factor set forth in subsection (n)(1) and one or more of the other aggravating factors set forth in subsection (n) are found to exist, the jury, or if there is no jury, the court, shall then consider whether the aggravating factors found to exist sufficiently outweigh any mitigating factor or factors found to exist, or in the absence of mitigating factors, whether the aggravating factors are themselves sufficient to justify a sentence of death. Based upon this consideration, the jury by unanimous vote, or if there is no jury, the court, shall recommend that a sentence of death shall be imposed rather than a sentence of life imprisonment without possibility of release or some other lesser sentence. The jury or the court, regardless of its findings with respect to aggravating and mitigating factors, is never required to impose a death sentence and the jury shall be so instructed.

(l) Imposition of sentence. Upon the recommendation that the sentence of death be imposed, the court shall sentence the defendant to death. Otherwise the court shall impose a sentence, other than death, authorized by law. A sentence of death shall not be carried out upon a person who is under 18 years of age at the time the crime was committed. A sentence of death shall not be carried out upon a person who is mentally retarded. A sentence of death shall not be carried out upon a person who, as a result of mental disability--

(1) cannot understand the nature of the pending proceedings, what such person was tried for, the reason for the punishment, or the nature of the punishment; or

(2) lacks the capacity to recognize or understand facts which would make the punishment

unjust or unlawful, or lacks the ability to convey such information to counsel or to the court.

(m) Mitigating factors. In determining whether a sentence of death is to be imposed on a defendant, the finder of fact shall consider mitigating factors, including the following:

(1) The defendant's capacity to appreciate the wrongfulness of the defendant's conduct or to conform conduct to the requirements of law was significantly impaired, regardless of whether the capacity was so impaired as to constitute a defense to the charge.

(2) The defendant was under unusual and substantial duress, regardless of whether the duress was of such a degree as to constitute a defense to the charge.

(3) The defendant is punishable as a principal (as defined in section 2 of title 18 of the United States Code) in the offense, which was committed by another, but the defendant's participation was relatively minor, regardless of whether the participation was so minor as to constitute a defense to the charge.

(4) The defendant could not reasonably have foreseen that the defendant's conduct in the course of the commission of murder, or other offense resulting in death for which the defendant was convicted, would cause, or would create a grave risk of causing, death to any person.

(5) The defendant was youthful, although not under the age of 18.

(6) The defendant did not have a significant prior criminal record.

(7) The defendant committed the offense under severe mental or emotional disturbance.

(8) Another defendant or defendants, equally culpable in the crime, will not be punished by death.

(9) The victim consented to the criminal conduct that resulted in the victim's death.

(10) That other factors in the defendant's background or character mitigate against imposition of the death sentence.

(n) Aggravating factors for homicide. If the defendant is found guilty of or pleads guilty to an offense under subsection (e), the following aggravating factors are the only aggravating factors that shall be considered, unless notice of additional aggravating factors is provided under subsection (h)(1)(B):

(1) The defendant--

(A) intentionally killed the victim;

(B) intentionally inflicted serious bodily injury which resulted in the death of the victim;

(C) intentionally engaged in conduct intending that the victim be killed or that lethal force be employed against the victim, which resulted in the death of the victim;

(D) intentionally engaged in conduct which--

- (i) the defendant knew would create a grave risk of death to a person, other than one of the participants in the offense; and
 - (ii) resulted in the death of the victim.
- (2) The defendant has been convicted of another Federal offense, or a State offense resulting in the death of a person, for which a sentence of life imprisonment or a sentence of death was authorized by statute.
 - (3) The defendant has previously been convicted of two or more State or Federal offenses punishable by a term of imprisonment of more than one year, committed on different occasions, involving the infliction of, or attempted infliction of, serious bodily injury upon another person.
 - (4) The defendant has previously been convicted of two or more State or Federal offenses punishable by a term of imprisonment of more than one year, committed on different occasions, involving the distribution of a controlled substance.
 - (5) In the commission of the offense or in escaping apprehension for a violation of subsection (e), the defendant knowingly created a grave risk of death to one or more persons in addition to the victims of the offense.
 - (6) The defendant procured the commission of the offense by payment, or promise of payment, of anything of pecuniary value.
 - (7) The defendant committed the offense as consideration for the receipt, or in the expectation of the receipt, of anything of pecuniary value.
 - (8) The defendant committed the offense after substantial planning and premeditation.
 - (9) The victim was particularly vulnerable due to old age, youth, or infirmity.
 - (10) The defendant had previously been convicted of violating this title or title III for which a sentence of five or more years may be imposed or had previously been convicted of engaging in a continuing criminal enterprise.
 - (11) The violation of this title in relation to which the conduct described in subsection (e) occurred was a violation of section 418 [*21 USCS Section 859*].
 - (12) The defendant committed the offense in an especially heinous, cruel, or depraved manner in that it involved torture or serious physical abuse to the victim.
- (o) Right of the defendant to justice without discrimination.
- (1) In any hearing held before a jury under this section, the court shall instruct the jury that in its consideration of whether the sentence of death is justified it shall not consider the race, color, religious beliefs, national origin, or sex of the defendant or the victim, and that the jury is not to recommend a sentence of death unless it has concluded that it would recommend a sentence of death for the crime in question no matter what the race, color, religious beliefs, national origin, or sex of the defendant, or the victim, may be. The jury

shall return to the court a certificate signed by each juror that consideration of the race, color, religious beliefs, national origin, or sex of the defendant or the victim was not involved in reaching his or her individual decision, and that the individual juror would have made the same recommendation regarding a sentence for the crime in question no matter what the race, color, religious beliefs, national origin, or sex of the defendant, or the victim, may be.

(2) Not later than one year from the date of enactment of the Anti-Drug Abuse Amendments Act of 1988 [enacted Nov. 18, 1988], the Comptroller General shall conduct a study of the various procedures used by the several States for determining whether or not to impose the death penalty in particular cases, and shall report to the Congress on whether or not any or all of the various procedures create a significant risk that the race of a defendant, or the race of a victim against whom a crime was committed, influence the likelihood that defendants in those States will be sentenced to death. In conducting the study required by this paragraph, the General Accounting Office shall--

(A) use ordinary methods of statistical analysis, including methods comparable to those ruled admissible by the courts in race discrimination cases under title VII of the Civil Rights Act of 1964 [42 *USCS* 2000e et seq.];

(B) study only crimes occurring after January 1, 1976; and

(C) determine what, if any, other factors, including any relation between any aggravating or mitigating factors and the race of the victim or the defendant, may account for any evidence that the race of the defendant, or the race of the victim, influences the likelihood that defendants will be sentenced to death. In addition, the General Accounting Office shall examine separately and include in the report, death penalty cases involving crimes similar to those covered under this section.

(p) Sentencing in capital cases in which death penalty is not sought or imposed. If a person is convicted for an offense under subsection (e) and the court does not impose the penalty of death, the court may impose a sentence of life imprisonment without the possibility of parole.

(q) Appeal in capital cases; counsel for financially unable defendants.

(1) In any case in which the sentence of death is imposed under this section, the sentence of death shall be subject to review by the court of appeals upon appeal by the defendant. Notice of appeal must be filed within the time prescribed for appeal of judgment in section 2107 of title 28, United States Code. An appeal under this section may be consolidated with an appeal of the judgment of conviction. Such review shall have priority over all other cases.

(2) On review of the sentence, the court of appeals shall consider the record, the evidence submitted during the trial, the information submitted during the sentencing hearing, the procedures employed in the sentencing hearing, and the special findings returned under this section.

(3) The court shall affirm the sentence if it determines that--

(A) the sentence of death was not imposed under the influence of passion, prejudice, or any

other arbitrary factor; and

(B) the information supports the special finding of the existence of every aggravating factor upon which the sentence was based, together with, or the failure to find, any mitigating factors as set forth or allowed in this section.

In all other cases the court shall remand the case for reconsideration under this section. The court of appeals shall state in writing the reasons for its disposition of the review of the sentence.

(4)

(A) Notwithstanding any other provision of law to the contrary, in every criminal action in which a defendant is charged with a crime which may be punishable by death, a defendant who is or becomes financially unable to obtain adequate representation or investigative, expert, or other reasonably necessary services at any time either--

(i) before judgment; or

(ii) after the entry of a judgment imposing a sentence of death but before the execution of that judgment;

shall be entitled to the appointment of one or more attorneys and the furnishing of such other services in accordance with paragraphs (5), (6), (7), (8), and (9).

(B) In any post conviction proceeding under section 2254 or 2255 of title 28, United States Code, seeking to vacate or set aside a death sentence, any defendant who is or becomes financially unable to obtain adequate representation or investigative, expert, or other reasonably necessary services shall be entitled to the appointment of one or more attorneys and the furnishing of such other services in accordance with paragraphs (5), (6), (7), (8), and (9).

(5) If the appointment is made before judgment, at least one attorney so appointed must have been admitted to practice in the court in which the prosecution is to be tried for not less than five years, and must have had not less than three years experience in the actual trial of felony prosecutions in that court.

(6) If the appointment is made after judgment, at least one attorney so appointed must have been admitted to practice in the court of appeals for not less than five years, and must have had not less than three years experience in the handling of appeals in that court in felony cases.

(7) With respect to paragraphs (5) and (6), the court, for good cause, may appoint another attorney whose background, knowledge, or experience would otherwise enable him or her to properly represent the defendant, with due consideration to the seriousness of the possible penalty and to the unique and complex nature of the litigation.

(8) Unless replaced by similarly qualified counsel upon the attorney's own motion or upon motion of the defendant, each attorney so appointed shall represent the defendant throughout every subsequent stage of available judicial proceedings, including pretrial proceedings, trial, sentencing, motions for new trial, appeals, applications for writ of

certiorari to the Supreme Court of the United States, and all available post-conviction process, together with applications for stays of execution and other appropriate motions and procedures, and shall also represent the defendant in such competency proceedings and proceedings for executive or other clemency as may be available to the defendant.

(9) Upon a finding in ex parte proceedings that investigative, expert or other services are reasonably necessary for the representation of the defendant, whether in connection with issues relating to guilt or sentence, the court shall authorize the defendant's attorneys to obtain such services on behalf of the defendant and shall order the payment of fees and expenses therefore, under paragraph (10). Upon a finding that timely procurement of such services could not practicably await prior authorization, the court may authorize the provision of and payment for such services nunc pro tunc.

(10) Notwithstanding the rates and maximum limits generally applicable to criminal cases and any other provision of law to the contrary, the court shall fix the compensation to be paid to attorneys appointed under this subsection and the fees and expenses to be paid for investigative, expert, and other reasonably necessary services authorized under paragraph (9), at such rates or amounts as the court determines to be reasonably necessary to carry out the requirements of paragraphs (4) through (9).

(r) Refusal to participate by State and Federal correctional employees. No employee of any State department of corrections or the Federal Bureau of Prisons and no employee providing services to that department or bureau under contract shall be required, as a condition of that employment, or contractual obligation to be in attendance at or to participate in any execution carried out under this section if such participation is contrary to the moral or religious convictions of the employee. For purposes of this subsection, the term "participation in executions" includes personal preparation of the condemned individual and the apparatus used for execution and supervision of the activities of other personnel in carrying out such activities.

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TITLE 21. FOOD AND DRUGS

CHAPTER 13. DRUG ABUSE PREVENTION AND CONTROL

OFFENSES AND PENALTIES

21 USCS Section 849 (1996)

Section 849. Transportation safety offenses

(a) Definitions. In this section--

"safety rest area" means a roadside facility with parking facilities for the rest or other needs of motorists.

"truck stop" means a facility (including any parking lot appurtenant thereto) that--

(A) has the capacity to provide fuel or service, or both, to any commercial motor vehicle (as defined in section 31301 of title 49, United States Code), operating in commerce (as defined in that section); and

(B) is located within 2,500 feet of the National System of Interstate and Defense Highways or the Federal-Aid Primary System.

(b) First offense. A person who violates section 401(a)(1) or section 416 [21 USCS Section 841(a)(1) or 856] by distributing or possessing with intent to distribute a controlled substance in or on, or within 1,000 feet of, a truck stop or safety rest area is (except as provided in subsection (b)) subject to--

(1) twice the maximum punishment authorized by section 401(b) [21 USCS Section 841(b)]; and

(2) twice any term of supervised release authorized by section 401(b) [21 USCS Section 841(b)] for a first offense.

(c) Subsequent offense. A person who violates section 401(a)(1) or section 416 [21 USCS Section 841(a)(1) or 856] by distributing or possessing with intent to distribute a controlled substance in or on, or within 1,000 feet of, a truck stop or a safety rest area after a prior conviction or convictions under subsection (a) have become final is subject to--

(1) 3 times the maximum punishment authorized by section 401(b) [21 USCS Section 841(b)]; and

(2) 3 times any term of supervised release authorized by section 401(b) [21 USCS Section 841(b)] for a first offense.

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TITLE 21. FOOD AND DRUGS

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OFFENSES AND PENALTIES

21 USCS Section 850 (1996)

Section 850. Information for sentencing

Except as otherwise provided in this title or section 303(a) of the Public Health Service Act [42 USCS Section 242a(a)], no limitation shall be placed on the information concerning the background, character, and conduct of a person convicted of an offense which a court of the United States may receive and consider for the purpose of imposing an appropriate sentence under this title or title III.

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TITLE 21. FOOD AND DRUGS

CHAPTER 13. DRUG ABUSE PREVENTION AND CONTROL

OFFENSES AND PENALTIES

21 USCS Section 851 (1996)

Section 851. Proceedings to establish previous convictions

(a) Information filed by United States Attorney.

(1) No person who stands convicted of an offense under this part [21 USCS Sections 841 et seq.] shall be sentenced to increased punishment by reason of one or more prior convictions, unless before trial, or before entry of a plea of guilty, the United States attorney files an information with the court (and serves a copy of such information on the person or counsel for the person) stating in writing the previous convictions to be relied upon. Upon a showing by the United States attorney that facts regarding prior convictions could not with due diligence be obtained prior to trial or before entry of a plea of guilty, the court may postpone the trial or the taking of the plea of guilty for a reasonable period for the purpose of obtaining such facts. Clerical mistakes in the information may be amended at any time prior to the pronouncement of sentence.

(2) An information may not be filed under this section if the increased punishment which may be imposed is imprisonment for a term in excess of three years unless the person either waived or was afforded prosecution by indictment for the offense for which such increased punishment may be imposed.

(b) Affirmation or denial of previous conviction. If the United States attorney files an information under this section, the court shall after conviction but before pronouncement of sentence inquire of the person with respect to whom the information was filed whether he affirms or denies that he has been previously convicted as alleged in the information, and shall inform him that any challenge to a prior conviction which is not made before sentence is imposed may not thereafter be raised to attack the sentence.